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Review

A review of near patient testing in primary care

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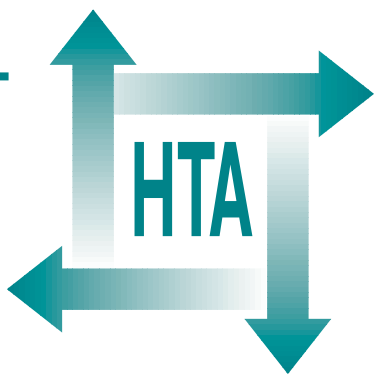
Health Technology Assessment
NHS R&D HTA Programme



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A review of near patient testing in primary care

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NHS R&D HTA Programme

The overall aim of the NHS R&D Health Technology Assessment (HTA) programme is to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and work in the NHS. Research is undertaken in those areas where the evidence will lead to the greatest benefits to patients, either through improved patient outcomes or the most efficient use of NHS resources.

The Standing Group on Health Technology advises on national priorities for health technology assessment. Six advisory panels assist the Standing Group in identifying and prioritising projects. These priorities are then considered by the HTA Commissioning Board supported by the National Coordinating Centre for HTA (NCCHTA).

This report is one of a series covering acute care, diagnostics and imaging, methodology, pharmaceuticals, population screening, and primary and community care. It was identified as a priority by the Primary and Community Care Panel and the Diagnostics and Imaging Panel (see inside back cover).

The views expressed in this publication are those of the authors and not necessarily those of the Standing Group, the Commissioning Board, the Panel members or the Department of Health.

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Contents

List of abbreviations

AST	aspartate transminase
ACT	activated clotting time
ALT	alanine transaminase*
APTT	activated partial thromboplastin time*
AST	aspartate transaminase
BCR	blood count rate*
β-HB	β hydroxy butyrate
BIDS	Bath ISI Data Service
CC	correlation coefficient*
CDDS	computerised diagnostic decision support
CI	confidence intervals
CK	creatine kinase
CK–mB	creatine kinase–mB isomer
CMV	cytomegalovirus*
CRP	C-reactive protein
CV	coefficient of variation*
DSS	decision support systems*
DVT	deep venous thrombosis
EDI	electronic data interchange
ESR	erythrocyte sedimentation rate
FBC	full blood count*
FSH	follicle-stimulating hormone
GGT	gamma glutyrate transferase*
GP	general practioner
Hb	haemoglobin*
HB	hepatitis B*
HbA_{1C}	glycosolated haemoglobin
hCG	human chorionic gonadotrophin
Hct	haematocrit*
HDL	high density lipoprotein
ICU	intensive care unit*
IDDM	insulin-dependent diabetes mellitus
INR	international normalised ratio
ISE	ion specific electrode*
ITU	intensive therapy unit
IVP	intravenous pyelogram*
LDH	lactate dehydrogenase
LDL	low density lipoprotein
LH	luteinising hormone
LPA	lipoprotein a
LR	likelihood ratio
MCH	mean corpuscular haemoglobin*
MCHC	mean corpuscular haemoglobin concentration*
MCV	mean corpuscular volume*
MI	myocardial infarction*
MPV	mean platelet volume
NIDDM	non-insulin-dependent diabetes mellitus
NPT	near patient test/testing
NPV	negative predictive value
PCA	portable clinical analyser*
PCP	phencyclidine
PPV	positive predictive value
PT	prothrombin time
RBC	red blood cells*
ROC	receiver operating characteristic
RAST	radio-allergosorbent test
RDW	red cell distribution width
SD	standard deviation*
SXT	sulphamethoxazole–trimethoprim *
TDM	therapeutic drug monitoring
THC	tetrahydrocannabinol*
TSH	thyroid stimulating hormone
U	urea*
URTI	upper respiratory tract infection*
VLDL	very low density lipoprotein
WBC	white blood cells*

* Only used in the appendices.

Executive summary

Aims and objectives

The aim was to identify publications relating to near patient testing (NPT), the use of alternative delivery systems between laboratory and general practice, including electronic data interchange (EDI), and computerised diagnostic decision support (CDDS), in the primary care setting to answer the following questions.

- What is the availability of NPT for primary care?
- What evidence is available to support the clinical effectiveness of NPT?
- What evidence is available on the accuracy and reliability of NPT within primary care?
- What evidence is available on the cost-effectiveness of different NPTs?
- How may CDDS improve the effectiveness of NPT?
- What evidence is available that compares NPT and existing laboratory services?
- What evidence is available on the cost-effectiveness of EDI or alternative delivery systems?

How the research was conducted

Eight databases were searched, and the bibliographies from relevant publications checked for completeness. Unpublished work and publications not included in the databases were obtained by personal contact with collaborators, and from a postal survey sent to heads of academic departments of general practice and clinical chemistry and to researchers active or interested in the field worldwide. Questionnaires were also sent to 150 commercial organisations.

Publications that met agreed definitions and reported original data were included in the systematic review. Of the 1057 publications identified, 102 (92 related to NPT, eight to CDDS, and two to EDI) were passed to the reviewers for appraisal of validity.

The limited amount of published research relating to any particular NPT prohibited meta-analysis. Scoring systems to assess the validity of evaluations were also difficult to apply.

Research findings

A wide variety of NPT systems have been developed. In general, the quality of the methods reported in the literature was poor. The issue of patient convenience and acceptability has not been adequately addressed.

No evaluations of alternative delivery systems met the review criteria.

No studies have evaluated the telephone or fax machine as a means of reporting results. For EDI, the majority of papers were descriptive.

EDI and alternative delivery systems are not a replacement for NPT when the provision of an immediate result might have an impact on the quality of care. EDI may have clinical and cost advantages over traditional means of communication, but this has not been evaluated.

The advisory role of the laboratory can be supported by CDDS. The use of CDDS and NPT has not, however, been fully evaluated.

Few economic analyses have been conducted, and most were simple cost analyses. There are insufficient data for conclusions to be drawn on the cost-effectiveness of NPT in primary care.

Recommendations

Further systematic reviews

Subject-specific systematic reviews are required that include laboratory and secondary care studies, and consider the potential for altering current management and patient acceptability.

Priority topics include:

- biochemistry profiles on desktop analysers
- cholesterol testing
- urinalysis for the diagnosis of urinary tract infection
- anticoagulation control
- NPTs for the identification of acute infection.

Assessment of NPT and EDI

A research programme to assess NPT in primary care would be appropriate:

- Phase one – initial reliability and safety
- Phase two trials – in selected populations (These could result from partnerships between

the research community, technology manufacturers and licensing authorities.)
- Phase three trials in unselected populations and cost-effectiveness and impact studies.

None of the EDI programmes currently being used in the NHS has been rigorously evaluated. Controlled trials against existing practice should be undertaken.

Guidelines for the evaluation of NPT

Evaluations should be preceded by an assessment of clinical practice to determine the need for and required performance of each diagnostic test in each particular clinical situation. Where the impact of a test is uncertain, or little is known about potential management strategies, the evaluation will need to begin by using qualitative methods and the collection of audit data to define the clinical problem itself. The problem, and the potential role of the test, should be structured in the form of a decision tree and utility assessments should be undertaken, together with some preliminary cost analyses to define the range of clinically-useful performance characteristics.

Once this information is available, studies can be designed to evaluate the performance of an NPT in the primary care setting (see full report for details of methodological issues).

Proposed research priorities

(Note: A modelling exercise to demonstrate the potential for health gain should be considered before embarking on a full-scale evaluation.)

Further primary research, if the quantitative systematic review indicates that knowledge is incomplete. Likely topics are those identified above for further systematic reviews.

Primary research into NPTs or EDI where promising evidence exists but where there is insufficient material to justify a further quantitative review. For example:

- screening for iron deficiency in the child development clinic
- NPT for the exclusion of deep venous thrombosis
- NPT for HbA1c in the practice diabetic clinic
- NPT for microalbuminuria in the practice diabetic clinic
- home monitoring of blood glucose by patients in tight control of diabetes
- NPT for cardiac muscle damage in the diagnosis of acute chest pain
- comparison of EDI for routine results with current practice
- comparison of CDDS with EDI and specialist advice.

The evaluation of newly-developed NPTs for which there is little evidence of their effectiveness.

Modelling/scoping exercises to assess the potential for NPT or EDI to provide clinical benefit to patients.

Conclusions

There is little evidence to support the general introduction of NPT in general practice in preference to existing laboratory services, other than as part of a rigorous, controlled evaluation.

There may be specific clinical areas where NPT may provide additional value to patients, particularly in the areas of early diagnosis, screening, and monitoring of chronic disease. The provision of additional diagnostic information during a consultation may enable primary care physicians to improve the quality and accuracy of their diagnoses, with potential benefit to patients. Such selective introduction of NPT should only take place after evaluation.

Even if there is a substantial increase in NPT in primary care, the laboratory service will continue to provide its existing service, and may need to expand its role in support of quality control and training of practice staff. Although unevaluated, one potential means of introducing NPT into primary care is through laboratory outreach.

Specific practice protocols that give details of the clinical indications for testing, staff training and the necessary quality control procedures may be required to support the introduction of NPT.

There is evidence to suggest that desktop multi-analysers for the analysis of 'routine' samples, and urine multi-test strips for confirming the diagnosis of urinary tract infection in the presence of dysuria, are of limited value in general practice.

EDI may present advantages over traditional means of communication, but its introduction should be subject to evaluation.

Chapter 1
Introduction

Near patient testing (NPT) is thought of as a relatively new health technology, but was documented as early as the mid-17th century when Thomas Willis (1621–75) reported the value of tasting urine to test for glycosuria,[1] * itself a practice undertaken in Ancient Egypt at the time of Ptolemy.

There has been a rapid growth in NPT in recent years, particularly in the USA and Germany.[2] The expansion was initially restricted to certain hospital environments, such as intensive therapy units or outpatient clinics, but NPT has become increasingly important in primary care, especially in the USA, where up to 20% of laboratory tests are now performed within primary care settings.[3] This recent extension of NPT within primary care has been made possible by technological advances, such as new developments in solid phase chemistry and the integration of microprocessors resulting in miniaturisation of equipment. A wide range of tests is available, from simple urine dipsticks to sophisticated haematological and chemical analyses[4] which, on their own, or in combination with computerised diagnostic decision support (CDDS) systems, may provide powerful diagnostic and management tools for primary care.[5]

This systematic review of NPT was commissioned by the NHS R&D Health Technology Assessment programme, in order to assess the scientific background to the expansion of NPT and to identify areas for possible future development. The involvement of Wolfson Research Laboratories in this review gave the authors access to trade publications, thus allowing information in areas of commercial development to be included which would not otherwise be generally available.

Previous reviews have outlined the potential benefits and also the limitations of NPT.[2] However, the rapid growth in this field has necessitated this systematic review so that the priorities for research and development in the primary care area can be assessed. To enable a broad appreciation of the applications of NPT, this review also included publications on CDDS and electronic data interchange (EDI). Both of these technologies may increase the utilisation of NPT.

There are a number of areas of clinical management where the availability of an immediate test result could influence the outcome of a consultation: for example, if the result was obtained while the patient was present, the need for a follow-up consultation could be eliminated. The most clear-cut situations where this might apply would be for single test results, such as prothrombin time, glycosolated haemoglobin (HBA1C) and throat cultures. For these, the usefulness of the result is clear but there remain important questions regarding the reliability, accuracy, and cost-effectiveness of the NPT used.

NPT may be more expensive when tests are performed within primary care (because, for example, of reduced efficiency in low volume activity, training needs, higher quality control costs). However, this potential for an increase in cost needs to be balanced against a possible reduction in overall costs, such as those resulting from delays in receiving results from the laboratory. Where such data exist, the health economic perspective for NPT is assessed in this review. In other areas there are less tangible benefits: the use of desktop analysers may lead to increased volume of testing because of availability, although the value to patients is uncertain. An attempt will be made in this review to highlight areas where the use and development of NPT appears to be most appropriate for primary care, given the limitations of current research evidence.

Alongside the issue of reliability, one of the main obstacles to the development of NPT within primary care is the difficulty associated with the interpretation of laboratory results. The use of CDDS may negate the need for expert interpretation; however, the sensitivity, specificity and positive predictive value (PPV) of any particular test need to be understood if NPT is be used at its optimum level. This review therefore includes an overview of issues linked to the potential of NPT, including the concept of decision analysis.

* **Note on referencing style** Throughout this document, references to the reviewed papers are in Harvard style (i.e. alphabetical by first author), with general references in Vancouver style (i.e. numerical order).

The following questions were addressed by the review.

- What is the availability of NPT for primary care?
- What evidence is available to support the clinical effectiveness of NPT?
- What evidence is available on the accuracy and reliability of NPT within primary care?
- What evidence is available on the cost-effectiveness of different NPTs?
- How may CDDS and EDI improve the effectiveness of NPT?

On account of the broad area under scrutiny and the wide range of clinical applications of a variety of NPTs, this inquiry was constrained to reporting a qualitative systematic review. The principal purpose was to 'map out' the field – to assess the quality and findings of research so far and to indicate where either the absence of good quality data and/or technological advances have created a need for further research.

Chapter 2
Background

The role of NPTs in primary care settings

The value of any diagnostic test, and an NPT in particular, is ultimately only clinically relevant to a positive or negative test's influence on disease diagnosis, management or prognosis. The evaluation of tests should, therefore, be closely related to the clinical issues of management and, specifically, to improving the quality of care. Evaluation of test performance should thus be accompanied by an assessment of the value of the test to diagnosis, disease management and outcome.

Models of clinical decision-making

The purpose of accurate diagnosis is to be able to use the disease-structured knowledge-base of medicine to determine prognosis and aid management decisions. There have been several attempts to analyse the diagnostic process, contrasting the differences between the model taught to medical students and the processes used by experienced doctors.

Hypothetico–deductive model

The hypothetico–deductive method is the model of clinical reasoning borrowed from Popper, and is the method by which medical students are taught to evaluate clinical problems. It consists of three steps:[6]

- data collection from symptoms, signs and investigations
- hypothesis generation using knowledge of basic pathophysiology
- sifting the differential diagnosis by finding data that eliminates alternative diagnoses until only one remains.

In practice, the necessity to structure this task in an appropriate fashion for human reasoning has led to a slightly different focus, as described by Eddy and Clanton.[7] Their process-tracing technique led them to identify six steps.

1. The aggregation of the findings into a summary statement which allows the physician to concentrate on the important features of the case.
2. The selection of a 'pivot'. Whereas most medical knowledge is learnt and stored in a disease-specific fashion, some common findings are remembered as list of 'causes of'. The selection of a pivotal finding bridges the gap from symptom list to differential diagnosis.
3. The generation of a cause list.
4. Pruning the cause list.
5. The selection of the final diagnosis. This is achieved by comparing diagnoses and their likely fit with the observed data in turn, selecting the most likely and moving to the next. This process should lead to the selection of the most likely outcome.
6. The validation of the clinical diagnosis. In this step, all of the data are compared with the diagnosis, thus seeking to explain all the features of the case. Ill-fitting data may lead to either a reconsideration of the findings or of the diagnosis.

Differences between novices and experts

Attempts to use policy-capturing models to generate rule-based CDDS systems have highlighted a number of differences between the 'pure' approach of the clinico-pathological method described above and typical diagnostic approaches of senior physicians.[8]

Heuristics allow experienced doctors to be economical, and yet accurate, in their use of time and investigations. Differences are apparent both in the timing of hypothesis generation, usually from the presenting symptoms, and in the accuracy of these hypotheses. Experts gain from a better knowledge of the prevalence of disease and the significance of symptoms and signs in the local population.

Experts start generating hypotheses early (pattern recognition) and modify their search for data to refute or confirm these early hypotheses, the equivalent in the Eddy and Clanton model,[7] of leaping from step two to five and then alternating between five and six as more data is acquired. The potential for missing the diagnosis completely by failing to consider it in the first place appears greater, but is usually avoided by the expert's greater accuracy in initial hypothesis generation.

The process by which experts make decisions is probably even more complex than this, as those attempting to develop expert systems that provide explanations for rules in operation have discovered. Much of the knowledge of expert doctors is highly context specific, defying clear explanation even by the practitioners themselves. It is this **hermeneutic** knowledge that, by virtue of being implicit, leads to much of the difficulty in implementing the findings of research.[9] To explore this issue further, it is necessary to turn to the concept of the cognitive continuum.

The cognitive continuum

The process of intuitive reasoning ascribed to expert decision-makers is brought about principally by the task under consideration. For most medical diagnoses, the structure of the problem is poorly defined, but only a few clues are required to reach a diagnosis. A premium is therefore set on rapid cognition, either because of emergency situations or the economics of the healthcare system (e.g. the average general practitioner's (GP) consultation time of 8 minutes).

Under these circumstances, intuitive (deductive) decision-making is a heuristic method that performs well. This contrasts with a scientific experiment where the task environment is precisely controlled, much data are available for analysis, and much time may be spent. The concept of task structure and complexity governing the appropriate cognitive mode has been proposed by Hammond as the 'cognitive continuum theory'.[10] In this model, there are six modes of practice, each mode having an appropriate set of task structures. The tasks of research and everyday practice are different and are represented by modes 1–3, namely, scientific experiment, controlled trial and epidemiological study, and modes 5–6, namely, peer-aided judgement, guidelines and intuitive judgement.

Dowie proposed that the difference in task structures and relevant cognitive modes explains much of the difference in 'research' and 'practice' cultures that hinders implementation of research findings.[11] However, the hidden nature of these cognitive modes will act as just as great a barrier to changing practice as the different mode itself. Decision analysis is a form of system-aided judgement that lies at mode 4 in the continuum and could act as a bridge to assist in implementing research findings.

A conflicting model has been provided by Dreyfus and Dreyfus.[12] In this model, the emphasis is not on the task structure but on the approach of the clinician. Novices move to become experts by sequentially developing intuitive judgement for more and more of their decision-making. By definition, intuitive judgment is seen as being superior in the Dreyfus' model. Both models would predict the use of intuitive modes of judgement in unfamiliar situations, but the Dreyfus model would not allow for quasi-analytic modes such as guidelines and decision analysis.

In terms of the role of NPT in clinical decision-making, these theories imply that the assessment of the contribution of any health technology to diagnosis must be grounded in analysis of both current and optimised practice in the given clinical area. Bayesian analysis and decision analysis are powerful tools that quantify the process of judgement, and enable the integration of research data (such as test performance or cost data) with practice.

Bayesian models of the diagnostic process

Bayesian analyses are based on subjective probabilities, where the probability, *p*, represents the decision-makers' judgement of the likelihood of an event. These subjective probabilities are subject to the rules and manipulations of conditional probability, as defined by The Reverend Thomas Bayes in 1764. The Bayesian view of uncertainty can be summarised as follows:[13]

- all uncertainties are inherently of the same kind
- probabilities can be used to measure uncertainties
- probabilities are personal degrees of belief about certain events.

In Bayesian terms the task of diagnosis can be represented most simply by an odds notation:[14]

	odds (predictive value)	=	odds (prevalence)	x	likelihood ratio
or:	odds (disease|findings)	=	odds (disease)		likelihood ratio

The likelihood ratio (LR) is a function of the chance of a symptom or sign occurring in the presence of the disease divided by the chance of the symptom or sign occurring in the absence of disease; that is, true positive rate divided by false positive rate. This figure is generally independent of the prevalence of the disease and can be determined by comparisons of the performance of the diagnostic sign or test against a 'gold standard'. For multiple signs or tests, the LRs are multiplied:

odds (disease|findings)	=	odds (disease)	x LR 1 x LR 2	

One particular problem that limits Bayesian approaches to diagnosis is that, for the formulae to remain relatively straightforward, the competing hypotheses must be mutually exclusive, and the symptoms and signs must be independent of each other. This latter criterion is hard to achieve. In practice, the significance of fever in the presence of cough and chest signs is quite different from the significance of fever in the absence of these features. What would be required here would be the LR for fever|cough|chest signs.[15] The relationship between prevalence, sensitivity, specificity, predictive values and LRs is demonstrated in the box below.[14]

The diagnostic value of tests

The diagnostic value of any test can be calculated in different clinical situations and different populations, providing that the criteria for determining whether a test is positive or negative, or the technical parameters of the test, do not alter between populations. Unfortunately, many practitioners confuse sensitivity and specificity with predictive value, and have a poor understanding of the interpretation of LRs.

For a continuous value test (quantitative test), rather than one which simply reports a positive or negative result (qualitative test), sensitivity versus specificity can be plotted on a graph at a series of cut-off points. This is known as a Receiver Operating Characteristic (ROC) plot, from the origins of this type of analysis in determining the performance of different radar receivers during World War II. The discriminating power of the test is given by the area under the curve: a test with perfect discriminating power would have its curve along the axes; a 'useless' test would be a 45° line (*Figure 1*).[16]

Decision analysis and diagnostic tests

The 'required' performance of a diagnostic test, that is, a predictive value sufficient to achieve a reasonable diagnostic certainty, depends on the balance between cost and benefit of the information provided by the test and the relative costs (in both financial and clinical terms), of false positive and false negative outcomes.

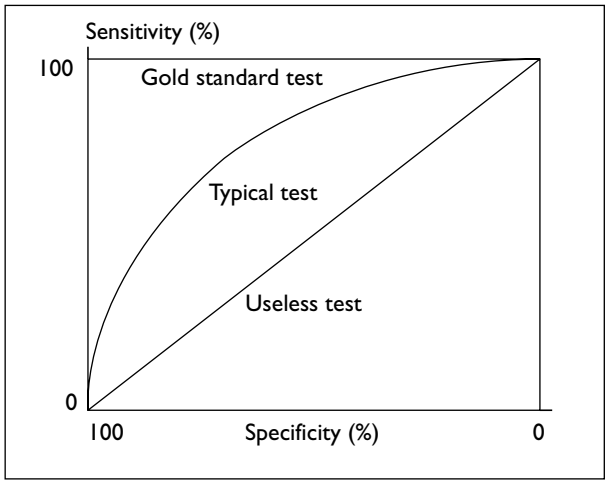

FIGURE 1 *ROC plot showing relationship between 'ideal' and 'useless' curves*

For ROC curves, it is possible to estimate the most useful cut-off point for diagnosis by plotting a line whose slope represents the trade-off between the costs of a false negative (for sensitivity) and a false positive (for specificity) and, taking as the cut-off, the point at which the ROC curve has the same slope as the cost–benefit line. Decision analysis gives a more axiomatically-correct figure. A standardised decision tree can be used to investigate the sensitivity of a diagnostic decision to the performance characteristics of the test in question (*Figure 2*). By evaluating utilities to the outcomes, either with or without testing, the minimum performance, in terms of the predictive value of the test, can be determined by sensitivity analysis to ascertain at what point the 'test strategy' becomes preferred. As the prevalence is known, the required LR for the test to perform adequately in the given

BOX 1 *Explanation of diagnostic value terms*[14]

	Gold standard +	**Gold standard –**	Σ
Test +	True positive	False positive	Total test positive
Test –	False negative	True negative	Total test negative
Σ	Prevalence disease (p)	Prevalence not disease (1 – p)	Total population

Sensitivity = True positive rate (TPR) = True positive/Prevalence disease
Specificity = True negative rate (TNR) = True negative/Prevalence not disease
Positive predictive value (PPV) = True positive/Total test positive
Negative predictive value (NPV) = True negative/Total test negative
LR + = TPR/False Positive Rate (FPR) = Sensitivity/(1 – Specificity)
LR – = False Negative Rate (FNR)/TNR = (1 – Sensitivity)/Specificity

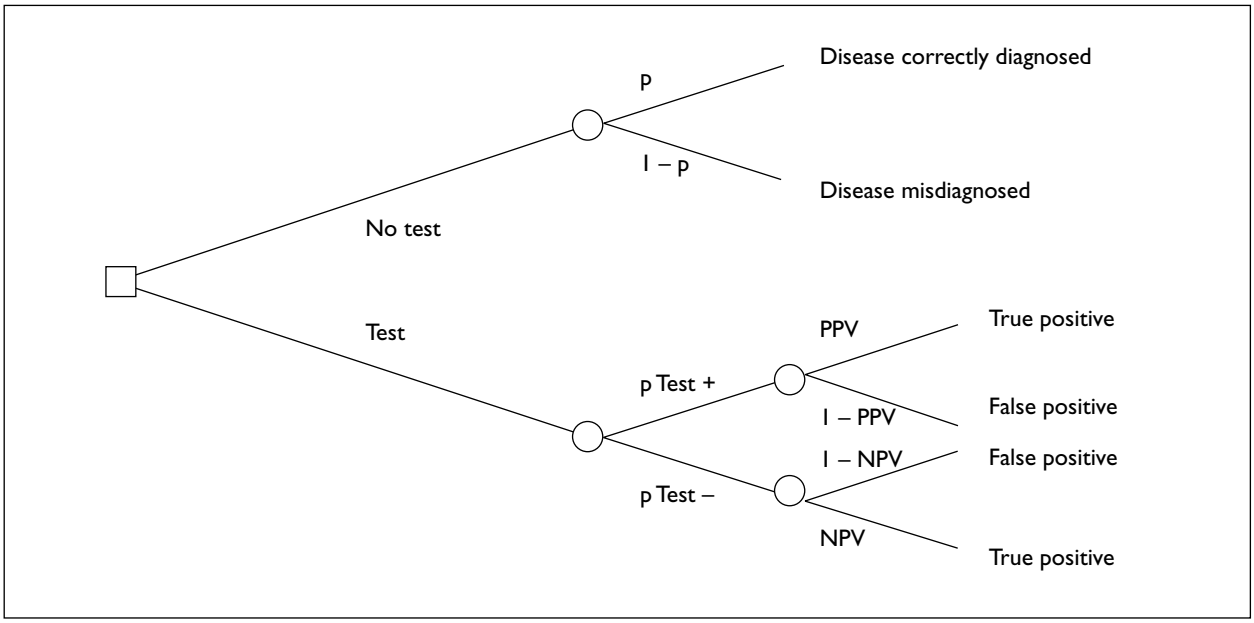

FIGURE 2 *Decision tree for calculating the effectiveness of a diagnostic test*

diagnostic scenario can be calculated using Bayes' Theorem.

Assessment of NPT in primary care

In view of the issues surrounding the function of tests and their diagnostic value, there are seven questions to be satisfied before the use of a NPT can be justified.

- Will the result of a diagnostic test affect management of the patient, by clarifying the diagnosis, or determine therapy or prognosis?
- Would having an immediate result be more useful than waiting for a laboratory result, in terms of value to decision-making?
- Does the NPT perform sufficiently well in the appropriate setting, that is, are the predictive values sufficient?
- Is the NPT cost-effective compared with the laboratory test?
- Is the NPT sufficiently reliable in terms of quality control?
- Is the NPT acceptable to patients?
- Do practitioners have sufficient clinical knowledge to interpret and use the result effectively in diagnosis, or is support readily available?

The answers to these questions can only come from careful cross-sectional studies of appropriate samples of patients, with and without the disorder being tested, undertaken in appropriate locations. Such studies need to address the issues of validity, acceptability, cost-effectiveness, and the implications of the test performance in everyday practice.

Requirements for successful adoption of an NPT in primary care

The need for information in diagnosis, therapy or prognosis

Although accurate diagnosis is usually a prerequisite for appropriate therapy and prognostic prediction, it is not an end in itself. Information is also required to assist in the management of the patient. An example would be the treatment of patients with cough and purulent sputum following an upper respiratory infection. Most GPs would prescribe an antibiotic to most patients presenting with crackles or wheeze on auscultation of the chest, but would not request a chest X-ray unless the patient failed to respond. The decision to prescribe has already been made and the chest X-ray will not alter management, unless the patient fails to respond to treatment or has persisting chest signs that suggest an underlying problem, such as a bronchial carcinoma.

Some diagnostic investigations are performed in order for the physician to 'check their diagnosis'. Such testing is of only indirect value to the individual patient, although such information could benefit future patients treated by that doctor. Post-mortem examinations have a similar role; however, such an *ad hoc* review of diagnosis is

highly prone to cognitive biases such as base rate error and the operation of the availability heuristic.[8] If the aim of improving the accuracy of diagnosis is to be achieved, additional educational support is needed in the form of a literature review and critical incident recording and audit.

The role of a diagnostic test in decision-making has been defined using Bayes' theorem and decision analysis. The adoption of any new medical technology should be on the basis of first demonstrating a need and then determining the necessary performance characteristics.

Immediate information will affect the outcomes of medical care

What separates NPTs from laboratory-based diagnostic tests is the (usually) immediate availability of the result and the ability of this to affect immediate management of the patient. There would be no disagreement over the value of an immediate ECG in the treatment of a patient with a cardio-respiratory arrest or of an immediate blood sugar test on an unconscious patient. The immediate nature and the value of NPTs in many primary care situations is less clear cut, with other factors being of relevance such as saving of time in future consultations or convenience for the patient or practitioner. It would be possible to use cost–benefit analysis, including appropriate time factors modelled by a Markov technique, to show if a reduction in patient contact followed the use of an NPT. However, this form of modelling has not yet been performed for any NPT technology.

Quality assurance

The technical performance of a test, under laboratory conditions and in clinical use, can be grouped under 'quality assurance'. The Association of Clinical Biochemists have produced guidelines on the implementation of NPT,[17] concentrating on the issues of quality control (repeated and ongoing), recording of data, training needs of staff using a test, and health and safety issues.

Validity and accuracy

The first question is whether a test actually measures what it is designed to measure. Manufacturers provide performance characteristics for their equipment under ideal conditions in comparison with an accepted reference standard (the gold standard) for the particular test. A further question for clinicians is to what extent the measurement of a substance 'X' contributes to the diagnosis. For example, in a glucose tolerance test, different levels of serum glucose have different predictive values for the diagnosis of diabetes, simplified into the definition of 'impaired glucose tolerance' for the intermediate values.

A problem arises when there is no accepted gold standard for a test, or when a gold standard comparison would be inappropriate. For example, if post-mortem diagnosis were used as the gold standard for a condition which is not invariably fatal, only the 'worst' cases would receive gold standard validation, and the predictive value of the test for less serious cases would be unknown. The calculation and application of performance characteristics are discussed above.

Reliability

Reliability includes two quality assurance components: internal reliability – how consistent are the results of a test on a day-to-day basis; and external reliability – how the results compare with an external standard. For some tests, regular calibration against standardised samples is required; in others, the equipment is self-calibrating or calibration is accomplished by the input of a predetermined code for a new set of reagents. The complexity of calibration is a major influence on the degree of staff training and the throughput of tests required to make an NPT cost-effective.

Precision

Precision is the statistical variation in a series of results based on the same sample, in the same way that the 95% confidence interval of a statistic describes the distribution of 95% of results of a series of identical experiments. Just as in statistical inference, there is no direct relationship with the 'true' test result; this is determined by the accuracy of the test as described above.

Local variation of performance

The performance of a diagnostic test may vary considerably in different situations for a number of reasons. The test may be affected by the underlying prevalence of the condition being tested. Tests with 'poor' LRs (that is, positive < 10 or negative > 0.1, indicating that a true result is ten times more likely than a false result) have less ability to raise a low prior probability to one that is diagnostically relevant posterior.

Some tests will be sensitive to sampling procedures and, therefore, to potential operator errors in, for example, the collection of a quantitative capillary sample, or the timing, preparation or storage of reagents. Other substances, either in the patient (such as drugs) or present, for example, as contaminants on swabs, may interfere with the test.

NPTs are particularly prone to operator-dependent errors, by virtue of their being performed in a multitude of situations with the potential for use in uncontrolled circumstances, by inadequately-trained staff or, indeed, in the patient's home. Manufacturers need to be particularly aware of the need to make tests simple to use (with few operator-dependent steps). The greater the number of steps involved, the greater the potential for variability in results between users.

Acceptability to patients

The sampling procedure of a test needs to be acceptable to patients. Part of acceptability is the degree of invasiveness of the test: finger-prick samples are less invasive than venous blood sampling (although some patients may prefer venepuncture) or an endoscopy. However, patients do differ in what they deem acceptable, especially with regard to such procedures as stool sampling.

The perceived seriousness of the condition being tested or screened for may also influence acceptability; for example, Hobbs and colleagues[18] found that most patients in a screening programme for colorectal cancer were prepared to collect their own faecal occult blood samples, despite the procedure being potentially unpleasant and requiring some manual dexterity.

Cost-effectiveness

Healthcare expenditure in all countries has to compete with other priorities, either personal or national, and budgets are fixed. Diagnostic test expenditure has to be balanced, therefore, against other health needs. Within a fixed budget, if the extra cost of an NPT cannot be justified by improved quality of care or by savings elsewhere, the use of that test is not justified. Health economic evaluation of NPTs needs to be complete, in that costs (both direct and indirect) to the different healthcare sectors and to the patient need to be considered.

The measurement of clinical benefit poses special difficulties as all the problems of utility measurement apply. Structural distortions of healthcare funding can play a key role in determining the local application of particular technologies, such as, in the UK, GP fundholders being able to vire part of their laboratory budget into NPTs, while non-fundholders are unable to recover any expenditure the practice makes on such items.

Health economic evaluation of NPT

What represents value for money in health care?

The core issue of value-for-money studies is to map out and measure the costs per unit benefit from a given healthcare intervention. Health economics is the general collection of techniques that can be used to establish value for money from healthcare expenditure.

International perspective

In the USA, there are many organisations that review healthcare technology including the Agency for Health Care Policy and Research (AHCPR), the National Institutes of Health (NIH) and the Office of Technology Assessment. Both the Medicaid and Medicare organisations are beginning to debate whether or not they will continue to pay for healthcare technologies without evidence of them representing good value for money. Decisions to reimburse for pharmaceuticals under the Medicare system are now based on their value for money. The extension of this policy to healthcare investigative technology is currently being debated.

Responsible organisations elsewhere include the Swedish Council on Technology Assessment in Health Care (SBU), the Danish Medical Research Council; the French Agence Nationale pour le Developement de l'Evaluation Medicale (ANDEM), the Association for Health Research and Development (ACINDES) in Argentina, and the Institute of Health Economics and Technology Assessment (IHETA) in Australia. There is interest in developing health technology assessment units in Eire, France, Germany, Norway and Scotland.

In 1991, the Catalan Office for Health Technology Assessment was set up to evaluate new technologies prior to consideration for inclusion in Catalonia's healthcare reimbursement system. In 1992, the Spanish Ministry of Health established a Technology Assessment Unit with a mandate to provide the ministry with cost-effectiveness data on new and established healthcare technology. In 1993, the Australian government introduced a mandatory requirement that if a pharmaceutical product was to be considered for public reimbursement in Australia, then the pharmaceutical company had to provide evidence that the pharmaceutical was good value for money. In 1995, the Basque Office of Health Technology Assessment began its economic evaluation of pharmaceuticals and is now considering extending the evaluations to medical technology and other healthcare interventions.

United Kingdom perspective

The UK government has a standing committee of technology assessment and is helping to finance some new information dissemination centres. These information/dissemination organisations do not make decisions on value for money from healthcare technology. Their primary function is information collation and dissemination. The NHS R&D Health Technology Assessment programme has research commissioning interests in technical, safety, efficacy, value for money and operational issues of healthcare technology. This systematic review was funded by this programme.

There are tentative signs of change. For example, the Department of Health has established a register of cost-effectiveness studies relating to value for money from healthcare intervention. This register contained, at a recent count, 147 studies, compiled from an academic review of 200 papers undertaken by the Centre for Health Economics, University of York, on behalf of the Government. Although the review used an assessment template, the authors acknowledged deficiencies in their template and deficiencies in the literature surveyed.

The Office of Health Economics, a pharmaceutical industry-sponsored organisation based in London, has started to assemble and review evidence of value for money from healthcare interventions. However, it is not clear if this is duplicating the Government's efforts or is a separate effort. It is also not clear how the Office of Health Economics is actually performing its review of the literature, or if its reviews will be subject to independent audit.

Health technology assessment

A similar story is true in healthcare technology. Although some suppliers are now making some progress in providing evidence of their products on the basis of value-for-money criteria, most have failed to provide any evidence of their products being good value for money (because no one has required them to provide it).

This dual deficiency in supply and demand for value-for-money data (a lack of evidence and a lack of requirement for evidence) may now be changing. The change is being driven by the tightening of healthcare finance, the delegation and appropriation of funds to local healthcare teams (the growth in GP fundholding is indicative of this trend), and the growth of information assemblers, reviewers and disseminators. The last group, the information organisers, are not unique to the UK and, given the common ground with other countries, may develop international networks to avoid duplicating effort and to speed up information diffusion. Such organisations are expected to have the advantage of being skilled in literature synthesis and dissemination, which health professionals can then access in a timely manner and at relatively low cost.

The inhibitors of the trend towards greater use of evidence of value for money are the quality of the evidence, the appropriateness of the evidence to any particular healthcare decision, various fears of clinical autonomy, and a deficiency in understanding of current practice.

The capital funding of NPT, CDDS and EDI is a further issue. Ease of finance usually drives demand for technology. However, in the current dynamic of the UK healthcare system, the purchasing of equipment in primary care may be driven by different purchasing rules and regulations to the hospital setting. The range of finance models available may also be considered antithetical to the spirit of a publicly-financed healthcare system. For example, there are few options to lease rather than buy equipment. Leasing has an advantage where technological change is rapid or the equipment is relatively expensive.

The potential benefits of near patient tests in primary care

Information value of result

The information value of a result in terms of medical diagnosis, is determined by the likelihood ratio of the test and the balance in utility between testing and not testing. If holistic utility measures are used, these will incorporate the reassurance value to the patient of a negative result.

Tests have an important value in reducing the uncertainty under which doctors practise. A study of the influence of a rapid transit erythrocyte sedimentation rate (ESR) test on the diagnosis reached by Dutch GPs, found that the result confirmed the original diagnosis in 82% of cases and was 'reassuring for both doctor and patient'.[19] Another benefit to the GP is the increased motivation that some will feel in being able to perform diagnostic tests in-house. By increasing the accuracy of primary care diagnosis, NPTs have the potential to enable GPs to undertake tasks previously in the domain of the specialist.

In screening

The use of NPTs in screening has received much attention; it ranges from simple urinalysis strips[20] and measurement of blood glucose to more complex desktop analysers for the measurement

of cholesterol.[21] Regular use of testing is more likely in screening programmes than in diagnostic use, thus increasing the economy of scale of an NPT. If patients are tested while still in the surgery, there are potential savings in administration costs and in ensuring follow-up of abnormal results.

Reduction in indirect costs

Costs of transport of a specimen to the laboratory, the processing of that specimen with all the laboratory overheads, and the transport of the result to the surgery are avoided. However, the need for a laboratory service for those hospitals and GPs not using NPT will, even if many tests are performed in general practice, reduce the ability of these savings to be realised.

GPs may often treat a 'probable' diagnosis, particularly a bacteriological problem such as a sore throat or a urinary tract infection, without testing: by the time a result is obtained, the potential to influence the course of the illness by treatment will have passed. There is potential for NPTs such as rapid streptococcal throat tests which, if sufficiently accurate, would enable bacteriological diagnosis and therapy to be either given or withheld, as appropriate.[22]

Reducing the need for follow-up consultations

If an NPT is performed while the patient waits, a return visit may be avoided. However, a study of desktop analyser use in London revealed that approximately 15% of patients were asked to return for the result, even though the analyser was used.[23] A number of GPs used laboratory tests in preference to NPTs, to provide delay (using time to resolve a diagnostic problem) while still satisfying the needs of patients for their symptoms to be taken seriously.

The potential costs of NPTs in primary care

Direct extra costs of NPT

GP fundholders may vire part of their budget to pay for the purchase of NPTs. The costs of capital equipment, such as optical readers, centrifuges and analysers, have to be accounted for as well as the recurring costs of reagents and consumable items, such as capillary tubes. If expensive equipment is infrequently used, the unit cost of an investigation can rise sharply.[23]

Opportunity costs

Just as in all parts of the healthcare system, resources are limited. If staff or practitioners are engaged in performing NPTs, they are not available to perform other tasks that might be more appropriate or more effective.

Staff time and training

The requirement for appropriate staff training, and the time taken to perform an NPT, need to be included in the costs of testing. If a test is performed by a GP, the unit cost is obviously much higher than if it is performed by a nurse or even by a technical assistant, although many local factors, such as ease of access and location of equipment, will influence this. Laboratories are able to benefit from economies of scale both in equipment costs and in their ability to delegate routine tasks to less highly trained (and therefore less expensive) staff.

Quality assurance

A primary concern in NPT is quality assurance. There have been several documents produced by clinical chemists, outlining guidelines for decentralised laboratory work.[24–26] The principal guidelines derive from a WHO conference held in 1988, in collaboration with the Nordic Clinical Chemistry Project (NORDKEM) and the European Committee for Clinical Laboratory Standards (ECCLS).[25] Collaboration between pathology laboratories and primary care units is essential if NPT is to be safe and effective in use.

GPs cannot ignore the issues of both internal and external quality control steps in the validation of test results. This will add to the unit costs of testing. Some NPTs, such as pregnancy tests, are single-use test strips or cards, into which the quality control has been built in during manufacture, often in the form of a visible 'negative test' indicator. Although convenient, these tests would be less cost-effective if many tests are performed daily.

Test availability increases testing

The 'Hawthorne effect' describes a change in the behaviour of subjects when their work is being studied.[27] Similarly, the availability of a test has been shown to increase the usage of that test.[23] It is not known whether such increases in use indicate a previously unmet need, or are an inappropriate response, or are long term. Studies have shown that in practices where desktop analysers have been introduced, the rate of testing increases but the extra tests do not lead to an alteration in diagnosis or management. However, none of these studies has examined the effect of apparently 'inappropriate' tests in reducing the degree of uncertainty experienced by both doctor and patient.

Decision-support systems and NPT

There has been such a considerable expansion in the use of microcomputers in general practice, that it is fast becoming the norm for a practice to possess one[28] (80% in the most recent survey[29]). Other than the usual tasks of repeat prescribing and list management, this level of computerisation offers the opportunity to apply a range of microcomputer-based software information systems, offering advice and support on clinical matters such as the appropriate use of diagnostic tests. With the most extensively computerised primary healthcare sector in the world, the UK has a unique opportunity to inform on the appropriate application of such information technology.

According to Buchanan,[30] expert systems should:

- provide a solution at the same level of performance as a human expert
- employ symbolic reasoning rather than numeric and algorithmic procedures
- store knowledge separately from inference procedures
- provide explanations for their reasoning.

There are two main types of expert system currently available: rule-based systems, where operations are performed subject to a set of rules obtained from a single or group of specialists in a given field; and probabilistic systems, where evidence is weighed and then the best option calculated according to Bayes' Theorem.[31]

Probabilistic systems

Probabilistic systems are normative in that they attempt to model the diagnostic or therapeutic decision according to logical rules and to predict what decision should be made in the light of available evidence.[32] However, such systems are limited in the availability of data and the complexity of possible outcomes.[33] In many areas of medicine, the necessary information on prognostic implications is missing and reliable base rates are available in very few areas.

Rule-based systems

Rule-based systems are simpler and cheaper but are descriptive rather than proscriptive in that they reflect the biases and logical errors of human thinking. Rule-based systems may be more or less explicit in the operation of the rules at any given point in the programme. The MYCIN system,[34] developed in the 1970s, is able to explain its reasoning at any point in a consultation by listing the rules under consideration at that moment.

Cognitive models

A few systems have been based on the concept of modelling human reasoning in the hypothetico-deductive model. Areas of related knowledge are held in 'frames' that can be brought under analysis according to a series of rules. The analysis may then be by a scoring system or by sophisticated rules known as semantic nets.

Ready availability of desktop systems in general practice has provided an opportunity to develop real-time clinical decision support, provided that it can be made acceptable and practicable for the user. Shortliffe has identified areas of constraint on the application of decision support (see Box 2)[35] – theoretical barriers, observable and recognised needs of users, sources of knowledge and system development.

BOX 2 *Shortliffe's constraints on the application of decision support*

- Avoidance of major theoretical barriers for the initial prototype system
- A recognised need for computer assistance by physicians
- A demonstrated need for computer assistance
- Identification of motivated collaborators
- Identification of the available medical knowledge that can be used
- The method to hand for introduction into daily practice

Timpka[36] used a conceptual model and an attitude questionnaire to analyse these constraints among GPs in Sweden. It was noted that much of the process of the consultation fell into the realm of hermeneutic knowledge and, thus, was not available to knowledge representation in a rule-based sense. Close attention must be paid to epistemological issues in both the content and form of knowledge representation in decision-support systems. The mode of data capture and its relevance to the process of the primary care consultation are vital if CDDS is to be of use to GPs.[37]

Barriers to the implementation of NPT in primary care

Shortliffe's constraints on the application of decision support[35] can be generalised to embrace the introduction of any technology into the arena of supporting professional judgment.

- **Avoidance of major theoretical barriers in the design of the technology.** The NPT should perform adequately in the primary care setting, with factors such as test reliability and validity being included. The test should be acceptable to patients, and simple in operation to avoid major capital and staff training costs.
- **A recognised need for information by the professional group.** If a diagnosis is deemed to be made on information readily available without the need for further testing, a test would not have widespread acceptance. For example, many GPs in the UK do not prescribe antibiotics for pharyngitis, as the impact of such treatment on the course of the illness is of doubtful significance and the risk of complications low. However, in countries such as New Zealand, where the prevalence of nephritic strains of streptoccoci is higher, treatment of pharyngitis is expected by both physicians and patients, and there would be a clear advantage in using a 'streptococcal throat' test.[38]
- **A demonstrated need for NPT.** The principal advantage of NPT over traditional laboratory testing lies in the ability of the test to influence management of a condition that has a 'window of opportunity' which may have passed by the time a laboratory test result is available. Such conditions include those where the condition may have progressed in the interval, as well as those where prompt diagnosis may save the patient further discomfort, such as a simple urinary tract infection. Areas where the result may alter management, but the condition is chronic in nature, such as diabetes or *Helicobacter pylori* infection are less dramatic, and evaluations of the need for NPT should centre around issues of cost and convenience.
- **Identification of motivated collaborators.** The successful development of an NPT involves close collaboration between basic science, clinical chemistry, clinical medicine (of the appropriate clinical setting and speciality, e.g. primary care) and industry.
- **Identification of available medical knowledge that can be used.** The evaluation of an NPT involves the establishment of evidence-based best practice in that area, and the use of decision analysis to determine the effect and desired performance of the test in that setting.
- A method to hand for introduction into daily practice. Guidelines or CDDS may be required to aid the introduction of a test into practice.

Previous reviews of diagnostic tests

There have been no previous systematic reviews of NPTs in primary care. Reid and colleagues[39] have recently criticised the extent to which diagnostic tests in general have been evaluated, pointing out that many new diagnostic tests prove to be disappointing in clinical practice. They suggest seven 'standards' which should be applied to evaluations of such tests.

- **Spectrum composition.** The evaluation should include at least three of the following – age distribution, sex, disease severity and entry criteria – as these may affect the performance characteristics of the test.
- **Analysis of pertinent subgroups.** Bayes' theorem indicates that the predictive value will differ in subgroups of the population with differing baseline risks; for example, symptomatic versus asymptomatic patients.
- **Avoidance of work-up bias.** This occurs if not all patients receive the gold standard investigation.
- **Avoidance of review bias.** Investigators should be blinded to gold standard or test results during data collection.
- **Precision.** 95% confidence intervals should be quoted for all results.
- **Presentation of indeterminate test results.** The frequency of indeterminate results (i.e. 'borderline' or uninterpretable results) should be noted, and the manner in which these values were treated in the subsequent analysis made explicit.
- **Test reproducibility.** Either instrument or observer variability should be examined in repeat samples.

Reid and colleagues searched Medline from 1978 to 1993 for articles published in *New England Journal of Medicine, Journal of the American Medical Association, The Lancet* and the *British Medical Journal* only.[39] They found 112 articles describing studies in which more than ten patients were recruited for the evaluation of a diagnostic test, and where performance characteristics were quoted. The proportion of studies meeting the above standards was very poor (see Box 3). The evidence-based medicine working group at McMaster University has also produced guidelines for use in evaluations of diagnostic tests.[40,41] The criteria were similar to those given above, in that work-up and review bias were considered in addition to spectrum composition, precision and reproducibility. The guidelines also emphasised the translation of research evidence into clinical

BOX 3 *Percentage of diagnostic test studies meeting criteria set by Reid and colleagues*[39]

Standard	Studies meeting standard (%)
Spectrum composition	27
Subgroups	8
Work-up bias	46
Review bias	38
Precision	11
Indeterminate results	23
Reproducibility	23

practice, and raised questions as to whether the results would change practice and improve patient care.

Irwig and colleagues[42] have published guidelines for meta-analyses of diagnostic tests, solving the dilemma of how to compare performance characteristics of tests using different criteria for positivity by plotting the results on a summary ROC curve. Logistic regression was then used to fit a curve to the data and calculate pooled LRs. The authors recommended that data are subject to sensitivity analysis on the validity inclusion criteria for papers.

Research objectives in evaluating NPT in primary care

In summary, a number of objectives should be satisfied before a new diagnostic test is introduced into routine clinical practice.

- Does the test have adequate reliability and validity in the development stage?
- Does the test have adequate performance in its application setting(s)?
- Does the test produce an increase in the effectiveness of management as judged by decision analysis?
- What parameters limit the effectiveness of the test in a sensitivity analysis?
- Are results of the decision analysis translatable into practice in pragmatic trial settings?
- Does the test perform well against alternative tests, or not testing, in an economic analysis?

Chapter 3

NPT systems available for use in general practice

Background

Systems suitable for use in NPT range from simple disposable dipsticks to complex desktop analysers, from 'over-the-counter' pregnancy tests to a rapid test for antibodies against HIV. The number, the technologies involved and the diversity of applications are increasing rapidly. In this chapter an attempt is made to outline the types of systems which are available and to give an indication of the technology involved. Also addressed briefly are the characteristics of the systems, approximate cost, manufacturer or distributor and the areas of application. A full listing of the systems identified is included in Appendix 3.

The review has not concentrated solely on the systems currently available for use by GPs in the UK. The market is evolving and could undergo significant and rapid change. Systems that are available in other countries, such as the USA and elsewhere in Europe, have also been included, even though these may not as yet be available in the UK. Simple distribution arrangements would quickly change this position. Several NPT systems have already been superseded, and distributors may change. However, these original systems have still been included because they are the subject of papers reviewed. Systems may also still be supported although not promoted by industry, and these are included to give an indication of what has occurred and the possibilities available.

A number of technological advances have allowed the use of NPT to increase, such as the performance of diagnostics assays in extra-laboratory situations (such as general practice) by inexperienced operators. In order to ensure accurate results, the number of operator-dependent steps should be minimal and, ideally, the systems should be rapid, inexpensive, have all the necessary reagents integrated into the device, and only require the addition of the sample. It should be possible to use whole blood and urine samples, for example, and the results should be clearly presented.

NPT systems can be classified in several ways. Classification may be by the technology used, such as whether the system is a non-instrumental one or if the use of an instrument is involved; alternatively, the clinical area of application may be used. For this review, the latter approach is the option adopted. Where systems are used in several areas, full details are presented in one section only to avoid repetition; brief details only, with a cross reference to the main entry, are provided in other areas of application.

The general classification of NPT systems that follows below is structured according to the following outline.

A CLINICAL CHEMISTRY
A1 General chemistry, desktop analysers
A2 Urinalysis
A3 Diabetes
A4 Lipids
A5 Cardiac screening
A6 Screening for drugs of abuse and therapeutic drug monitoring
A7 Fertility and pregnancy
A8 Cancer screening
A9 Allergy testing

B MICROBIOLOGY
B1 Infectious diseases – HIV; hepatitis B; *H. pylori; Streptococcus A/B;* Chlamydia; Miscellaneous; ESR/C-reactive protein (CRP)
B2 Urinalysis – multiple test strips

C HAEMATOLOGY
C1 General haematology – haemoglobin
C2 Coagulation

Where appropriate, NPT systems are subdivided into those involving no instrumentation, hand-held or small desktop analysers, and large desktop analysers.

NPTs in clinical chemistry

Desktop analysers (A1)

These range from relatively complex desktop instruments, capable of performing a wide repertoire of single tests or of performing

simultaneous multiple tests on a single specimen, to small hand-held instruments capable of measuring a single analyte on one specimen at a time. Most recently introduced systems are capable of using relatively small volumes of a whole blood specimen directly from a finger-stick capillary sample. This avoids centrifugation and separation procedures associated with systems using serum or plasma samples. Simultaneous testing for multiple analytes can be performed using such samples. Calibration of systems for use in NPT must be simple. Any systems not pre-calibrated by the manufacturer, or without an extremely simple calibration procedure, have major limitations. A complex calibration procedure presents an important operator-dependent step and may necessitate laboratory staff involvement.

All the reagents needed for most individual tests are supplied by the equipment manufacturers. Several tests employ a final colorimetric reaction to quantify the concentration of analyte present, whereas other use biosensor technology. Most systems only require sample addition to initiate reactions. Many systems are based on dry phase reagents incorporated either into reagent strips or into some form of reaction vessel. Others employ pre-aliquoted liquid reagents contained in some form of reaction cuvette or cassette.

Several of the larger desktop systems are capable of performing a wide repertoire of general clinical chemistry tests. These can include urea and electrolytes, lipids, glucose and a range of metabolites and enzymes important in monitoring renal, liver, bone and cardiac function. Several may also provide limited haematology tests, such as haemoglobin or prothrombin time.

Typical analytes or measurements available on NPT desktop analysers include the following:

amylase; bilirubin; cholesterol; creatine kinase; creatinine; γ-glutamate transferase; glucose; aspartate transaminase; alanine transaminase; potassium; high density lipoprotein; haemoglobin; sodium; triglycerides; urea; uric acid; albumin; lactate dehydrogenase; total protein; chloride; calcium; alkaline phosphatase; creatine kinase; lipid fractions; HbA1c; ammonia; haematocrit; erythrocytes; pH; P_{CO_2}; P_{O_2}; T_{CO_2}; base excess; HCO_3; lactate; lithium; CRP; lipase; thyroxine; prothrombin; magnesium; phosphate; iron; cholinesterase.

The size and composition of the range of tests available varies from system to system. Several of the larger systems have evolved from laboratory-based instruments. Once set up, such systems may be extremely easy to use and potentially offer a very wide range of tests, together with comparability of results. The more complex a desktop instrument and its laboratory equivalent, the more laboratory involvement and back-up there may need to be.

The range of tests available on NPT systems tend to mimic those of laboratory systems: some provide general clinical chemistry assays, similar to those used in profiles; others provide blood gases and electrolytes, similar to the technology used in emergency or critical care areas.

Desktop analysers capable of performing multiple tests may perform a series of different tests sequentially on the same instrument. Others, such as the Vision™, are capable of performing several different tests from one or more specimens simultaneously. An increasing number of systems are being developed that can perform several tests simultaneously from one whole blood specimen. These include several systems designed to produce a general chemistry profile, lipid profiles, and electrolyte and blood gas measurements.

Conventional instrumentation for performing simultaneous multiple assays for analytes such as electrolyte and blood gas have developed from laboratory and critical care analysers. Although such systems may find some application in certain general practices, cost and maintenance issues would appear to preclude their widespread use. Systems have recently been simplified to perform simultaneous multiple assays for analytes such as electrolytes and blood gases on hand-held instrumentation and individual reagent cassettes.

Smaller desktop systems performing multiple different tests sequentially have been designed to cover a limited number of analytes commonly requested in general practice. These include glucose, haemoglobin, cholesterol, triglycerides, erythrocytes, haematocrit, and high density lipoprotein (HDL) cholesterol. These assays can be used with whole blood samples. However, the range may be further increased to include analytes such as urate and bilirubin, if serum/plasma samples can be obtained.

A wide range of hand-held instruments are available for general practice or home assay of single analytes on whole blood samples. These include glucose, cholesterol and haemoglobin.

Urinalysis (A2)

Simple reagent tablets and dry phase chemistry reagent dipsticks have been available for urinalysis for many years. Systems generally involve briefly dipping the reactive area in the sample and then comparing the colour change against an accompanying colour chart. A range of semi-quantitative dipsticks for use with urine samples are available. These include general chemistry systems monitored via colorimetric reactions and immunoassays based on antibodies or antigens.

Simple chemical systems are available for single analytes such a glucose, protein and ketones (A3) and the numerous reactive chemical pads now available can be incorporated on to a single dipstick enabling approximately nine different tests to be carried out simultaneously. Other tests generally include: specific gravity; pH; leucocytes; nitrite; protein; urobilinogen and blood. Such multiple strips have found wide applicability in microbiological investigations (B2).

Dipsticks for glucose and ketones have been widely used in diabetic studies, and single and multiple tests are commercially available. These have been supplemented by similar assays for microalbumin based on immunoassay technology (A3).

Non-radioactive labels and monoclonal antibodies have enabled the development of rapid and simple immunoassays in dipstick or dipstick-like format. The presence of an analyte can be indicated by a coloured response on the device. Alternatively, the intensity of the colour change can be proportional to concentration, or the response is used to produce positive or negative symbols to indicate the presence or absence of the analyte. Such systems have proved to be both sensitive and rapid, and have been applied in diverse areas, including screening for drugs of abuse (A6) and assays of luteinising hormone (LH) (A7). The systems can be designed to incorporate integral procedural controls which indicate that the operator has performed the test correctly and that the reagents are active. A range of qualitative/semiquantitative disposable immunoassays are commercially available for use with urine samples. These include dipstick or related tests for use in fertility testing, ovulation prediction (A7) and the detection of drugs of abuse (A6). Devices can be constructed so that they may be held directly in the urine stream, or dipped into a urine sample, or held in a plastic platform on to which several drops of a urine sample may be added. There are a range of devices with a minimal number of operator-dependent steps; these involve sample addition and visual assessment of the result, and are termed one-step devices.

Diabetes (A3)

A very wide range of NPT systems are available for application in diabetes investigations. These include: visually-monitored reagent tablets or strips; simple hand-held meters; and desktop analysers capable of performing blood glucose and other chemical assays. Many systems can be used by members of the general public, and measurement systems have significantly increased in sophistication, eliminating many of the operator-dependent steps associated with earlier devices. Meters are relatively inexpensive and sophisticated data management facilities are also now available.

A wide range of small dedicated instruments are available to perform assays for glucose. These are based on dry reagent strips or electrode sensors. Even inexpensive instruments have sophisticated features and many of the operator-dependent steps associated with previous systems have been eliminated. The systems are pre-calibrated, require a very small undefined sample of whole blood, automatically time reactions, and can produce a result in under 45 seconds. Self-checks include the ability to detect the addition of an insufficient sample and when the instrument requires cleaning. In addition, the hand-held systems can store results from numerous patient and quality control tests, and download these for subsequent review.

Lipids (A4)

The blood lipids most commonly measured on NPT systems include total cholesterol, HDL cholesterol and triglycerides. Several analysers allow determination of total:HDL cholesterol ratio, and only a small number enable determination of low density lipoprotein (LDL), very low density lipoprotein (VLDL) fractions and certain apolipoproteins. Two non-instrumental systems are available for semi-quantitative and quantitative determination of blood cholesterol.

A range of small desktop analysers dedicated to lipid measurement are commercially available. Most allow the use of whole blood specimens taken directly from a finger-stick. The systems range in complexity from meters using single dry-phase reagent strips, for determination of cholesterol, to small desktop analysers using simple cassettes, for simultaneous measurement of total cholesterol, HDL cholesterol, triglycerides and glucose, combined with calculation of LDL, VLDL and total: HDL cholesterol ratio. Most large desktop general clinical chemistry analysers include several lipid assays in their range.

Cardiac screening (A5)

For some time, several small and large desktop analysers have permitted the assay of a small number of analytes associated with cardiac screening. These have included creatine kinase (CK), creatine kinase–myoglobin isomer (CK–mB), lactate dehydrogenase (LDH) and aspartate transaminase (AST).

Recently, a series of rapid, visually monitored, non-instrumental disposable immunoassays for cardiac screening were introduced. Their range has been extended to allow the use of whole blood samples and to determine if markers, such as CK–mB, and troponin T, are present above a threshold concentration. Single disposable devices allowing simultaneous measurement of up to four markers, including myoglobin, CK–mB, myosin light chains and troponin I, are now being introduced.

Screening for drugs of abuse (A6)

A range of qualitative non-instrumental systems are available for screening for drugs of abuse in urine samples. Most are platform or dipstick, visually-monitored, disposable immunoassays, merely requiring the addition of a sample or dipping into a urine sample. Similar technology has been incorporated into a plastic collection vessel which can be used to screen samples and then act as a container to send the sample to a laboratory for confirmation or further analysis.

Such systems can be designed to check for a single analyte; however, several can test for a range of drugs simultaneously. Assay kits are available for a wide range of drugs, including cocaine, cannabinoids, amphetamine, phencyclidine (PCP), metamphetamine, barbiturates, morphine (opiate, heroin), benzodiazepine, and methadone.

Disposable immunoassay kits are available in dipstick or dipstick-like formats. Simultaneous multi-test panels are becoming increasingly available, with two, three, four or seven tests on one device. Qualitative and semi-quantitative non-instrumental devices are also available for the measurement of salivary alcohol.

Therapeutic drug monitoring (A6)

A few small desktop analysers have the facility to perform quantitative assays for blood levels of a limited number of therapeutic drugs. The range of assays available on desktop analysers include theophylline, phenytoin, carbamazepine and paracetamol. Two quantitative, non-instrumental immuno-chromatography systems for whole blood theophylline have been described.

Fertility and pregnancy (A7)

An extremely wide range of sensitive non-instrumental quantitative assays are available for investigation of pregnancy and fertility by human chorionic gonadotrophin (hCG) or LH assay. Both types of assay can be performed at home simply by the patient introducing part of the assay device into the urine stream, waiting for a few minutes, and then visually interpreting any colour changes on the surface of the device.

Assay kits for use in general practice are constructed using similar technology. Either a few drops of urine sample are added to the device and the reaction performs in a similar manner or additional reagents are added sequentially. Some kits are also capable of performing assays on both urine and serum samples. Qualitative urine assays for follicle stimulating hormone (FSH) have recently been described. Two systems are available to aid studies of male fertility. Simple instrumentation and disposables allow a series of quantitative measures to be made on semen samples.

Over-the-counter dipstick immunoassay kits for LH, and oestrone-3-glucuronide, used with a hand-held reader, have recently been introduced as an adjunct to the 'rhythm method' of contraception.

Cancer screening (A8)

A series of disposable non-instrumental systems are available for the qualitative detection of faecal occult blood. These vary from simple colorimetric systems, which detect enzyme activity associated with any haemoglobin present, to disposable immunoassay devices for haemoglobin in stool samples.

A disposable immunoassay and dipstick are available for use with urine samples to detect the basement membrane proteins which act as tumour markers for bladder cancer. Disposable qualitative assays for serum alpha-feta protein (AFP) and prostate specific antigen (PSA) have been described, although their sensitivity and clinical usefulness are at present unknown.

Allergy screening (A9)

In addition to conventional skin testing, a series of disposable systems are available for determination of total IgE or the detection of allergen specific IgE in serum samples. Most are based on immunoassay methodology using specific allergens immobilised on to a disposable solid

support. If IgE is present, it is indicated by means of a second antibody conjugated to some kind of label. One device can be used to screen for groups of up to 36 allergens simultaneously.

TSH screening

A disposable immunoassay device for detection of thyroid-stimulating hormone (TSH) has recently been described. The device can be used with serum, plasma, or whole blood samples and, in 10 minutes, can detect TSH levels greater than 5 or 15 μIU/ml in adult and paediatric samples, respectively.

NPTs in microbiology

A range of NPTs are available for microbiological applications in general practice. Small microscopes have microbiology (and haematology) applications, and several small desktop analysers are available to determine markers of infection, such as ESR and CRP.

A very wide and increasing number of non-instrumental systems are available for microbiology applications. These include multiple dry chemistry urine dipsticks and disposable immunoassay-based systems.

Infectious diseases (B1)

Latex agglutination tests (based on specific antibodies or antigens) have been available for some time to aid diagnosis of infectious diseases. Assays for a range of analytes are available, in which suspensions of coated latex particles are mixed with the sample and any agglutination is visually assessed.

There has recently been an increase in the number of disposable immunoassay kits for markers of infectious disease. These are based on flow-through or flow-along immunochromatography devices, where the presence of an analyte is indicated by the appearance of a coloured marker in the form of a simple line or symbol. These forms of assay have been adapted in a series of formats (platforms and dipsticks), for a range of specimens, including urine, whole blood, serum/plasma, swab extracts, faeces and saliva.

In subsections of Appendix 3, details are given of the assay systems available for antibodies to HIV 1 and 2, hepatitis B antigens and antibodies, and antibodies against *H. pylori* in blood samples. A range of assays for streptococcus group A and B antigens, and Chlamydia antigen in swab samples are also grouped together. The final, non-instrumental section of Appendix 3 is a list of assays for antibodies to TB, infectious mononucleosis, Mycoplasma and rubella, together with antigen assays for rotavirus, respiratory syncytial virus, adenovirus, herpes, influenza A and *Plasmodium falciparum*.

Urinalysis: multiple test strips (B2)

Urine dipsticks have been available for many years and are available in numerous combinations. Analytes that may be measured include leucocytes, nitrite, pH, specific gravity, proteins, blood, glucose, ketones, bilirubin, and urobilinogen. The dry reagent strips are dipped briefly into a urine sample, and the colour change produced is compared visually with the colour chart provided. Small instruments are also available to aid interpretation of the colour changes by taking readings from the reaction pads.

NPTs in haematology

General haematology (C1)

A limited number of non-instrumental immunoassay kits are available for the detection of haemoglobin variants (S, C and E) and analytes such as D-dimer. Several small desktop analysers are available to measure individual haematology parameters, including total haemoglobin, haematocrit, erythrocytes and ESR. Many desktop clinical chemistry analysers (A1) also include some of these in their range of tests.

One small desktop analyser, the QBC Autoread™, enables a series of haematology parameters to be measured simply from a capillary blood specimen. These include haemoglobin, haematocrit, mean cell haemoglobin concentration, platelet count, total white cell count, and absolute and percentage granulocyte and lymphocyte/monocyte ratios. These, plus additional tests, can also be performed in general practice on larger, standard automatic analysers that are more usually found in hospital laboratories.

Coagulation (C2)

A range of hand-held instrumental systems are now available for coagulation studies in general practice (C2). These range from systems for the determination of prothrombin time to those that are also capable of determining activated partial thromboplastin time, fibrinogen, thrombin time, intrinsic and extrinsic coagulation factors, and antibodies to streptokinase.

Summary

Recent technological advances have increased the number and capabilities of systems potentially available for use in NPT testing in general practice. The large number of systems which have been described and a few of the application areas are illustrated in Appendix 3. The number and type of systems available is expected to continue to increase significantly.

Chapter 4
Methods

Hypotheses tested in the review

This review covered an extremely wide field. The scarcity of reliable publications relating to any particular NPT meant that it was not feasible to test any specific hypothesis. A qualitative systematic review was therefore undertaken to explore the extent and strengths/weaknesses of the existing literature with the following aim:

- **to identify all the published literature relating to the field of NPT, EDI (links) and CDDS in primary care.**

These would include papers on performance, quality control, impact and cost-effectiveness across a wide range of technologies.

Inclusion criteria and definitions

The review panel was obliged to formulate definitions for the main topics covered by the systematic review, because there were no formal or internationally-accepted definitions of these.

Primary care

Any medical practice taking place in a community rather than a hospital setting and representing the first point of contact with medical care for the patient. It includes GPs (as in the UK, Australia, New Zealand and The Netherlands), family practitioners and primary care physicians (as in USA) and family medicine (as in Canada).

Near patient test

An NPT is any pathology testing performed outside a hospital laboratory where the result is available without the sample being sent to a laboratory for analysis.

Computerised diagnostic decision support

CDDS is any computer program designed to give advice on the significance of results and their implications for subsequent patient management.

Electronic data interchange

EDI covers any transmission of results from laboratory to primary care settings using electronic links rather than paper mail. This category was originally termed GP–laboratory links and included alternative specimen delivery systems. Since no original data was obtained in this category, the term EDI was adopted for the whole category.

As explained later in the discussion, no method of transport, other than a physical connection between a laboratory and a nearby health centre, could offer the potential of some NPT systems for a patient to be given the result of a test during a consultation with the clinician. Comparisons between existing transport systems and NPT are to be found in the studies of the impact of desktop analysers.

Definitions used in determining the efficiency of the search strategy

Sensitivity

The proportion of the gold standard papers identified by each source. Sensitivity is also described, by some authors, as 'recall'. A source is defined as having high sensitivity if it identifies a high proportion of all the relevant articles.

Precision

The proportion of papers retrieved by each source that were actually gold standard papers. A source is defined as being precise if a high proportion of the papers that it identifies are relevant. Precision of searching is akin to estimates of specificity for diagnostic tests.

Gold standard

The collection of papers that was deemed by the critical review panel to relate to NPT in primary care. These papers were identified by a combination of hand-searching, electronic database searches and lists of references identified by people working in the field. The gold standard is our best possible estimate of the total number of papers relevant to this systematic review and it is against this gold standard that each individual source is measured in terms of sensitivity and precision.

Example

A systematic review was undertaken using two electronic databases, Medline and BIDS, and each identified 20 papers that appeared relevant to the review, giving a total of 40 references. Ten of the

papers were identified by both sources; hence, a collection of 30 different papers were available for review. Of these, the reviewers deemed 15 to be ineligible, leaving the 'gold standard' to be 15 papers. Twelve of these 15 papers were identified by the Medline search.

Sensitivity of Medline: 12/15 = 0.8
Precision of Medline: 12/20 = 0.6

Search strategy

In order to establish a comprehensive database of existing published literature in NPT, CDDS systems, specimen delivery systems and EDI in primary care, together with unpublished studies, reports of current research in progress, and workers active or interested in the various fields, the following strategy was employed.

Published literature

On-line computer searches, covering the period 1986–95, were undertaken using the databases listed below. Only one decade was selected for searching because NPT is a new and rapidly-evolving technology. Any of the few papers that might have been published before 1986 would now relate to obsolete equipment.

(i) Medline
(ii) BIDS (Bath Information and Data Service)
  (a) Science Citation Index
  (b) Index to Scientific & Technical Proceedings
(iii) Department of Health
(iv) Embase
(v) GPLit–Database at the Royal College of General Practitioners
(vi) CINAHL (Citation Index for Nursing and Allied Health Sociofile)
(vii) PsychLit

A strategy was devised, using the appropriate key words and combination of key words, for each search of these databases. These search strategies are listed in Appendix 6. The key words used in the literature search were as follows.

Near patient testing	near patient test point of care home test rapid test desktop technology desktop laboratory office laboratory set testing
Computerised decision support	computerised decision support expert systems
Family practice	family practice general practice primary (health) care physician's office
Electronic data interchange	electronic data interchange computer communication networks laboratory results services electronic links

A comprehensive examination of all the bibliographies from all the publications identified was undertaken to ensure that all relevant publications were included in the systematic review. The total number of publications was recorded from each literature database search. Cross-referencing of publications obtained from each database was undertaken to exclude duplication. The percentage of relevant papers exclusive to each database was recorded, together with the percentage of relevant papers found in one or more literature databases.

To determine the precision of the keywords used for the search strategy, a verifying search was carried out using BIDS and Medline. A random selection was made of 33% of the total number of papers selected for the review and published during the period 1992–96. Using Medline and BIDS, author names were used to establish whether any publications not identified by the initial searches were present in these databases. Any additional keywords to those used in the original search strategy were noted if any papers were identified. In addition, the bibliographies of randomly-selected papers were examined to determine the number of papers in which technical reports were cited.

For purposes of data handling, a database (Microsoft Access 2™) was constructed. The fields coded and the results for each paper are shown in Appendix 1.

Unpublished work

Personal networking of collaborators, known to be active or interested in the field of NPT, CDDS and EDI was undertaken. Also, a comprehensive international postal survey, incorporating a questionnaire and explanatory letter was sent to the following.

- Heads of academic departments of general practice and clinical chemistry in the UK.

- Researchers world-wide known to be active or interested in the field of NPT or CDDS. This information was obtained by examining published abstracts, from 1986 (where available) until September 1995, of the major international primary care scientific conferences (World Organisation of National Colleges, Academies and Academic Associations of General Practitioners/Family Physicians, North American Primary Care Research Group, Association of University Departments of General Practice, and Department of Health Workshops).
- Further names of workers in the field were obtained from responses to the initial mailing of the questionnaires.

The additional information was incorporated into the database, together with the names of other workers active or interested in the field of NPT, CDDS and EDI, and the publications obtained from the postal survey.

Bibliographies from all these sources were examined to ensure that no relevant publications were excluded or overlooked. Examination of the bibliographies from all relevant publications yielded a small number of references to papers published before 1986. It was therefore decided that certain pertinent pre-1986 publications should be included in the database, if they were considered to represent important data (principally within the area of CDDS).

Commercial data

A questionnaire, together with an explanatory letter, was sent to commercial organisations known to have an interest in NPT or CDDS. The names of these commercial organisations were obtained by personal contact, from trade conference exhibitions, advertisements in commercial journals and publications, and product literature.

The additional information, including publications and names of other workers in the field of NPT or CDDS, obtained from these commercial sources was incorporated into the database. Further questionnaires were sent to any workers whose names were obtained from the original survey.

The bibliographies of all publications obtained from commercial sources were examined; any publications pertaining to any of the three areas of interest were obtained and included in the database.

Trade conference exhibitions studied included those associated with meetings organised by the following.

- American Association for Clinical Chemistry
- Association of Clinical Biochemists
- Institute of Biomedical Sciences
- International Federation of Clinical Chemistry
- British Diabetic Association

The following publications associated with NPT systems were hand-searched.

BioTech Products International; Clinica; Clinical Laboratory International; Clinical Laboratory News; European Clinical Laboratory; European Medical Device Manufacturer; International Hospital Equipment; International Labmate; Lab Products International; Laboratory Equipment Digest; Laboratory News; Laboratory Products Technology; Laboratory Product Update; Medical Laboratory World; UK Product Review.

Assessments of relevance of publications

All the publications obtained from these sources were examined independently by two internal assessors who had expertise, experience and had published original research in the field of NPT or CDDS. Conflicts in their blinded interpretations were discussed by the whole steering group. Foreign language papers and papers that did not describe NPT, CDDS or EDI, or were not based in primary care were excluded. All publications meeting the agreed definitions and reporting original data (thereby excluding most letters, abstracts and advertising material) were sent to external reviewers. The selected publications were grouped according to type of test and likely clinical application.

The papers excluded fell into one of five categories:

(i) not NPT
(ii) not based in primary care
(iii) not a **diagnostic** decision support system
(iv) not EDI
(v) foreign language paper.

Assessments of validity of publications

The external review panel comprised expert workers from academic departments, commercial and non-commercial sources who were active or interested in

the field of NPT or CDDS, and were willing to participate in the review. This panel was formed by personal contact and information derived from the postal surveys (see Appendix 7 for details).

The internal review panel comprised academic members from within the Department of General Practice at the University of Birmingham (clinical and non-clinical, with fundholding and non-fundholding experience), plus a laboratory scientist, a public health academic and a health economist.

Each paper was reviewed twice, by an internal and an external reviewer. Each member of **both** review panels was sent an average of four papers for assessment. A standard proforma (see Appendix 6), derived from the worksheet on appraising a diagnostic test paper used by the Evidence-Based Medicine Working Group and published in the User's Guides to Medical Literature, was adopted for the review process and sent with each paper to each member of both review panels. The first five criteria aimed to assess the validity of each paper. Reviewers scored each paper, awarding one point if the paper fulfilled each criteria and no points if the paper failed the criteria or the paper provided insufficient information to assess whether the criteria was fulfilled. This review process resulted in an overall score by each reviewer, for each paper, ranging from 5 (most reliable papers) through to 0 (poor methodology).

The level of agreement between the internal and external reviewers has been measured using kappa (κ) scores. The value of κ is 1.0 when agreement is perfect and zero when the observed level of agreement is no better than chance, negative values indicating a worse-than-chance agreement. This statistic is by no means a perfect indicator of inter-reviewer agreement as the value of κ is strongly influenced by the proportion of papers in each category. However, this statistic is most commonly used for describing inter-rater reliability and is more appropriate than measures of the linear association between the scores.

After the main review process had been completed, a further six papers for inclusion were identified. Due to the time factor, these remaining papers were reviewed independently by two members of the internal review panel.

The responses to the critique from both Review Panels were coded and entered into the database accordingly. A comparison was made of the scores given to high scoring papers (4 or 5) by both review panels. Papers in which any discrepancy of scoring occurred between the two review panels were re-examined in a blinded fashion by two members of the steering group to determine the final score. The publications scoring highly on the methodological assessment were further independently appraised by a member of the steering group with extensive experience in undertaking systematic reviews. All publications in which a cost analysis was included were further independently evaluated by the health economist member of the steering group.

Development of the health economics proforma

The health economics proforma developed for this study addressed the following issues.

- Was a clear question addressed?
- Was the question answered?
- Was the need for evaluation justified?
- Were the patient entry criteria stated and appropriate?
- What was the method of analysis?
- Was a cost measurement included?
- Was a benefit measurement included?
- Was a satisfaction measurement included?
- Was a sensitivity analysis performed?
- Was discounting considered?
- What comparisons were made?
- Were any vested interests declared (or not)?
- Did the conclusions follow from the results of the analysis?

Chapter 5

Overall results

The 13 sources searched yielded 1057 unique references potentially eligible for inclusion in the review (see *Table 1*). The largest number of references possibly relevant for inclusion in the review were identified from Medline (n = 335, 32%), followed by questionnaires sent to people known to be working in the field (n = 200, 19%). The Department of Health and PsychLit databases each identified less than 2% (n = 1057).

TABLE 1 *Total number of potential references identified by source*

Source	Number	Percentage (n = 1057)
Medline	335	31.7
Questionnaires	200	18.9
BIDS	185	17.5
Department academics	142	13.4
References	129	12.2
CINAHL	48	4.5
Abstracts	44	4.2
Embase	40	3.8
Index to Conference Proceedings	32	3.0
Reports	29	2.7
GPLit	26	2.5
DHSS	18	1.7
PsychLit	10	0.9
Unique references	1057	100

A maximum of three sources, for each of the references identified, have been recorded on the database (see *Table 2*). Most references (n = 911, 86%) were identified by only one of the 13 sources; 111 references (11%) were identified by two sources, and 35 (3%) were identified by three or more sources. Over half (n = 580, 55%) of the potentially relevant references were identified by at least one of the eight electronic databases searched, 32% by people working in the field and less than 20% from hand-searches of abstracts, references and reports.

Cases excluded from the systematic review

An internal review, by two of the internal assessors, of the 1057 papers identified as potentially eligible for inclusion, resulted in 657 (62%) being excluded as not relevant (see *Table 3*). A further 298 (28%) papers were deemed to be relevant to the field of NPT, CDDS or EDI in the area of primary care but were excluded from the critical review process as they contained no original data.

Therefore, only 102 (10%) of the publications identified were finally included in the systematic review, illustrating the difficulty of undertaking a comprehensive literature review in this area, where there are no standard keywords or index terms. Papers excluded from the critical review process were further classified (see section below on the efficiency of sources of references).

TABLE 2 *Total number of potential references identified by broad source*

First source	Second source	Third source	Number
Electronic database	–	–	454
Electronic database	Electronic database	–	65
Electronic database	Electronic database	Electronic database	17
Electronic database	Electronic database	References in reports and abstracts	6
Electronic database	Electronic database	Working in field	8
Electronic database	References in reports and abstracts	–	5
Electronic database	References in reports and abstracts	Working in field	2

continued

TABLE 2 contd *Total number of potential references identified by broad source*

First source	Second source	Third source	Number
Electronic database	Working in field	–	22
Electronic database	Working in field	Working in field	2
References in reports and abstracts	–	–	172
References in reports and abstracts	Working in field	–	17
Working in field	–	–	285
Working in field	Working in field	–	2

TABLE 3 *References excluded from review by reason*

Reason	Number	Percentage
Not NPT	87	9
Not primary care	136	14
Not primary care or NPT	3	0.3
Not CDDS	97	10
Not NPT or CDDS	16	2
Not EDI	7	1
Foreign language	29	3.0
Not primary care, NPT or CDDS	282	29.5
Subtotal	657	
Relevant publication but no original data	298	31
TOTAL	955	

Cases included in the review: summary of findings

In *Tables 4* and *5*, the numbers of references identified from each source are shown, together with the proportion of relevant references that each source identified. Sources have been ranked to denote those sources that identified the greatest proportion of relevant papers. Although eight electronic databases were used, only three of these (Medline, BIDS, Embase) identified any references that met the inclusion criteria (see *Table 4*). The most productive sources of eligible references were: the BIDS database which provided 32 (31%); questionnaires sent to people working in the field (n = 24, 24%); hand-searches of references (n = 24,

TABLE 4 *Number of included references by source*

Source	Number	Percentage (n = 102)	Rank
BIDS	32	31	1
Questionnaires	24	24	2=
References	24	23	2=
Medline	20	20	4
Department academics	18	18	5
Embase	11	11	6
Reports	7	7	7
CINAHL	0	–	–
DHSS	0	–	–
PsychLit	0	–	–
Abstracts	0	–	–
Index to Conference Proceedings	0	–	–
GPLit	0	–	–
Unique references	102		

TABLE 5 *Number of included references by broad source*

Source	Number of citations	Number of unique references	Percentage (n = 102)
Electronic databases	63	50	49
People working in the field	42	40	39
References and reports	31	31	30
Unique references	102	102	

23%); and the personal knowledge of academics based within the Department of General Practice at the University of Birmingham (n = 11, 11%). These four sources yielded 83% of references included in the review. The inclusion of the results of the Medline search provided nearly 94% of the relevant papers (see *Table 6*).

BIDS and hand-searches of the citation lists of references identified from the electronic database searches or questionnaire responses, identified over half (54%) of all the publications included in the review. Almost half of all the references included in the review (n = 50, 48%) were identified by just three of the electronic databases; almost 40% of relevant publications were submitted to the steering group by people working in the field; and almost one-third of references (30%) were identified from hand-searches of bibliographies of relevant papers and reports (see *Table 5*).

The electronic databases identified 63 citations (BIDS = 32, Medline = 20, Embase = 11). However, there was duplication between these databases in the references identified, each reference being identified on average by 1.3 electronic sources (see *Table 5*), that is, 27% of those references identified from searches of electronic databases were identified by more than one of the databases. In contrast, there was almost no overlap of interests with references identified by people working in the field. Hand-searches of references and reports yielded no duplicates as the references already selected were deliberately not re-selected.

Routine literature searches are sometimes completed only by accessing the commercially available databases. The BIDS database was found to be the most effective of the eight electronic sources used in identifying relevant publications for this review; however, this database alone identified only 31% of relevant publications. A systematic review based only on papers identified from the electronic databases would only have included 49% of papers relevant to this field (see *Table 5*).

Although a literature review based only on the four most productive sources would have yielded 83% of the publications included in this review, it is important to note that only one of the four sources is routinely available (BIDS). A literature review based only on the awareness of those working in the field (results from questionnaires and departmental academics) and citations from known publications would have yielded 54 (53%) relevant publications. However, a survey of people working in the field is not a source of references routinely available to researchers.

Type of reference

The 102 studies eligible for review were classified by the type of references (*Table 7*). The vast majority of references included (96%) are papers from academic journals. Only four publications that contained original data were not journal articles.

Subject category

Twelve categories were designed to describe the subject matter of each reference (see *Table 8*). Almost 90% of the papers identified for inclusion in the critical review related to NPT (n = 92, 90%), 8% to CDDS, and only 2% to EDI.

Most publications containing original data related to NPT were in the area of microbiology (n = 92, 26%) followed by desktop analysers (22%) and diabetes (16%). No publications with original data were identified addressing the use of NPT for HIV, and very few publications related to other biochemical tests, skin tests or cancer screening.

TABLE 6 *Number of additional included references by source*

Source	Number of additional references identified	Percentage (n = 102)	Cumulative number of references identified	Percentage (n = 102)
BIDS	32	31	32	31
References	23	22	55	54
Questionnaire	19	19	74	72
Department academics	11	11	85	83
Medline	11	11	96	94
Embase	5	5	101	99
Reports	1	1	102	100

TABLE 7 *Number of included references by type*

Reason	Number	Percentage (n = 102)
Paper	98	96
Report/discussion paper	2	2
Letter	1	1
Short communication	1	1
TOTAL	102	

TABLE 8 *Number of cases included by subject category*

Category	Number	Percentage
NPT/Clinical chemistry – other	2	2
NPT/Desktop analysers	20	20
NPT/Lipids	8	8
NPT/Diabetes	15	14
NPT/Haematuria	4	4
NPT/Pregnancy test	5	5
NPT/Allergy test	2	2
NPT/Haematology	12	12
NPT/Microbiology	24	23
NPT/HIV	–	0
NPT/Review	1	1
CDDS	8	8
EDI	2	2
TOTAL	102	

Year of publication

The review concentrated on papers published during the period 1986–95 (94% of selected references), although important publications as early as 1977 have been included (*Table 9*). The use of computers in clinical practice, and the availability of diagnostic technology for use outside hospital laboratories, is a recent phenomenon. However, limiting the main search to the past decade still produced over 1000 references which needed to be scrutinised. The number of relevant publications has increased since 1988, illustrating the increasing interest in this field and the growth of new technologies requiring evaluation. It is probable that the number of publications identified for 1994–95 is artificially low because of delays in indexing publications for electronic databases *(Table 10)*.

TABLE 9 *Number of references per quinquennia*

Years	Number
1976–80	2
1981–85	4
1986–90	40
1991–95	56
TOTAL	102

TABLE 10 *Number of references per year*

Years	Number
1977–79	1
1980–85	5
1986	5
1987	9
1988	8
1989	12
1990	6
1991	12
1992	11
1993	16
1994	9
1995	8
TOTAL	102

Journals

Potential references for inclusion in this review were selected from 418 different sources illustrating the diverse interests of people working within the field of NPT, and the lack of a specific journal with an interest in this field. Relevant references were found in only 47 (11%) publications. A total of 44 (92%) sources of relevant publications were journals, one was a book, two were conference proceedings and one was a discussion paper (see *Table 11*).

Most of these sources contained only one relevant publication (n = 27, 63%). Eight sources contained two relevant publications (17%), seven contained three (15%), and five or more relevant publications were found in only 10% of the sources accessed.

TABLE 11 *Number of included references per journal*

Journal	No	%	Journal	No	%
Academic Emergency Medicine	1	1.0	*Journal of the American Board of Family Practice*	1	1.0
Addiction	1	1.0	*Journal of the American Medical Association*	6	5.8
American Journal of Clinical Pathology	3	2.9	*Journal of General Internal Medicine*	1	1.0
American Journal of Obstetrics & Gynecology	1	1.0	*Journal of Clinical Pathology*	5	4.8
American Journal of Public Health	1	1.0	*Journal of Family Practice*	3	2.9
Annals of Allergy, Asthma & Immunology	1	1.0	*Journal of Pediatrics*	1	1.0
Annals of Clinical Biochemistry	2	1.9	*Journal of Reproductive Medicine*	1	1.0
Annals of Internal Medicine	1	1.0	*Journal of Urology*	3	2.9
Archives of Internal Medicine	3	2.9	Proceedings (unspecified)	2	1.9
Archives of Pathology & Laboratory Medicine	1	1.0	*The Lancet*	2	1.9
British Journal of General Practice	3	2.9	*Medical Journal of Australia*	2	1.9
British Journal of Obstetrics & Gynaecology	1	1.0	*Medical Laboratory Sciences*	2	1.9
British Medical Journal	11	11	*New Zealand Medical Journal*	1	1.0
Canadian Medical Association Journal	1	1.0	*Occupational Medicine*	1	1.0
Cancer	1	1.0	*Pediatric Infectious Disease Journal*	2	1.9
Centre for Health Economics, York Univ: Paper	1	1.0	*Practical Diabetes*	1	1.0
Clinical Chemistry	10	9.6	*Research in Clinic & Laboratory*	1	1.0
Clinical & Laboratory Haematology	2	1.9	*Scandinavian Journal of Clinical Lab Investigation*	2	1.9
Clinical Therapeutics	1	1.0	*Scandinavian Journal of Infectious Diseases*	2	1.9
Computers in Biology & Medicine	1	1.0	*Scandinavian Journal of Primary Health Care*	5	4.8
Diabetic Medicine	3	2.9	*Therapeutic Drug Monitoring*	1	1.0
European Journal of Clin Chem & Clin Biochem	1	1.0	*Thrombosis & Haemostasis*	1	1.0
Family Practice	3	2.9	Clinical biochemistry nearer the patient II. Marks V, Alberti KGMM, editors[24]	1	1.0
Immunology & Allergy Practice	1	1.0			
			TOTAL	102	

The only journal in which more than 10% of relevant publications were found was the *British Medical Journal* (n = 11); the next most common source of relevant publications was *Clinical Chemistry,* from which ten papers were identified. American journals were the source of 12 papers included in the review, and nine papers were found in Scandinavian journals.

Efficiency of sources of references

Thirteen different reference sources of were used to identify papers relevant for inclusion in this review (see *Tables 12* and *13*). The relative efficiency of each of these sources can be summarised by estimating sensitivity and precision.

Efficiency by source

Of the 1057 publications identified, only 400 were relevant to the subject of this review, giving an overall precision of 38% for our search criteria. For the purposes of the critical review, only papers that contained original data were included (n = 102), and this reduced the precision of searching to 10%.

The efficiency of the various sources varied considerably in the sensitivity and precision with which relevant papers were identified and in the proportion of the total review data-set identified by each

TABLE 12 *Number of references identified and included by source*

Source	Number of references identified	Number eligible for inclusion in review	Sensitivity (Eligible/Total)	Precision (Eligible/Identified)
BIDS	185	32	0.31	0.17
Questionnaires	200	24	0.24	0.12
References	129	24	0.24	0.19
Medline	335	20	0.20	0.06
Department academics	142	18	0.18	0.13
Embase	40	11	0.11	0.28
Reports	29	7	0.07	0.24
CINAHL	48	0	–	–
DHSS	18	0	–	–
PsychLit	10	0	–	–
Abstracts	44	0	–	–
Index to Conference Proceedings	32	0	–	–
GPLit	26	0	–	–
TOTAL – unique	1057	102		0.10

TABLE 13 *Number of references identified and included by broad source*

Source	Number of references identified	Number eligible for inclusion in review	Sensitivity (eligible/total)	Precision (eligible/identified)
Electronic databases	581	50	0.49	0.09
People working in the field	338	40	0.39	0.12
References, reports & abstracts	202	31	0.30	0.15
TOTAL – unique	1057	102		0.10

source (see *Table 12*). Although the Medline database contained the largest number of references potentially relevant to this review (n = 335), only 6% (n = 19) were eligible for inclusion in the review. The most sensitive individual source was the BIDS database, from which 31% (n = 32) of the 102 relevant publications were identified. However, these 32 publications were only 17% of the 185 potential publications found by this source. The most precise source of references was hand-searching the citation lists included in pertinent reports, with seven of 29 references found being eligible for inclusion in the critical review (precision: 24%). However, these hand-searches only achieved a sensitivity of 7%.

The Medline database contained 90 papers relevant to the subject of the review (sensitivity: 22%, precision: 8.5%), although only 20 of these contained original data and were eligible for inclusion in the critical review (sensitivity: 19%, precision: 6%) (see *Table 12*). Our results are at the lower range of those reported by a previous review of Medline (searching for randomised controlled trials) in which the sensitivity of Medline was reported as ranging from 17–82% (weighted mean of 51%) and the precision from 2–82% (weighted mean 33%), depending on the subject. The low precision and sensitivity of the searches of the eight electronic databases taken together (overall sensitivity: 49%, precision: 9%) again confirm the lack of common indexing terms in this area. The references suggested by people working in the field and identified by hand-searching the citation lists of publications (521 unique references identified, 63 relevant) have a sensitivity of 62% and a precision of 12%.

Searches of the GPLit, PsychLit, CINAHL and BIDS Index to Conference Proceedings electronic databases found no references that were both relevant and contained original data; these databases could have been excluded from the search without loss.

Efficiency by subject category

In all, 1057 references were identified as potentially eligible for inclusion, of which 657 (62%) were excluded as not relevant to the subject. Of the remaining 400 papers, review articles in the area of NPT (n = 103, 26%) was the most common subject category *(Table 14)*. The next largest group of potential references were in the area of CDDS (n = 67, 17%) and, again, few of these papers contained original data (n = 8, 12%). The best source of relevant publications, by subject matter, related to NPT in the areas of other biochemical tests, cancer screening and skin tests, where all the potential papers identified contained original data and could be included in the critical review. None of the nine papers concerned with NPT for HIV and only two of the 25 papers relating to EDI contained original data (see *Table 15*).

Results by year

The number of publications potentially eligible for inclusion increased by 75% in the two quinquennia of this review (625 in 1991–95 versus 357 in 1986–90). However, the proportion of papers found to be not directly relevant also increased (58.5% for 1986–90, 64% for 1991–95) and the proportion of potential publications that related to the review and contained original data reduced correspondingly from 11% in the first quinquennia to 9% in the second (see *Table 16*).

Verification of the search terms

In order to verify the search terms used, a random sample of 14 of the 43 (33%) relevant papers published between 1992 and 1996, were selected to check the comprehensiveness of the search criteria. Checking was restricted to the two most commonly used electronic databases, Medline and BIDS. *Table 17* shows the identification numbers of the selected papers, the sources of the papers and whether the paper could be found on Medline and BIDS when the search was by first author. The final column indicates any key words or MeSH subject headings used for papers that were not identified on Medline and/or BIDS during the initial searches of these databases.

The original searches undertaken for this review identified nine (64%) of these 14 papers from the BIDS database and only three (21%) on Medline. Searching by first author confirmed that all 14 papers were present on Medline and 13 (93%) were on BIDS. The MeSH headings used for the ten papers not identified by the original search are diverse and tend to be disease/condition-specific. No MeSH headings that could usefully be added to the overall search criteria were identified.

A Medline search (1992–96) was undertaken to identify how many potential papers would have been obtained if the additional search terms,

TABLE 14 *Number of references by type*

Paper type	Identified	Excluded: not relevant	Excluded: no new data	Review
Paper	483	255	130	98
Abstract	110	29	81	–
Letter	45	18	26	1
Report/Discussion paper	41	24	15	2
Editorial	33	13	20	–
Short communication	24	5	18	1
Book	10	5	5	–
Poster	5	2	3	–
Correction	1	1	–	–
Not classified	305	305	–	–
TOTAL	1057	657	298	102

TABLE 15 *Number of cases per subject category*

Category	Identified	Excluded: not relevant	Excluded: no new data	Review
NPT/Clinical chemistry – other	2		–	2
NPT/Desktop analysers	40		20	20
NPT/Cholesterol	17		9	8
NPT/Diabetes	39		24	15
NPT/Haematuria	4		–	4
NPT/Pregnancy tests	9		4	5
NPT/Allergy tests	2		–	2
NPT/Haematology	28		16	12
NPT/Microbiology	55		31	24
NPT/HIV	9		9	–
NPT/Reviews	103		103	–
CDDS	67		59	8
EDI	25		23	2
Not relevant	657	657		
TOTAL	1057	657	298	102

TABLE 16 *Number of cases per year of publication*

Year	Identified	Excluded: not relevant	Excluded: no new data	Review
1960–69	3	3	–	–
1970–74	5	3	2	–
1975–79	8	6	1	1
1980–81	14	10	3	1
1982–83	11	6	4	2
1984–85	24	16	5	3
1986	60	29	26	5
1987	69	39	21	9
1988	60	38	14	8
1989	78	48	18	12
1990	90	55	29	6
1991	107	79	16	12
1992	105	72	22	11
1993	148	84	48	16
1994	155	100	46	9
1995	110	65	37	8
1996	4	2	2	–
Not classified	6	2	4	–
TOTAL	1057	657	298	102

TABLE 17 *Verification of search terms and MeSH headings not in the original search*

Paper identity	Original source(s)	Verification Medline	BIDS	Key words/MeSH subject headings not in original search	
8	BIDS	✔	✔	*MeSH*	False negative reactions Gonadotropins, chorionic Pregnancy/pregnancy tests Quality control Reagent kits, diagnostic Self care
142	Medline/BIDS	✔	✔		
144	Medline/BIDS	✔	✔		
182	Embase	✔	✘	*MeSH*	Blood sedimentation C-reactive protein Diagnosis, differential Leukocyte count Pharyngitis Physical examination Predictive value of tests Regression analysis Reproducibility of results Sensitivity/specificity Streptococcal infections/pyogenes
286	Medline	✔	✔	*BIDS*	Knowledge
428	BIDS Questionnaire Academic	✔	✔	*MeSH*	Blood sedimentation C-reactive protein Evaluation studies Family practice Inflammation Reagent strips Reference standards Sensitivity/specificity
429	BIDS	✔	✔	*MeSH*	Adenocarcinoma Bladder neoplasms Carcinoma, transitional cell Costs/cost analysis Follow-up studies Haematuria Kidney calculi Mass screening Neoplasm invasiveness/staging Prostatic neoplasms Reagent strips Reproducibility of results Self care Urinary tract infections
438	BIDS	✔	✔	*MeSH*	Antibodies, monoclonal Enzyme-linked immunosorbent assay Fibrin/fibrinogen degradation products Filtration Immunohistochemistry Latex fixation tests Predictive value of tests Prospective studies Reagent kits, diagnostic Reproducibility of results Sensitivity/specificity Thrombophlebitis

continued

TABLE 17 contd *Verification of search terms and MeSH headings not in the original search*

Paper identity	Original source(s)	Verification Medline	BIDS	Key words/MeSH subject headings not in original search	
449	Reference	✔	✔	*BIDS* *MeSH*	Prothrombin time/capillary Anticoagulants Haematology Monitoring, physiological Photometry Reference values Reproducibility of results
450	Reference	✔	✔	*BIDS* *MeSH*	Different intensities Warfarin therapy Administration, oral Anticoagulants Drug monitoring Equipment design Feasibility studies Prothrombin time Questionnaires Self care
467	BIDS Academic	✔	✔	*MeSH*	Bilirubin Blood glucose Evaluation studies Glucose dehydrogenases Haematocrit Photometry Quality control Triglycerides
779	BIDS Questionnaire	✔	✔	*MeSH*	Blood chemical analysis England Family/group/private practice Predictive value of tests
828	BIDS	✔	✔	*MeSH*	Albuminaria, diagnosis/urine Diabetes mellitus Evaluation studies False positive reactions Nephelometry/turbidimetry Predictive value of tests Reagent kits, diagnostic
1151	Reference	✔	✔	*BIDS* *MeSH*	No key words Diabetes mellitus Monitoring Self care Triglycerides/blood

identified above, had been included in the search strategy. The total number of references that occurred for this 5-year period, indexed according to these additional MeSH subject terms, was 935,296 (see *Table 18*).

In addition, electronic literature searches were carried out using commercial names of the systems cited in the reviewed papers. A list of all NPTs used was produced and each unique system (and its corresponding paper) was given a reference number, from 1 to 46. Ten of these reference numbers were chosen at random. For each of them, a search was carried out on Medline for the years 1965–96 and on BIDS for 1981–96, searching for the title and abstract. The lists of references thus produced were searched for the particular paper included and for papers not found in the original searches.

TABLE 18 *Results of Medline search (1992–96) when additional terms were included*

MeSH terms	Number	MeSH terms	Number
False negative reactions	1471	Administration, oral	10,456
Gonadotropins, corionic	2564	Anticoagulants	–
Pregnancy	51,275	Drug monitoring	1340
Pregnancy tests	120	Equipment design	7000
Quality control	2998	Feasibility studies	2023
Reagent kits, diagnostic	1161	Prothrombin time	692
Self care	1474	Questionnaires	14,293
		Self care	–
Blood sedimentation	510	Bilirubin	1310
C-reactive protein	988	Blood glucose	9213
Diagnosis, differential	25,916	Evaluation studies	–
Leukocyte count	5777	Glucose dehydrogenases	58
Pharyngitis	538	Haematocrit	2523
Physical examination	2062	Photometry	–
Predictive value of tests	9125	Quality control	–
Regression analysis	12,044	Triglycerides	4720
Reproducibility of results	15,960		
Sensitivity/specificity	19,527		
Streptococcal infections	2305		
Streptococcal pyogenes	1167		
Blood sedimentation	–	Blood chemical analysis	969
C-reactive protein	–	England	5145
Evaluation studies	15,283	Family practice	–
Family practice	6657	Group practice	230
Inflammation	3924	Predictive value of tests	–
Reagent strips	237	Private practice	641
Reference standards	2263		
Sensitivity/specificity	–		
Adenocarcinoma	10,623	Albuminuria, diagnosis	50
Carcinoma, transitional cell	1789	Albuminuria, urine	109
Costs/cost analysis	2896	Diabetes mellitus	4732
Follow-up studies	45,254	Evaluation studies	–
Haematuria	737	False positive reactions	2284
Kidney calculi	1063	Nephelometry/turbidimetry	448
Mass screening	6156	Predictive value of tests	–
Neoplasm invasiveness	4271	Reagent kits, diagnostic	–
Neoplasm staging	9275		
Prostatic neoplasms	5923		
Reagent strips	–		
Reproducibility of results	–		
Self care	–		
Urinary tract infections	1919		
Antibodies, monoclonal	23,107	Diabetes mellitus	–
Enzyme-linked immunosorbent assay	13,192	Monitoring, physiological	–
Fibrin/fibrinogen degradation products	540	Self care	–
Filtration	924	Triglycerides, blood	548
Immunohistochemistry	25,602		
Latex fixation tests	403		
Predictive value of tests	–		
Prospective studies	31,489		
Reagent kits, diagnostic	–		
Reproducibility of results	–		
Sensitivity/specificity	–		
Thrombophlebitis	2023		

continued

TABLE 18 contd *Results of Medline search (1992–96) when additional terms were included*

MeSH terms	Number	MeSH terms	Number
Anticoagulants	2046		
Haematology	271		
Monitoring, physiological	4093		
Photometry	302		
Reference values	19,620		
Reproducibility of results	–		

The Medline search yielded eight out of the ten papers. Those missed were for Hemastix™ and Daisy 2™, where neither the title nor abstract contained the commercial name. The BIDS search was less successful, finding only four out of ten papers. The remaining two papers not found by Medline were also missed by BIDS, and two other searches were unsuccessful due to the publication date being outside the range covered by the BIDS database. The final two papers not found contained the commercial name in the abstract; however, further searching showed that BIDS does not hold the abstracts of these two papers and it was therefore not possible to locate them.

The lists of references obtained from this literature search were examined to discover whether there were any papers not found with the original search criteria. The ten terms searched via Medline gave 372 references in total, 352 of them unique. A total of 33 papers had already been found, leaving 329 additional references. The BIDS search gave 503 references, 497 of them unique. Of these 23 were previously found giving 474 additional references to these products. The large number of additional references is accounted for by many of them being irrelevant to the subject of the review. Others were not in a primary care setting or were written in a foreign language. For example, using the search term Daisy for the Daisy 2 test gave 47 references from Medline and 161 from BIDS. Closer inspection showed that almost none of the papers had any relevance and were on a wide range of topics from protective gloves to dental practice. No BIDS papers and only two Medline papers on the subject of pregnancy tests were found.

In order to determine any potential bias in not having foreign language papers translated, the titles and abstracts (where available) of the 29 papers in this category were examined to determine the significance of omitting these papers. Five papers were found which could have been included in the review, all relating to the evaluation of the diagnostic performance of an NPT; a French–Canadian evaluation of the Phiadirect *Streptococcal A*™ test (Razongles & Bastien, 1993), a Danish evaluation of the Reflotron (Staehr *et al,* 1991), and three papers (in Dutch) from the Maastricht group (Accumeter glucose (Tersmette *et al,* 1995), ESR (Dinant *et al,* 1988) and Reflotron Cholesterol (Hamer-van Lange *et al,* 1992)). A final report from the ESR study has been published in an English language journal and is included in this review (Dinant *et al,* 1989). It is unlikely that the inclusion of these five papers would have altered the findings of this qualitative review, although their inclusion in any further, topic-specific quantitative reviews would be necessary.

Survey of unpublished material (grey literature)

In all, 342 questionnaires were circulated: 190 were sent to academics known to be working or to have published work on NPT, and 152 were sent to commercial companies believed to be active in this field (see *Table 19*). Overall, 45% of questionnaires were returned, 48% of those sent to academics and 35% of those sent to commercial companies.

Reliability in scoring between internal and external reviewers

Of the 102 papers eligible for inclusion in the critical review, 100 (98%) were reviewed by both an external and internal assessor. Each of the 92 papers relating to NPT was reviewed according to nine criteria, specified in a defined schedule (see Appendix 6).

The internal reviewers were more likely to record that the paper could not be assessed on the specific criteria than the external reviewers (see *Table 20*):

$$\chi^2_{(1df)} = 6.13,\ p < 0.05$$

The internal reviewers appeared more conservative in their scoring of the papers; nine (9.8%) papers

TABLE 19 *Questionnaire responses*

Category	Number mailed	Number returned	Percentage returned
Academics	176	85	48
Public health	10	4	40
Chemical pathologists	4	2	50
Commercial companies	152	53	35
Replies from people other than addressee		8	
Returned – not known at this address		2	
Total	342	154	45

TABLE 20 *Variation in coding criteria as 'not known' between internal and external reviewers*

Reviewer	Score		Total
	Not known	Known (Yes/No)	
Internal	77	383	460
External	51	409	460
Total	128	792	920
92 papers were reviewed on five criteria producing 460 individual scores ($\chi^2_{(1df)} = 6.13, p = 0.0132548$)			

TABLE 21 *Variation in scoring between internal and external reviewers*

Reviewer	Score			Total
	0	1–4	5	
Internal	9	77	6	92
External	4	80	8	92
Total	13	157	14	184
($\chi^2_{(2df)} = 2.27, p = 0.322$)				

were assessed as having an overall score of zero and only six (6.5%) were awarded the highest score of 5. In contrast, the external reviewers rated only four (4.3%) papers as having a score of zero and eight (8.7%) as having a score of 5 (see *Table 21*).

Inter-rater agreement, the ability of the different reviewers to classify papers according to these criteria, varied both in the individual paper under review and by criteria (see *Tables 22* and *23*). The proportional agreement rates were in excess of 50% for all five questions, ranging from 58% for Question 2 to 79% for Question 4. The overall κ score was 0.11, ranging from 0.13 for Question 2 to 0.41 for Question 3; poor agreement between reviewers was observed for Questions 2 and 5, fair agreement for Questions 1 and 4, and moderate agreement for Question 3. Although the overall κ score is only 0.11, indicating poor agreement between the reviewers, this is influenced by the number of categories (see *Table 23*). Only 27 (29.3%) papers were given exactly the same score by the internal and external reviewers. However, if scores plus or minus 1 were considered comparable, the proportional agreement rate rises to 77.2%.

TABLE 22 *Inter-reviewer agreement rates by question*

			Internal reviewer									
			Question 1 score		Question 2 score		Question 3 score		Question 4 score		Question 5 score	
			0	1	0	1	0	1	0	1	0	1
External reviewer	Question 1	0	2	14								
		1	14	36								
		%	69.6									
		κ	0.39									
	Question 2	0			19	17						
		1			22	34						
		%			57.6							
		κ			0.13							
	Question 3	0					23	13				
		1					13	43				
		%					71.7					
		κ					0.41					
	Question 4	0							6	6		
		1							13	67		
		%							79.3			
		κ							0.27			
	Question 5	0									64	10
		1									13	5
		%									75.0	
		κ									0.15	

%, proportional agreement rate (e.g. Question 4, reviewers agreed on 73/92 papers = 79.3%)
κ, kappa score

TABLE 23 *Inter-reviewer agreement rates by paper score*

		Internal reviewer						
	Paper score	0	1	2	3	4	5	TOTAL
External reviewer	0	2		1		1		4
	1	3	1	2	1	3		10
	2	2	3	6	10	1		22
	3	2	2	8	9	5		26
	4		3	3	3	8	5	22
	5			1	1	5	1	8
	TOTAL	9	9	21	24	23	6	92

Chapter 6

Review findings – NPT evaluations in primary care

The main purpose of this chapter is to report important parameters of the studies in the review and summarise the key results. The results of high quality papers are emphasised. However, many papers are composite and a paper may have received a high rating for one particular aspect, for example, test performance, whereas other aspects examining, for example, impact or effectiveness, may demonstrate a weak method which has very little validity. Results for any particular area are not summarised quantitatively, even if the results all say exactly the same thing. Since the number of studies is small, it would be unwise, for statistical reasons, to draw any overall conclusions.

Clinical chemistry NPTs

Clinical chemistry evaluations fall into two categories, desktop multi-analysers and technology related to the management of diabetes.

Desktop clinical chemistry multi-analysers

Eight commercially available analysers have been evaluated. These are: Reflotron™, Cholestech LDX™, Abbot Vision™, Ames Seralyzer™, Chrometrics cholesterol test system, Kodak DT-60™ (Ektachem DT™), Easy ST™ and i-Stat PCA™.

Quality control and performance

The Reflotron (Skinner *et al,* 1990; Ng *et al,* 1992), the Kodak DT-60 (Belsey *et al,* 1987) and the i-Stat PCA (Erickson & Wilding, 1993; Sands, 1995; Jacobs *et al,* 1993) have all been evaluated for precision in the laboratory setting.

Nanji and colleagues (1988a; b; c) have examined the accuracy of four analysers in a variety of settings, including an outpatient clinic, an intensive therapy unit (ITU) and a physician's office. The papers scored 3 on methodology, since confidence intervals were not quoted. They compared the results obtained by nurses, office personnel and doctors against the results obtained by trained medical technologists for standardised quality control samples provided by the manufacturers. The results are given as coefficients of variation for each test and as the percentage of results outside 10% of the standard. The results showed that nurses were more consistent in their results than either doctors or office personnel, and that the results for the two machines (the Seralyzer and DT-60) that did not require user-dependent steps such as pipetting or dilution, were significantly more accurate when used by non-technologists. The range of coefficients of variation for non-technologists was as follows: Reflotron, 2.4–7.9%; Seralyzer, 1.4–18.7%; Vision, 1.5–2.7%; DT-60, 2.5–46.8%.

Similar results were obtained by Belsey and colleagues (1987a; b) using the Kodak DT-60 and comparing the results obtained by medical technologists and family medicine residents. The authors noted that the average bias in the instruments obtained by non-trained personnel would be sufficient to affect clinical decision-making for many analytes.

Gottlieb and colleagues (1986) reported that the Ames Seralyzer performed satisfactorily when used by a dedicated medical technologist working in a primary care centre, but that the results were not obtained quickly enough for them to be available during a consultation.

The i-Stat PCA (portable clinical analyser) is a hand-held, disposable cartridge, whole blood analyser for sodium, potassium, chloride, glucose, urea and haematocrit. The analyser has been evaluated for reliability and accuracy for use by nurses in an emergency room and in an ITU in the USA. There have been no primary-care based evaluations but the analyser is included in this review because the technology may be appropriate in primary care in the UK. Tsai (1994) and Sands (1995) have both attempted to assess the impact of the i-Stat PCA system in secondary care settings, focusing, in particular, on the outcomes of: reduced turnround time for the test result; whether test results influenced decisions to admit or discharge patients; whether test results influenced treatment decisions; and, by inference, whether earlier availability of a result would have altered the time taken to make admission, discharge or treatment decisions. Tsai (1994) also made some attempt to include costs.

Unfortunately the designs of both studies, observational with no control groups, are very susceptible to bias and any results should be interpreted cautiously. One particular problem was that two of the main outcomes were based on a retrospective determination of the physician's decisions.

Impact evaluation

There have been four primary-care based comparative evaluations of desktop analysers (Leese & Hutton, 1989; 1990; National Health Technology Advisory Panel, Australia, 1991; Hobbs *et al,* 1992; Hilton *et al,* 1994). These evaluations were only able to score a maximum of 3 on the validity score as the score was designed for a single test performance evaluation, not for studies examining the impact of test availability on practice.

Leese and Hutton (1989) studied the effect of the availability of the Reflotron on test requests and costs in two practices in a before-and-after design. The tests available at the time were haemoglobin, glucose, cholesterol, urea, uric acid, amylase, triglycerides, gamma glutyrate transferase, AST and LDH. The results included the pattern of testing in two weeks before and during the week of Reflotron use, an assessment of therapeutic impact in terms of changed decisions and interviews with GPs. The most frequently requested tests (excluding microbiology and cervical smears) were for haemoglobin, glucose, ESR, urea and electrolytes, and thyroid function. As only haemoglobin, glucose and urea tests were available on the Reflotron, the GPs preferred to request all the tests from the laboratory if, for example, a white cell count or potassium measurement was needed. Of the tests available, GPs thought that glucose, haemoglobin and cholesterol were the most useful, and that a potassium test would be the most useful addition to the Reflotron's range.

Hobbs and colleagues (1992) evaluated the Reflotron, the Vision, the Ektachem and the Easy ST in six practices in a controlled trial for 3 months. Outcomes were the uptake of laboratory and NPTs, costs and staff views. Nurses performed 70% of the NPTs in this study; only 4.2% of the tests were performed as an emergency, with 79% of the testing being accounted for by screening activities, diabetic clinics and measurement of haemoglobin. Cholesterol, glucose and haemoglobin were again found to be the most frequently used tests; for these three tests there was a considerable increase in the level of testing during the NPT trial, accompanied by a slight decrease in laboratory usage. By the time of the trial, the Ektachem range of tests now included sodium and potassium, and these proved the sixth and seventh most requested tests overall. The ratio of quality controls to tests in the study approached unity in some practices, and thus had an adverse effect on the costs of NPT.

A smaller Dutch study (Gilio *et al,* 1993) examined the effect of Reflotron use on test requests in an 8-week prospective controlled trial of 16 single-handed GPs and two group practices. There was no increase in the overall number of tests in this trial but only 7.6% of the tests were performed on the Reflotron (n = 685).

Hilton and colleagues (1994) have carried out a larger study to evaluate four types of NPT, the Reflotron and Nova 1™ ion analyser (a small analyser for electrolytes alone, but including potassium, which at that time the Reflotron did not) being relevant here (the Multistix 8SG™ and the Clearview Chlamydia™ test are discussed elsewhere). The trial consisted of a prospective, cross-over design in twelve practices, with a 4-month run in period, 6 months of biochemistry and 9 months of microbiology NPT, or vice-versa. Cholesterol, haemoglobin and gamma glutyrate transferase tests were available on the Reflotron, and sodium and potassium on the Nova 1 ion analyser. All consultations, tests, reasons for tests and costs were recorded. Overall, there was a 16.5% increase in the rate of testing, with GPs tending to use NPT in addition to their usual use of a laboratory. The increase in electrolyte measurement was largely accounted for by increased monitoring for heart disease and hypertensive patients, the increased cholesterol testing by greater screening activity.

In an Australian study (Non-Laboratory Pathology Working Party, 1991), a cross-over controlled trial of five desktop analysers is reported (Seralyzer, Ektachem, Reflotron, Vision and the Hemocue™) in 28 general practices. The practices recorded all laboratory tests and analyser use for 3 months without NPT and for 3 months with NPT. The study also aimed to evaluate the detection of anaemia and the control of diabetes, gout and electrolyte imbalance in the practices. Only 22 of the 28 practices supplied data for analysis. The total number of patients studied is not documented but, during analyser use, it accounted for 36% of total test usage with cholesterol (23%), glucose (22%), triglycerides (17%), potassium (13%) and haemoglobin (11%) being the most commonly used tests. The study supports the findings of Hilton and colleagues (1994), with an overall increase (46%) in the total number of tests in the study period, but it also indicated a decrease in both biochemical

and haematological tests sent to the laboratory when the analyser was available (although this was not statistically significant). The study did not detect any increase in the rate of detection of anaemia, in the control of diabetes, (as judged by HbA1c), or in the number of patients with electrolyte imbalance or hyperuricaemia. It is not clear what the power of the study to detect alterations in the clinical management of patients would have been, as no power calculations are quoted.

Cholesterol-only NPTs

In six papers an evaluation of the accuracy of desktop analysers in measuring cholesterol in primary care or community screening settings was undertaken, although none of the papers scored more than 3 for methodology. Three of the studies used the Reflotron (Phillips *et al,* 1988; Sedor *et al,* 1988; Broughton *et al,* 1989). Phillips and colleagues in the top-scoring paper overall (4) found that the Reflotron compared similarly in accuracy (as judged by reproducibility of paired samples) to the laboratory system, when used by a trained operator in a hospital occupational health setting. Sedor and colleagues (1988) found a similar performance (as judged by a correlation coefficient) when the instrument was used by either trained technologists or high school students, but not when the capillary sample was taken by non-medical personnel. Broughton and colleagues (1989) found that testing of reference samples in general practice produced 1.3 times the dispersion of results compared with the hospital laboratory. They concluded that this was due to poor technique but did not report any evidence to support this; this paper only scored 1 on methodology.

Three other studies have examined the accuracy of several analysers in the same study; all of these papers scored 4 for methodology. A Swedish study (von Schenck *et al,* 1987) has compared the results obtained on the Ektachem, the Reflotron and the Seralyzer, as used by a trained technician in a primary care centre, with local laboratory results. Correlation coefficients were calculated to lie between 0.97 and 0.98 for the three instruments. Koch and colleagues (1987) have evaluated five analysers (Vision, Seralyzer, Reflotron, Chrometrics, Ektachem) in a community setting, where the samples were analysed by a trained medical technologist. The study reported coefficients of variation between 1.5 and 4.5%, but no information is given as to the likely clinical significance of these figures. Naughton and colleagues (1990) studied the accuracy of cholesterol testing by commercial screening organisations at four sites, including a fairground and a grocery store. A standard of ± 8.9% of the laboratory level was set (although no indication is given in the paper for this choice of standard) and the four locations met this in 100% down to only 67% of tests. If the repeatability and performance of these tests could be achieved by workers in primary care, all the devices examined would seem to have potential applications as NPTs. However, this cannot be assumed and the absence of research is a difficulty in this area.

A short report (Stewart *et al,* 1993) has described a pilot study of the effects of self-monitoring of triglyceride concentrations on the management of hyperlipidaemia in patients with non-insulin-dependent diabetes mellitus (NIDDM).

NPTs in diabetes

Glucose meters

Studies of NPT measurement of blood glucose fall into four groups – laboratory evaluations of test accuracy, clinic or practice performance, accuracy of the meters used at home, and the effect of home monitoring on glycaemic control. This area causes problems, because there has been considerable technical advance in the near patient measurement of blood glucose in recent years, so most of the meters referred to in the studies are now obsolete.

Clark and colleagues (1991) and Weiner (1993) have demonstrated that enzyme-strip meters will over-read by a clinically significant amount (up to 160%) in patients with a low haematocrit (e.g. anaemia in chronic renal failure). The Hemocue device is not subject to this error, but its cost and greater complexity make it unsuitable for home use.

Two studies have examined the impact of glucose self-monitoring on glycaemic control. Walford and colleagues (1978) suggested that use of the Reflomat™ improved overall glycaemic control in 32 of 67 patients with diabetes. Klein and colleagues (1993) failed to detect an improvement in control in patients monitoring at home. However, the study was retrospective, and the monitoring group had more complications and poorer control than the non-monitoring group, indicating that the two groups of patients were not comparable.

NPTs for glycosylated haemoglobin A1c

Measurement of HbA1c provides an estimate of the degree of blood sugar control in diabetics during the previous 3 months. It has become particularly important since studies correlated HbA1c with the development of complications, and the DCCT trial showed that tight control of HbA1c led to fewer

diabetic complications in patients with insulin-dependent diabetes mellitus (IDDM).[45] Pope and colleagues (1993) evaluated the Ames DCA 2000™ NPT. The analyser uses a finger-prick whole blood sample in a cartridge-based system, producing a result after 9 minutes. The study determined the accuracy of the NPT against a laboratory standard of the DIAMAT™ HPLC system, both in hospital clinics and a primary care diabetic clinic. Numbers were small (only 15 patients in the GP clinic), but the instrument produced consistently lower readings than the laboratory assay in all settings (mean difference: –0.77% (95% CI, –1.3, –0.24) at the GP clinic). The equipment was simple to use and, in nine out of 18 randomly selected cases, management was altered by the NPT result. However, that part of the study to which these comments refer was not a primary objective and the method used is heavily biased towards obtaining a favourable result.

NPTs for microalbuminuria

Microalbuminuria is defined as a urinary albumin excretion rate of 20–200 µg per minute in a 24 hour collection. At this level, the urinary albumin concentration will be below the level of detection of standard urinary dip tests. The development of microalbuminuria predicts the development of diabetic nephropathy and retinopathy in IDDM and cardiovascular disease in NIDDM. Tighter control of diabetes and hypertension can decrease the progression to renal failure in IDDM.

Two NPTs are available for the detection of microalbuminuria in diabetic patients, the Micral™ test, a semi-quantitative dipstick, and the Nycocard™ U-Albumin, which involves pipetting urine on to a well in a card. The interpretation of microalbuminuria papers is complicated by the fact that microalbuminuria is defined in terms of a daily albumin excretion rate, but the test is designed to measure a spot albumin concentration. There is a relationship between the definition and the measurement but this may differ widely between patients and with time.

Both papers reviewed in this section were given a high validity score by the external assessors, although the above point may have been missed by non-specialists. De Grauw and colleagues (1995) evaluated the performance characteristics of the Micral test in general practice in Holland. A total of 401 patients with NIDDM from ten practices were tested for microalbuminuria by the Micral test, using immuno-nephelometry as the gold standard, on three consecutive, stored, early-morning urine samples. Performance characteristics, LRs and an ROC curve were calculated. A screening cut-off of 20 mg/l gave: sensitivity, 67%; specificity, 93%; PPV, 74%; NPV, 90%; LR+, 9.6; LR–, 0.35. The authors point to a wide range in sensitivity and specificity at different cut-off points. Furthermore, in a situation where the cost of false negatives is very high, sensitivity is the most important attribute. The test has a relatively high sensitivity, but only by producing many false positives; these would need repeating and further investigation. A cost analysis of two alternative strategies is discussed elsewhere.

Kouri and colleagues (1994) evaluated the Micral test and the Nycocard U-Albumin in 206 patients with IDDM or NIDDM in a hospital diabetic clinic. Nephelometry was again used as the standard. The authors contend that, as the relationship between albumin concentration and excretion rates is very variable, a cut-off level of 20 mg/l would exclude 30% of patients. Predictive values for the two tests at the cut-off levels of 10 mg/l and 20 mg/l are presented. The Micral test performed slightly better than the Nycocard but the study would need to be repeated in a primary care setting.

NPTs for haematuria (bladder cancer screening)

Britton and colleagues (1989) evaluated the role of screening for haematuria in primary care using the Multistix™ NPT. A total of 855 men, aged 60–85 years were invited to attend the practice for a screening check. In all, 578 men attended and a freshly voided urine sample was tested with the Multistix 10SG; the patients were then invited to test their urine once a week for 10 weeks with Hemastix™. On their initial visit, 78 men (13%) had haematuria; 54 (9%) had haematuria intermittently during the 10-week screening period. On urological investigation, four bladder tumours and one prostatic cancer were discovered. The study did not determine the likely impact on survival or the cost-effectiveness of screening.

Messing and colleagues published three studies, two on the evaluation of screening for haematuria in the home (1987; 1995), and one to determine the optimum screening interval (1989). Testing an initial population of 231 men over a period of 3 months yielded 23 abnormal tests with five cancers; haematuria was intermittent, being present in no more than one-third of samples. However, of the 626 men approached, 333 agreed to enter the study, but only 231 actually complied.

Home pregnancy NPTs

Four studies have examined the accuracy of home pregnancy testing kits. Most tests are purchased

over the counter; the principal determinant of accuracy seems to be the ease of use, and hence the level of operator error (Daviaud *et al,* 1993). Some of the 27 over-the-counter tests studied were accurate and performed well against gold standard laboratory tests, even when used for self-testing.

Cardiac enzymes NPTs

Antman and colleagues (1995) have evaluated an NPT for cardiac troponin T, for the early detection of myocardial ischaemia. Some 100 patients, admitted to the coronary care unit with probable cardiac chest pain were tested. The gold standard was a clinical diagnosis of myocardial infarction, based on accepted history, ECG and cardiac enzyme criteria. The test produced a result within 20 minutes. Sensitivity increased from 33% within 2 hours to 86% after 8 hours. Specificity ranged from 86% to 100%. The prevalence of myocardial infarction was 34%, the likelihood ratio of a positive test was 6.3, and a negative test increased from 0.8 to 0.15 over time.

Allergy NPTs

The Quidel Allergy Screen™ is a dipstick test identifying specific IgE to ten common allergens. The test has been compared to the radio-allergosorbent test (RAST) in a laboratory study (Nalebuff & Prasad, 1990) and against skin testing and RAST in a community programme (Hamburger *et al,* 1991).

Microbiology, virology and immunology NPTs

In all, 29 papers were found reporting evaluations of microbiological NPT; the majority, 13, were for streptococcal throat tests. There were also several papers on the Clearview Chlamydia test, urinalysis test strips, and ESR/CRP. We found one paper each on Epstein Barr virus, HIV, and on a test for *H. pylori* and *Borrelia burgdorferi*.

Streptococcal throat NPTs

Three types of NPT are available, co-agglutination tests, latex agglutination and enzyme immunoassays. The more recent, primary-care based studies have used the rapid immunoassays (Abbot TestPack Strep A™). In one paper, the 'First response' immunoassay was evaluated in the home setting.

Most published evaluations of rapid streptococcal throat tests are subject to doubt because of the reliability of their 'gold standard'. Wegner and colleagues (1992), in the paper with the highest validity score (5), pointed out that a single blood-agar plate is inferior in detecting Group A haemolytic streptococci to a two-plate, aerobic/anaerobic culture on selective media. When the most commonly used streptococcal tests were evaluated against this new standard, their sensitivity fell to below 50%. The clinical implications of this are, however, unclear.

Streptococcal throat co-agglutination NPTs

Andersen and colleagues (1992) have evaluated the Phiadirect Strep A test in Danish primary care. A total of 105 patients with sore throat were investigated using the test and by laboratory culture. The paper, which scored 4 on validity, reports a lower sensitivity than previously obtained in laboratory-based studies (sensitivity, 97%, CI 91–100; specificity, 68%, CI 48–84; PPV, 90%, CI 70–99; NPV, 89%, CI 81–95).

Streptococcal throat latex NPTs

The Respiralex™ rapid latex agglutination test has been evaluated in two Finnish studies. The test was compared with throat culture in 849 primary care patients with a sensitivity of 92%, specificity 84%, PPV 59%, and NPV 98% (Makela, 1989). The further cost–benefit analysis is discussed separately. The paper scored poorly on methodological grounds.

Culturette™ has been evaluated in three studies – in an outpatient paediatric clinic in Argentina (Bodino *et al,* 1987) and in a family practice office in the USA (True *et al,* 1986; Wright *et al,* 1987). Both the family practice studies scored highly on validity. The device performed similarly in the two settings against single blood–agar culture, but Wright and colleagues (1987) used selective media and demonstrated a sensitivity of only 38%. The abnormally low test performance result may have arisen by chance as the study was small and the results had very wide CIs. True and colleagues (1986) reported a study in which the investigators undertook the tests, showing that the use of the test resulted in a reduction in unnecessary antibiotic prescribing. However, attributing this to the use of the rapid test is complicated because of the use of a pre-post study design, where the effects of any trend with time cannot be accounted for.

Hjortdahl and Melbye (1994) have evaluated the role of clinical judgment, the Patho DX™ latex agglutination test, ESR, CRP, and white cell count in the diagnosis of streptococcal sore throat in 174 Norwegian primary care patients. On the basis of a gold standard of sheep-blood–agar anaerobic plates

alone, LRs and ROC curves, clinical judgment performed best followed closely by the latex test. ESR did not have the power to influence diagnostic probability greatly.

Streptococcal throat immunoassay NPTs

Joslyn and colleagues (1995) have evaluated two treatment strategies employing the Directigen Group A Strep™ NPT in family practice in the USA, using only a single plate culture, and with throat swabs performed by laboratory technicians. The performance characteristics were higher than in previous studies, the NPV of 99% leading the authors to conclude that the NPT could be relied upon to exclude infection without a back-up culture.

The Abbot TestPack Strep A has been evaluated in primary care settings in both the UK and New Zealand. Burke and colleagues (1988) pointed out that, in the UK, most sore throats are treated with antibiotics on clinical features and throat swabs are rarely performed. Patients were entered into the study by 69 GPs. The range of antibiotic prescribing was high (20–100%), but antibiotics were more likely to be prescribed in the presence of exudative tonsillitis or cervical adenopathy. A total of 272 patients had the NPT and a two-plate selective laboratory culture as a gold standard. The paper, interestingly, compares the performance of GPs' clinical judgement with the performance of the rapid test. The sensitivity of the test and clinical judgement were similar at 63% and 74%, respectively. However, the specificity of the NPT was greater (92% versus 58%). It is possible that failure to take the two swabs simultaneously may have reduced the sensitivity of the NPT. The authors concluded that the test would add little to clinical judgment in UK general practice. In the New Zealand study (Carey *et al,* 1991), only one agar plate was used and the performance characteristics were higher.

NPTs for Chlamydia trachomatis

Three Chlamydia NPTs are available, but all of the evaluations took place in laboratories, after the sample had been taken and transported; the results may therefore not be applicable to the test when used in primary care. The only primary care-based evaluation is that of Rink and colleagues (1993), who included the Clearview Chlamydia test in the evaluation of the impact of NPT in primary care. Practices performed on average fewer than one test per week (95% for diagnosis). An 8% increase in overall testing and a 20% decrease in laboratory tests was seen over the study period.

Urine multi-test strips

The gold standard for urinary tract infection is regarded as more than 1,000,000 organisms per ml (106/ml) and a pure growth on culture of mid-stream urine. The Ames Multistix 10SG™ and the Ames Microstix-3™ were evaluated in a hospital ward in 698 elderly patients (Flanagan *et al,* 1989). The Multistix 10SG has different performance characteristics depending on which combination of the four pads (nitrite, leucocyte esterase, protein and blood) are positive. The NPV was consistently in the low 90% range, showing a good ability to exclude infection in this setting; the PPV varied from 44% to 66%. A similar study, but using the Nephur-Test™ plus leucocytes test in 325 primary care patients in a single practice (Ditchburn & Ditchburn, 1990), showed similar performance, although urine microscopy was more accurate than the dip tests. The fact that this was a single-handed rural practice may be relevant to the generalisability of this particular result.

In contrast, the highest scoring paper methodologically (Winkens *et al,* 1995) found that the ability of Nephur-Test plus leucocytes test to exclude urinary tract infection (NPV) was at most 57%. This study included 16 GPs in 12 practices, and recruited 1388 patients. The prevalence of urinary tract infection was higher than in the study by Ditchburn and Ditchburn (1990), possibly because the definition of the condition was $> 10^5$/ml, without the proviso of a pure culture. A wide variation in performance between practices was demonstrated, with the likelihood ratio for a positive nitrite test varying from 1.8 to 9.4.

Hilton and colleagues (1993) also examined urinalysis using the Multistix 8SG with the Clinitek 10™ reader, as part of a multicentre trial of NPT in primary care (discussed previously under desktop analysers). The number of laboratory mid-stream urine cultures fell and the number of NPTs rose to produce a 30% increase in tests. The study was not designed to evaluate performance but the impact on clinical practice. Most (80%) urinalyses were performed for diagnostic purposes.

NPTs for ESR and CRP

Five studies have evaluated the NycoCard™-CRP NPT – one laboratory evaluation, one paper evaluating the usefulness of the test in the differential diagnosis of appendicitis in patients admitted to hospital with acute abdominal pain, and three primary care studies. Urdal and colleagues (1992) have shown that the NycoCard-CRP results correlate well with a

laboratory standard ($r = 0.96$) and are not affected by the presence of bilirubin, serum amyloid P and rheumatoid factor. Hjortdahl (1991) showed that NycoCard-CRP is a repeatable test, although these results were obtained with hospital laboratory technicians operating the kit.

Søndenaa and colleagues (1992), in a top-scoring paper on validity, studied 158 patients admitted with suspected appendicitis, 62 (40%) of whom subsequently proved to have appendicitis at laparotomy. In terms of their diagnostic performance for appendicitis, both the NPT and a reference CRP performed equally poorly (sensitivity, 0.69; specificity, 0.67; PPV, 0.63; NPV, 0.72). Sensitivity and specificity varied with the cut-off value chosen, that is, the maximum sensitivity was 58% at a threshold of > 10 U and the maximum specificity of 85% at a threshold > 40 U. The CRP level only rose significantly after 24 hours of symptoms, raising the possibility that the test may have adequate predictive value to exclude appendicitis in combination with leucocytes and neutrophils, when symptoms have been present for more than 24 hours.

Three primary-care based evaluations of the Nycocard-CRP have been undertaken, one each in Norway, Sweden and The Netherlands. Hjortdahl and colleagues (1991) have evaluated the Nycocard-CRP serum test, now superseded by the whole blood test, in a paper scoring 4 for validity. Correlation with laboratory reference was lower than Søndenaa and colleagues (1992) ($r = 0.85$). The clinical significance of the reduced value of r is uncertain. However, the NPT results were the same as the reference method in 138 out of 277 cases and within plus or minus one category in 268 out of 277 cases. The primary care physicians felt that the test had contributed to the diagnosis in 60% of patients with possible infectious disease. However, this element of the study was open to considerable bias and the value of these results as a measure of the impact of the NycoCard-CRP must be assessed with caution.

Dinant and colleagues (1994) compared the Nycocard whole blood CRP with a laboratory standard and ESR in 433 Dutch primary care patients 'indicated for ESR'. The precise spectrum of patients was not given. The paper quotes results as 'false elevated' and 'false normal', rather than sensitivity and specificity; predictive values or LRs are not given, making their data difficult to compare with other authors', and resulting in a validity score of 2. Dinant (1989) examined the reliability of ESR in primary care, and demonstrated that the accuracy of results relative to laboratory ESR and the repeatability could be dramatically improved through standardisation.

Hansson and colleagues (1995) have evaluated the NycoCard serum and whole blood tests against laboratory CRP tests in 607 primary care patients. The paper scored 5 on validity and has been included in the detailed review. They confirmed that there is good agreement with NPT and laboratory methods. They also present data showing good agreement between visual methods of assessing the results and instrument readings. The results of the comparison between NPT CRP and laboratory ESR is extremely difficult to interpret, particularly as the authors state that their aim is not to measure sensitivity and specificity, in which case the use of ESR as a gold standard might be a matter for debate. It is difficult to understand how the data presented sustain the authors' conclusions that 'in clinical situations with suspected inflammatory disease the CRP test appears to yield more useful results than ESR'.

A paper evaluating the accuracy and reliability of the Nycocard-CRP in primary care settings has been recently published,[46] but was too late for full inclusion in the review (although it met the inclusion criteria).

NPTs for HIV

The Genie™ immunochromatogaphic NPT for HIV has only been evaluated in the laboratory (Krieger *et al*, 1991). Of 200 clinical serum specimens, only one tested positive on the NPT, and this was not confirmed by the gold standard western blot. A panel of 56 reference samples were all correctly identified.

Other immunochromatographic NPT assays

Although immunochromatogaphic assays are being widely developed, only one paper, a discussion paper describing the ChemTrak Accumeter™ *Borrelia burgdorferi* and *H. pylori* assay was found to meet the review criteria.

Haematology NPTs

Twelve publications were categorised as haematology with ten papers relating to oral anticoagulation, one paper on haemoglobin measurement and one on measurement of D-dimer for the diagnosis of deep venous thrombosis (DVT). These results are summarised below.

Anticoagulation NPTs

Ten papers related to anticoagulation, with nine relating specifically to results obtained with NPT compared to laboratory assay. Of these nine papers, four were concerned with the Coumatrak™ device (Ansell *et al,* 1989; Belsey *et al,* 1991; White *et al,* 1989; McCurdy & White, 1992), three with the Biotrak 512™ device – also known as Protime Monitor 1000™ and now marketed as Coaguchek™ – (Anderson *et al,* 1993; Jennings *et al,* 1991; Lucas *et al,* 1987) and two with the COAG™ devices – now marketed as TAS™ (Oberhardt *et al,* 1991; Rose *et al,* 1993).

It is important to emphasise some of the controversy associated with oral anticoagulant measurement. The International Normalised Ratio (INR) was an attempt to standardise the reporting of results relating to the intensity of oral anticoagulation. This grew out of a recognition that different centres were using different thromboplastins to measure prothrombin time, which resulted in widely differing results on the same sample. Whilst the INR has undoubtedly improved the standardisation both of reporting of results and, more importantly, dosing of anticoagulation, there remains controversy over what represents the gold standard for INR measurement. This makes any comparison in terms of either correlation coefficient or sensitivity and specificity difficult to interpret. Because of the lack of standardisation both in the measurement of INRs and in the reporting of results between different centres, direct comparison in terms of performance characteristics between the different monitors reported in this text is not possible.

Of the four papers on the Coumatrak, two achieved methodology scores of 2 (White *et al,* 1989; Ansell *et al,* 1989), one of 3 (Belsey *et al,* 1991) and one of 4 (McCurdy & White, 1992). Overall, the results showed that the Coumatrak gave a good correlation of INR result compared with the laboratory results ($r = 0.91$), with a slight bias towards the Coumatrak, especially as the INR increased (the monitor measured 0.3 INR units high at a criterion standard value of 2.0). One study (Ansell *et al,* 1989) suggested that this device could be used at home, although the methodology was criticised by reviewers.

Two of the three studies relating to the Biotrak 512 scored 4 for methodology (Anderson *et al,* 1993; Jennings *et al,* 1991), whilst one scored 2 (Lucas *et al,* 1987). Anderson and colleagues (1993) investigated home use of Biotrack and found good agreement between results obtained with the device compared with laboratory analysis, with 83% of results agreeing with standard criteria (95% CI = 79–87%). The majority (97%) of patients preferred using Biotrak 512 at home to hospital testing. This study is important because it highlights the difference between actual discrepancies in INR reporting and clinically significant differences. By using the criteria specified, that is, agreement to either within, above or below the therapeutic target range, this paper supplies more clinically-relevant information than purely laboratory criteria referenced evaluations.

Jennings and colleagues (1991) reported a laboratory evaluation of Biotrak 512. This study showed good agreement in INR results between the monitor and Manchester reagent but poor correlation with Thrombotest™. The implications of this study are that the NPT is not a technically difficult procedure for INR monitoring; however, care must be taken in interpreting results. This applies particularly when changing patients from hospital monitoring where different thromboplastin reagents may be used. The resolution of the problems regarding standardisation remain outside the scope of this review, but do not preclude the use of NPT for INR measurement in primary care. Both of these studies were criticised for lack of cost comparisons.

The paper investigating the Protime Monitor 1000 (Lucas *et al,* 1987) achieved a methodological score of 2. When results from the monitor were compared with laboratory assay, there was good correlation between those from both normal volunteers and patients receiving warfarin ($r = 0.92–0.94$), that haematocrit had no effect on measurement of prothrombin time. The study demonstrated that the machine could be used easily by non-technical staff.

The two COAG papers achieved methodological scores of 3 and 4, respectively. Both were laboratory evaluations that found a good correlation between prothrombin times derived on the monitor and those within the laboratory ($r = 0.96–0.98$). The COAG monitor also estimates partial thromboplastin time.

Mennemyer and Winkelman (1993) investigated the impact of prothrombin testing in primary care on health outcomes. The paper achieved a methodological score of 3. The results showed that health outcomes were improved in larger clinics, specifically those performing more than 40 tests per month.

Overall, the ten papers reporting studies into NPT for therapeutic oral anticoagulation monitoring were generally given good scores for methodology, with five papers being submitted for detailed review. This is surprising given that the proforma for methodology assessment includes a score for LRs. Since the INR is a continuous variable, LRs are not relevant, thus negating the possibility of a maximum score of 5 for this group of papers. The possibility of aggregating scores to enable sensitivity and specificity of testing is made difficult by the problems of poor standardisation of reporting results.

The most useful method of reporting found within these papers used criteria-based analysis to look for agreement between results obtained at home and those obtained within a hospital laboratory. The generally good agreement found by Anderson and colleagues (1993) reflects the clinically important parameters for primary care use. In contrast, the laboratory-based studies using correlation coefficients and coefficients of variation make interpretation by the clinician difficult.

The papers report on essentially three different NPT monitors, Coumatrak, Biotrak, and COAG, although a variety of names are used for the same instruments. It is surprising that no papers were reviewed which investigated the Thrombotrak™ machine. All three machines give good correlation between INRs or prothrombin times compared with laboratory assays. Three papers (Anderson *et al,* 1993; Ansell *et al,* 1989; Lucas *et al,* 1987) report successful home monitoring, although the frequency of home monitoring was rather intense (weekly). Despite this, patients appeared to prefer home monitoring to hospital. Only one study addressed the issue of quality control. This study (Belsey *et al,* 1991) showed that by using traditional hospital laboratory quality assurance techniques, reliable results could be obtained by non-laboratory personnel. It is of concern that quality control was not considered within the framework of the home testing experiment, and this needs to be explored in future studies.

One study (White *et al,* 1989) compared health outcomes (haemorrhagic or thrombotic events) in patients attending either a primary care anticoagulation clinic or a private pathology laboratory. This study revealed that health outcomes were significantly worse for patients attending clinics where the volume of tests performed was less than 40 per month. The issue of quality assurance was again not discussed but would be important in eradicating such discrepancies.

NPTs for haemoglobin

Neville (1987) has evaluated the HemoCue for the measurement of haemoglobin in general practice and in the hospital laboratory. The paper achieved a methodological score of 4. The main finding was that the monitor was accurate in a hospital setting ($r = 0.99$) but performed erratically when used by practice nurses in general practice ($r = 0.61$). The sensitivity and specificity for the detection of anaemia were reported as 88% and 78%, respectively. However, it is difficult to determine exactly how these figures were derived. For the study, samples were pipetted from tubes containing venous blood and it was suggested that insufficient mixing in the tubes may account for the variation, this error not being a problem with capillary samples (not examined in this study). Without further data, it is difficult to determine the validity of this hypothesis.

It is not clear whether the measurement of haemoglobin is a suitable test for NPT. The clinical areas where there is a need for a rapid reply to a request for a haemoglobin test are clearly in secondary and tertiary care alone. More work is needed to establish whether this is an appropriate area for further research.

NPT for D-dimer

One paper (Dale *et al,* 1994) investigated the use of the D-dimer NPT, for the diagnosis of DVT, compared with laboratory techniques and contrast venography. The NPT showed good sensitivity (100%) and NPV (100%), but poor sensitivity (42%) and PPV (57%) when compared to venography. The NPT performed well when compared with more complex laboratory tests. Given a 100% NPV it would be an ideal test for the exclusion of DVT. The test requires serum and would, therefore, need centrifugation before testing. Further work will be needed to establish the place of this test within primary care for the exclusion of diagnosis of DVT.

Chapter 7

Review findings – EDI between laboratories and general practice

The results of the search on EDI and rapid transit of laboratory results was very disappointing. As has already been stated, only two of the papers contained reports of any form of objective evaluation. One paper excluded at a late stage on the grounds of being a secondary care evaluation, reported the stability of reference samples to passage in a hospital's pneumatic tube system (Nosanchuk & Salvatore, 1977). All the other papers described various EDI projects in progress or planned, the only evaluation being that undertaken on the Apeldoorn project in the Netherlands. No reports of communication by fax machine or rapid telephone results services were found that contained original data.

The Apeldoorn project was very similar to many of the EDI projects now being undertaken in the UK (Branger *et al,* 1992; see also, Branger & Duisterhout, 1991, a proceedings report of the same data). EDI is based on the exchange of messages between healthcare providers using a commercial electronic mailbox facility. Messages are exchanged using the EDIFACT (Electronic Data Interchange For Administration Commerce and Transport) European standard.

The Apeldoorn study covered the exchange of admission/discharge reports and laboratory results between 33 GPs, 12 pharmacists and two hospitals. The study consisted of four phases; baseline data, observation of message flow, efficiency, and a survey of user satisfaction. Only the laboratory results are discussed here. Using traditional paper mail, the median time for receipt of laboratory results by the GPs was 2 working days. For samples analysed on the day of collection (174/542 samples at one hospital and 443/854 at the other), the result was available to the GP the same day via EDI. GPs valued the integration of the result with the electronic clinical record and ten out of 24 commented on a decrease in paperwork. There was no evaluation of the impact of EDI on patient care, or on the use made of the results.

Chapter 8

Review findings – CDDS systems and NPT

Eight papers on CDDS systems were reviewed. The reviewers scoring schedule was the same as that used for the NPT papers, which resulted in relatively low scores for these papers, particularly in relation to the questions of comparison to a gold standard and LRs.

Seven of the eight papers were concerned with warfarin management. The remaining paper (Ahlfeldt *et al,* 1994) investigated the use of data-driven decision support in three different environments; a healthcare centre, a clinical laboratory, and a research department. This paper was given a methodological score of 0, reflecting a lack of data.

Of the seven papers concerned with warfarin management, three were concerned with the Hillingdon program, one with the PARMA program (Mariani *et al,* 1990), one with the Coventry program (Ryan *et al,* 1989), one with the Virginia program (Carter *et al,* 1988), and one compared the Hillingdon, Coventry and Charles Anticoagulant Clinic Manager programs (Poller *et al,* 1993).

The three Hillingdon papers scored methodology marks of 0 (Kubie *et al,* 1989), 1 (Wylde *et al,* 1988) and 2 (Wilson & James, 1984), respectively. The highest scoring paper reported an improvement in anticoagulation control following the introduction of an automated system to deal with the adjustment of warfarin dose. Paradoxically this resulted in more patient visits.

The paper by Mariani and colleagues on the PARMA program (1990) received a methodology score of 1. This study showed that good therapeutic control can be achieved within a secondary care setting using CDDS, but highlighted the fact that a consistent approach is necessary for multicentre evaluations to take place. This paper also reports the first use of the mean INR, plus or minus one standard deviation, as a method of comparing anticoagulant clinics in different settings.

Ryan and colleagues (1989), in their paper on the Coventry program, achieved a methodology score of 2. The paper describes an improvement in therapeutic INR control following the introduction of CDDS. It is difficult to ascertain the level of performance before the introduction of CDDS and if the reported improvement is genuine or merely demonstrates the learning curve associated with the introduction of the CDDS system.

The paper by Carter and colleagues (1988) achieved a methodological score of 1. The authors describe a program for predicting warfarin dosage following a loading dose of 30 mg over 3 days. This is essentially a secondary care study which may have implications for primary care workers who wish to commence warfarin therapy in the community. The specific program is unlikely to have widespread applicability because of the equipment requirements.

The paper in which three CDDS systems were compared with human performance (Poller *et al,* 1993) achieved a methodological score of 4. This highlights the fact that the study attempted a randomised controlled trial to assess the relative merits of three different CDDS systems for warfarin management and compare them with human performance. The study was flawed in that one system (Hillingdon) was suspended from randomisation during the study. Neverthless, it demonstrated that improvements in therapeutic INR control can be achieved by the use of CDDS, particularly as the target INR increases.

Two further studies, from the authors' department, were published too late to be included in the systematic review, one being a prospective controlled trial of a rule-based CDDS system for lipid management in general practice (PRIMED™).[47] This study highlighted the need for integration of CDDS with practice-based data handling systems and for careful study of the needs of practitioners before the design of such systems.

The second recently published study was a primary-care based evaluation of a CDDS system for interpretation of INR results (it provides advice on closing and recall dates).[48] The study reported a highly significant improvement in patient control from previous (hospital-based) care, and significantly extended the intervals for re-testing. This study has now been extended to include the evaluation of this CDDS alongside an NPT for INR in primary care.[49]

In conclusion, the majority of work relating to CDDS systems remains within the field of oral anticoagulant therapeutic monitoring. This work has been of variable quality but does suggest a possible role for CDDS, although the published work has, until recently, been exclusively in secondary care. Further work needs to be undertaken to establish the applicability of this technology in primary care.

Chapter 9

Health economics evaluation

The overall standard of health economic assessment in the 18 papers containing health economic data was very poor. It was not possible to draw any overall conclusions as to the cost-effectiveness of any particular NPT. The individual papers all contained health economics data in addition to data on such matters as performance characteristics and the effect of tests on clinical decision-making. The health economics sections alone were judged against the proforma (see *Table 24*).

TABLE 24 *Results of the health economic evaluation against the proforma*

	Yes	No
The question		
Did the author(s) set a clear question to be answered?	18	0
Did the author(s) actually answer the question set?	17	1
The burden		
Did authors indicate the problem and its relevance to health care?	18	0
Method		
What method of assessment was claimed as being used?	Name	See text
What method of assessment was actually used?	Name	See text
Patient inclusion		
Was it clear how patients were included in the study?	10	8
Were the inclusion criteria appropriate?	14	4
Identification of costs and benefits		
Were direct costs identified?	16	2
Were indirect costs identified?	7	11
Were intangible costs identified?	6	11
Were direct benefits identified?	16	2
Were indirect benefits identified?	8	10
Were intangible benefits identified?	7	11
Measurement of costs and benefits		
Were direct costs measured?	11	7
Were indirect costs measured?	1	17
Were intangible costs measured?	0	18
Were direct benefits measured?	9	9
Were indirect benefits measured?	18	0
Were intangible benefits measured?	1	17
Identification of marginal, average and total costs		
Were marginal costs identified?	18	0
Were average costs identified?	9	9
Were total costs identified?	1	17
Were marginal benefits identified?	0	18
Were average benefits identified?	0	18
Were total benefits identified?	0	18
Measurement of marginal, average and total costs		
Were marginal costs measured?	0	18
Were average costs measured?	0	18
Were total costs measured?	1	17
Were marginal benefits measured?	0	18
Were average benefits measured?	0	18
Were total benefits measured?	0	18

continued

TABLE 24 contd *Results of the health economic evaluation against the proforma*

	Yes	No
Identification of fixed and variable costs		
Were fixed costs identified?	10	8
Were variable costs identified?	13	5
Measurement of fixed and variable costs		
Were fixed costs measured?	2	16
Were variable costs measured?	11	7
Quality of life		
Was the impact of the tests on patients' quality of life identified?	9	10
If so what instrument(s) was/were used?	Name the instrument	
What, if any, were the results?	See text	
Was a generic instrument used?	See text	See text
Was the use of each instrument appropriate?	5	13
Satisfaction		
Was the degrees of care satisfaction of the stakeholders reported?	7	11
If so, what degrees of satisfaction were achieved for each party?	See text	
Sensitivity analysis		
Was a single parameter sensitivity analysis reported?	2	16
Was a multiple parameter sensitivity analysis reported?	2	16
Did the authors conduct/report a single parameter threshold analysis?	0	18
Did the authors conduct/report on multiple parameter threshold analysis?	0	18
Differential timing		
Was any time differences in the costs or benefits reported?	7	9
What discount rate was used to align future costs/benefits to current values?	See text	
Comparator		
Was the test compared with an alternative intervention?	15	5
Were clear reasons for the choice of comparator stated?	9	9
If a comparator was used was it appropriate?	13	5
Was site of test compared with alternative (e.g. GP versus hospital)?	8	10
If so, was it an appropriate comparison?	8	10
Vested interests		
Were any vested interests clearly identified?	0 & see text	18
Were all vested interests declared?	0	18
Impact on action and decision-making		
Did author(s) identify how test results would impact on care?	18	0
Did author(s) identify any barriers to impact or use of the test?	17	1
If barriers need to change, did author(s) suggest solutions?	13	5
Are there any gaps in logic or data of the paper?	18	0
Are any of these gaps important to the results?	18	0
Are any gaps important to using the results in decision-making?	18	0
Do the conclusions of the paper come from the results reported?	14	4

Identification of the health economic question and its importance

All the papers set out to answer a defined question and demonstrated their relevance to the healthcare system.

Methods of economic analysis used in the reviewed papers

Four studies claimed to use a value-for-money methodology. Makela and Sintonen (1991) stated that they explored the cost-effectiveness of diagnosis and treatment of Group A streptococci in

primary care patients with pharyngitis; Carey and colleagues (1991) considered the cost-effectiveness of an NPT for group A beta-haemolytic *streptococcus* in general practice; Tsai and colleagues (1994) performed a cost-effectiveness analysis of point-of-care versus central laboratory blood tests; and Greendyke and colleagues (1992) undertook a cost-effectiveness analysis of bedside blood glucose testing. There were deficiencies in the methods used in all of these studies.

Makela and Sintonen (1991) did not include intangible costs or benefits, while Carey and colleagues (1991) failed to include indirect costs and benefits as well as failing to consider intangible costs and benefits. Tsai and colleagues (1994) used a time-and-motion prospective analysis methodology, rather than a cost-effectiveness analysis, and Greendyke and colleagues (1992) performed a cost analysis rather than the cost-effectiveness analysis described in the method.

Other methodologies used in the review papers were cohort studies, a case study, a prospective time-and-motion study, a prospective cross-over study, a two-period cross-over study, a resource use and impact study, a randomised controlled trial of the Reflotron test, a retrospective data analysis, a cost analysis and, one paper claimed, a benefit and implication analysis

Identification of costs and benefits

Two papers failed to identify direct costs (Burke *et al,* 1988; Walker *et al,* 1989) and nine failed to identify indirect costs (George & Braithwaite, 1995; Rink *et al,* 1993; Carey *et al,* 1991; Greendyke *et al,* 1992; Gilio *et al,* 1993; Hobbs *et al,* 1992; Corson, 1986; Walker, 1989; Mennemeyer & Winkelman, 1993). Burke and colleagues (1988) did not identify direct costs but did actually include indirect costs. Makela and Sintonen (1991) did identify and go on to measure indirect costs of healthcare technology intervention, using the unit costs of patients' sick leave. Since this estimated cost was the largest item in their calculation it is not too surprising that the authors found their results sensitive to the amount of sick leave involved.

Eleven papers failed to identify intangible costs (George & Braithwaite, 1995; Makela & Sintonen, 1991; Rink *et al,* 1993; Burke *et al,* 1988; Carey *et al,* 1991; Greendyke, 1992; Gilio *et al,* 1993; Hobbs *et al,* 1992; Corson, 1986; Walker, 1989; Mennemeyer & Winkelman, 1993). None of the papers included marginal costs, and only nine of the papers identified average costs.

Quality of life

Nine papers identified some of the impact of the healthcare intervention on the patients' quality of life, although no standard quality-of-life instruments were used in any of the papers reviewed. Authors used general references or made rudimentary comments on how the healthcare intervention may affect a patient's quality of life. Mennemeyer and Winkelman (1993) commented on inaccuracies of INR measurement in NPT settings, suggesting that patients' quality of life would be affected if they were tested in a physician's laboratory rather than in a commercial laboratory. For a patient tested in the physician's laboratory, the risks of experiencing a stroke or an acute myocardial infarction were 1.96 and 3.43 times higher, respectively, than for those tested in the commercial laboratory.

Satisfaction with NPT

Seven papers reported on the degree of healthcare satisfaction. Hobbs and colleagues (1992) reported the satisfaction of practice staff on the quality and appropriateness of the test machine. Rink and colleagues (1993) reported on the perceived usefulness of the equipment, insofar as revealing the decision of the practices in the study when offered the equipment free of charge at the end of the study period. Urine dipstick readers were retained by all the practices offered them and only one practice refused to keep a Reflotron analyser. None of the practices wished to keep the machines for measuring electrolytes or the Chlamydia testing kits. Only one paper reported any form of patient satisfaction from the healthcare intervention.

Differential timing

Time differences in the costs and benefits from the healthcare technology intervention were reported in seven papers (Tsai *et al,* 1994; Voss, 1992; Greendyke *et al,* 1992; Leese & Hutton, 1990; Leese & Hutton, 1989; Hobbs *et al,* 1992; Walker, 1989). There was no consensus on the discount rates to used, preventing standardisation or direct comparison of the papers. However, the variety of healthcare technology equipment tested (for

example, cholesterol testing machines and blood testing machines) prohibited a common discount rate for different machines.

Some of the papers did test the same machines but used different discount rates. Two papers (Leese & Hutton, 1989; 1990) used a 7-year life for the Reflotron analyser but Hobbs and colleagues (1992), in a UK study, worked on the assumption of a 5-year life for the equipment. Tsai and colleagues (1994) used an 8-year capital discount rate for the test equipment, without any explanation of why this rate was appropriate. Hobbs and colleagues (1992), studying another NPT, worked on the basis of a 7-year life for the test equipment.

Greendyke (1992) addressed the issue of blood glucose testing in two test settings: for one, the author estimated the instrument costs to be 'depreciation and maintenance materials of $0.23 per test' but, for the other, the author estimated the instrument costs to be 'depreciation, maintenance and repair costs of $0.43 per test' (with depreciation at $0.30 per test, and maintenance and repair at $0.13 per test). No reason was given for the depreciation rates or for the difference in the rates between settings. None of the authors offered any clear explanation for their choice of a particular discount rate.

Greendyke and colleagues (1992) used 1985 cost data: this could seriously undermine the validity of the results. No attempt was made to update the data (using the inflation index) to bring them up to the then (1991) current value. In addition, no attempt was made by Greendyke and colleagues to use what would then have been more recent data (e.g. 1989 or 1990). An alternative would have been to use sensitivity analysis. The authors did use sensitivity analysis on other parameters but did not establish how responsive their results were to changes in the 1985 cost data.

Use of an appropriate comparator

In 15 papers, one NPT was compared with an alternative intervention, that is, another test. In only nine papers were reasons for the choice of comparator given. Eight papers reported on tests in at least two different settings. In one paper (Walker, 1989), the alternatives were either testing at home or testing in a GP practice. In another paper (Leese & Hutton, 1989), the test sites were either primary care or hospital. All of the eight papers in which the sites of tests, as opposed to the types of test, were compared were deemed to be appropriate for comparative purposes.

Conclusions

Only a minority of studies incorporated any form of economic evaluation. Most of these used relatively simple methods, such as cost analysis. However, the diversity of technologies tested, and the difficulties over the identification of a gold standard and easily measurable outcome, may limit the development of more robust cost-effectiveness studies. Since the majority of studies under review were feasibility rather than clinical outcome trials, full cost–benefit or cost-effective analyses were not possible.

Chapter 10

Detailed review of 'high-scoring' NPT papers

Introduction

It was always likely that a systematic review of the literature in as broad and ill-defined a topic as NPT would result in a collection of articles which would be extremely difficult to summarise using quantitative techniques, that is, meta-analysis. Limitations in the quality and scope of the research identified were the most important factors, suggesting that attempts to perform any meta-analyses as part of this project would be premature.

However, in order to inform such activities as would be logical extensions of this broad overview, a detailed analysis was undertaken of those articles which were most likely to be included in a meta-analysis. Our objective was to review in detail the characteristics of those research articles which apparently offered the most internally valid sources of information on NPTs.

Method

All papers scoring 4 or more in the initial assessment of study quality were passed to one reviewer (CH), who was working independently of the steering group. This reviewer had not been involved in the initial quality scoring of the papers. Each article was re-read and reassessed in detail. The total time taken per paper was at least 2 hours, each paper being examined on at least four separate occasions for the following purposes:

- general familiarisation
- confirming and recording those aspects of the studies relating to validity
- abstracting and recording of all other characteristics of the studies
- confirmation of consistency with any general conclusions presented.

Validity and data abstraction details were recorded by entry into databases created on Blackwell Idealist software. For confirming and recording aspects of the studies relating to validity, the quality checklist employed by Reid and colleagues for assessing 'accuracy and reproducibility' of diagnostic tests was used.[39] In concentrating on internal validity, particularly dealing specifically with issues such as 'work-up bias' and 'review/verification bias' this checklist was felt to offer the most detailed and stringent assessment of study quality available. It contains seven standards – spectrum composition, analysis of pertinent subgroups, avoidance of work-up bias, avoidance of review bias, precision of results for test accuracy, presentation of indeterminate results and test reproducibility. The 'Reid checklist' was modified in two ways.

(i) The standard on test reproducibility was omitted, as information on this important characteristic was treated separately (see below).
(ii) A judgment on the appropriateness of the comparator/gold standard was included.

Thus, the total number of standards which could, or could not, be met remained at seven and, hence, the results of this second assessment of validity are expressed as a score out of seven. Where the Reid checklist could not be applied, because the study did not address "accuracy and reproducibility", general comments were made on the internal validity with reference to other published checklists, for example, the *Users' guide to the medical literature* series.[50] When little or no detail about study method was available, this fact was recorded rather than any attempt being made to apply any sort of validity checklist.

With respect to abstraction and recording of all other characteristics of the studies, the parameters targeted flowed directly from issues raised in the introduction to this report. These were as follows.

(i) The test apparatus is not the only important variable that needs to be considered in assessing whether a diagnostic test should be applied near-the-patient. In this detailed review, the NPT was thus considered as a package that consisted of:

    - the test apparatus
    - the operator (trained/untrained)

- the interpreter of the test result (trained/untrained)
- the location (especially home or primary care versus laboratory versus hospital).

(ii) A complete assessment of whether a diagnostic test should be applied near-the-patient requires information on a number of different aspects of that test.

- **Repeatability/reproducibility** Given that the NPT package remains constant, does the test give the same result when repeated on the same sample or the same patient? In the latter case there is a need to consider to what extent a parameter will vary over time, or 'biological variability'; that is, a patient's blood pressure will vary over a period of days, whereas bone density will not.
- **'Test' performance** How well does the test indicate the measurement or diagnosis it is designed to measure? This is usually considered by comparison with the existing 'best' test apparatus or gold standard. Because of the decision to consider NPTs as packages of test apparatus, operator, interpreter and location, the term test performance includes comparisons where the test apparatus may remain the same, but the operator and/or the interpreter and/or the location vary. Such comparisons are often described generally as inter-observer variability, and are considered to be part of the measurement of repeatability/reproducibility. In this framework, repeatability/reproducibility refers to intra-observer variation only.
- **Effect/impact of NPT package** The comparison of the test with existing facilities for diagnosis of a particular condition for outcomes such as: 'satisfaction' of both the recipients of the test and the operators/interpreters of the test (acceptability); the process of care – Is treatment started more quickly?; health outcomes – Do more patients survive? (effectiveness); cost – Does the introduction of the NPT package increase or decrease cost? (efficiency).

It should be noted that the terms used to describe various measures of diagnostic tests and their grouping are different from those used earlier in this review. In particular, aspects referred to as 'quality assurance' in the introduction are included as either test repeatability or test performance.

Results

The main output of the detailed analysis is presented in Appendix 2. The following sub-sections and accompanying tables summarise selected aspects of this analysis, particularly as they relate to points developed further in the discussion.

Composite nature of most articles

The single most remarkable result of the detailed analysis was that 29 of the published articles contained at least 188 potentially relevant comparisons informing an assessment of diagnostic tests considered by the review panel to be, or potentially to be, NPTs.

The large number of comparisons in relation to the relatively small number of articles arose because some articles addressed the assessment of:

- more than one NPT; for example, Daviaud and colleagues (1993) assessed all 27 over-the-counter home pregnancy test kits available in France in 1989
- the same NPT against more than one comparator; for example, Søndenaa and colleagues (1992) compared NycoCard CRP against a standard laboratory instrument measuring CRP concentration and against confirmed diagnoses of appendicitis
- different aspects of the same NPT; for example, Dinant and colleagues (1989) examined the repeatability, test performance and effectiveness of ESR testing.

The mean number of comparisons per article was 6.5; the mode was two comparisons per article; the median was four comparisons per article; and the range was 1 to 49 comparisons per article.

Quality scores

Where the Reid checklist could be applied, the scores obtained generally confirmed the initial impression that the articles were indeed of high quality in respect of those elements of the articles which examined test performance. Only three of the 29 articles (Messing *et al,* 1987; Nanjii *et al,* 1988a; b) contained no assessment of test performance scoring 4 or more.

However, this conceals a number of important issues relating to study quality.

(i) Many articles contained more than one assessment of test performance, and for these there was often not complete concordance in the 'quality' as judged by the scores obtained

from the Reid checklist. Thus, Neville (1987) examined two assessments of the test performance of the HemoCue compared with an automated FBC machine in a hospital laboratory. In the first, a comparison was made using trained laboratory staff operating the HemoCue; the quality score was 4. In the second, trained nursing sisters operated the HemoCue; the comparison scored 5. The difference was accounted for by the fact that review bias could not be excluded in the first comparison, but was unlikely in the second. Other articles (Søndenaa *et al,* 1992; Pope *et al,* 1993; Daviaud *et al,* 1993) show similar discordance between quality scores, although the maximum difference is never greater than 2 points.

(ii) There was, however, much greater discordance in quality, where there were attempts to assess completely different aspects of tests within the same article. This was particularly true where articles addressed both test performance and impact. Thus, Hjortdahl and colleagues (1991) achieved a high quality score of 6 in measures of test performance of NycoCard CRP in comparison with a laboratory turbidimetric assay of CRP; however, the parallel assessment of impact involved no comparator/control group and was based on subjective assessment by clinicians. Further examples of this phenomenon are seen in other articles (Sands *et al,* 1995; Pope *et al,* 1993; True *et al,* 1986).

(iii) Some articles contained information on repeatability of test results. Although not all aspects of the Reid checklist could be appropriately applied to such comparisons, some aspects could, such as protection from the equivalent of review bias. However, in very few cases were details of the methods used to assess repeatability expressed in any detail, thus making even general assessments of the validity of measures of repeatability impossible.

(iv) The most frequent failure in assessing test performance was in giving an indication of the precision of the estimate. Of 130 assessments of test performance, only 24 (18.5%) presented any meaningful information indicating the effect of chance, for example, confidence intervals for sensitivity or specificity. A reliance on correlation coefficients in assessing agreement between sets of continuous data undoubtedly contributed to this, as it is difficult to convey the effect of random variation. This is despite the availability of alternatives, such as expressing agreement in terms of mean differences, which are not only much more easy to interpret but also make calculation of CIs much easier.[51]

(v) Difficulty in judging whether a comparator or standard was appropriate. Two examples, demonstrating inconsistency within given areas of NPT application, illustrate this.

- For testing of microalbuminuria, Kouri and colleagues (1994) demonstrated the shortcomings of using urinary albumin concentration measured by nephelometry whereas, in a further paper by de Grauw and colleagues (1995), urine concentration by nephelometry had been accepted as an adequate gold standard.
- For rapid tests of streptococcal sore throat, Wegner and colleagues (1992) threw doubt on appropriateness of single culture methods of detecting Group A streptococci. This method had been accepted as an adequate gold standard in other papers examining this subject (Andersen *et al,* 1992; Wright *et al,* 1987; True *et al,* 1986).

Distribution of articles and comparisons

The distribution of studies examining NPTs was of particular interest. In *Table 25,* the number of assessments and articles addressing particular topic areas are presented, sub-divided both by whether the setting was directly relevant to primary care and by the type of assessment being examined. The original references for these studies are given in *Table 26*.

The first important point emphasised in these tables is that because each article on diagnostic tests is likely to contain a number of relevant assessments of different aspects of that test or tests, a count of articles alone underestimates the total amount of information which may be available for consideration in making an overall assessment of whether a particular diagnostic test is suitable for use as an NPT. Thus, if the numbers of articles in any given test area in *Table 25* are considered, the benefit gained from a more focused systematic review of the literature might seem to be relatively small. However, considering the number of assessments made in each of the test areas clearly identifies a much greater volume of information needing to be considered, thus increasing the benefit likely to be gained from such an approach.

TABLE 25 *Distribution of assessments in papers with greatest validity, by area, setting and type*

Area of test	Setting in which test applied	Types of assessment of diagnostic tests*							
		Repeatability		Test performance		Impact		Total	
Haematology/anticoagulation/ INR, prothrombin time, activated partial thromboplastin time	Primary care/home	0		1 [1]		2 [1]		3 [1]	
	Laboratory-based	2 [2]	5	2 [1]	6	0	2	4 [2]	13
	Hospital/other	3 [2]	[3]	3 [2]	[4]	0	[1]	6 [2]	[4]
Haematology/full blood counts/haemoglobin	Primary care/home	0		1 [1]		0		1 [1]	
	Laboratory-based	0	0	1 [1]	2	0	0	1 [1]	2
	Hospital/other	0		0	[1]	0		0	[1]
Haematology/ inflammation/CRP	Primary care/home	0		3 [1]		2 [1]		5 [1]	
	Laboratory-based	1 [1]	1	9 [2]	12	0	2	10 [3]	15
	Hospital/other	0	[1]	0	[3]	0	[1]	0	[3]
Haematology/inflammation/ ESR	Primary care/home	4 [1]		2 [1]		1 [1]		7 [1]	
	Laboratory-based	0	4	0	2	0	1	0	7
	Hospital/other	0	[1]	0	[1]	0	[1]	0	[1]
Clinical chemistry/desktop analysers/chemistry profiles	Primary care/home	4 [2]		4 [2]		0		8 [2]	
	Laboratory-based	5 [3]	19	1 [1]	15	0	2	6 [3]	36
	Hospital/other	10 [4]	[3]	10 [4]	[3]	2 [2]	[2]	22 [5]	[4]
Clinical chemistry/lipids cholesterol, profiles	Primary care/home	0		0		0		0	
	Laboratory-based	7 [2]	8	6 [2]	7	0	0	13 [2]	15
	Hospital/other	1 [1]	[3]	1 [1]	[3]	0		2 [1]	[3]
Diabetes/blood glucose	Primary care/home	0		0		0		0	
	Laboratory-based	2 [1]	2	0	4	0	0	2 [1]	6
	Hospital/other	0	[1]	4 [1]	[1]	0		4 [1]	[1]
Diabetes/HbA1c	Primary care/home	1 [1]		0		0		1 [1]	
	Laboratory-based	0	2	1 [1]	4	0	1	1 [1]	7
	Hospital/other	1 [1]	[1]	3 [1]	[1]	1 [1]	[1]	5 [1]	[1]
Diabetes/urine microalbumin/ nephelometry, dipstick	Primary care/home	0		1 [1]		0		1 [1]	
	Laboratory-based	2 [2]	2	5 [1]	6	0	0	7 [2]	8
	Hospital/other	0	[2]	0	[2]	0		0	[2]

* *Figures in the table refer to the number of separate assessments/comparisons of a particular type undertaken in any given test target area/setting combination. Figures in parentheses indicate the number of articles in which the separate assessments/ comparisons were reported. Thus 12 [3] indicates that 12 separate assessments/comparisons were contained in three articles.*

continued

TABLE 25 contd *Distribution of assessments in papers with greatest validity, by area, setting and type*

Area of test	Setting in which test applied	Types of assessment of diagnostic tests*							
		Repeatability		Test performance		Impact		Total	
Microbiology/group A β haemolytic streptococci	Primary care/home	0		8 [4]		1 [1]		9 [4]	
	Laboratory-based	0	0	0	8	0	1	0	9
	Hospital/other	0		0	[4]	0	[1]	0	[4]
Microbiology/urine testing/ dipstick, microscopy	Primary care/home	6 [1]		13 [2]		0		19 [2]	
	Laboratory-based	0	6	0	13	0	0	0	19
	Hospital/ other	0	[1]	0	[2]	0		0	[2]
Cancer screening/haematuria	Primary care/home	0		1 [1]		0		1 [1]	
	Laboratory-based	0	0	1 [1]	2	0	0	1 [1]	2
	Hospital/other	0		0	[1]	0		0	[2]
Pregnancy/home tests	Primary care/home	0		22 [1]		0		22 [1]	
	Laboratory-based	0	0	27 [1]	49	0	0	27 [1]	49
	Hospital/other	0		0	[1]	0		0	[1]
ALL TESTS	Primary care/home	15 [5]		56 [15]		6 [4]		77 [16]	
	Laboratory-based	19 [11]	49 [16]	53 [11]	130 [27]	0	9 [7]	72 [17]	188 [29]
	Hospital/ other	15 [8]		21 [9]		3 [3]		39 [10]	

* *Figures in the table refer to the number of separate assessments/comparisons of a particular type undertaken in any given test target area/setting combination. Figures in parentheses indicate the number of articles in which the separate assessments/ comparisons were reported. Thus 12 [3] indicates that 12 separate assessments/comparisons were contained in three articles.*

Areas with more than ten assessments in more than one article would seem to be a particular priority for such focused reviews. Examining the distribution of assessments identified in any given area, reveals five such areas:

- anticoagulation therapy control
- CRP
- chemistry profiles on desktop analysers
- cholesterol testing, either alone or as part of a profile
- urine testing for diagnosis of urinary tract infection by dipstick or microscopy.

That a much more focused quantitative systematic review would be essential to obtain a valid summary of the available information in these areas is further emphasised by the following.

- The variation in the measures used to assess diagnostic tests. Thus, by referring to Appendix 2, it can be seen that results of diagnostic test performance are expressed in at least five different ways: mean difference from the mean; percentage of results in agreement; correlation coefficients; sensitivity/ specificity; LRs. One way to clarify this heterogeneity of measures would be to reanalyse the results of the original studies using a common measure.

- The need to give an indication of the role of chance in accounting for the observed results. The fact that few studies provide any useful information on this point would make re-analysis of most of the studies, even viewed individually, essential. Undertaking this as part of a meta-analysis would have the advantage of further reducing the impact of chance in interpreting the results by increasing the number of observations on which estimates were based.

TABLE 26 *Papers with greatest validity which addressed particular test areas, in given settings with specified assessment types*

Area	Setting in which test applied	Types of assessment of diagnostic tests		
		Repeatability	**Test performance**	**Impact**
Haematology/anticoagulation/ INR, prothrombin time, activated partial thromboplastin time	Primary care/home		Anderson *et al,* 1993. *Arch Intern Med*;**153**:1441–7.	
	Laboratory-based	Jennings *et al,* 1991. *J Clin Pathol*;**44**:950–3.		
		(Rose *et al,* 1993. (see below)		
	Hospital/other	Rose *et al,* 1993. *Arch Pathol Lab Med*;**117**:611–17.		
		McCurdy *et al,* 1992. *Arch Intern Med*;**152**:589–92.		
Haematology/full blood count/ haemoglobin	Primary care/home		Neville, 1987. *BMJ*;**294**:1263–5.	
	Laboratory-based		–	
Haematology	Primary care/home		Hjortdahl *et al,* 1991. (see below)	
Inflammation/CRP	Laboratory-based	Hjortdahl *et al,* 1991. *Scand J Prim Health Care*;**9**:3–10.	Søndenaa *et al,* 1992. *Scand J Clin Lab Invest*;**52**:585–9.	
			Hansson *et al,* 1995. *Scand J Prim Care*;**13**:39–45.	
Haematology/ inflammation/ESR	Primary care/home	Dinant *et al,* 1989. *Scand J Prim Health Care*;**7**:231–5.		
Clinical chemistry/lipids/ cholesterol	Laboratory-based	Koch *et al,* 1987. *Clin Chem*;**33**:2262–7.		
	Hospital/other	Phillips *et al,* 1988. *Med J Aust*;**149**:122–5.		
Clinical chemistry/desktop analysers/chemistry profiles	Primary care/home	Nanji *et al,* 1988c. *J Clin Pathol*;**41**:223–5. Nanji *et al,* 1988b. *Can Med Assoc J*;**138**:517–20.		
	Laboratory-based	Erickson *et al,* 1993. *Clin Chem*;**39**:283–7.		
		Nanji *et al,* 1988b. Nanji *et al,* 1988c.		
	Hospital/other		Sands *et al,* 1995. *Acad Emerg Med*;**2**:172–8.	
		Nanji *et al,* 1988b. Nanji *et al,* 1988c. Erickson *et al,* 1993. (see above for references)		Tsai *et al,* 1994. *Clin Ther*;**16**: 898–910.
Diabetes/HbA1c	Primary care/home	Pope *et al,* 1993. (see below)		
	Laboratory-based		Pope *et al,* 1993. (see below)	
	Hospital/other		Pope *et al,* 1993. *Diabet Med*;**10**:260–3.	

continued

TABLE 26 contd *Papers with greatest validity which addressed particular test areas, in given settings with specified assessment types*

Area	Setting in which test applied	Types of assessment of diagnostic tests		
		Repeatability	**Test performance**	**Impact**
Diabetes/urine microalbumin/ nephelometry, dipstick	Primary care/home		de Grauw *et al,* 1995. *Diabet Med*;**12**:657–63.	
	Laboratory-based	de Grauw *et al,* 1995.		
		Kouri *et al,* 1994. *Eur J Clin Chem Clin Biochem*;**32**:419–23.		
Microbiology/group A β haemolytic *streptococci*	Primary care/home		True *et al,* 1986. *J Fam Pract*;**23**:215–19.	
			Wright *et al,* 1987. *J Fam Pract*;**25**:505–8. Andersen *et al,* 1992. *Scand J Prim Care*;**10**:223–5. Wegner *et al,* 1992. *JAMA*;**267**:695–7.	
Microbiology/urine testing/ dipstick, microscopy	Primary care/home	Winkens *et al,* 1995. *Fam Pract*;**11**:290–3.		
			Ditchburn & Ditchburn, 1990. *Br J Gen Pract*;**40**:406–8.	
Cancer screening/ haematuria	Primary care/home		Messing *et al,* 1987. *J Urol*;**137**:919–22.	
	Laboratory-based		Messing *et al,* 1987.	
Pregnancy/home tests	Primary care/home		Daviaud *et al,* 1993. *Clin Chem*;**39**:53–9.	
	Laboratory-based		Daviaud *et al,* 1993.	

- In none of the areas examined is there complete agreement on all important aspects of the assessment of particular diagnostic tests where they have been examined by different studies. For example, various aspects of test performance of urine dipsticks for the diagnosis of urinary tract infection in primary care were examined by Ditchburn and Ditchburn (1990) and Winkens and colleagues (1995). There were marked differences in the common measures, sensitivity and specificity, reported. A quantitative systematic review focused on urine testing would help resolve what the true values were, and/or explore what the reasons for the different results were. As far as the latter is concerned, the framework employed to abstract data in this detailed review begins to explicitly identify those variables in NPTs which should have a considerable influence on their overall performance. A more focused systematic review would allow this to be developed further in ways specific to the test areas being examined.

Returning to the distribution of assessments, there are many specific points which could be developed. However, only two additional points will be made here, beyond the distribution of assessments by test area discussed above.

(i) There is a relative poverty of assessments undertaken in a primary care or home setting, that is, in that location where it is most important that the various aspects of the assessment of an NPT should be replicated. Although, apparently, the numbers of assessments made in primary care/home settings were approximately equal with those which were wholly laboratory-based (77 versus 72), this needs to be interpreted in the knowledge that there was a very strong bias in the initial

search and subsequent sorting of literature to select those articles directly relevant to primary care. It should also be noted that articles categorised as 'hospital/other' generally do provide some information on the test performance estimates of NPTs to primary care settings, particularly through the use of test operators who are not technically trained, such as doctors, nurses and clerks, that is, those who would be those most likely to be performing NPT in primary care.

(ii) Assessments of impact are rare. Again, although there was some bias against identifying assessments of impact by the way potentially relevant articles were initially assessed for quality, the very small number of assessments, nine assessments in seven articles, together with their generally poor validity, was remarkable and a major shortcoming in the identified body of research literature on NPT.

Conclusions

It is clear from this detailed review of a sample of the literature (the highest scoring papers on validity), identified in the wider search for research on NPTs, that the volume of information is such that a number of more focused, quantitative systematic reviews are feasible. Indeed, these would be essential in order to gain a clear impression of exactly what the implications of introducing particular NPTs might be.

However, there are problems, and in this respect the most important contribution of this detailed review is to draw out those features of the literature on NPTs which have implications for the manner in which such reviews should be undertaken. Suggestions on ways of overcoming identified problems are developed further in the discussion section, in relation to the main phases of undertaking systematic reviews as described by the NHS Centre for Reviews and Dissemination.[52]

Chapter 11
Discussion

This systematic review has been very wide ranging in that it has covered three broad areas, NPT in primary care, rapid laboratory results (EDI) and CDDS in association with NPT.

Within NPT there are a wide range of different technologies, ranging from simple test strips to complex analysers, and a range of applications from diagnosis to monitoring and from haematology to virology. In addition, for each test and application there are a range of studies from determinations of accuracy, diagnostic performance, impact and satisfaction, to cost-effectiveness evaluations. One aim of this review is to provide a snapshot of the technology available, and the extent and quality of its evaluation. To this end, information has been included on all published data, together with further critical appraisal of the papers scoring highly on the validity assessment, a separate evaluation of all the papers with cost analyses, and a survey of the available technology by direct contact with the suppliers.

What this review is unable to provide is a list of technologies and applications that have been proven to be cost-effective. This is principally because, even in areas where there are a number of publications, such as the rapid streptococcal throat tests, gaps and inconsistencies in the literature are too great. However, this discussion aims to provide an agenda for further research and a blueprint for the design of future studies. The discussion is divided into three sections: comments relating to the progress and robustness of the review itself; comments general to all evaluations of NPTs in the primary care setting; and specific comments relating to studies in the most evaluated areas.

The review process

The review itself was complicated by a number of factors, principally problems with a lack of agreed terms, the wide range of different sources of literature, the fact that the majority of published articles consisted solely of opinion with no data on which to base that opinion, and the fast-moving nature of the field. A number of papers have been published since the literature searches were completed. This has been further complicated by the long delay before articles in 'lesser known' journals are indexed in Medline and BIDS (a situation exacerbated during the period of the review by financial difficulties at the US National Library of Medicine, who are responsible for Medline). For this reason, it is impossible to give a definite cut-off time, since articles and papers apparently published in the relevant time-frame may have been missed by searches of the electronic databases.

In common with most systematic reviews, the most fruitful source of references were the three most comprehensive electronic databases (BIDS, Medline and Embase), although only 25% of the references obtained were relevant. In the case of this review, 24% of the papers were obtained solely from a survey of those with a known interest in the field.

It must be made clear that, for the reasons detailed below, it is likely that a number of papers may have been missed by the search strategy. A number of recommendations regarding the conduct of future reviews in this area are made in chapter 12.

Difficulty in defining the subject

One considerable difficulty with this review was the lack of a universally understood definition of the technologies described as 'near patient tests'. Many papers used the terms 'rapid test' or 'dipstick' or referred to specific technologies such as desktop analysers or slide agglutination tests. Searching for each specific diagnostic test would not have been feasible, or economic, as a means of identifying NPTs. In addition, there seems to exist considerable confusion in the literature as to what constitutes an NPT; many 'rapid tests' are designed as rapid laboratory-based methods, particularly in the field of microbiology.

As a practical solution, the term had to be defined and the search conducted widely; the reference list could then be reduced by excluding inappropriate papers manually. Papers involving rats or space exploration were straightforward exclusions but, for some papers the decision to include or exclude relied on the reviewers' interpretation of the authors' description of the test methodology. For

example, a paper describing a 'rapid assay' for Chlamydia trachomatis in primary care was excluded because the methodology made it clear that, although swabs were taken in the surgery, the assay was performed by trained personnel in the laboratory setting, that is, it was not near the patient. In all, 87 papers were excluded from the review because the test described was not an NPT, according to the definition.

Problems over definition resulted in the search net being spread very widely, thus explaining why the 1057 unique references yielded only 400 papers that were relevant to the review topics. The grounds for exclusion of the majority (282) of the papers were those of having no connection whatsoever with either primary care, NPT or the other two categories. As there are no key journals for NPT, the papers came from a wide range of generalist, primary care and clinical pathology journals; in total, 47 different journals. Hand-searching of any particular journal would not have been justified.

The fields of CDDS and laboratory rapid transit systems were even more difficult. The decision support papers were limited to only those systems where advice was offered on the use to be made of a diagnostic test result. Papers reporting on generalised computer record-keeping, prescribing advice systems or computerised protocols not requiring the use of a test were excluded. On this basis, 97 papers were excluded.

The results of searching on rapid transit of laboratory results were disappointing; only 28 papers were retrieved and only two of these contained any data. There is also the question of appropriate comparisons of technology to be addressed. Although a fax machine or EDI will facilitate the receipt of results from a laboratory, the NPT could only currently be replaced by a rapid specimen transmission service. However, future technologies will conceivably enable primary-care based analysers, connected to desktop PCs, networked to distant laboratories, where the analyte results are quantified and interpreted for a result to be returned electronically to primary care.

Difficulty with defining the setting

Other than the aforementioned difficulty of defining terminology for the specified technology, there are problems internationally in defining primary care. The differences between different healthcare systems should lead to caution in generalising from, for example, US primary care physicians to UK general practice. Much of the literature on the measurement of cholesterol and the use of desktop analysers pertains to US 'office laboratories'. These are often staffed by trained technologists and subject to accreditation procedures. Techniques such as primary care (office) based throat swab or urine culture are commonplace in the USA but unusual in the UK.

Further, many papers are vague about the actual location of the study, it being unclear whether patients were recruited from outpatient departments or from primary care. Some 'primary care clinics' seemed to be secondary-care based open-access services or outreach clinics. This difficulty was made more pronounced by the poor quality of abstracts and use of misleading titles. A total of 136 papers were excluded on the basis of not relating to primary care.

Lack of original data

Of the 400 papers deemed to be relevant to the topics of the review, 298 were excluded as not being an original research publication. Of these, 81 were abstracts, 26 were letters, and the remainder were review articles, reports, short papers, books, posters or editorials (see *Table 14*). This lack of data and wealth of unsupported speculation was most evident in the areas of CDDS, where 59 out of 67 papers reported no data, and EDI, where 23 out of 28 papers were descriptive only. The lack of serious clinical evaluation of these technologies is a major gap in the evidence needed to underpin the NHS information technology strategy.

Issues general to NPT evaluations

The methodology for evaluating diagnostic tests has benefited from a number of recent publications. Many of the recommendations are general to all diagnostic tests, although the case of NPTs demands the inclusion of other factors, as discussed previously. The Evidence-Based Medicine (EBM) Working Group and the Cochrane Collaboration Methods Working Group on Screening and Diagnostic Tests have both summarised the literature in this area – the EBM group from the context of appraisal of papers and the Cochrane Collaboration with respect to the effect of study design on bias and generalisability. In addition, the latter group have recently produced guidelines for the conduct of systematic reviews and meta-analyses of evaluations of diagnostic tests.[53] These guidelines contain a checklist for the assessment of quality and applicability which has been used as a template for this discussion, but was published after this review had been conducted.

Valid reference standard

Valenstein[54] has commented that many evaluations are based on imperfect gold standards as proxies for disease. Such problems are common, arising from the inability to perform invasive tests in asymptomatic patients, the absence of an agreed gold standard, or 'post mortem' definitions of many diseases. Examples include the use of ECG and creatine phosphokinase measurement to define myocardial infarction, the use of more than 10^5 bacteria in urine to define infection, and the lack of a true gold standard for determining the presence of *H. pylori* infection.[55]

The use of an imperfect reference standard may either inflate or reduce the sensitivity or specificity, depending on whether the misclassification errors of the test and the standard are conditionally independent or not. For example, the difficulty in evaluating the rapid streptococcal sore throat tests caused by the lack of an accepted standard for culture has been highlighted. Asymptomatic carriage of Group A *Streptococcus* in individuals with viral sore throat will produce false positive cultures, the use of a single-plate culture may produce false negative cultures. However, a major cause of false negative tests is an inadequate throat swab, a result which will affect both the NPT and culture.

If the above situation were not complex enough, the effect on predictive values is potentially greater and differs between high and low prevalence populations. Valenstein has suggested that the use of an imperfect standard could be partly compensated for by the authors.[54] Possible techniques include: studying sensitivity and specificity with different definitions of disease or in different populations; framing the problem in terms of clinical outcome (i.e. myocardial infarction will be managed according to the ECG and enzyme results, regardless of the actual pathological state of the myocardium); evaluating and correcting for potential bias.[54] In addition, iterative Bayesian techniques such as Gibbs sampling can produce 'best' estimates in the face of uncertain data.[55]

Unfortunately, of the authors of the reviewed papers, only Wegener and colleagues (1992), addressed the issue of imperfect reference standards, although this would certainly apply to the streptococcal throat tests, the urinalysis and the CRP papers, at least. This failure may have major consequences for the evaluations, as the lower prevalence of disease in primary care will produce different performance characteristics from secondary care studies, solely as a result of an imperfect standard. This makes the interpretation of the studies virtually impossible without further data on the reliability of the gold standard in primary care.

Blinding of NPT and gold standard measurements

Although many authors did not comment on this, this is likely to be due to failure to report it, as this criterion is fairly easy to achieve where NPT and laboratory samples are analysed separately from each other.

Verification bias

Verification bias represents the selective application of the reference standard to patients with positive (or negative) test results. This does not seem to be a particular problem with NPT studies as, in most studies, the strategy adopted is to apply the reference test to all patients.

Comparisons

In studies where two or more tests are being compared, the allocation of tests to patients should either be randomised or both tests performed independently on all patients. In these studies, both designs are represented, the comparisons of different streptococcal throat tests being examples of tests done on all subjects.

The question of randomisation is, however, a more vexed issue. Most studies have approached this by either stratified randomisation of practices or by employing prospective cross-over designs, with before and after comparisons. If the unit of comparison is a practice standardised rate of testing, this is satisfactory. However, analysis by individual, such as to determine the effect of NPT use on individual patient care, would show less effect on account of the fixed between-practice variation.

Spectrum of disease and non-disease

Spectrum bias refers to the differing performance of a test in populations of patients with a different prevalence of disease. Lachs and colleagues have demonstrated this in the application of urinalysis to the emergency room setting.[56] Clearly, as the predictive value (diagnostic probability) of a test is related to the underlying prevalence of disease and the likelihood ratio of the test, it will vary from one setting to another. However, although axiomatically the likelihood ratio (and sensitivity and specificity) should be a property of the test and not the setting, in certain circumstances these parameters also change. This arises when the test is being evaluated against an imperfect gold standard (as in the example quoted) or when certain NPT or reference results are either uninterpretable or indeterminate and are excluded from the analysis (the

number of these in different populations not being conditionally independent of the test and biasing the results).

There are two levels of allowing for spectrum bias in studies. First, the study may calculate predictive values for the test in different clinical situations using Bayes' Theorem. Second, the study may calculate performance characteristics separately for subsets of the data with high and low probabilities of disease. None of the studies in this review examined their data directly for spectrum bias, although several studies commented on the difference between their results and those obtained in secondary care settings with higher disease prevalence. It is impossible to determine with any accuracy whether differences in test performance are due to operator variability or subject variability, unless an investigation of possible spectrum bias has been undertaken.

Setting

In addition to the operation of spectrum bias, many other factors operate to alter the performance characteristics of tests in different settings. Many tests, particularly those tests with many operator-dependent steps (as illustrated by the desktop analysers), perform poorly in the less controlled settings of primary care or when used by lay personnel. A number of studies comment on this finding, for example, the Hemocue (Neville, 1987); the desktop analysers (Hilton *et al,* 1994); the rapid streptococcal throat tests (Wegner *et al,* 1992). Other factors could be the difficulty of interpretation of the result (e.g. with the Nycocard if an optical reader is not used) or unfamiliarity with the equipment due to infrequent use. Unfortunately, although most studies speculate on the reasons for this differing performance, none are able to offer any data to support their speculations.

Clinical interpretation

The interpretation of any test is dependent upon the prior probability of the condition being tested for in the population of patients being tested. For interpretation of clinical applicability it is necessary to have some information about the patients in the study, how they were selected, previous tests and co-morbid conditions. Although most studies report demographic details, clinical details are less common. All evaluations of performance characteristics should quote prevalence and predictive values at the very least. LRs are very rarely reported in the literature; only a handful of papers included these, even though such data are necessary to implement the research findings.

One striking feature of general practice is its variability in all aspects of practice. Only one paper (Winkens, 1995) addressed the issue of variability of test performance, not only with respect to patient subgroups but also by practice, providing a range of LRs and a summary by practice. This paper represents a model for the evaluation of NPTs in primary care.

Test descriptions

Very few evaluations give detailed descriptions of the type of technology in use, its complexity and the number of operator-dependent steps required to produce a result. Two examples of papers that do so are those by Rink and colleagues (1994) and Hobbs and colleagues (1993), where there are simple but clear explanations of, for example, the operation of the desktop analysers being used, the sample required, and whether centrifugation of whole blood was needed. Many of the papers reporting 'evaluations' were excluded on the basis of being purely descriptive of the technology, with no objective evaluation.

Sample size calculations

Simel and colleagues[57] have provided the statistical background to providing confidence intervals for LRs; none of the reviewed papers did this. In addition, Lilford[58] has suggested that, for randomised controlled trials, the effect size sought in a clinical trial, δ, should be based on prior decision analysis. The minimum LR for a test to be clinically useful can be calculated in the same fashion. This LR can be used in sample size calculations for diagnostic test studies. However, none of the papers in this review described sample size calculations.

Conclusions not justified by the results

As mentioned earlier, authors often speculate extensively in the discussion section of their paper, particularly with regard to poor technical performance or cost implications. This speculation can appear in the conclusions in a manner that is unjustified by the data presented.

Economic analysis

If there is no demand for evidence of value for money in healthcare technology, there is little incentive for health technology companies to provide such evidence. The review of the literature noted only limited insight into the question of value for money from healthcare technology intervention. Much of the literature does, however, provide some simple cost analysis that could be incorporated into a value-for-money assessment of the technology.

Given the policy concern for value-for-money data, the simplest way to effect change is for those involved in healthcare decision-making to require that they will not purchase or use any intervention unless it is proven to be good value for money. This would drive the providers of healthcare technology and research sponsors to establish research evidence of the merits of new technologies.

Issues relating to specific categories of NPT

It can be seen from the wide variety of technology available, and the lack and poor quality of evaluation of this technology, that there is a considerable gap between the marketplace and evaluation in respect of NPT. If evaluation of NPT from the laboratory to practice is divided into three phases, as suggested in the introduction, then:

- most technologies are evaluated for accuracy and safety by the manufacturer prior to marketing and perhaps by the Medical Devices Agency (see Appendix 4); this form of evaluation was deliberately not searched for in this review
- some tests have been evaluated for their performance characteristics in primary care; however, many of these evaluations are of limited scope and quality
- only desktop analysers have been subject to a trial of impact on practice and cost-effectiveness.

Furthermore, in addition to all these limitations, most trials have been very affected by the onward march of innovation, in that technology evaluated only 5 years ago is now largely obsolete.

This raises the question of whether prospective trials in this area are worthwhile, as the technology will have moved on by the time the result is available. It may be that high quality evaluations of performance in primary care, coupled with careful systematic reviews of the need for diagnostic evaluation in a given clinical area, would allow much faster answers to be given on the basis of techniques such as decision analysis and cost-effectiveness modelling. The latter is crucial since, without data on the potential for new technologies to contribute to improved care in a defined clinical environment, there will be limited stimulus for technology providers to develop appropriate systems.

The enhanced role of primary care in most healthcare systems, in earlier disease recognition, and better monitoring of established disease, can only occur safely if primary care physicians have access to accurate and functional diagnostic technologies. More research effort also needs to be directed at how primary care physicians manage particular clinical problems before the effects of NPT can be accurately predicted. Such research would be more generic in that the results could be applied to a range of different technologies rather than being a costly 'stand-alone'.

Issues relating to clinical chemistry NPTs

In the following section, the findings of the systematic review are summarised in terms of the level of knowledge, and some of the priorities for further research are identified for each area of the review.

Desktop multi-analysers

The use of desktop analysers in general practice is one of the most extensively investigated areas of NPT. Comparison between studies is limited by the extent to which progressively more technologically-advanced equipment is evaluated in later studies, Furthermore, analysers have continued to evolve since even the most recent studies, both in the range of tests and ease of use. However, some general conclusions can be drawn from the published studies.

- Quality control (or quality assurance) is an important issue if reliance is to be placed on NPT results. The need for quality control, coupled with a low turnover of tests, seriously undermines the cost-effectiveness of NPT in many practices.
- Most studies indicate that only a proportion of test requests can be replaced by NPT, although as more tests become available on the analysers (particularly if they are shown to be more relevant to primary care), this conclusion may no longer hold. The reasons why NPT is not more extensively used suggest that the role of testing in primary care is more complex than the simple need for a result. Such issues as the role of such investigations in 'playing for time' and the role of reassurance from negative results need to be examined further before the usefulness of NPT can be more fully appreciated. Physicians in UK primary care also appear to use a different range of tests than the US hospital doctors whose needs dictated which tests were available on many early machines.
- NPT may take longer to become integrated into practice than the length of studies carried out so far would allow. NPT is not immune

from the effects of inertia and the need to manage change.

- All the studies, except the small study of Gilio and colleagues (1993), indicate that the introduction of NPT results in a lowering of the threshold at which a GP decides to investigate, with, overall, more tests being performed when NPT was available. A consistent finding across the studies was that the increase in testing was largely due to increased screening activity (cholesterol, haemoglobin) and monitoring (electrolytes in patients on diuretics). Although the Australian study (Non-laboratory Working Party, 1991) failed to detect any improvement in a range of clinical processes, there is doubt as to whether the study had the power to detect significant outcomes. On policy grounds, these are desirable activities by primary care physicians. However, there is no evidence on the necessary level of monitoring in these areas. How frequent are electrolyte imbalances in primary care patients? How significant are they? Is the increase in monitoring at an appropriate level? There is an urgent need to establish baseline clinical requirements in these areas before proceeding to full test evaluation.
- Although three of the studies have addressed the issue of costs, the cost-effectiveness analyses are far from robust.

Diabetes

Glucometers

There is a need to establish whether home glucose monitoring is effective in improving overall glycaemic control. Early studies were encouraging but need to be developed. The general practice diabetic clinic would be an ideal setting for such a long-term trial.

HbA1c

In one study (Pope *et al,* 1993), the performance of the Ames DCA 2000 NPT was evaluated in a variety of settings. However, the general practice arm was limited to one clinic, with generalisation being limited. As most general practice patients are non-insulin dependent, the results of the DCCT trial are not directly applicable.[45] It would seem prudent, however, to obtain trial evidence as to whether NPT monitoring of HbA1c in general practice improves control. This would be an important step in implementation, should ongoing trials of tight control of NIDDM have similar results in decreased complications to the DCCT trial.

Microalbuminuria

Two tests are available for the detection of microalbuminuria, although Nycomed are currently unable to supply the Nycocard U-Albumin test. The evaluation of these tests is greatly complicated by the lack of an appropriate reference standard, as the definition of microalbuminuria is based on 24-hour albumin excretion, and these tests measure albumin concentration (Kouri *et al,* 1994). A prospective evaluation of the clinical effects of screening in a pragmatic trial of intention-to-treat, using the albumin concentration as an initial screen, is required to properly evaluate these tests.

Haematuria

The papers by Britton and colleagues (1989) and Messing and colleagues (1987; 1989; 1995) do not provide sufficient evidence to warrant widespread adoption of screening for haematuria. The role of NPT is subject to the necessary demonstration of the cost and effectiveness of screening *per se*.

Issues relating to NPTs in microbiology, virology and immunology

Streptococcal throat tests

The interest in these tests internationally is heavily influenced by the prevailing practice of local primary-care physicians, who are, in turn, subject to influence by the level of risk (perceived or objective) from nephritic and arthritic strains of streptococci. In the UK, there is no consensus on the appropriate management of sore throat. GPs are heavily influenced by factors such as patient expectation and clinical signs such as pyrexia or tonsillar exudate. Until the role of investigations in the management of suspected streptococcal pharyngitis is better understood, it as unlikely that streptococcal throat tests will be widely used in the UK.

Urine multi-test strips

The excellent paper by Winkens and colleagues (1995) demonstrates the poor predictive value of these tests in primary care. Although the accepted standard, mid-stream urine is an imperfect gold standard and urinalysis is thus subject to spectrum bias. If confirmed, these results suggest that urinalysis is unhelpful in the diagnosis of uncomplicated urinary tract infections in primary care. These tests are widely used and possibly abused; urgent re-evaluation of their role is therefore needed.

ESR and CRP

In combination, the papers in which the performance of CRP as an NPT is examined (Dinant *et al,* 1989; Hansson *et al,* 1995; Hjordtal *et al,* 1991;

Søndenaa *et al,* 1992; Urdal *et al,* 1992) demonstrate that NycoCard is an accurate and precise test, but they do little to convince that measurement of CRP is effective, that is, that it improves the early identification of disease, particularly differentiation between bacterial and viral aetiologies. There is no empirical evidence showing NycoCard's effectiveness in appropriately influencing clinical practice. Thus, although NycoCard can be used in primary care, its wider uptake should be dependent on clinical effectiveness data; such data are lacking.

Issues relating to NPTs in haematology

Anticoagulation

The studies demonstrate that the use of NPT for the measurement of INR is feasible and practical, but concerns have been expressed about discrepancies between the results obtained on these monitors and those obtained within hospital laboratories. However, two external issues complicate this viewpoint. The first is that the INR system, although designed to standardise results between centres, is imperfect and is dependent upon the thromboplastin reagent used to derive the result. The second is that while small differences in INR measurement may appear, it is the effect on clinical management that is essential, and none of these papers indicate significant clinical management differences associated with the use of NPT.

More work is needed to investigate the effect of quality assurance on the performance of these monitors, particularly on the effect of anticoagulant dose. More work is also needed to assess patient satisfaction with this form of healthcare delivery, both in primary care and in the home.

Haemoglobin

There was only one (9-year-old) paper that reported a primary-care evaluation of the Hemocue (Neville, 1987). The results were found to be less reliable in primary care but the methodology of the study would suggest that it may not be possible to generalise from this result. Further research is needed to assess the performance characteristics of this test, together with the haemoglobin now available on most desktop analysers, in primary care. Haemoglobin was identified in several desktop analyser trials as a test desired by GPs.

D-dimer

The D-dimer test has not been evaluated for its performance characteristics in primary care; further work is needed to determine whether the high NPV (suggesting the ability to exclude DVT) obtained in the secondary care outpatient setting will apply in primary care. If this remains the case, a prospective trial of DVT diagnosis and management in general practice, possibly using NPT anticoagulant control, could be mounted.

Contribution of CDDS to NPT in primary care

The entire literature reporting in this field has, until this review, been associated with computer software designed to optimise anticoagulation with warfarin. A recently published paper, coming too late for inclusion, has described an evaluation of the rule-based decision support system for lipid management in primary care (PRIMED).[47] A number of papers indicate that the use of CDDS can lead to better control of anticoagulation in secondary care, with data now available on CDDS in primary care anticoagulation clinics.[45,46]

Can CDDS can offer any advantages to NPT outside the anticoagulation area? It is not difficult to envisage a role, for example, prompting for electrolyte measurement in patients taking diuretics, or for TSH in patients on thyroxine. The drawback of the PRIMED system is that it does not encompass an NPT for cholesterol in addition to the CDDS.[47] If it had, more use may have been made of the system as the need for a cholesterol result was a key point at which patient, system and results became disconnected.

Further effort should be put into exploratory research examining the information needs of GPs in common clinical situations where diagnostic tests are initiated. Too little is known about why tests are ordered and what other information is used in interpreting their results. Knowledge of these issues largely centres on two small observational studies from the early 1980s, suggesting that GPs tend to under-investigate,[59] and that patient characteristics (such as social class) play a major role in determining rate of testing.[60]

A logical starting point for the determination of the usefulness of NPT, and the need for information to support clinical decisions, would be the demonstration of that need, as suggested by Shortliffe.[35] One means of promoting this could be a consideration of the information needs of GPs in the light of the NPTs discussed in this review.

Comparison of NPT with rapid specimen transport and results services

NPT and rapid specimen and results services are not synonymous technologies in all circumstances. NPT has the potential to deliver a result at the point of decision-making, when the patient is sitting opposite the doctor at the initial consultation. The most that a rapid laboratory service can achieve with current technology is a 'same-day' results service. However, EDI results may offer similar advantages of economies of scale, built-in quality control, and availability of specialist advice on test interpretation to the central laboratory.

For most clinical applications in primary care, the instant availability of a result may offer little more than saving the patient a telephone call. EDI should therefore be compared with paper mail for the efficient transfer of 'routine' results, rather than with NPT in specific clinical areas where an 'in-consultation' result may offer the potential for health gain. The potential for EDI to offer advantages in terms of convenience and acceptability to patients has not yet been examined in any rigorous fashion.

Whether EDI will prove cost-effective depends on many local factors outside the scope of this review. Experience in The Netherlands suggests that EDI can greatly improve results turnround time, with increased storage of results within GPs electronic clinical record (Branger *et al,* 1991; 1992). The moves towards 'paperless' practices and the NHS-wide network in this country indicate that such changes are already taking place in the UK without any rigorous evaluation.

The papers evaluating the impact of desktop analysers (Gilio *et al,* 1993; Hilton *et al,* 1994; Hobbs *et al,* 1992; Non-laboratory Working Party, 1991) offer a direct comparison between this particular type of NPT and the existing laboratory service. Issues such as quality control, economies of scale, 'playing-for-time in diagnosis', and the requesting of multiple tests, go some way to explaining the lack of evidence in support of the general substitution of the laboratory service with NPT-equipped 'office laboratories'. This statement must be qualified because technological advances may invalidate some of the findings of the earlier trials.

The potential additional benefit to patients of selective application of NPT, in situations with a demonstrated clinical need for information at the point of decision-making in a consultation, has not been tested in appropriate trials. The appropriate comparison in such trials would be the existing service, possibly augmented by a 'same-day' results service using EDI.

Chapter 12

Implications

Implications of this study for further reviews

All aspects of reviewing diagnostic tests, within both secondary and primary care settings, are in the early stages of development and any further systematic reviews should be undertaken in close collaboration with groups involved in these developments, particularly the Cochrane Methods Working Group on Systematic Review of Screening and Diagnostic Tests. Their recently published document on recommended methodology is likely to be particularly useful.[53]

This study has provided a qualitative systematic review of the overall field of NPT in primary care. More detailed quantitative reviews of discrete aspects of NPT or CDDS would further help inform research priorities.

Problem specification

With regard to question definition, it is clear that attempting to assess the effect of NPTs generally has generated a large data-set which has been difficult to manage and interpret. However, considering the available literature, at the level of NPTs targeted at specific areas and based on solving clinical problems, for example, control of anticoagulant therapy and diagnosis of urinary tract infection, appears to yield a manageable and potentially meaningful data-set, in which the wider relevance of the question posed is retained. This is likely, therefore, to be the most appropriate level to attempt to focus systematic reviews of NPTs.

However, based on the experience obtained in this review, other elements need to be incorporated into the basic questions driving future reviews.

1. The review should take into account that, within a given area, different pieces of test apparatus may perform in markedly different ways. This is clearly indicated by Nanjii and colleagues (1988a; b) for desktop analysers.

2. The review should incorporate, as sub-sections, all potential aspects of the NPTs assessment, that is, repeatability, test performance and impact, rather than focusing on one particular aspect. The work by Anderson and colleagues (1993) in assessing the use of Biotrack in monitoring anticoagulation provides a useful illustration of the importance of assessing test performance in parallel with impact. In this study, the correlation coefficient for the agreement of INR measured by patients using Biotrack at home with that obtained in a hospital laboratory was relatively poor (r = 0.73; 95% CI, 0.63–0.81). However, the implications of this apparently poor test performance are challenged by an assessment of harm. This assessment suggested that operationally the impact of this level of disagreement was minimal, since no complications attributable to over- or under-anticoagulation were detected in 533 patient months of follow-up.

   This illustration might suggest that if assessments of overall impact are available, particularly those using designs with high internal validity, such as randomised controlled trials, then other aspects of assessing the effect of NPTs are likely to be irrelevant. However, this would not be sensible, given that interpretation of the impact of an NPT can only be made when it is known whether an NPT was actually performed properly (which requires knowledge of the repeatability and test performance of the NPT concerned).

3. The review should take into account the influence of variables other than the test apparatus, particularly the nature of the operator and the setting in which the apparatus is used. These variables should be as close to the conditions in which the NPT is to be employed as possible. The potential influence on NPT test performance is well illustrated in the study by Neville (1987), where the test performance of the HemoCue (a haemoglobinometer) varied markedly, depending on whether the operator was a laboratory technician or a trained nursing sister in primary care (r = 0.99 versus r = 0.61, for comparison with automated laboratory-based measurement of haemoglobin).

   Daviaud and colleagues (1993) also demonstrated the potential influence of the operator on test performance for over-the-counter home

pregnancy kits. However, such effects are not invariable, as shown by Pope and colleagues (1993), in a study where only small differences in the test performance of the Ames DCA 2000 for measuring HbA1c were observed between use by laboratory staff and medical and nursing staff with 15 minutes training (mean difference of HbA1c by Ames DCA 2000 and HbA1c by DIAMAT HPLC for each group: laboratory staff, –0.69% [–1.42 to +0.04]; medical staff, –0.93% [–1.93 to +0.07] and –0.29% [–1.09 to +0.51]; nursing staff, –0.77% [–1.30 to –0.24]).

4. The review should take into account the effect of training, instruction and standardisation of equipment. The impact of this is suggested by Dinant and colleagues (1989) in a study where repeatability and test performance of ESR measurement in primary care were shown to be amenable to substantial improvement over the period of a year.

Literature searching and study retrieval

The difficulties in undertaking computer searches for articles based on terms such as 'near patient test' and synonyms thereof have already been commented on. These difficulties probably reflect an understandable lack of clarity in the minds of authors/indexers as to exactly what should and should not be tagged with these identifiers, particularly as the concepts and definitions of 'near patient testing' are still evolving. It is probable that any such searches relying on the use of terms describing only the general nature of the diagnostic test desired will miss relevant articles.

The basic approach used for searching bibliographic databases used in this project would need to be augmented in more focused reviews. Searching based on disease/condition specific terms would seem to be the main addition, particularly as this would help capture all potentially relevant articles assessing repeatability or test performance undertaken in non-primary care/home settings. Free text searches based on trade names of particular tests known to have been employed in a particular test area might also be a useful adjunct. Hand-searching of key journals would be a further extension not employed in this review, even though the decision on which journals to target would cause problems, although less so for a single-topic review.

Assessment of studies for inclusion/exclusion

Some of the issues described under the section on question definition could be reflected in the more focused reviews, by setting appropriate inclusion/exclusion criteria. Thus, the need to consider that results of research undertaken using operators and settings likely to be encountered when a diagnostic test is used 'near-the-patient' may be different from those in more ideal circumstances, could be handled by exclusion of all wholly laboratory-based assessments. This, however, would not be in the interests of providing the breadth of information suggested as being necessary in order to make a full assessment of an NPT. It is likely that reflecting the importance of operator/setting by defining sub-groups in the original question would be the more appropriate approach.

The importance of keeping the volume of literature manageable has been alluded to and the approach described above is generally inclusive. Stringent thresholds for study validity should be incorporated into the inclusion/exclusion criteria. The nature of such measures of validity is discussed further below.

Assessing the validity of the studies

In any future systematic review focused on a specific NPT test area, some effort will be required to modify the range of existing validity checklists dealing with the range of study designs which would be considered most internally valid in assessing repeatability, test performance and impact–effectiveness, as a minimum. The last of these seemingly presents the least problems, since a randomised comparison would probably be the threshold used and quality checklists for this type of study design are well developed.

However, despite their frequent use, the detailed review revealed that established checklists for test performance/diagnostic accuracy are not easy to apply to assessments of NPTs, particularly within the framework outlined. The most important problems encountered are listed below.

(i) Interpreting 'pertinent sub-group analyses' is very difficult when an attempt is made, as here, to consider the often multiple individual assessments reported within a single article, rather than considering the article as a whole.
(ii) 'Avoidance of review bias' is virtually redundant as a standard since, in most cases, an NPT is by definition unlikely to be susceptible. The test result is generally available more quickly and in a different location from any laboratory-based gold standard so that, even if independent blind assessment is not mentioned, it is usually possible to award a point for avoidance of review bias.
(iii) Judgements on the appropriateness of a gold standard can be difficult, as discussed earlier.

This suggests that the review panel assessing validity should include someone with enough technical expertise in a given area to identify situations where an inappropriate test apparatus/culture technique has been suggested as a gold standard. This contrasts with the need for someone with laboratory experience to be a member of the overall review group.

The main issue in any assessment of the validity of measures of repeatability is the cursory manner with which methods and results tend to be reported. Some attempts to contact original authors may need to be considered in order to gain this information, although additional data may not be easy to obtain and will add considerably to the costs of the review. However, such a step may be necessary to confirm other important study characteristics and results, since poor reporting was not uncommon in the studies examined.

Data extraction

The most important feature of data extraction is the composite and extremely complex nature of many assessments of NPTs. Hence, each component of a potentially relevant article must be identified, assessed and abstracted individually. It is inappropriate to deal with research literature in this area at the level of the whole published article.

The process is time-consuming and demands frequent re-examination of the original papers. To ensure the accuracy of the data abstracted, it should be undertaken by two individuals working independently. The framework and table developed in this review provide a useful means of simplifying data abstraction, as well as being one by which results of assessments in individual articles on NPTs can be summarised.

Data synthesis

No additional insight on this can be offered as no attempt has been made to synthesise data in this project, beyond presenting assessment details and results in tabular form. There has been enormous development in statistical methods in this area, which suggests that specialist statistical advice would be essential if a meta-analysis is to be performed in conjunction with a focused systematic review of NPTs.

Implications for health technology assessments of NPT in primary care

The development of a successful NPT requires the satisfactory completion of a series of phases, analogous to the development of a new pharmaceutical. First, there must be a recognised need for the rapid availability of test data at the point of decision-making, and that need should be translated into the appropriate design of the NPT and its initial trials of accuracy, reliability and safety. Second, the theoretical impact of the test on clinical management should be used to delineate the parameters of desirable test performance. This performance should be tested first in selected patients with the disease and then in appropriate patients in primary care. Only then should formal studies of impact and cost-effectiveness be undertaken.

Formal guidelines for the commissioning and conduct of research in this area have been derived from the analysis of shortcomings in the published research and the recommendations of the Cochrane Working Party on Diagnostic Tests.

- The most appropriate reference standard for the primary care setting should be chosen, even though most are recognised as imperfect. To allow for this, the limits of the standard may need to be explored using, for example, Bayesian (probabilistic) analysis.
- Sample size calculations, based on the ability to detect clinically-significant LRs, are required.
- Verification bias, selection bias and treatment paradox should be avoided.
- Patients enrolled should be described in both demographic and clinical detail, e.g. severity of symptoms, co-morbid conditions.
- Sensitivity of results to variation in setting or test operator should be determined.
- Results should be calculated for subsets of high and low probability of disease to test for the presence of spectrum bias.
- An evaluation should be made of the likely impact of the test in relevant clinical situations, with predictive values calculated for a range of disease prevalence rates, so that clinicians may evaluate the results against their own practice.
- Further study is required of the impact and cost-effectiveness of tests, with controlled collection of data to evaluate the accuracy of predictions made at the planning stages.
- Recommendations for dissemination of the results are needed to encourage GPs to use successful tests, and to alert them to potentially misleading tests.

Assessment of information need

Much qualitative work is needed to assess the way in which doctors use diagnostic tests and to determine which tests, in which conditions, would constitute an appropriate development of NPT. Such studies should include advantages, such as saving of patients' time, practice administrative costs and higher uptake of screening or monitor-ing programmes, and disadvantages such as anxiety, over-investigation, and over-treatment. Initial studies will need to be wide-ranging and qualitative; further quantitative work will be needed to define performance.

Assessment of required performance characteristics

To evaluate NPT 'bottom up' rather than 'top down', it is necessary to consider what the performance characteristics of a particular test **should** be. This can be undertaken by decision analytical modelling of the clinical problem to which it is proposed to apply a particular NPT. These performance characteristics should be summarised as acceptable limits for the LRs of the test, which can then be used to determine the sample size for the subsequent evaluation of the test against the most appropriate reference standard.

Assessment of performance in relevant setting

Since the NPT will be performed in primary care, it is necessary to evaluate it there. The evaluation should report LRs with 95% confidence intervals, based on prior calculations of sample size to detect clinically-relevant effects as above. The sensitivity of the results to variations in operators and natural variation in performance between practices should be determined. In addition, the presence of any potential spectrum bias should be examined by separately calculating LRs for high and low prevalence subsets of patients. It may be necessary to perform a sensitivity analysis for this bias, or to adjust the results for the use of an imperfect reference standard using Bayesian or similar techniques.

Impact and cost-effectiveness

The final phase of the evaluation is to assess the actual impact of an NPT on disease management and to measure its cost-effectiveness. This may be accomplished either as a prospective trial of the new test in comparison with existing practice or by the collection of audit data (similar to the post-marketing surveillance of drugs). In practice, both methods are likely to be needed.

Implications for the application of NPTs in primary care

Even if particular NPTs prove to be effective in particular clinical situations in primary care, there still exist financial and structural constraints on their widespread adoption in practice. Such barriers are in addition to the expected difficulty of implementing research findings.

In terms of finance in the UK, GP fundholders may vire part of their budget into NPT, but it is unlikely, on current evidence, that sufficient savings would be made from the laboratory budget to cover the cost of the investment. Savings would therefore have to be made in other areas and justified in terms of overall clinical care. Non-fundholders can only purchase NPTs out of practice profits, barring the unlikely scenario of a health authority setting aside a budget for NPT.

A negative cycle exists, therefore, whereby in the absence of good evidence of cost-effectiveness, health authorities are unwilling to fund NPT but, in the absence of such funding, assessment of cost-effectiveness of NPT has not been a priority. A proper programme of NPT assessment must be linked with a willingness on the part of purchasers to establish a method of funding its implementation if it is shown to be appropriate and cost-effective.

In addition to financial constraints, there are also practical problems. Practices may have insufficient space for equipment such as desktop analysers and centrifuges. Attention needs to be paid to the safe handling of specimens and health and safety at work legislation. Another most important factor is the need for a quality control programme.

In the USA, congressional legislation has implemented a programme of standards and inspection of 'office laboratories'. In the UK, the Association of Clinical Biochemists have produced guidelines for primary care[17] and it may be necessary to link funding reimbursement to compliance with these.

Local hospital laboratories should have a major role to play in supporting NPT in primary care, particularly with respect to staff training and provision of quality control. NPT should not be seen as an alternative to the hospital laboratory but as an enhancement of the existing service. Indeed, one option for the implementation of NPT in UK primary care would be for the equipment to be provided and maintained by hospital laboratories, as an outreach component of their service contracts with general practice.

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Appendix 1

Systematic review summary tables

Contents

CDDS

Author, country, and objectives	Key words, sources, trade name, test samples, type of DSS, and type of system	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Ahlfeldt *et al* (1994) Sweden The implementation and use of data-driven decision support based on the Arden Syntax in three different environments	Data-driven DS, Arden Syntax, medical logic modules, clinical applications Medline Arden Syntax N/A Rule-based Network PC	Other – – Primary care, laboratory and other n = 3	– Not stated – Patient satisfaction: no Quality control: no	Not stated	The presented systems are closely integrated with surrounding information systems, which is one of the key factors for the successful introduction of DSS in clinical medicine.	More information is needed Lacks practical information and detail regarding DSS applications Methodology score: 0
Carter *et al* (1988) USA To evaluate an analogue computer program used to predict warfarin dosages after an initial dose of 10 mg three times daily	Computer, dosage, predictions, warfarin Academic staff Not stated Other Stand-alone PC	Cohort study 24 months – Secondary-care in-patients n = 29	– Therapeutic INR Parametric Patient satisfaction: no Quality control: no	There was a statistically significant correlation between predicted prothrombin time (PT) response and actual PT response ($p < 0.005$) for all predictions made. However, when actual and predicted responses were compared with a paired t-test, they were significantly different ($p < 0.05$).	This program is useful for predicting initial warfarin requirements for the majority of patients.	GPs are unlikely to have access to an analogue computer Performing INR (or PT) would be better Methodology score: 1
Kubie *et al* (1989) UK To evaluate a computer-assisted anticoagulant clinic	Anticoagulant, warfarin, computer Academic staff Not stated Rule-based Stand-alone PC	– – – Secondary-care out-patients –	– Therapeutic INR, medical and secretarial time Parametric Patient satisfaction: no Quality control: no	Mean interval between visits was 6.0 weeks and mean level of undertreatment was 10%. There is saving of medical and secretarial time. The system provides letters (or labels), lists and continuous statistics, and it allows the selection of various options that make it adaptable to the requirements of other hospitals.	A microcomputer is envisaged as an intelligent terminal, using PAS and laboratory system data and facilities.	Outdated methodology Old paper, 1989 Purely descriptive paper Methodology score: 0

continued

CDDS *contd*

Author, country, and objectives	Key words, sources, trade name, test samples, type of DSS, and type of system	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Mariani *et al* (1990) Italy To evaluate the software, PARMA, in the management of oral anticoagulant clinics	Computer-assisted patient surveillance, computer software, oral anticoagulant therapy Academic staff PARMA – Rule-based Stand-alone PC	Cohort study 12 months Patients with prosthetic heart valves attending anticoagulant clinics in either Parma or Rome Secondary-care out-patients n = 695	– Mean INR, weekly dose of warfarin Parametric Patient satisfaction: no Quality control: no	Mean INR 3.19 (Parma), 3.25 (Rome), mean warfarin dose (weekly/mg) 20.7 (Parma), 18.2 (Rome). More than 70% of checks were within therapeutic range at both centres.	A computerised program for oral anticoagulation management that allows multicentre studies.	Few implications for primary care Lack of comparisons in evaluation No control group Confusing description Methodology score: 1
Poller *et al* (1993) UK To compare the effectiveness of three computerised systems for assisting warfarin control in out-patients with the customary dosing method used by experienced medical staff	– Questionnaire Hillingdon AC 3.1, Charles Anticoagulant Clinic Manager, Coventry program – Rule-based Stand-alone PC	Randomised controlled trial 13 months New patients attending an anticoagulant clinic Secondary-care out-patients n = 186	– Therapeutic INR Parametric Patient satisfaction: no Quality control: no	The computerised systems give satisfactory control compared with the traditional dosing method. For patients receiving more intensive treatment, with an assigned target range of 3.0–4.5, computerised dosage programs achieved significantly better control; the medical staff undertreated such patients by 50%.	Computer-based programs can assist out-patient antico-agulant control with warfarin during both early and long-term treatment. The computers were significantly more successful in the higher range.	Important Secondary care study but could be used in primary care. Computer diagnosis at least as good if not better than traditional dry methods. Methodology score: 4
Ryan *et al* (1989) UK To improve the standard of managing anticoagulant treatment and provide a basis for therapeutic quality control	– Academic staff Not stated – Rule-based Stand-alone PC	Cohort study 6 months South Warwickshire anticoagulation patients Secondary-care out-patients n = 688	– Therapeutic INR Parametric Patient satisfaction: no Quality control: no	688 patients' visits were analysed statistically and a 38% improvement was achieved in the results of INRs falling within the therapeutic ranges recommended by the British Society for Haematology.	The implementation of a computerised anticoagulant support system resulted in better management of patients. The system provides a basis for uni-form management of treatment and a common platform for national or international trials.	GPs may benefit from computerised assessment of anticoagulant needs. DSS software should be compatible to GP systems Methodology score: 2

continued

CDDS *contd*

Author, country, and objectives	Key words, sources, trade name, test samples, type of DSS, and type of system	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Wilson & James (1984) UK To evaluate an automatic system which adjusts the dose of warfarin designed using a formula devised after a survey of prescribing habits	– Reference & academic staff Not stated – Rule-based Stand-alone PC	Cohort study 16 months Patients attending an oral anti-coagulant clinic Secondary-care out-patients –	Average blood count rate (BCR), average interval between visits Parametric Patient satisfaction: no Quality control: no	Average BCR increased from 2.52 to 2.79. Average interval between visit increased from 4.84 to 3.91 weeks, % outside BCR decreased from 17.4 to 14.2. The results after 16 months were at least as good as those achieved manually. Medical and secretarial time was saved, and statistics about the clinic and its efficacy are made available.	The system would be helpful to many hospitals and improve the standard of anticoagulant maintenance.	No mechanism to ensure adequate communications with GPs or hospital specialists Valuable example of DSS Detailed evaluation of impact would be helpful Methodology score: 2
Wyld *et al* (1988) UK To evaluate the effectiveness of a computer program for the management of anticoagulation therapy	– Academic staff Hillingdon software – Rule-based Stand-alone PC	Cohort study 13 months Patients attending an oral anti-coagulation clinic Secondary-care out-patients n = 540	– Therapeutic INR – Patient satisfaction: no Quality control: no	Number of patients under-anticoagulated reduced from 14 to 6% with no increase in over-anticoagulated patients. Decreased medical time (2.5 hours to 40 minutes) in clinic with nursing time unchanged.	A more comprehensive system would make this a valuable asset in any hospital anticoagulant clinic.	Omissions in statistical analysis (no *p*-values and confidence intervals) Methodology score: 1

EDI

Author, country, and objectives	Key words, sources, trade name, test samples, type of EDI, and type of system	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Branger *et al* (1991) The Netherlands	(see below)	(see below)	(see below)	(see below)	(see below)	(see below)
Branger *et al* (1992) The Netherlands To study the effects of the introduction of EDI between primary and secondary-care providers	– Reference – – – –	Cohort study 3 months GPs Primary care n = 24	Paper records Speed of communication transfer, user satisfaction Patient satisfaction: yes Quality control: no	Paper admission–discharge reports took a median of 2–4 days, laboratory reports 2 days, to reach GPs. EDI admission–discharge reports available to GPs within 1 h of generation. Laboratory reports available to GP the same day via EDI. 15/24 GPs reported that EDI reports provided more accurate and complete information on care delivered to patients. Ten GPs reported that EDI laboratory reports reduced the work of processing the data.	Electronic communication between primary and secondary-care providers is a feasible option for improving communication.	Methods used for evaluation are not robust, but a useful paper Methodology score: ?

Desktop clinical chemistry multi-analysers

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Belsey *et al* (1987a) USA To evaluate the Kodak DT-60	– Questionnaire Kodak DT-60 Serum, whole blood	Laboratory evaluation, technical report – – Laboratory –	Control material – Linear regression Patient satisfaction: no Quality control: no	DT-60 tests exhibited acceptable precision and, except for the glucose method, accuracy. The accuracy of the glucose method was indeterminate. Throughput under field conditions was found to be < 50% manufacturer's claim. The supply cost per test could vary from $1.20 to $5.49 per test, depending on the test type and the number of assays performed daily.	The instrument is accurate, precise and generally reliable when operated by professional medical technologists.	Only commercial quality control materials used Complex NPT Potential benefit to primary care Methodology score: 2
Belsey *et al* (1987b) USA To evaluate the Kodak DT-60	– Questionnaire Kodak DT-60 Whole blood	Laboratory evaluation, technical report 2 months Technical and non-technical operators Primary care	Control material U+Es, glucose, lipids Linear regression, parametric, chi-squared Patient satisfaction: no Quality control: no	The variability of the results increased when the test performed by non-trained compared with trained technicians. The source(s) of increased variance needs to be identified.	Objective information about the reliability of results produced by systems for use in physician's office laboratories is needed.	No reference to clinical significance Interesting evaluation Methodology score: 2
Erickson & Wilding (1993) USA To evaluate a novel system designed for rapid, point-of-care measurement of sodium, potassium, chloride, urea nitrogen, glucose, and haematocrit	Point-of-care testing, electrolytes, glucose, urea nitrogen, thin film electrode biosensors Medline, BIDS, reference i-STAT Portable Clinical Analyzer (PCA) system Whole blood	Laboratory evaluation – – Secondary-care in-patients; secondary-care out-patients –	Laboratory assay Concentrations of sodium, potassium, chloride, urea nitrogen, glucose and haematocrit Deming regression analysis Patient satisfaction: no Quality control: no	Precision did not differ significantly between the two locations, (co-efficients of variation (CV) = sodium, 0.46–0.89%; potassium, 1.06–1.45%; chloride, 0.69–2.76%; urea nitrogen, 2.54–6.12%; glucose, 4.39–5.19%). Regression statistics were acceptable for all analytes except chloride. Mean haematocrit (Hct) values differed significantly between the PCA and the Coulter ST. PCA technology may overcome many of the currently perceived problems of bedside testing.	No cost–benefit analysis.	False conclusions from statistical analysis Methodology score: 1

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Desktop clinical chemistry multi-analysers *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Gilio *et al* (1993) Belgium To evaluate the influence of a desktop analyser, in general practice, on the number of blood tests per contact, prescribed or analysed by GPs	– BIDS, questionnaire Reflotron Whole blood, serum	Randomised controlled trial 4 months GPs Primary care n = 50	– Mean number of blood tests per contact Wilcoxon signed rank test, parametric Patient satisfaction: no Quality control: no	In the Reflotron group, there was a slight increase in the median of the relative differences between the intervention and the baseline period (3%). In the control group, the median of the relative differences decreased (–7%). The difference between both groups was not statistically significant (p = 0.17). In both groups the size and direction of the relative differences of the individual practices were very different. No statistically significant differences were found in any subgroup.	Further studies needed.	Power of study very weak No data on tests ordered and likelihood ratios Not relevant to UK primary care Methodology score: 2
Gottlieb *et al* (1986) Denmark To evaluate the use of the Ames seralyzer in the doctor's office	– Questionnaire Ames Seralyzer Whole blood, serum	Cohort study 5 months – Primary care	Laboratory assay – Analysis of variance Patient satisfaction: no Quality control: no	Acceptable accuracy for all analyses except serum LDH.	The Ames Seralyzer may prove useful in places where access to hospital laboratories is difficult.	Test too slow Paper lacks detail Methodology score: 3
Hilton *et al* (1994) UK To determine the attitudes of practice staff to NPT, and the extent to which staff undertook quality assessment	NPT, practice-based diagnostic test, doctors'/nurses' attitudes, quality in general practice Medline, BIDS, Embase – –	Satisfaction survey – – Primary care –	– – Parametric Patient satisfaction: no Quality control: no	80% of GPs expected to change patient management with NPT; only 40% had done so after six months. Nurses were enthusiastic initially. Time pressure was the most important factor restricting uptake of NPT. Nurses performed quality control regularly but complete local external quality assurance procedures were established in only half the practices. All the practices participated in a national scheme for cholesterol assays.	GPs did not find NPT a very useful addition to their resources. Pressure on nurses' time was the most frequently reported limitation.	Results not clear Subjective opinions only used Very dubious conclusion Methodology score: 0

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Desktop clinical chemistry multi-analysers *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Hobbs *et al* (1992) UK To compare four of the analysers available in the UK, in six urban general practices	Office analyser, primary care, NPT, practice-based diagnostic tests, desktop analysers, diagnostic techniques BIDS Vision, Reflotron, Ektachem DT, Easy ST Whole blood	Cohort study 6 months General practices Primary care n = 6	– Number of tests performed, costs Parametric Patient satisfaction: no Quality control: yes	Of 2619 tests, 55.8% were performed when transport to a hospital laboratory was not possible. Commonest measurements were cholesterol (14.4 tests per 5000 patients per 30 days), glucose (6.0 tests) and haemoglobin (Hb) (5.6 tests). < 5% tests were performed as emergency. Main reasons for testing were screening or case-finding (56.9%). Hospital laboratory blood tests reduced by 24–40% pre-study levels. Increased testing for cholesterol (three-fold) and Hb (eight-fold) on the desktop analysers, compared with pre-study laboratory tests requested. Cost per test of NPT is closely related to the level of activity. Quality control tests were within the specified limits on 98% of occasions.	The range of tests available on desktop analysers is expanding and should they become more relevant to the needs of GPs in the UK then greater uptake is likely.	No mention of standard reference sample for external quality assurance No data recorded on patient outcomes Highly relevant Useful and appropriate Descriptive report Methodology score: 2
Jacobs *et al* (1993) USA To evaluate the i-STAT Portable Clinical Analyzer	Point-of-care testing, biosensors, electrochemical sensors, emergency analyses, critical care medicine, electrolytes, glucose, urea nitrogen GT, reference i-STAT Portable Clinical Analyzer Whole blood, serum	Laboratory evaluation, cohort study – – Laboratory –	Laboratory assay Concentrations of electrolytes, urea nitrogen, glucose and Hct Analysis of variance Patient satisfaction: no Quality control: yes	Intrarun imprecision (CV) ranged from 0.34% to 3.97%. Total imprecision over a 2-month period ranged from 0.42% to 4.83%, with urea nitrogen and glucose analyses generating the higher values. Patients' results from the PCA correlated well with those obtained for whole blood or plasma by the Nova Stat Profile 5, the Beckman Synchron CX3, or the Technician H1 Hematology Analyser, with Sy/x values < 0.2 mmol/l for potassium; < 1.5 mmol/l for sodium, glucose and urea nitrogen; < 2.4 mmol/l for chloride; and < 2.4% for Hct. There were no significant differences in either the imprecision or the accuracy of the system in an intensive care unit.	Operator technique is not a factor in the analytical performance of the system.	No relationship to clinical outcomes recorded Need cost–benefit analysis for primary care Study sponsored by grant from manufacturer Methodology score: 3

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Desktop clinical chemistry multi-analysers *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Leese & Hutton (1989) UK	–	Discussion paper	–	Most useful tests were for Hb, glucose and cholesterol, with electrolytes considered to be the most useful additional test. The 10% variation in comparative figures for some tests was viewed with concern and it was felt that training of staff with emphasis on quality control was essential.	Practices which choose to control their own budgets could find the Reflotron a useful addition to their practice-dependent hospital laboratory charges for diagnostic tests.	No validation of data Lack of data Inadequate description Discussion paper Methodology score: 1
	Questionnaire	–	–			
	Reflotron	–	–			
	Whole blood, serum	Primary care	Patient satisfaction: no			
		–	Quality control: no			
Leese & Hutton (1990) UK To evaluate the utility of the Reflotron as perceived by GPs	Economics, financing, government, general practice, laboratories, hospital	Satisfaction survey	–	There is little incentive for GPs to perform diagnostic tests. The most important factors necessary for the spread of desktop analysers are the availability of more tests, guarantees of reliability, and competitive prices.	Desktop analysers could fulfil a role in practices which control their own budgets.	Few data. Mainly a review of Reflotron use Methodology score: 1
		–	–			
	BIDS, report, questionnaire	GPs	Parametric			
		Primary care	Patient satisfaction: no			
	Reflotron	n = 12	Quality control: no			
	Whole blood, serum					
Nanji *et al* (1988a) Canada To evaluate the quality and reliability of four desktop analysers in the out-patient clinic	Proficiency testing, cholesterol measurement, external quality assessment	Performance evaluation, laboratory evaluation, cohort study	Control samples	The range of CVs for the analysers with NTs was as follows: Reflotron: 2.4–7.9%; Seralyzer: 1.4–18.7%; Vision: 1.5–2.7%; DT-60: 2.5–46.8.	Differences in performance is related to the complexity of procedure for each analyser and was the lowest for the Vision analyser and greatest for the Seralyzer.	Clear methodology and concepts Credible results Important elements for NPT (accuracy, reliability and precision) Methodology score: 3
	Medline, BIDS, report	–	Concentrations of glucose, urea, cholesterol, triglycerides, alkaline phosphatase, and uric acid			
	Kodak DT-60, Reflotron, Ames Seralyzer, Abbott Vision	Nontechnologists				
	Whole blood, serum	Secondary-care out-patients	Analysis of variation			
		n = 27	Patient satisfaction: no			
			Quality control: yes			

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Desktop clinical chemistry multi-analysers *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Nanji *et al* (1988b) Canada To evaluate the quality of results obtained by 14 non-technical medical office personnel using desktop analysers	Proficiency testing, blood cholesterol measurement, external quality assessment BIDS Reflotron, Ames Seralyzer, Abbott Vision analyser, DT-60 analyser Serum, whole blood	Technical report, cohort study 0.5 months Not stated Primary care n = 352	Results obtained by trained technologist Concentration of electrolytes, lipids, glucose, urea, creatinine and urates CV Patient satisfaction: no Quality control: yes	The CVs for the office personnel ranged from 3.0% to 8.1% with Reflotron, 6.3% to 26.5% with Seralyzer, 1.0% to 4.1% with Vision, and 1.4 to 16.7% with DT-60. The correlation coefficient ranged from 0.970 to 0.997 with Reflotron, from 0.779 to 0.997 with Seralyzer, from 0.975 to 0.998 with Vision and from 0.963 to 0.995 with DT-60. The proportion of results obtained by the office personnel that differed by more than 10% from those obtained by the technologist was 7% with Reflotron, 42% with Seralyzer, 2% with Vision and 21% with DT-60.	The instrument whose operation involves the least number of steps gives the most reliable results in the hands of medical office personnel.	Lacks detail Greater training and practice advocated for accurate results Methodology score: 4
Nanji *et al* (1988c) Canada To evaluate the quality and reliability of four desktop analysers	– Medline, BIDS Reflotron, Ames Seralyzer, Abbott Vision analyser, DT-60 analyser Whole blood, serum	Cohort study – Physicians, medical office personnel, nurses Primary/secondary care (out-patients and in-patients) n = 53	– – – Patient satisfaction: no Quality control: no	2/320 tests performed on Vision differed by more than 10% between the specialist staff and other groups. Seralyzer = 95/254, Reflotron = 19/199, DT-60 = 50/318. Nurses were more adept at using analysers than physicians and medical office personnel.	The issues of training and safety will have to be carefully considered.	No follow-up data. No CI quoted on the significance or findings Methodology score: 3

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Desktop clinical chemistry multi-analysers *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Ng *et al* (1992) USA To evaluate the Reflotron	– Medline Reflotron Whole blood, serum	Technical report, laboratory evaluation – – Laboratory	Laboratory assay (IL643, Beckman Synchron CX3) Potassium concentration Analysis of variance Patient satisfaction: no Quality control: no	Analysis of 30 µl of plasma or serum takes approximately 140 s. Within-day imprecision (CV) was 1.0–1.2%. Total CVs over 1 month = 1.0–1.4%. Patients' results from the Reflotron correlated well with those from IL 643 and the Beckman Sychron CX3 methods. The accuracy of Reflotron values was also verified with Standard Reference Material 956 from the National Institute of Standards and Technology.	The Reflotron is useful for quick determinations of potassium in NPT or small laboratories.	Type of patients and reasons for measurements needs clarification No information on costs Unlikely to be of great value in primary care Methodology score: 2
Non-laboratory Working Party of the National Health Technology Advisory Panel (1991) Australia To examine the impact of the introduction of dry chemistry pathology in general practice	– Reference Ames Seralyzer, Ektachem DT, Reflotron, Abbott Vision – Whole blood, serum, other	Randomised controlled trial, satisfaction survey, technical report 9 months 28 general practices Primary care n = 9076	Laboratory tests Test imprecision. Patients and GPs perceptions of NPT Parametric Patient satisfaction: yes Quality control: no	Use of analysers associated with a 2% non-significant reduction in the use of laboratory tests. For those tests with a direct analyser equivalent, there was a 9–13% reduction in tests; 46% increase in the total number of biochemical tests by laboratory or analyser. No effect on the detection of new disease or the control of existing disease was observed. Patients rated analysers highly. GPs reported that analysers made a minor contribution to their practice. The level of analytical reliability of the analysers was not always acceptable.	The application of dry chemistry pathology in general practice is limited.	Methodology seems flawed Further UK research should be encouraged, using a more acceptable methodology and including cost–benefit analysis Methodology score: 3

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Desktop clinical chemistry multi-analysers *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Rink *et al* (1993) UK To assess the clinical and economic impact of surgery-based NPT in general practice for six commonly used biochemical and bacteriological tests	Technology, care Medline, BIDS, Embase – Whole blood, urine, swabs	Randomised controlled trial 15 months 88, 523 consultations in 12 general practices in the West Midlands and SW Thames Primary care n = 88,523	Not applicable Investigation rates, reason for requesting investigation. Health economic Paired t-tests, chi-squared, odds ratios Patient satisfaction: no Quality control: no	Investigation rates rose by 16.5% (from 78.6/1000 consultations to 91.6/1000) when equipment was available in the surgery and reverted to baseline rates when it was withdrawn. Average weekly number of tests when equipment was available ranged from 0.5 to 10.5 (mean 9.0). Cholesterol tests were used as an addition to laboratory testing, usually for screening. Mid-stream urine was often performed in the surgery instead of the laboratory (30% of samples tested by both methods). Doctors' reasons for investigation and conditions tested were largely unaffected by availability of surgery tests. Costs for surgery tests were higher for all tests except mid-stream sampling.	Availability of surgery-based testing increased the number of tests performed. It was cost-effective only for midstream urine analysis.	Comments? Methodology score: 3
Sands *et al* (1995) USA To assess the potential effects of rapid bedside blood analysis on patient management in the Emergency Department	Blood (test), laboratory (test, analysis), point-of-care testing, Hct BIDS, academic staff i-Stat PCA system Whole blood	Laboratory evaluation 10 months All patients with blood sampled for laboratory analysis Secondary-care out-patients n = 960	Laboratory analysis (Ektachem 700XRC, Bechman CX-3, Coulter S+IV counter, NOVA StatProfile-6 Analyzer) Analysis of sodium, potassium, chlorine, blood urea nitrogen, glucose, and/or Hct Parametric Patient satisfaction: no Quality control: no	PCA results were available 31 min (mean) sooner than central laboratory results for Hct; 43 min for sodium, potassium, chlorine; 44 min for blood urea nitrogen, glucose. Except for Hct and glucose, values obtained from the PCA were not significantly different from the central clinical blood analyser laboratory values. When surveyed, the physicians caring for the patients reported that had the PCA results been available, a different or an earlier therapeutic approach would have resulted in 9.5% cases. The decision to release or admit the patient was based on one or more of the laboratory values for 10.7% patients sampled. In no case in this series did a physician report that final Emergency Department clinical outcome would have been affected.	The PCA gave faster reporting of laboratory values. These earlier results might have reduced the length of stay in the Emergency Department for 17.3% of patients studied. Selective use of a handheld portable analyser might decrease time to therapeutic interventions and time to disposition.	Limited implications for primary care. No benefit in obtaining blood test results rapidly for majority of patients in primary care Methodology score: 4

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Desktop clinical chemistry multi-analysers *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Skinner *et al* (1990) UK To evaluate the Reflotron	Blood chemical analysis, evaluation studies, quality control Medline Reflotron Whole blood, serum	Laboratory evaluation 9 months – Laboratory –	Laboratory assay Concentration of lipids, glucose, urease, GGT, Hb, AST, urea, ALT bilirubin and amylase Analysis of variance Patient satisfaction: no Quality control: yes	Imprecision was observed between 2% and 6.5% CV (between-day) for enzyme analyses and 1% and 6% CV for endpoint methods. Analytical ranges for each range were similar to those expected, with the exception of ALT bilirubin, where the range was lower although adequate. Delay between sample application and measurement should not exceed 60 s. Variations in packed cell volume of whole blood samples does not affect results adversely.	In the hands of semi-trained staff the instrument produced adequate results.	Methodology unclear Unsuitable for primary care. Further studies required: effect on patient management and cost–benefit analysis Laboratory study Methodology score: 3
Thue & Sandberg (1993) Norway	– BIDS Reflotron, Ames Seralyzer Whole blood	Satisfaction survey – NPT users/non-users Primary care n = 860	– – Parametric Patient satisfaction: no Quality control: no	Response rate = 77–79% (200 users, 281 non-users). More GP users were single-handed and more users had a cell counter in the office; fewer occupational healthcare users kept computerised records. Users reported improvement in diagnosis and treatment and improved patient satisfaction. Non-users perceived problems regarding cost, workload and analytical quality as well as good service from the hospital laboratory as reasons for not implementing the use of such instruments in their practice.	Not stated.	Good study Interesting results Fully applicable to implementation of NPT in primary care Methodology score: 1
Tsai *et al* (1994) USA To determine cost-effectiveness	– Medline, BIDS PCA i-Stat Whole blood	Cohort study, cost-effectiveness 1 month Patients presenting to the emergency department Secondary-care out-patients n = 210	Laboratory analysis Test turnround time, physician determination of impact of rapid turnround time, and laboratory values on therapeutic approach, cost per test Parametric Patient satisfaction: no Quality control: no	Point-of-care turnround time (mean), 8 min; central laboratory turnround time (mean), 59 min; therapeutic turnround time (mean) 1 h 25 min. Physicians reported that point-of-care testing, independent of other rate-limiting steps, would have resulted in earlier therapeutic action for 40/210 (19.0%) patients. Cost per test for Chem-7 and CBC tests was $11.14 and $9.48, respectively. Cost per test for point-of-care analysis ranged from $14.37 to $16.67, depending on test volume and the personnel performing test.	Increasing volume of point-of-care tests performed per unit time, reduces costs for such testing.	Study adds nothing to primary care evaluation of new technologies A & E and time aspect of laboratory testing study Methodology score: 4

Cholesterol NPTs

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Broughton *et al* (1989) UK To evaluate BCL Reflotron in primary care	– Report, questionnaire Reflotron Serum	Laboratory evaluation – – Primary care –	Control material. Cholesterol concentration Analysis of variance Patient satisfaction: no Quality control: no	8.6% results differed by 1.0 mmol/l or more from target values. Common sources of error were poor technique and the use of outdated reagent strips.	Outside the laboratory advice and help with training is needed. Users should establish contact with a local clinical chemistry laboratory for training and support and participate in external quality assessment schemes.	Old paper Technology 'out of date' Lack of details Methods well described Methodology score: 1
Koch *et al* (1987) USA To evaluate bias and precision of serum cholesterol analysis by physician's office analysers	Enzymic methods, source of variation, coronary heart disease Reference, questionnaire Abbott Vision, Ames Seralyzer, BMD Reflotron, Chrometrics Cholesterol Test System, Kodak DT-60 Whole blood, serum, capillary blood	Laboratory evaluation 4 months Volunteers and selected out-patients Laboratory, secondary-care out-patients n = 109	Laboratory reference method Cholesterol concentration Parametric, CV Patient satisfaction: no Quality control: yes	Total imprecision (CV range, %) for analysis of serum pools was: Abbott Vision 1.5–1.9%; Ames Seralyzer 3.9–4.5%; BMD Reflotron 2.3–3.8%; Chrometrics Cholesterol Test System 2.3–2.8%; Kodak DT-60 1.6–2.2%. The Ames Seralyzer exhibited an excessive between-run component of variation. For assays with serum, the BMD Reflotron and Kodak DT-60 exhibited negative bias. All systems gave lower results for plasma and whole blood than for serum. All systems except the Kodak DT-60 were less precise for analysis of patients' sera than for analysis of serum pools.	Between specimen variables may influence the results of these systems.	Technology 'out of date' No description of instrument use nor likely errors in technique Methodology score: 4
Majeed *et al* (1993) UK To formulate a policy for the use of Reflotron in cholesterol testing	– Medline Reflotron Whole blood, capillary blood	Cohort study, laboratory evaluation 10 months Staff members attending occupational health clinics Secondary-care out-patients n = 352	Laboratory assay (BM UK 737 analyser) Cholesterol concentration Linear regression Patient satisfaction: no Quality control: no	The correlation between the two methods was 0.95. Reflotron had a negative bias compared to the laboratory, with the mean difference between the two methods of measurement being –0.21 mmol/l (95% CI, –0.18–0.25 mmol/l). The scatter of Reflotron–laboratory differences was broad. For Reflotron results of 5.50 mmol/l and greater, the sensitivity and specificity of the Reflotron in detecting subjects with laboratory cholesterol levels greater than 6.5 mmol/l were 100% and 70%, respectively.	Reflotron is an acceptable screening device in the detection of hypercholesterolaemia.	No age/gender details of participants in study No comment on possible need to repeat quality assessment audit at regular intervals Quite important paper Methodology score: 3

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Cholesterol NPTs *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Naughton *et al* (1990) USA To determine the accuracy of portable cholesterol analysers in public settings	– Reference – Vision, Kodak DT-60, Reflotron Capillary blood, serum	Case control, laboratory evaluation – Patients attending for cholesterol screening – Laboratory, other n = 417	COBRAS FARA analyser Cholesterol concentration Sensitivity, specificity Patient satisfaction: no Quality control: no	Only one of the organisations produced cholesterol measurements entirely within the acceptable range (± 14.2%), while the accuracy of the other three organisations ranged from 76.5% to 96.4%.	The use of fingerstick method of cholesterol level sampling may lead to error.	Population variation not discussed Does not take into account user characteristics Good discussion regarding acceptable 'errors' Methodology score: 3
Phillips *et al* (1988) Australia To compare measurements of total cholesterol by Reflotron drychemistry system with a standard laboratory method	– Reference Reflotron Capillary blood, serum	Laboratory evaluation Volunteers – Secondary-care out-patients n = 80	Hitachi 705 analyser Cholesterol concentration Parametric, regression analysis Patient satisfaction: no Quality control: no	Ranges of total cholesterol levels were 3.38–8.45 mmol/l (Reflotron) and 3.59–8.83 mmol/l (Hitachi). The mean (± standard deviation (SD)) difference between the two methods was 0.22 ± 0.30 mmol/l. All the subjects provided a second finger-prick sample of blood on the next day to assess the reproducibility of the Reflotron. These results did not differ significantly (mean difference, 0.079 mmol/l; standard error, 0.045 mmol/l).	Provided that the operator is trained appropriately, the Reflotron system gives rapid, accurate and reproducible results.	Cost may be a problem for primary care May be suitable for use in primary care settings Probably costs a fortune to purchase, but every GP should have one Methodology score: 4
Sedor *et al* (1988) USA To evaluate the Reflotron for the measurement of cholesterol	Sample handling, reflectance photometry Reference Reflotron Whole blood, serum	Laboratory evaluation – Hospital patients and out-patient volunteers Secondary-care in-patients, population screening n = 37	Ektachem 100 analyzer Cholesterol concentration CVs Patient satisfaction: no Quality control: no	CVs for whole-blood cholesterol were: within-day 2.0% and 2.2% at 1680 and 2670 mg/l, respectively; between-day 1.8% and 2.4% (n = 9 and 8). Results similar for serum and heparinised or EDTA-treated single-donor plasma (CV, 1.4%–2.6%). CVs of results for two reconstituted commercial quality control materials were 3.4% and 4.6%. Comparability was observed when the analysis was performed by briefly trained high-school students: $r = 0.980$, $y = 0.949x + 23$ mg/l. Performance decreased when both collection and analysis were performed by laymen: $r = 0.880$, $y = 0.870x + 186$ mg/l.	Under proper conditions, the Reflotron is suitable for use in cholesterol screening programmes.	Statistical methodology questioned No test on variation across groups Sophisticated study Methodology score: 4

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Cholesterol NPTs *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Stewart *et al* (1993) UK To determine whether self-monitoring of plasma triglyceride concentrations improved lipid concentrations	– Reference Reflotron Capillary blood, serum	Randomised controlled trial 6 months Patients attending a diabetic clinic Home testing, secondary-care out-patients n = 12	Hospital laboratory Triglycerides, cholesterol, apolipoprotein B, HbA1c concentration Regression analysis, chi-squared Patient satisfaction: no Quality control: yes	Mean plasma triglyceride fell significantly from 2.7 (SD 0.7) to 1.6 (SD 0.4) with home testing (95% CI, –0.1–2.3). Also decreased plasma cholesterol (6.6–6.1) and apolipoprotein B (1.18–0.96). No significant change was found in HbA1c or body weight. Good correlation between patient results and laboratory results ($r = 0.88$, $p < 0.001$).	Among patients using blood testing for glycaemic control, this may be a useful adjunct to self management.	Whether NPT of triglycerides in addition to monitoring of glucose is of extra benefit needs to be developed Hawthorne effect could not be excluded Not clear if self-monitoring would lead to a reduction in cardiovascular mortality Methodology score: 2
von Schenck *et al* (1987) Sweden To evaluate three desktop instruments for assays of blood cholesterol and triglycerides in physician's office testing	Physician's office testing Reference Ektachem DT-60 (E), Reflotron (R), Seralyzer (S) Serum, capillary blood	Technical report – People attending clinic Secondary-care out-patients, primary care, laboratory n = 587	Automated centrifugal analyser (A) Precision Regression analysis Patient satisfaction: no Quality control: no	Regression equations for cholesterol determinations were: E = 0.92A + 0.7 (n = 331, $r = 0.94$), R (capillary blood) = 0.96A + 0.3 (n = 256, $r = 0.95$), and S = 0.93A + 0.6 (n = 260, $r = 0.92$). For triglycerides, E = 1.02A (n = 331, $r = 0.97$), R (capillary blood) = 0.88A (n = 213, $r = 0.97$), R = 0.94A + 0.1 (n = 90, $r = 0.99$), and S = 0.96A (n = 266, $r = 0.98$). Duplicate and within-day precision was < 8%. Between-day precision (during one month) was < 10%.	The need of both laboratory and field evaluation is stressed, and the benefit of quality control is emphasised.	Difficult to follow methodology Well-described evaluation Methodology score: 5

NPTs for diabetes

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Ashworth *et al* (1992) UK To assess the HemoCue system for measuring glucose in 5 µl of whole blood	Enzymatic methods, point-of-care testing BIDS, academic staff HemoCue Whole blood	Laboratory evaluation – – Laboratory –	Laboratory assay (Cobas-Bio, YSI 23AM) Glucose concentration Linear regression Patient satisfaction: no Quality control: yes	Overall imprecision (CV) was better than 4.5%, with no significant differences in results between three different HemoCue photometers and four batches of microcuvettes. Regression slopes (± SE) were 0.947 (0.011) with the YSI and 0.966 (0.015) with the hexokinase method. The system proved stable and robust under a wide range of storage and handling conditions; performance was impaired only at high ambient temperature (37 °C).	The HemoCue system should prove useful for glucose measurement; further testing outside the laboratory is warranted.	Complex test Accurate results Methodology and statistical analysis sound Cannot predict usefulness and accuracy in primary care Methodology score: 2
Burrin *et al* (1985) UK To asses the accuracy of results from blood glucose meters outside the laboratory	– Questionnaire Glucometer, Dextrostix Whole blood	Laboratory evaluation, other 0.5 months General practices Laboratory, primary care n = 16	Laboratory assay (GDH method) Blood glucose concentration Linear regression Patient satisfaction: no Quality control: no	Accuracy of results from these blood glucose meters outside the laboratory was below generally-accepted laboratory standards; 30% results fell outside ± 20% of laboratory value. Only 58% of filter paper strips sent out were returned for analysis.	A lack of awareness of the benefits and importance of such a scheme by the GP Glucometer users.	Flawed by high level of non-reporting and by lack of control in handling the specimens in storage and in transit No description of patients Methodology score: 3
Clark *et al* (1991) UK To evaluate the reliability of glucose testing strips in diabetic patients with renal failure	Hct, blood glucose reagent strips, renal failure Reference BM Glycemien 1–44, Glucostix, ExaTech Whole blood	Cohort study – Diabetic patients with renal failure Secondary-care in-patients n = 8	Laboratory assay (Glucose oxidase method) Blood glucose concentration Regression analysis Patient satisfaction: no Quality control: yes	Test strips over-read compared with the laboratory (BM Glycemien 1–44 strips 118 ± 1%, Glucostix 132 ± 2%, ExacTech strips 163 ± 4%) and percentage over-read was negatively correlated with the Hct for each strip (all $p < 0.001$).	It is important to bear this source of error in mind when blood glucose levels are measured by strip methods in diabetic patients with low Hct.	No cost–benefit analysis Assuming methodology acceptable, results are important Methodology score: 2

continued

NPTs for diabetes *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
de Grauw *et al* (1995) The Netherlands To evaluate the Micral test in a primary care setting	Microalbuminuria, Type 2 diabetes, general practice, Micral test Questionnaire Micral Urine	Cohort study 12 months Type 2 diabetic patients in the Nijmegen Monitoring Project Primary care n = 401	Immuno-nephelometry Albumin excretion Sensitivity, specificity, predictive values, LRs Patient satisfaction: no Quality control: no	Micral test sensitivity = 67%, specificity = 93%. Sensitivity range, 58–81%; specificity, 87–95%. Microalbuminuria was found in 66 patients (21%). The first Micral test correctly picked out these patients with micro-albuminuria in 70% cases and in 90% those patients without microalbuminuria. The diagnostic performance of the Micral test was further proved by an ROC curve. The area under the curve of the Micral test was 0.84 (95% CI, 0.78–0.90). Micral tests results of 0 and 10 should be regarded as negative.	Micral testing can only be supported if strict standardisation procedures are followed and repeat measurements are performed.	Time dependency Newer test developed which is not time-dependent (Micral 2) Methodology score: 5
Dougherty *et al* (1994) USA An independent evaluation of commercially available blood glucose meters	Efficiency, blood glucose meters, coefficient of variation, diabetes mellitus Academic staff Not stated Capillary blood	Laboratory evaluation – – Home testing n = 1	– Blood glucose concentration Linear regression, Student's t-test. Patient satisfaction: no Quality control: no	CVs for the difference between the first and second measurements obtained for three instruments was: A, ± 28.7%; B, ± 36.5%; C, ± 10.2%.	Instrument C worked much better than either A or B in reproducing blood glucose values on the same sample under field conditions.	Limited value as 'stand-alone' procedure Instruments not identified Proposed strategy useful Methodology score: 2
Drucker *et al* (1983) UK To assess one method of glucose analysis outside the laboratory using a pilot external quality assessment scheme	– Questionnaire Glucometer, Dextrostix Other	Laboratory evaluation 5 months Laboratory, secondary-care in-patients, primary care –	Laboratory assay (IL919 analyser-modified Trinder method) Blood glucose concentration Parametric Patient satisfaction: no Quality control: yes	In the laboratory reliable results were obtained when the Glucometer was used by experienced laboratory personnel giving a good correlation of results (r = 0.96) when compared with an automated method. External quality assessment scheme revealed that 44% hospital ward glucose estimates would be considered unsatisfactory by conventional laboratory criteria, that is, > ± 2 SD of the mean laboratory result. This level of performance must, however, be considered in relation to the number of times that a clinically misleading result is obtained.	No analytical system should be used in clinical practice without a continuous, objective assessment of its performance.	Patient selection not clear Methodology score: 2

continued

NPTs for diabetes *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Forrest & Pitt (1991) UK To assess the performance of the Glycotronic C blood glucose meter	– Medline Glycotronic C blood glucose meter Capillary blood, whole blood	Laboratory evaluation – – Secondary-care in-patients, laboratory n = 53	Laboratory assay (YSI 23AM glucose analyser) Blood glucose concentration CC Patient satisfaction: no Quality control: no	The Glycotronic C meter gives results 20% greater than a conventional instrument when used to measure plasma glucose and about 15% less for neonates.	The Glycotronic C is easy to use and gives an acceptable performance for near-patient use; it compares well with its current British competitors.	Technology 'out of date' No description of patient data and range of results Data does not support conclusion Small sample size Limited usefulness Methodology score: 2
Greendyke (1992) USA Cost analysis of the bedside blood glucose testing programme	Bedside blood glucose testing, cost analysis, cost-effectiveness Reference Accu-Chek IIm system Capillary blood	Other – – Secondary-care in-patients –	Laboratory assay Cost – Patient satisfaction: no Quality control: no	The extra cost of the bedside blood glucose testing programme is estimated to be in excess of $3 million per year.	It seems legitimate to question such an expenditure.	No details of derivation of costs, nor clinical feasibility of withdrawing bedside tests, no comment on saving from rapid availability of test result, etc Methodology score: 0
Klein *et al* (1993) USA To determine whether home blood glucose monitoring improves glycaemic control or reduces use of the out-patient laboratory	Diabetes mellitus, blood glucose monitoring, laboratory utilisation, HbA1c, laboratory utilisation Medline, BIDS, Embase Chemstrips bG, Glucoscan, Ketodiastix Capillary blood	Cohort study – Patients with diabetes Secondary-care out-patients n = 229	– Mean HbA1c, use of laboratory services Parametric Patient satisfaction: no Quality control: no	Mean HbA1c for an unselected group monitoring glycaemic control by urine testing only was 11.32% and for those using blood monitoring was 11.37%. Frequency and duration of monitoring had no apparent impact on glucose control. There was no decrease in the use of the laboratory by those patients practising home blood glucose monitoring.	For patients with NIDDM followed in a non-research clinic setting, the benefits of home blood glucose monitoring remain to be proven.	Demographics not described in detail Methodology score: 3

continued

NPTs for diabetes *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Kouri *et al* (1994) Finland To evaluate new semi-quantitative methods against nephelometric measurements of nightly albumin excretion rates	Diabetes mellitus, urinary albumin excretion, nephropathy, overnight BIDS Nycocard U-Albumin, Micral-Test Urine	Cohort study – Patients with type I or II diabetes Secondary-care in-patients n = 159	Laboratory nephelometry Albumin excretion rate Sensitivity, specificity, predictive values Patient satisfaction: no Quality control: no	The NPVs were 95–100% for both tests. PPVs were 38% (NycoCard U-Albumin(R)) and 44% (Micral-Test(R)), if the designated value of 10 mg/l was used as the limit of positivity. By using 20 mg/l as the limit, the PPVs were 62% (NycoCard U-Albumin(R)) and 72% (Micral-Test(R)).	Both methods can be safely applied for screening of intact renal function even at a strict prediction limit for incipient nephropathy of albumin excretion rate = 15 µg/min (standardised specimens collected at bed-rest).	Significance of prevalence not discussed, nor clinical usefulness and cost-effectiveness Methodology score: 4
Petranyi *et al* (1984) UK To examine the reliability of patients glucose readings at home	– Questionnaire BM 20-800 strips, Dextrostix, Glucochek Capillary blood	Cohort study, laboratory evaluation – Diabetics with experience of home testing Home testing, laboratory n = 24	Laboratory assay (Autoanalyser) Blood glucose concentration Spearman's rank correlation, parametric Patient satisfaction: no Quality control: no	A significant relation existed between performance ratings and the rank correlation coefficients ($p < 0.01$). Poor readings occurred with both low and high glucose concentrations in patients using either monitoring method.	To achieve better control of diabetes, quality control for home monitoring is needed.	Small sample size Inappropriate statistical tests used Insufficient detail of patients Methodology score: 3
Pope *et al* (1993) UK To evaluate a novel technique for measuring HbA1c	HbA1c, immunoassay Reference Ames DCA 2000 Capillary blood	Cohort study – Diabetic, paediatric, obstetric, general practice patients Primary care, secondary-care out-patients, laboratory n = 106	DIAMAT HPLC system CV Regression analysis Patient satisfaction: no Quality control: no	Mean differences between the two results (AMES DCA 2000-DIAMAT) (95% CIs) were: laboratory, –0.69% (–1.42–0.04%); paediatric clinic, –0.93% (–1.93–0.07%); obstetric clinic, –0.29% (–1.09–0.51%); general practice clinic, –0.77% (–1.3–0.24 %). For the AMES DCA 2000, CV for HbA1c of 5.2% was 1.6% and for HbA1c of 13%, 2.4%. This instrument was used without difficulty by four different operators. Intra-assay CV for each operator was < 3.4%.	Methodology of this type may be used successfully in diabetic clinics in both primary care and hospital environments.	Capital and running costs may be the limiting factor Test useful in a general practice diabetic clinic Methodology score: 5

continued

NPTs for diabetes *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Walford *et al* (1978) UK To evaluate the feasibility and value of teaching patients to monitor their own blood glucose profiles	– Questionnaire Reflomat, Reflotest Capillary blood	Cohort study 8 months Patients with IDDM Home testing n = 69	Laboratory assay (Autoanalyzer) Blood glucose concentration Correlation coefficients, parametric Patient satisfaction: no Quality control: no	Self-monitoring especially useful in elucidating problems in diabetic control, preventing hypoglycaemia and managing diabetes in pregnancy. Patients found self-monitoring more informative than urine tests. 32/67 patients had profiles in which no more than one blood glucose value exceeded 10 mmol/l.	Smaller and more portable machines will make the technique more widely applicable.	Omission of data: number of patients who had an independent reference standard carried out on them Lack of data 'Historic' paper Methodology score: 3
Webb *et al* (1980) UK To evaluate the four blood glucose monitors available in the UK for use at home	– Questionnaire Hypocount, Glucocheck, Eyetone, Reflomat Capillary blood	Cohort study 0.5 months Patients with IDDM Home testing n = 24	Laboratory autoanalyser Blood glucose concentration CVs Patient satisfaction: yes Quality control: yes	Of the two battery-operated monitors, patients preferred the Hypocount (15) to the Glucocheck (9). The mains-operated units were less popular, with little to choose between Eyetone and Reflomat. Under field conditions the blood glucose results obtained with the Glucocheck correlated poorly with the standard reference method. In contrast the Hypocount, Eyetone and Reflomat machines produced good correlations.	Of the four monitors evaluated the assessment gave first place to Hypocount.	Old test – superceded Trial well done Paper too old now to comment Methodology score: 1
Wiener (1993) UK To evaluate the effect of Hct on the HemoCue	Near patient testing, accuracy, precision, glucose strip tests Academic staff HemoCue Other	– – – Laboratory –-	Laboratory assay (YSI-2300 STAT analyser) Blood glucose concentration CV Patient satisfaction: no Quality control: no	The HemoCue exhibited no appreciable influence of Hct. The instrument was easy to use, stable and had good precision (CV 1.8%).	Results tended to be a little higher than those produced by a conventional laboratory analyser on whole blood. The factory calibration of newer HemoCue instruments has been modified to correct for this.	Very limited study Not an appropriate addition to NPT in primary care Methodology score: 1

NPTs for haematuria/cancer screening

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Britton *et al* (1989) UK To investigate the prevalence and relevance of dipstick haematuria in a group of men in the community	– Report, questionnaire Hemastix Urine	Cohort study – Men aged 60–85 Primary care, population screening n = 578	– Urological abnormalities Parametric Patient satisfaction: no Quality control: no	78 men (13%) had dipstick haematuria on a single test and a further 54 (9%) had evidence of dipstick haematuria when testing their urine once a week during a subsequent 10-year period. Investigation of 87 men disclosed urological disease in 45, including four with a bladder tumour and seven with epithelial dysplasia.	Dipstick haematuria is a common incidental finding in men over 60. The introduction of less invasive methods of investigation has made investigation of these patients simple and safe and makes screening for bladder cancer in the community more feasible.	True value, cost and workload implications needed Methodology score: 2
Messing *et al* (1987) USA To assess the significance of asymptomatic micro-haematuriausing urinary dipsticks	– Medline Not stated Urine	Cohort study, laboratory evaluation 12 months Men aged 50+ without known causes of haematuria Secondary-care out-patients n = 231	Microscopic urinalysis Urinary tract pathology Parametric Patient satisfaction: no Quality control: no	23 patients had haematuria. 5/23 had urinary cancers, 5/23 had other serious underlying diseases requiring immediate treatment. In 3/10 (1 with cancer) haematuria occurred in more than a third of the testings or on subsequent microscopic urinalysis. The degree of haematuria was unrelated to the seriousness of its cause.	Haematuria in this population, regardless of quantity, implies that serious underlying pathological conditions must be ruled out aggressively. Regular haematuria home testing offers an economical means to detect urinary cancers and other serious diseases in asymptomatic men 50+ years old.	Well conducted study Further studies needed on management of non-serious haematuria and cost analysis of this screening programme Methodology score: 4
Messing *et al* (1995) USA To determine at what interval screening should be repeated to detect bladder cancer before it becomes muscle invasive	Urine, haematuria, urination disorders, bladder neoplasms, carcinoma BIDS – Urine	Cohort study – Men with previously negative home testing for haematuria Population screening n = 856	– Urinary tract abnormalities Parametric Patient satisfaction: no Quality control: no	50 (5.8%) had at least one positive test during the second 14-day screening period and 38 were evaluated, 15 of whom (39.5%) had significant urological pathological conditions, including eight with malignancies. Bladder cancer was noted in seven men with no tumour invading the muscularis propria.	Bladder cancer has a brief pre-clinical duration and that testing must be repeated at least annually for screening to detect bladder cancer consistently before invasion occurs.	Problems: Yield appears high No verification of negative results Interesting study Applicable to primary care Methodology score: 1

continued

NPTs for haematuria/cancer screening *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Messing *et al* (1989) USA To evaluate the value of home testing for haematuria	– Medline Hemastix Urine	Cohort study 12 months Asymptomatic men, 50 years of age and older without known causes of haematuria Secondary-care out-patients n = 235	– Urological abnormalities – Patient satisfaction: no Quality control: no	44 men had haematuria at least once, 31 had full urological evaluation. Of these, eight had urinary cancers, seven had non-malignant diseases warranting immediate treatment. In 6/15 (only two with cancer) haematuria occurred in over one-third of the testings and, in four, haematuria was found on microscopic urinalysis at the time of urological evaluation. The degree of haematuria was unrelated to the seriousness of its cause.	In this population haematuria occurs intermittently and when found, regardless of quantity or symptoms, serious underlying pathology must be ruled out. Furthermore, regular haematuria home testing offers a promising means of detecting urinary cancers and other diseases that warrant therapy in asymptomatic men aged 50 years plus.	No predictive values No evidence to support widespread use of test Methodology score: 3

Home pregnancy tests

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Cole *et al* (1993) USA To investigate the variation in human chorionic gonadotropin with different commercial kits	Human chorionic gonadotropin (hCG), pregnancy, immunoassay BIDS – Urine, serum	Laboratory evaluation – Women with spontaneous singleton pregnancies Secondary-care out-patients n = 137	Laboratory assay Total hCG (nicked + non-nicked), free B subunit, and B core fragment Parametric Patient satisfaction: no Quality control: no	Median levels of total, non-nicked, and B hCG (total + free B + B core) were similar (< 12% difference). Individual values varied significantly. For non-nicked hCG, values ranged from 41% to 145% and for B from 101% to 145% total hCG. In urine, individual non-nicked values varied from < 1% to 148% and B values from 102% to 547% of the total hCG level. A survey of 29 kits revealed that ten were types detecting total hCG, five detecting non-nicked only, and 14 were B assays.	Results from total, non-nicked, and B hCG kits are not inter-convertible. Individual variations in levels of nicked hCG, free B and B core, and differences in their recognition by immunoassays causes discordant results.	Methodology weak Results are of little value for general practice No gold standard/inter-test agreement Dubious value. Esoteric and confusing Theoretically interesting Methodology score: 1

continued

Home pregnancy tests *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Corson (1986) USA To compare an enzyme immunoassay for LH with other ovulation monitoring methods	– Academic staff Ovutime, OvuSTICK Urine	Cohort study, laboratory evaluation 78 months Women attending infertility clinic Secondary-care out-patients n = 45	Basal body temperature LH surge Parametric Patient satisfaction: no Quality control: no	Urinary test kit correctly identified LH surges in 98.7% cycles compared to basal body temperature chart.	The convenience and accuracy of urinary enzyme immunoassay are important benefits in ovulation prediction in the treatment of infertility.	Methodology not clear Important for fertility evaluation Methodology score: 3
Daviaud *et al* (1993) France To evaluate the reliability and feasibility of pregnancy home-use tests	hCG, diagnostic specificity, diagnostic sensitivity BIDS 27 qualitative pregnancy tests available in France in 1989 Urine	Laboratory evaluation, cohort study – Laywomen volunteers Population screening n = 638	(Abbott Testpack hCG-urine) Pregnancy Specificity, sensitivity Patient satisfaction: no Quality control: no	Diagnostic specificity was 86–100% for ten kits, 85–100% for five kits at 2 dl and two at 1 dl. 230/478 positive urine samples distributed were falsely interpreted as negative. The main explanation for such a high percentage of false-negative results was difficulty in understanding the explanatory leaflets accompanying the kits.	Pregnancy home-use tests should be subjected to rigorous analytical controls and evaluated by a panel of potential users before being released on the market.	Results not directly applicable to UK Accuracy of results would improve if tests carried out by practice nurses Methodology score: 4
Doshi (1986) USA To assess the accuracy of the in-home pregnancy test in early pregnancy detection	– BIDS Answer, Daisy 2, early pregnancy test Urine	Laboratory evaluation – Women of childbearing age whose menses were 6–20 days late Primary care, secondary-care out-patients n = 109	Sensi-Tex Pregnancy Parametric, sensitivity, specificity, predictive values Patient satisfaction: yes Quality control: no	Kit accuracy ranged from 45.7% to 89.1% , differing from the 97.4% average of manufacturers' claims. Sensitivity = 56%, specificity = 83%. Predictive value of a negative result = 56%, predictive value of a positive test = 83%.	Manufacturers should emphasise vast sources of error, and include control samples with each test kit.	Old test No laboratory standard Results clearly presented May be advantage for nurses in primary care to use these home kits Measured accuracy of patient testing rather than product Methodology score: 2
Voss (1992) UK To investigate the number of pregnancy tests performed and proportion repeated in one health district in relation to the number of conceptions	– Medline, BIDS – –	Other 12 months – – –	– Pregnancy Parametric Patient satisfaction: no Quality control: no	Five pregnancy tests were performed for each proven pregnancy. Two-thirds of tests were purchased over the counter. Very few women had their pregnancy diagnosed on clinical grounds alone and a small number of ultrasound examinations were performed in lieu of chemical tests. Repeated testing was more likely in primiparous women ($p < 0.005$).	Chemical pregnancy tests trusted more than clinical examination for the diagnosis of pregnancy by women and doctors. When no medical urgency for confirmation of pregnancy, home testing kits will provide quickest results.	Patient-related benefits Cost implications Unless good medical reasons, patients should purchase self-test kits Methodology score: 1

NPTs for allergy tests

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Hamburger *et al* (1991) USA To compare results by prick-puncture skin testing to those obtained with QUIDEL Allergy Screens on patients with allergic symptoms	– Reference QUIDEL Allergy screen, Phadezym RAST, QUIDEL Total IgE, Pharmacia Phadezym PRIST Total IgE Serum, other	Laboratory evaluation – Patients with allergic symptoms Secondary-care out-patients n = 103	Skin test Presence of allergy Sensitivity, specificity Patient satisfaction: no Quality control: no	Compared with skin testing, the Allergen Screen sensitivity = 85%, specificity = 94% for identifying a patient with allergies. On an allergen-by-allergen basis, the skin testing and Allergen Screen methods showed an 85% agreement.	Skin testing and *in vitro* testing can be useful for screening the patient suspected of having IgE-mediated allergic disease.	Difficult to assess whether this rapid test is really applicable in primary care This NPT compares favourably with skin testing Methodology score: 2
Nalebuff & Prasad (1990) USA To compare the results obtained with the Quidel Allergy Screen to those obtained with Modified RAST.	– Reference Quidel Allergy screen Serum	Cohort study – Patient numbers Primary care n = 22	Modified RAST Allergy Sensitivity, specificity Patient satisfaction: no Quality control: no	The Quidel Allergy Screen was 100% effective in identifying those patients defined as allergic by the Modified RAST. On an allergen basis, the sensitivity and specificity were 89% and 96%, respectively, and the overall accuracy was 92%.	The Quidel Allergy Screen is a cost-effective, easy-to-perform test that does require instrumentation but is still sensitive and specific.	Technical report No blinding was used No details given of patient characteristics Difficult to assess whether this rapid test is really applicable in primary care Methodology score: 3

NPTs for cardiac enzymes

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Antman *et al* (1995) USA To evaluate a rapid, qualitative, bedside immunoassay for cardiac-specific troponin T	– Medline, questionnaire Not stated Whole blood	Cohort study 6 months Patients with suspected myocardial infarction (MI) Secondary-care in-patients n = 100	Laboratory analysis (ES-300 analyser) Diagnosis of MI Sensitivity, specificity, LRs, relative risk for serious cardiac events Patient satisfaction: no Quality control: no	Sensitivity of the rapid cardiac-specific troponin T assay increased from 33% within 2 hours from the onset of chest pain to 86% after 8 hours ($p < 0.001$); specificity ranged from 86% to 100% over the same periods. The odds of MI increased six-fold with a positive assay result within 2 hours of chest pain and decreased six-fold with a negative assay result after 8 hours. The relative risk of experiencing death or non-fatal MI was 6.8 for patients presenting with a positive rapid cardiac-specific troponin T assay.	The rapid cardiac-specific troponin T assay is a simple, efficient test that for the first time provides clinicians with a useful tool for point-of-care evaluation of patients with chest pain.	No cost–benefit analysis Potentially invaluable Test done in laboratory with experienced technicians Cannot assume that similar data would derive from nurses, house officers, etc, performing tests Methodology score: 3

Microbiology
Streptococcal throat tests

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Andersen *et al* (1992) Denmark To determine the value of Phadirect Strep A kit	Group A streptococcal tonsillitis, technology evaluation, rapid diagnostic test, family practice Embase Phadirect Strep A kit Swabs	Cohort study 4 months – Primary care n = 105	Laboratory culture Group A streptococcal tonsillitis Sensitivity, specificity, predictive values Patient satisfaction: no Quality control: no	The outcome of the rapid test was significantly correlated to the degree of growth determined by throat culture, and it was superior to the clinical judgement. Specificity (95% CI) = 97% (91–100), sensitivity = 68% (48–84), PPV = 90% (70–99), NPV = 89% (81–95).	Although the co-agglutination test was superior to the clinical diagnosis, the sensitivity of this test is rather low when compared with other recently evaluated rapid tests for use in family practice.	Potentially useful test Reliable for positive result Properly trained personnel needed More research needed into significance of results to the clinical situation Methodology score: 4
Bodono *et al* (1987) Argentina To evaluate whether the Culturette 10-minute Group A STREP ID would be a suitable substitute for laboratory culture in a paediatric office	Group A streptococcal pharayngitis, acute rheumatic fever, rapid detection BIDS Culturette 10-minute Group A STREP ID Swabs	Cohort study, laboratory evaluation 1 month Children with suspected Group A beta-haemolytic streptococcal pharyngitis Secondary-care out-patients, laboratory n = 256	Laboratory culture Group A beta-haemolytic streptococcal pharyngitis Sensitivity, specificity, predictive values. Patient satisfaction: no Quality control: no	Sensitivity 90.6%, specificity 93.6%, PPV 87.5%, NPV 95.2%.	Back-up culture should be performed in all patients with negative rapid testing.	Further research needed Controversial topic False negative results may be a problem Methodology score: 3
Burke *et al* (1988) UK To evaluate Abbot TestPack Strep A and determine whether the availability of the test influences prescribing behaviour in general practice	– Report, questionnaire Abbot TestPack Strep A Swabs	Cohort study Laboratory evaluation – Patients with sore throat Primary care n = 1461	Laboratory culture Streptococcal throat infection, prescribing of antibiotics Parametric, sensitivity, specificity Patient satisfaction: no Quality control: no	69 GPs recorded prescribing for 1189 episodes of sore throat. Antibiotics were prescribed in 763 (64%) episodes and broad spectrum antibiotics in 161 (21%) of these. If there was dysphagia, hoarseness, cervical adenopathy, and inflamed or purulent tonsils a prescription was more likely to be written. Among 23 GPs and 250 patients, the sensitivity of the test was 63% and the specificity 91.7% compared with 74% and 58% for clinical assessment alone. Test results rarely caused previous prescribing decisions (155 episodes (13%)) to be altered.	The time is not right for the use of the enzyme immunoassay rapid test on a wide scale in the routine assessment of sore throats.	Test not as sensitive or specific as previously reported Reduction in unnecessary antibiotic prescriptions Training of medical professionals needed for maintaining/improving test accuracy Methodology score: 3

continued

Streptococcal throat tests *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Carey *et al* (1991) New Zealand To assess the efficiency of Abbott TestPack Strep A compared with throat culture for the diagnosis of group A beta-haemolytic streptococcus in general practice	– BIDS Abbott TestPack Strep A Swabs	Cohort study, laboratory evaluation – Patients with suspected streptococcal pharyngitis Primary care n = 154	Laboratory culture Streptococcal pharyngitis Sensitivity, specificity, PPV, NPV Patient satisfaction: no Quality control: no	Sensitivity of the rapid diagnostic test was 79.4%, specificity 93.3%. The NPV of the test was 94.1%; the PPV 77.1%.	Maximum cost-effectiveness is achieved, by diagnosing and treating solely on the basis of Abbott TestPack Strep A results. When possible complications are taken into consideration, initial testing by Abbott TestPack Strep A followed by confirmatory laboratory testing of negative Testpack results becomes a feasible alternative.	Criteria not discussed: acceptable sensitivity and specificity in general practice Very good study Evaluation of clinical usefulness needed Methodology score: 3
Joslyn *et al* (1995) USA To determine the accuracy of diagnosing group A beta haemolytic streptococci with rapid antigen testing compared with throat culture methods	– Questionnaire Directigen 1-2-3 Group A strep Swabs	Cohort study, laboratory evaluation – Patients with acute pharyngitis Primary care n = 826	Laboratory culture Group A beta haemolytic streptococci pharyngitis Sensitivity, specificity, predictive values Patient satisfaction: no Quality control: no	For the initial 182 patients the prevalence of Group A haemolytic streptococci pharyngitis was 12%. Sensitivity, 95.45%; specificity, 96.25%; PPV, 77.78%; NPV, 99.35%. In the second group of subjects, four false negatives were present (NPV = 99.18%).	< 1% subjects with Group A haemolytic streptococci escaped detection with the rapid screening test methods. Results from this study support treatment protocols based on a rapid screening test as a single diagnostic test.	Important area of practice Lack of information re: cost/cost-effectiveness Difficult to assess full implications for introduction to primary care Further research required Methodology score: 2
Makela (1989) Finland To study the introduction of a latex test for Group A streptococci in primary care	– Embase Respiralex Swabs	Cohort study, laboratory evaluation 2.5 months Patients with sore throat Primary care n = 849	Laboratory culture Group A streptococci pharyngitis Sensitivity, specificity, predictive values Patient satisfaction: no Quality control: no	78% were tested. 11% of the rapid test results uncertain, 15% conflicted with traditional culture results. NPV = 98%, PPV = 59%. 52% patients received antibacterials, the rapid test result influencing the treatment decisions clearly but not solely. Nurses used the rapid test more often than the physicians.	There are difficulties inherent in introducing new tests in primary care and illustrates the realities of overutilisation of the test and overmedication despite test results.	Not clear if any selection bias Wrong use of calculation of sensitivity of treatment Easy test Potentially useful Methodology score: 1

continued

Streptococcal throat tests *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Makela & Sintonen (1991) Finland To evaluate the rationality and cost-effectiveness of several strategies for diagnosing and treating patients with sore throats	Acute rheumatic fever, decision making, accuracy BIDS, Embase Respiralex Swabs	Cohort study, laboratory evaluation – Patients with sore throat Primary care n = 2016	Laboratory culture Group A streptococci pharyngitis Sensitivity analyses Patient satisfaction: no Quality control: no	The amounts of unnecessary medication varied from 19% to 33%, with 2.2–8.9% untreated Group A streptococci infections. Strategies based on bacteriology achieved more rational and economic results than treating no-one, treating all patients, or using clinical evaluation without bacteriology. The cost-effectiveness of the latex agglutination test depended on the sensitivity of the test. The results were also sensitive to sick leave length, cost of anti-bacterials, clinical accuracy, but not test cost.	Rapid tests for Group A streptococci detection can be recommended, if the sensitivity of the test in the actual working conditions is acceptable.	Calculations based on theoretical analysis Flawed study. 'Gold standard' not used Insufficient data Methodology score: 1
Roddey *et al* (1986) USA To compare the Strep ID test and several culture methods in terms of accuracy and practicality for paediatric practice	– BIDS Culturette Swabs	Laboratory evaluation 15 month Patients with acute pharyngitis Primary care n = 512	Culture (4 types) Evidence of Group A beta haemolytic streptococci infection Sensitivity, specificity Patient satisfaction: no Quality control: no	The anaerobic (GasPak) and Detekta-Kit methods produced the highest recovery rates, but aerobic incubation of 5% blood agar plates gave very acceptable results (sensitivity 92%, or 98% if the 1+ positive cultures were eliminated; specificity 100%), and had fewer disadvantages. The Culturette test had < 72% sensitivity and 98% specificity compared with the GasPak method and 77% and 97%, respectively, compared with standard aerobic cultures.	Culturette appears too insensitive to be used alone, but might complement culture methods in selected patients.	Study over 10 years old, probably not representative of practices today Not appropriate for UK Methodology score: 3
True *et al* (1986) USA To evaluate sensitivity and specificity of a rapid identification test for group A beta haemolytic *streptococcus* and its impact on prescribing antibiotics	– Embase Culturette Group ID test Swabs	Cohort study 3 months Patients with clinical indications of pharyngitis Primary care n = 283	Laboratory culture Pharyngitis Parametric, sensitivity, specificity, PPV, NPV Patient satisfaction: no Quality control: no	The calculated sensitivity, specificity, PPV, and NPV were 82%, 92%, 76%, and 94 %, respectively. Throat cultures were ordered for 98% patients with acute pharyngitis regardless of the method of testing available. After use of the rapid identification test within the office, a reduction was observed in physician prescribing of antibiotics before the throat culture results were known. Physicians were more likely to initiate antibiotics immediately when rapid test results for streptococcal infection were positive and provide patient education regarding symptomatic treatment when the results were negative.	The rapid identification test is an acceptable alternative to the standard culture technique in the family practice office. The rapid test was apparently responsible for the observed reduction in antibiotic prescribing and should reduce unnecessary cost and antibiotic exposure in the ambulatory setting.	Reference standard not gold No cost details Lack of discussion Methodology score: 4

continued

Streptococcal throat tests *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Walker (1989) USA To identify elements of analysis of benefits of a home screening test for streptococcal pharyngitis	– BIDS First response Swabs	Health economic evaluation – – Home testing –	– – Bayesian Patient satisfaction: no Quality control: no	Home screening tests must be evaluated as an aid to self-referral to a physician.	Use of home screening test is likely to increase the number of patient-physician contacts among persons with sore throats.	Clinical benefit by treatment is assumed No consideration of overall cost-effectiveness Methodology score: 0
Wegner *et al* (1992) USA To compare the sensitivity of five group A streptococcal antigen detection systems and single blood agar plate culture with a two-plate culture method for diagnosing streptococcal pharyngitis	– Reference Culturette, Ventrescreen, Testpack, Reveal Swabs	Cohort study, laboratory evaluation 1 month Patients suspected of having streptococcal pharyngitis Primary care n = 755	Two-plate culture Streptococcal pharyngitis Sensitivity, specificity Patient satisfaction: no Quality control: no	Sensitivity ranged from 31% to 50%, while specificity ranged from 95% to 100%. The two-plate culture method should be the standard of practice to rule out streptococcal pharyngitis.	No data on likelihood ratios.	Predictive values of clinical usefulness cannot be calculated from data presented Methodology score: 4
Wright *et al* (1987) USA To evaluate the accuracy of the Culturette Brand 10-Minute Group A Strep ID	– Embase Culturette Brand 10-Minute Group A Strep ID Swabs	Cohort study 4 months Patients with pharyngitis Primary care n = 104	Laboratory culture (sheep blood agar) Group A beta haemolytic streptococcal pharyngitis Sensitivity, specificity, predictive values Patient satisfaction: no Quality control: no	Sensitivity 38%, specificity 95%, PPV 69%, NPV 84%.	The need for a sensitive rapid test for streptococci remains.	Test sensitivity low. Little saving in cost and time Flawed study Low numbers resulting in lack of statistical significance Methodology score: 5

Urine test strips

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Ditchburn & Ditchburn (1990) UK To determine the most useful method for diagnosis of urinary tract infection in general practice	– Academic staff, questionnaire Nephur-test plus leuco Urine	Cohort study 15 months Patients with urinary symptoms Primary care n = 325	Laboratory culture Urinary tract infection Sensitivity, specificity Patient satisfaction: no Quality control: no	Neither cloudy appearance nor haematuria were sufficiently specific for the diagnosis of urinary tract infection. In the prediction of a 'positive' culture the sensitivity and specificity of the other tests were as follows: drop method microscopy 95% and 76%, respectively: cytometer count 95% and 81%: leucocyte-esterase estimation 89% and 68%: and nitrite 57% and 96%.	The most useful aid to the diagnosis of urinary tract infection is low-power microscopy of a drop of urine.	Limited statistical analysis LRs needed Well described Appropriate analysis Methodology score: 4
Flanagan *et al* (1989) UK To evaluate four screening tests for bacteriuria	– Report, questionnaire Multistix A-D Urine	Laboratory evaluation Patients admitted to a geriatric medical unit Secondary-care in-patients n = 418	Laboratory culture Urinary tract infection Sensitivity, specificity, predictive values Patient satisfaction: no Quality control: no	The sensitivity of the tests varied from 85.6% to 98.3%, and the specificity from 18.4% to 82.9%. A combination of visual appearance and dipstick testing for nitrite and leucocyte esterase gave a sensitivity of 96.1% with a specificity of 50.6%, and could have reduced by almost one-third the number of urine samples submitted to the laboratory for processing.	Screening tests for bacteriuria can be used accurately in elderly subjects.	Work-up not relevant for primary care Patient selection unsatisfactory Good, practical, useful Methodology score: 2
Winkens *et al* (1995) The Netherlands The validity of urine tests for urinary tract infections determined under daily practice conditions	– Academic staff Nephur test, leuco Urine	Cohort study, laboratory evaluation – Patients presenting with urinary symptoms Primary care n = 1388	Laboratory culture Urinary tract infection Sensitivity, specificity, LRs Patient satisfaction: no Quality control: no	Sensitivity of test strips ranged from 45% to 91%, 27% to 81%. The LR of a positive result lies between 1.2 and 2.6, while for a negative test the LR ranges from 0.3 to 0.8.	If increased quality of urinalysis in general practice cannot be guaranteed, its benefit in diagnosing urinary tract infection should be re-examined.	First class paper methodologically NPV of multistick GP test is at most 57%. Important finding for practice Methodology score: 5

NPTs for CRP/ESR

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Dinant *et al* (1994) The Netherlands To compare the reliability of the whole blood Nyco Card CRP measurement with the ESR	Acute phase protein, CRP, ESR, reliability BIDS, questionnaire NycoCard CRP Serum, whole blood	Laboratory evaluation, cohort study 4 months Patients for whom ESR investigation was considered Primary care n = 443	Laboratory assay (turbidimetry) CRP and ESR Correlation, regression analysis Patient satisfaction: no Quality control: no	The dichotomised CRP values measured at general practices corresponded with the laboratory values in 88% of cases. Kappa was 65% ($p < 0.00001$). Using a 20 mm cut-off point, ESR values corresponded in 96% cases ($\kappa = 90\%$, $p < 0.00001$). Interpractice variabilities and learning effects did not influence the results. 'False normal' rates for CRP and ESR were 8% and 1%; 'false elevated' rates were 28% and 12%, respectively.	The reliability of the NycoCard CRP measurement in whole blood disappointing. In particular the 'false elevated' rate is unacceptably high for daily general practice. The background to the poor reliability remains unclear.	Difficult to evaluate due to design and handling of data Research question raised is of great practical importance Further, larger study needed Methodology score: 2
Dinant *et al* (1989) The Netherlands To evaluate the reliability of ESR testing in general practice	ESR, reliability, intervention study, general practice Academic staff, questionnaire – Whole blood	Laboratory evaluation – – Primary care, laboratory –	Control sample ESR Analysis of variance Patient satisfaction: no Quality control: no	Clinically important intra- and inter-practice variability was found in the ESR values measured. The experiment was then repeated 1 year later under more standardised conditions, which resulted in a significant decrease in the intra- and interpractice variability ($p = 0.04$ and 0.003, respectively). Vibrations within the hospital building could not account for the systematically higher ESR values measured in the hospital laboratory.	A considerable increase in the quality of ESR performance in general practice can be achieved.	Test is non-specific, varies with age and has been replaced by plasma viscosity tests Results slightly misleading and incorrectly interpreted Methodology score: 4
Hansson *et al* (1995) Sweden To evaluate the Nyco-Card CRP test in relation to ESR in consecutive patients in general practice	CRP, ESR, general practice, inflammatory diseases, infections BIDS, questionnaire, academic staff NycoCard CRP Serum, whole blood	Cohort study, laboratory evaluation – Consecutive patients Primary care n = 607	Laboratory assay (Multistat turbidimetric CRP method) CRP Parametric Patient satisfaction: no Quality control: no	Consistent results in 71% cases. In 20%, CRP was increased more than ESR, while ESR was increased more than CRP in 9%. CRP was increased in 16% while ESR was below the upper reference limit for age and sex. ESR was increased while CRP was below 10 mg/l in 5% patients. In most of the cases where there was a discrepancy, CRP results were more clear cut. Using the NycoCard test the CRP concentration can be measured directly in a whole blood sample with the result available in minutes. Comparison of the NycoCard CRP test with the reference method of CRP quantitation showed good agreement.	In clinical situations with suspected inflammatory diseases, the CRP test appears often to yield more useful results than ESR. The NycoCard CRP test is suitable for use in general practice.	Relevance to disease outcomes not discussed fully Excellent method Methodology score: 5

continued

NPTs for CRP/ESR *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Hjortdahl & Melbye (1994) Norway To assess the efficacy of NPT laboratory testing for A beta haemolytic streptococci throat infection	Pharyngitis, sore throat, near to patient testing, ESR, leucocyte count, CRP, rapid immunological assays, primary care Embase PathoDx Swabs, serum	Cohort study 5 months Patients with sore throat Secondary-care out-patients n = 174	Laboratory culture, antistreptococcal antibodies Group A streptococcal throat infection Sensitivity, specificity, predictive values, LRs, ROC curves Patient satisfaction: no Quality control: no	The discriminatory ability of ESR was not satisfactory and added little useful clinical information. Leucocytes and CRP both yielded clinically significant information and had similar test characteristics.	ESR may, in addition to clinical evaluation, contribute to the differential diagnosis of streptococcal pharyngitis in adults.	Possible reduction in prescribing of antibiotics Cost–benefit analysis needed Test employed not easily translated to primary care Methodology score: 3
Hjortdahl *et al* (1991) Norway To evaluate the accuracy of NycoCard for the measurement of CRP	CRP, ESR, immunological tests, near to patient testing, rapid testing, decentralised testing, clinical usefulness of a test Embase, academic staff Nycocard Serum –	Cohort study, laboratory evaluation 1.5 months Patients with a diagnosis of infectious disease Primary care n = 194	Cobas Bio centrifugal analyser CRP concentration Regression analysis Patient satisfaction: no Quality control: no	The two procedures had an acceptable correlation (r = 0.85). CRP was helpful in indicating the presence, or absence of bacterial infection in > 50% consultations caused by new infections.	CRP appears to have advantages as an infectious disease parameter in primary care, and to yield more information of clinical value than ESR.	No major impact on patient care Test lacks clinical specificity This serum test superceded by whole blood test Methodology score: 4
Søndenaa *et al* (1992) Norway To test the accuracy and diagnostic performance of a new rapid test kit for CRP in patients with acute appendicitis	Acute appendicitis, CRP, rapid CRP BIDS Nycocard Serum	Cohort study 8 months Patients with a tentative diagnosis of appendicitis Secondary-care in-patients n = 158	T-antiserum CRP Acute appendicitis Non-parametric, regression analysis, sensitivity, specificity, predictive values Patient satisfaction: no Quality control: no	The values obtained for CRP by the rapid test correlated well (r = 0.92) with the reference method for measuring CRP. The sensitivity, specificity and predictive values were calculated at different cut-off values. At values > 10 mg/l a sensitivity of 58% and an NPV of 72% were found. Higher values of sensitivity were observed for men than for women, 69% and 44% respectively. Patients with acute appendicitis who had symptoms for more than 24 h, had elevated CRP values (cut-off > 10 mg/l) in more than 80% cases.	The rapid CRP test and the reference CRP test gave an almost identical result.	Important, but clinical value of test in primary care setting not discussed Methodology score: 5

continued

NPTs for CRP/ESR *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Urdal *et al* (1992) Norway To evaluate an instrument free test CRP in whole blood	Intermethod comparison, gold-conjugated antibody Reference NycoCard CRP Whole blood	Laboratory evaluation 6 months – Laboratory n = 234	Laboratory assay (Cobas-Bio) CRP concentration Linear regression Patient satisfaction: no Quality control: no	CVs were 6.7–12.5% within series and 10.1–14.7% between series. The detection limit was 12 mg/l. Intralipid added to blood increased measured CRP by 10–20%, whereas no change was seen with added bilirubin, added serum amyloid P component, or the presence of rhuematoid factor. In 234 patients' blood samples the results of the NycoCard Whole Blood test correlated well (r = 0.96) with those of a turbidimetric serum method.	The test allows reliable measurement of CRP from a small volume of whole blood (25 µl) without using expensive equipment; it should be useful for decentralised testing in hospital departments, emergency units and primary healthcare centres.	Further validation of reproducibility of results needed Test prone to errors Suitable test for general practice Methodology score: 3

Other microbiology NPTs

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
George & Braithwaite (1995) UK To evaluate five rapid detection kits for drugs of abuse screening	– Medline Not stated Urine	Laboratory evaluation – – Laboratory –	Laboratory assay – Sensitivity, specificity Patient satisfaction: no Quality control: no	All of the kits evaluated were found to lack both sensitivity and specificity. An unacceptable proportion of false negative and false positive results were observed for most kits. This raises the question of their usefulness in the near-patient and clinic situation.		Kits not suitable for primary care More thorough cost–benefit analysis needed Methodology not clear Lack of data Methodology score: 3
Krieger *et al* (1991) USA Whether relatively untrained personnel could perform HIV test and obtain accurate results	Human immunodeficiency virus, acquired immunodeficiency syndrome, antibodies, viral antibodies BIDS, Embase Genie Serum	Laboratory evaluation – – Secondary-care out-patients –	Western blot. Presence of HIV-1 – Patient satisfaction: no Quality control: no	Personnel who were previously unfamiliar with immunoassays learned the test procedure within 30 minutes. All reference specimens were interpreted correctly. One clinical sample reacted in the test but the result was not confirmed by Western blot.	The rapid, peptide-based test was easy to use and performance was comparable to currently licensed tests performed at clinical laboratories.	Test not specific Secondary-care study Further study worthwhile in general practice setting Methodology score: 3

continued

Other microbiology NPTs *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Ma *et al* (1994) USA To evaluate ChemTrak AccMeter in non-traditional testing environments	– Academic staff ChemTrak AccMeter Whole blood	Technical report – – Laboratory –	Control material – – Patient satisfaction: no Quality control: no	Test results are confirmed by Western blot analysis of the specimens.	The assay is simple, accurate and is completed in about 10 minutes.	Wider evaluation needed Too small a sample Further evaluation should consider clinical and financial factors Methodology score: 2

Haematology

INR

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Anderson *et al* (1993) Canada To determine the feasibility and accuracy of home use of portable PT monitor	– Reference Biotrak Capillary blood	Cohort study 24 months Patients attending oral anticoagulation clinic Home testing n = 40	Laboratory analysis INR Parametric Patient satisfaction: yes Quality control: no	40 patients (19 men and 21 women, aged 25 to 74 years) were followed-up for 6–24 months by means of the portable PT monitor. Mean level of agreement achieved per patient was 83% (95% CI, 79–87%) by the standard criteria and 96% (94–98%) by expanded criteria. 27 patients (68%) and 39 patients (98%) achieved more than 80% agreement by the standard and expanded criteria, respectively. Questionnaire results revealed that 97% patients preferred using the portable monitor to measure their PT.	The use of the portable monitor as the primary method for measuring PT can be recommended in selected patients receiving long-term anticoagulant treatment.	No economic analysis Methodology score: 4
Ansell *et al* (1989) USA To assess the ability of patients to regulate their own therapy based on fingerstick PTs	– Reference Coumatrak Whole blood	Cohort study 12 months Patients on long-term oral anticoagulation Home testing n = 16	Laboratory assay (MLA 700) INR Parametric Patient satisfaction: no Quality control: no	458 PTs measured by patients at home. 393 were in therapeutic range and patients correctly continued their dosages. Of the 65 non-therapeutic PTs, patients made correct dose adjustments in 49 and incorrect adjustments in 16. No complications of therapy occurred during the study.	Patient self-management is feasible and that this model of coagulant care offers the potential for improved care at reduced cost.	Larger study needed Study needs to be repeated with use of standardised treatment guidelines An excellent alternative for the management of patients on oral anticoagulation Methodology score: 2

continued

INR *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Belsey *et al* (1991) USA To evaluate the reliability of PT test results obtained by individuals using the Coumatrak who had minimal laboratory training	PT, comparative study, laboratories, reagent kits, diagnostic BIDS Coumatrak Whole blood, capillary blood	Technical report, laboratory evaluation 1 month Not applicable Primary care n = 1000	MLA 70/Dade Thromboplastin C Precision Regression analysis, chi-squared, t-test, F-test Patient satisfaction: no Quality control: yes	The results produced by a trained technologist and nontechnically trained staff were comparable. Test results obtained with the Coumatrak were approximately 10% higher than results obtained using standard laboratory equipment and methods using comparable blood samples from the same patients.	Coumatrak can rapidly provide PT test results. The system is easy to operate, appropriate for use by individuals with little laboratory experience.	Good correlation of NPT results in general practice with laboratory results Attention would need to be paid to quality control issues Methodology score: 3
Jennings *et al* (1991) UK To evaluate Biotrak 512	– Medline Biotrak 512 Capillary blood, whole blood	Cohort study – Patients receiving warfarin Secondary-care out-patients n = 104	KC10 INR CV Patient satisfaction: no Quality control: no	Biotrak 512 compared well with Manchester Reagent. The inability of the monitor to allow for locally determined geometric mean normal PTs in the calculation of the INR, and possibly the high International Sensitivity Index of the thromboplastin used with the monitor, resulted in poor comparability with some other thromboplastins, particularly Thrombotest.	These problems need to be addressed if the monitor is to be used for decentralised anticoagulant control.	No cost analysis Lack of description Potential savings Secondary care study Methodology score: 4
Lucas *et al* (1987) North America To evaluate the Protime Monitor 1000	PT, capillary blood, bedside testing, anticoagulant therapy Reference Protime Monitor 1000 Whole blood	Cohort study Laboratory evaluation – Normal volunteers and patients receiving anticoagulant therapy Secondary-care out-patients n = 732	Laboratory evaluation (MLA 700) INR Linear regression Patient satisfaction: no Quality control: no	PT for normal volunteers (n = 193) was 11.8 ± 0.9 s with the use of the new instrument and 12.1 ± 0.5 s with the reference method. In samples from 539 patients receiving anticoagulants, the correlation coefficient (CC) between the two methods was 0.96. Venous whole blood without anticoagulant and capillary whole blood gave equivalent results. Variation in Hct between 23.4% (0.34) and 53.8% (0.538) did not alter the performance of the instrument.	The new instrument is easy to use and may allow testing by non-laboratory personnel and patients. It obviates the need for venepuncture, provides immediate results, and is comparable in accuracy to current reference methods.	No comparison of costs is made Good methodology Easy to carry out in general practice Methodology score: 2

continued

INR *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
McCurdy & White (1992) USA To evaluate an office-based anticoagulation monitor	– Reference Not stated Whole blood	Cohort study Laboratory evaluation Patients attending oral anticoagulant clinic Secondary-care out-patients n = 143	Laboratory analysis (MLA 700) INR Regression analysis Patient satisfaction: no Quality control: no	Within the range of 2.0–3.0 INR units, the monitor yielded values that were up to 0.3 units higher on average than the laboratory values. Within the range of > 3.0–4.5 INR units, the monitor yielded values that were up to 0.5 units lower on average than the laboratory values. 75% paired monitor and laboratory values were within 0.7 INR units.	The monitor differed systematically from the laboratory and was moderately less precise. The magnitude of these effects was not great, however, and accuracy was best at around INR = 3.0, the border between high and low therapeutic ranges. The clinic-based monitor is useful for patients requiring frequent surveillance of anticoagulation status.	Good methodology Methodology score: 4
Mennemeyer & Winkelman (1993) USA To determine if the occurrence of health outcomes following clinical laboratory testing can be used to identify types of laboratories that may be having higher than expected error rates	– Medline Not applicable Capillary blood	Case control 24 months Medicare patients receiving a PT test in either a physician office-laboratory or a commercial laboratory Primary care, laboratory n = 14,755	No gold standard PT, incidence of stroke/MI Odds ratios Patient satisfaction: no Quality control: no	In physician office-laboratories where PT test volume is below 40 per month, the odds that a tested patient will experience a stroke or an acute MI are up to 1.96 and 3.43 times greater, respectively, than for a similar patient tested in a commercial laboratory. Switching from one laboratory to another between successive PT tests increased the odds of a stroke or an acute MI by 1.57 and 1.32, respectively. Patients in two states with strong laboratory regulatory programmes had fewer adverse outcomes.	Examining patient outcomes subsequent to clinical laboratory testing may be a useful tool for clinical laboratory quality assurance.	No cost–benefit analysis Excellent study UK research should be encouraged since this is an American study Methodology score: 3
Oberhardt *et al* (1991) USA To evaluate dry reagent technology for measurements of blood coagulation and fibrinolysis	Fibrinogen, plasminogen, thrombolytic therapy, paramagnetic iron oxide particles Reference COAG-1, COAG-2 Whole blood	Technical report, laboratory evaluation – – Laboratory –	Coag-a-Mate X2, Coatron Jr PT, APTT Linear regression, parametric Patient satisfaction: no Quality control: no	Applications to one-stage PT and one-stage APTT tests have yielded assays with consistently good correlations with other test methods. Applications to fibrinolysis studies have yielded global assays of thrombolytic activity, in that the assay results reflect the interactions of multiple factors associated with the effectiveness of thrombolytic therapy.	Use of these assays in a clinical setting should provide a rapid convenient alternative to conventional testing of coagulation variables and a reliable method for monitoring thrombolytic therapy.	Limited use for NPT in present climate Complex equipment Difficult technical paper Important paper Methodology score: 3

continued

INR *contd*

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Rose *et al* (1993) USA To examine the deployment of COAG-1 in decentralised hospital settings	– Reference COAG-1 Whole blood, capillary blood	Laboratory evaluation – Intensive care, coronary care, cardiology – Secondary-care out-patients, secondary-care in-patients n = 440	Laboratory analysis PT, APTT CC Patient satisfaction: no Quality control: no	CCs between the dry chemistry system and the hospital laboratory under these conditions were in an acceptable range at all the sites studied.	With appropriate training and quality assurance, the dry chemistry system provides an acceptable alternative to the hospital laboratory for PT and APTT determinations.	Sound, reliable test for primary care One operator to use instrument to avoid error Methodology score: 4
White *et al* (1989) USA To evaluate the efficacy and accuracy of monitoring PTs at home	– Reference Coumatrak Whole blood n = 50	Cohort study 2 months – –	Laboratory assay Therapeutic INR, bleeding and thromboembolic episodes Parametric, Spearman's rank correlation Patient satisfaction: no Quality control: no	For 46 patients who completed the 8-week study, the median percentage of time that patients in the home monitor group (n = 23) were within a range equal to the target prothrombin ratio ± 0.3, but always above 1.25, was 93%, compared with 75% for patients in the clinic group (n = 23) (p = 0.003). The percentage of time that patients were subtherapeutic was significantly greater in the clinic group (p < 0.001). There were no major thromboembolic or haemorraghic standard anti-coagulation complications in either group. Differences between home monitor measurements using blood samples drawn within 4 hours of the home test were comparable to differences observed between measurements using two different clinical laboratory instruments.	Use of a portable PT monitor by patients at home is feasible and provides accurate measurements. Patients doing home monitoring achieve superior anticoagulation control compared with those receiving clinic care.	Costings not clear Excellent concept Further studies required Methodology score: 2

NPTs for haemoglobin

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Neville (1987) UK To evaluate HemoCue in a hospital laboratory and operated by trained staff and a general practice health centre and operated by practice staff	– Report HemoCue Whole blood	Cohort study, laboratory evaluation 6 months Patients requiring full blood count Laboratory, primary care n = 238	ELT 800 WS automated full blood count method Hb concentrations Regression analysis Patient satisfaction: no Quality control: no	HemoCue gave excellent results when used within a laboratory environment (on 103 paired samples) but disappointing ones when evaluated by practice nurses in general practice (on 235 paired samples).	The most likely source of error was inadequate mixing of the blood specimens before sampling, which might be obviated by using a rotating mixer. It is emphasised that equipment intended for use in general practice should be evaluated under normal working conditions.	False readings Methodology score: 4

NPTs for D-dimer

Author, country, and objectives	Key words, sources, trade name, and test samples	Type of study, length, population, setting and sample size	Gold standard, outcomes, statistics, patient satisfaction, quality control	Study results	Implications of the research as stated by author(s)	Reviewers' comments. Methodology score based on criteria (0–5, max = 5)
Dale *et al*[22] (1994) To compare the utility of Nycocard D-dimer in the diagnosis of DVT	DVT, markers BIDS Nycocard D-dimer Serum	Cohort study, – Patients with suspected DVT Secondary-care out-patients/in-patients n = 92	D-dimer EIA and latex Diagnosis of DVT Sensitivity, specificity, predictive values Patient satisfaction: no Quality control: yes	Venography verified the diagnosis in 40, and excluded the diagnosis in 52 patients. The sensitivity, NPVs, specificity and PPVs were for ELISA 98%, 95%, 38% and 54% , for NycoCard D-dimer 100%, 100%, 42% and 57%, and for the latex test 73%, 78%, 75% and 69%, respectively. Sensitivity and specificity were inversely related with increasing pathological cut-off value. Comparison of test results by concentration category revealed a good agreement between ELISA and NycoCard D-dimer, but to a lesser extent between latex and two other tests.	NycoCard D-dimer and D-dimer ELISA are well suited in exclusion tests for DVT. A plasma sample is tested with NycoCard D-dimer in less than 2 min. Thus this test combines advantageous analytical properties comparable with the ELISA test, with rapidity and simplicity comparable to the latex test.	Tests not at present appropriate for use in general practice Results not analysed by subgroup Methodology score: 2

Appendix 2

Summary tables: top scoring papers on validity

Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Jennings 1991 (0101)	Haematology/ anticoagulation/ INR	Biotrack 512 (Ciba Corning, UK)	Laboratory technician (Same)	Hospital laboratory (UK)	Same	Same (Same)	Same	Repeatability (n = 20 aliquots each of 2 control samples: A. INR 0.79 B. INR 4.3)	No detail	CV; A 7.5% B 4.5%
Jennings 1991 (0101)	Haematology/ anticoagulation/ INR	Biotrack 512 (Ciba Corning, UK)	Laboratory technician (Same)	Hospital laboratory (UK)	Nycomed capillary thrombotest (Nycomed, Oslo, Norway)	Same (Same)	Same	Test performance (n = 104 patients anticoagulated for a variety of conditions)	4	Mean diff from mean INR = –0.76 (± 2 SD 0.65–2.17)
Jennings 1991 (0101)	Haematology/ anticoagulation/ INR	Biotrack 512 (Ciba Corning, UK)	Laboratory technician (Same)	Hospital laboratory (UK)	Five other commercial thromboplastins on KC10 coagulometer (Baxter Bade, Dudingen, Switzerland)	Same (Same)	Same	Test performance (n = 104 patients anticoagulated for a variety of conditions)	4	Best performance; Manchester reagent. Mean diff from mean INR = –0.07 (± 2 SD 1.13–1.27)
McCurdy & White 1992 (0449)	Haematology/ anticoagulation/ INR	"Portable INR/PT monitor" ?Biotrack	Single clinic nurse: manufacturer's instructions (Same)	Hospital out-patient dept (USA)	Same	Same	Same	Repeatability (n = 54 paired fingerprick samples taken within 2 minutes of each other)	No detail	SD = 0.23 INR units (SD = 0.19 INR units for MLA 700, (reference method used in test)
McCurdy & White 1992 (0449)	Haematology/ anticoagulation/ INR	"Portable INR/PT monitor" ?Biotrack	Single clinic nurse: manufacturer's instructions (Same)	Hospital out-patient dept (USA)	MLA 700, photo-optical coagulation measuring device (Medical Laboratory Automation Inc, Mt Vernon, NY)	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 143 paired blood specimens, from 85 patients. 7 pairs excluded as ref INR > 6.0)	4	Overall: 75% INR within 0.7 units 90% INR within 0.9 units INR 2.0–3.0: 75% INR within 0.4 units 90% INR within 0.6 units INR 3.0–4.5: 75% INR within 0.7 units 90% INR within 0.9 units
Anderson 1993 (0450)	Haematology/ anticoagulation/ INR	Biotrack (Biotrack, USA)	Patients instructed by study nurse (Same)	Home (Canada)	Not specified; specimens taken within 4 hours of Biotrack at home	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 49 patients, 9 excluded, providing 5–28 pairs of samples; mean: 12.1 pairs per patient)	6	CC = 0.73 (95% CI 0.63–0.81) 'Standard agreement' [1. Both tests in target range 2. Both tests above or below target range 3. Tests within 0.4 INR units of each other] Mean level of agreement per patient – 83% (95% CI 79–87%). 68% patients had standard agreement in > 80% of their dual readings

continued

Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Anderson 1993 (0450)	Haematology/ anticoagulation/ INR	Biotrack (Biotrack, USA)	Patients instructed by study nurse (Same)	Home (Canada)	?Usual method of monitoring prior to start of study	?Laboratory technician (Same)	?Hospital out-patient dept	Impact – acceptability (Questionnaire, 6 months after start of study, n = 40, response rate 100%)	NFA	95% would prefer to use portable monitor in future
Anderson 1993 (0450)	Haematology/ anticoagulation/ INR	Biotrack (Biotrack, USA)	Patients instructed by study nurse (Same)	Home (Canada)	None	None (None)	None	Impact – harm (Follow-up of complication rates, bleeding and thrombosis for 0.5–2 y; 533 patient-months in total) [No indication of completeness or intensity of follow-up]	NFA	Only one complication in one patient – spontaneous sub-arachnoid haemorrhage; INR at time of event = 1.3 (target 1.5–2.5)
Rose 1993 (0447)	Haematology/ anticoagulation/ PT	COAG-1: portable dry chemistry anticoagulation analyser (Cardiovascular Diagnostics Inc, USA)	'Operator with no previous experience in laboratory or of instrument', with brief training (Same)	?Hospital laboratory (USA)	Same	Same (Same)	Same	Repeatability (n = 20 aliquots each of 20 control samples: A. Normal control B. Abnormal control)	No detail	A. Mean = 12.2 s; SD = 0.4 s; CV = 3.7% B. Mean = 22.0 s; SD = 0.8 s CV = 3.6%
Rose 1993 (0447)	Haematology/ anticoagulation/ PT	COAG-1: portable dry chemistry anticoagulation analyser (Cardiovascular Diagnostics Inc, USA)	Trained nurses (n = 50), with daily quality control by laboratory staff (Trained nurses, n = 50)	Hospital (i) surgical ICU (ii) coronary CU (iii) cardiology out-patient dept (USA)	Coag-A-Mate X-2 (General Diagnostics Div, Organon Teknika Corp, USA)	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 204 pairs of samples from unknown number of patients)	4	CCs: (i) surgical ICU (n = 117); r = 0.75 (after removal of 2 outliers, r = 0.86) (ii) cardiac CU (n = 37); r = 0.73 (after removal of 1 outlier, r = 0.87) (iii) cardiology outpatients (n = 50); r = 0.86
Rose 1993 (0447)	Haematology/ anticoagulation/ APTT	COAG-1: portable dry chemistry anticoagulation analyser (Cardiovascular Diagnostics Inc, USA)	'Operator with no previous experience in laboratory or of instrument', with brief training (Same)	?Hospital laboratory (USA)	Same	Same (Same)	Same	Repeatability (n = 20 aliquots each of 2 control samples: A. Normal control B. Abnormal control)	No detail	A. Mean = 32.0 s SD = 2.1 s CV = 6.5% B. Mean = 53.5 s SD = 2.4 s CV = 4.6%
Rose 1993 (0447)	Haematology/ anticoagulation/ APTT	COAG-1: portable dry chemistry anticoagulation analyser (Cardiovascular Diagnostics Inc, USA)	Laboratory technician (Same)	Hospital laboratory (USA)	Same	Same (Same)	Same	Repeatability (Daily quality control for 44 days using A. Normal control B. Abnormal control)	No detail	A. All measurements within specified manufacturer's range, 22.5–32.7 s B. All measurements within specified manufacturer's range, 49.4–69.1 s

continued

Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Rose 1993 (0447)	Haematology/ anticoagulation/ APTT	COAG-1: portable dry chemistry anticoagulation analyser (Cardio-vascular Diagnostics Inc, USA)	Trained nurses (n = 50), with daily quality control by laboratory staff (Trained nurses (n = 50))	Hospital (i) surgical ICU (ii) coronary CU (USA)	Coag-A-Mate X-2 (General Diagnostics Div, Organon Teknika Corp, USA)	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 236 pairs of samples from unknown number of patients)	4	CCs (i) surgical ICU (n = 111) r = 0.67 (after removal of 3 outliers, r = 0.82) (ii) coronary CU (n = 125) r = 0.81
Neville 1987 (0444)	Haematology/ full blood count (FBC)/Hb	HemoCue	Trained laboratory technician (Same)	Hospital laboratory (UK)	Standard automated FBC method (ELT 800 WS: Ortho Diagnostic Systems Ltd)	Same (Same)	Same	Test performance (n = 103 random selection of samples from hospital and surrounding general practices)	3	CC = 0.99
Neville 1987 (0444)	Haematology/ FBC/Hb	HemoCue	Nursing sisters given training (Same)	Primary care (UK)	Standard automated FBC method (ELT 800 WS: Ortho Diagnostic Systems Ltd)	Trained laboratory technician (Same)	Hospital laboratory	Test performance (n = 235 random selection of samples from 3 urban general practices; combined list – 14,000 patients)	4	CC = 0.61 HemoCue: Mean (SD) = 137 (23) g/l Range: 64–192 g/l; Laboratory standard: Mean (SD) = 135 (17) g/l Range: 78–180 g/l Results reclassified as low/normal/high. *Sensitivity of abnormal test = 80%* *Specificity of abnormal test = 90%* (Values calculated incorrectly in paper)
Hjortdahl 1991 (0224)	Haematology inflammation/ CRP	NycoCard CRP [serum] test (Nycomed Pharma AS, Norway) using best guess of exact value in diagnosing cause of presumed infection	Laboratory technician (Results read by laboratory technician	Hospital laboratory (Norway)	Same	Same (Same)	Same	Repeatability (n = 244; samples from 288 consultations by 36 doctors in primary care, where clinical diagnosis of infectious disease was entertained and vene-puncture indicated where frozen serum samples were available to retest: 2 tests per sample)	No detail	CC = 0.95

continued

Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Hjortdahl 1991 (0224)	Haematology inflammation/ CRP	NycoCard CRP [serum] test (Nycomed Pharma AS, Norway) using best guess of exact value in diagnosing cause of presumed infection	Auxiliary staff, mainly office nurses, given training (Same)	Primary care (Norway)	Turbidimetric assay (reagents from Orion Diagnostics, Finland, applied to a Cobas Bio centrifugal analyser)	Laboratory technician (Same)	Hospital laboratory	Test performance (n = samples from 288 consultations by 36 doctors in primary care where clinical diagnosis of infectious disease was entertained and venepuncture indicated)	6	CC = 0.85, for 194 samples where "best guess of exact value was available"
Hjortdahl 1991 (0224)	Haematology inflammation/ CRP	NycoCard CRP [serum] test (Nycomed Pharma AS, Norway) using manufacturer's categories (< 10, 10–19, 20–39, 40–59, 60–99, 100–200, > 200 mg/l) in diagnosing cause of presumed infection	Auxiliary staff, mainly office nurses, given training (Same)	Primary care (Norway)	Turbidimetric assay (reagents from Orion Diagnostics, Finland, applied to a Cobas Bio centrifugal analyser)	Laboratory technician (Same)	Hospital laboratory	Test performance (n = samples from 288 consultations by 36 doctors in primary care where clinical diagnosis of infectious disease was entertained and venepuncture indicated)	6	(i) Exact agreement in 138/277 samples where paired data available (ii) Agreement within plus/minus one category in 268/277 samples where paired data available
Hjortdahl 1991 (0224)	Haematology inflammation/ CRP	NycoCard CRP [serum] test using clinically relevant group categories for new infections (< 20, 20–39, 40–99, > 100 mg/l) for presumed infection	Auxiliary staff, mainly office nurses, given training (Same)	Primary care (Norway)	Turbidimetric assay (reagents from Orion Diagnostics, Finland, applied to a Cobas Bio centrifugal analyser)	Laboratory technician (Same)	Hospital laboratory	Test performance (n = samples from 288 consultations by 36 doctors in primary care where clinical diagnosis of 'new' infectious disease as opposed to follow-up was entertained and venepuncture indicated)	6	(i) Exact agreement in 182/208 samples (ii) Agreement within plus/minus one category in 206/208 samples
Hjortdahl 1991 (0224)	Haematology inflammation/ CRP	NycoCard CRP [serum] test (Nycomed Pharma AS, Norway) for diagnosis of presumed infection	Auxiliary staff, mainly office nurses, given training (Results read by auxiliary staff, interpreted by GPs)	Primary care (Norway)	None	None (None)	None	Impact – effectiveness: measured by responses to requests for 'clinical information' gained from CRP test (n = 208, from 208 consultations for 'new infections' and 68 from 80 consultations for 'follow-up' of probable infectious disease) [Design has no control group and outcome measure is subjective and not corroborated]	NFA	'Clinical information gained' (i) New infections (n = 208) Bacterial infection absent, 31% Bacterial infection present, 29% Level of disease activity, 41% Effect of treatment, < 1% Little or no information, 7% Other, 2% (ii) 'Follow-up' (n = 68) Bacterial infection present, 18% Bacterial infection absent, 28%& Level of disease activity, 40% Effect of treatment, 18% Little or no information, 16% Other, 9%

continued

Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Hjortdahl 1991 (0224)	Haematology inflammation/ CRP	NycoCard CRP [serum] test (Nycomed Pharma AS, Norway) for diagnosis of presumed infection	Auxiliary staff, mainly office nurses, given training (Results read by auxiliary staff, interpreted by GPs)	Primary care (Norway)	ESR – no details of method used	Laboratory technician (Laboratory technician/ GP)	Hospital laboratory/ primary care	Impact – effectiveness Effect measured by scores on 10 cm visual analogue scale (0 = no impact, 10 = very great impact) of CRP (n = 286) vs ESR (n = 282) [Assessment of impact of ESR likely to have been heavily influenced by prior availability of CRP result]	NFA	Impact (visual analogue scale scores) (i) ESR, mean (SD) = 3.7 (2.5) (ii) CRP, mean (SD) = 4.9 (2.7) Results subdivided by new and follow-up, for different infection sites. CRP VAS mean score > ESR score in all but one of 18 sub-categories examined.
Søndenaa 1992 (0422)	Haematology inflammation/ CRP	NycoCard CRP (Nycomed Pharma AS, Norway) using best guess of exact value in diagnosing acute appendicitis	?Laboratory technician (Read by laboratory technician, interpreted by clinician)	?Hospital laboratory (Norway)	T-antiserum CRP (Roche, Switzerland) quantitative immuno-turbidimetric assay	Same (Same)	Same	Test performance (n = 158 consecutive patients admitted with tentative diagnosis of appendicitis)	4	CC (r_s) = 0.92
Søndenaa 1992 (0422)	Haematology inflammation/ CRP	NycoCard CRP (Nycomed Pharma AS, Norway) using manufacturer's categories (< 10, 10–19, 20–39, 40–59, 60–99, 100–200, > 200 mg/l) in diagnosing acute appendicitis	?Laboratory technician (?Read by laboratory technician, interpreted by clinician)	?Hospital laboratory (Norway)	T-antiserum CRP (Roche, Switzerland) quantitative immuno-turbidimetric assay	Same (Same)	Same	Test performance (n = 158 consecutive patients admitted with tentative diagnosis of appendicitis)	4	All cases: CC (r_s) = 0.93 (i) Exact agreement, 126/158 (80%) (ii) Agreement plus/minus one category, 157/158 (100%). For those without appendicitis: (i) Exact agreement, 86/96 (90%) (ii) Agreement plus/minus one category, 95/96 (99%)
Søndenaa 1992 (0422)	Haematology inflammation/ CRP	NycoCard CRP (Nycomed Pharma AS, Norway) using manufacturer's categories (< 10, 10–19, 20–39, 40–59, 60–99, 100–200, > 200 mg/l) in diagnosing acute appendicitis	?Laboratory technician (?Read by laboratory technician, interpreted by clinician)	?Hospital laboratory (Norway)	Diagnosis of appendicitis, confirmed by histological examination	N/A (N/A)	?Hospital laboratory	Test performance (n = 158 consecutive patients admitted with tentative diagnosis of appendicitis)	5	Using cut-off for diagnosis of CRP > 10 mg/l: All cases: (i) Sensitivity = 58% (ii) Specificity = 70% (ii) PPV = 55%; NPV = 72% Men: (n = 78) (i) Sensitivity = 69% (ii) Specificity = 67% (iii) PPV = 63%; NPV = 72% Women: (n = 80) (i) Sensitivity = 44% (ii) Specificity = 70% (iii) PPV = 43%; NPV = 71%

continued

Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Søndenaa 1992 (0422)	Haematology inflammation/ CRP	NycoCard CRP (Nycomed Pharma AS, Norway) using manufacturer's categories (< 10, 10–19, 20—9, 40–59, 60–99, 100–200, > 200 mg/l) in diagnosing acute appendicitis	?Laboratory technician (?Read by laboratory technician, interpreted by clinician)	?Hospital laboratory (Norway)	Diagnosis of appendicitis, confirmed by histological examination	N/A (N/A)	?Hospital laboratory	Test performance (n = 158 consecutive patients admitted with tentative diagnosis of appendicitis)	5	Using cut-off for diagnosis of CRP > 20 mg/l: All cases: (i) Sensitivity = 43% (ii) Specificity = 76% (iii) PPV = 54%; NPV = 68% Using cut-off for diagnosis of CRP > 40 mg/l: All cases: (i) Sensitivity = 29% (ii) Specificity = 85% (iii) PPV = 56%; NPV = 65%
Søndenaa 1992 (0422)	Haematology inflammation/ CRP	NycoCard CRP (Nycomed Pharma AS, Norway) using best guess of exact value	?Laboratory technician? (Read by laboratory technician, interpreted by clinician)	?Hospital laboratory (Norway)	None	None (None)	None	Test performance Sub-analysis of CRP values in those confirmed to have appendicitis (n = 62) by duration of symptoms	NFA	Mean (SD) rCRP mg/l: (i) < 12 h, 22.7 (11.3) (ii) 12-24 h, 43.0 (9.9) (iii) > 24 h, 68.8 (18.1) Patients with elevated levels: (i) < 12 h, 5 (33%) (ii) 12–24 h, 19 (58%) (iii) > 24 h, 12 (86%)
Hansson 1995 (0428)	Haematology inflammation/ CRP	NycoCard CRP [serum] test (Nycomed Pharma AS, Norway) using best guess of exact value in diagnosing suspected inflammatory diseases	?Laboratory technician? (Laboratory technician)	?Hospital laboratory (Sweden)	Standard turbidimetric method (Multistat, Instrument Laboratory, USA)	Same (Same)	Same	Test performance (n = 379)	No detail	Results given in table Not summarised further
Hansson 1995 (0428)	Haematology inflammation/ CRP	NycoCard CRP [blood] test (Nycomed Pharma AS, Norway) using best guess of exact value in diagnosing suspected inflammatory diseases	?Laboratory technician (?Laboratory technician)	?Hospital laboratory (Sweden)	Standard turbidimetric method (Multistat, Instrument Laboratory, USA)	Same (Same)	Same	Test performance (n = 102)	No detail	Results given in table Not summarised further
Hansson 1995 (0428)	Haematology inflammation/ CRP	NycoCard CRP [blood] test (Nycomed Pharma AS, Norway) using best guess of exact value in diagnosing suspected inflammatory diseases	?Laboratory technician (?Laboratory technician)	?Hospital laboratory (Sweden)	Rate-nephelometer CRP assay (Array, Beckman, USA)	Same (Same)	Same	Test performance (n = 74)	No detail	CC = 0.97

continued

Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Hansson 1995 (0428)	Haematology inflammation/ CRP	NycoCard CRP [blood] test (Nycomed Pharma AS, Norway) using best guess of exact value	?Laboratory technician (?Laboratory technician)	?Hospital laboratory (Sweden)	NycoCard CRP [blood] test – reflectometric NycoCard reader	Same (Same)	Same	Test performance (n = 77)	No detail	CC = 0.96
Hansson 1995 (0428)	Haematology inflammation/ CRP	NycoCard CRP [serum] test (Nycomed Pharma AS, Norway) using best guess of exact value in diagnosing suspected inflammatory diseases	?Laboratory technician (?Laboratory technician)	?Hospital laboratory (Sweden)	ESR by vacuum technique (Becton Dickinson) using reference values, as follows: Women: < 40 y 2–16 mm; ≥ 40 y 2–35 mm Men: < 60 y 2–13 mm; ≥ 60 y 2–24 mm	Same (Same)	Same	?Test performance (n = 607 consecutive patients in 4 community health centres in southern Sweden for whom the attending physician had ordered an ESR)	4 (Doubt about nature of comparator as standard)	(i) 65% ESR & CRP normal – patients asymptomatic (ii) 6% ESR and CRP raised – mostly URTI (iii) 20% CRP raised more than ESR [In 99/121, ESR normal] – tonsillitis, sinusitis, bronchitis, mononucleosis, pneumonia and cystitis (iv) 9% ESR raised more than CRP [32/54 CRP was < 10 mg/l]; no predominant diagnosis
Dinant 1989 (1074)	Haematology inflammation/ ESR	Unspecified ESR measurement by any technician in 1987 usually employed by group practice	General practice staff from 5 practices (General practice staff)	Primary care (The Netherlands)	Same	Same (Same)	Same	Repeatability – within practice (n = 19 pairs; 3 or 4 per practice)	No detail	CVs presented for each of 19 pairs. Mean values for each practice calculated, but not presented in paper
Dinant 1989 (1074)	Haematology inflammation/ ESR	Unspecified ESR measurement by any technician in 1987 usually employed by group practice	General practice staff from 5 practices (General practice staff)	Primary care (The Netherlands)	Same	Same, but different practice (Same, but different practice)	Same	Repeatability – between practices (n = unknown, repeat estimates by different practices)	No detail	Mean CVs calculated – data not presented in paper
Dinant 1989 (1074)	Haematology inflammation/ ESR	Unspecified ESR measurement by any technician in 1987 usually employed by group practice	General practice staff from 5 practices (General practice staff)	Primary care (The Netherlands)	Laboratory estimation: Westergren's method	Laboratory technician (Same)	Hospital laboratory	Test performance (n = unknown, approx 10 samples per group practice)	4	CC = 0.83
Dinant 1989 (1074)	Haematology inflammation/ ESR	ESR: Sterilin holding devices (Continental Pharma, Zutphen, The Netherlands) in 1988	General practice staff given detailed instructions (Same)	Primary care (The Netherlands)	Same	Same (Same)	Same	Repeatability – within practice (n = 23 pairs; 3 or 5 per practice)	No detail	CVs presented for each of 23 pairs. Mean values for each practice calculated, but not presented in paper

continued

Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Dinant 1989 (1074)	Haematology inflammation/ ESR	ESR: Sterilin holding devices (Continental Pharma, Zutphen, The Netherlands) in 1988	General practice staff given detailed instructions (Same)	Primary care (The Netherlands)	Same	Same, but different practice (Same)	Same	Repeatability – between practices (n = unknown, repeat estimates by different practices)	No detail	Mean CVs calculated – data not presented in paper
Dinant 1989 (1074)	Haematology inflammation/ ESR	ESR: Sterilin holding devices (Continental Pharma, The Netherlands) in 1988	General practice staff given detailed instructions (Same)	Primary care (The Netherlands)	Laboratory estimations – Westergren's method	Laboratory technician (Same)	Hospital laboratory	Test performance (n = unknown, approximately 10 samples per group practice)	4	CC = 0.97
Dinant 1989 (1074)	Haematology inflammation/ ESR	ESR: Sterilin holding devices (Continental Pharma, The Netherlands) in 1988	General practice staff given detailed instructions (Same)	Primary care (The Netherlands)	ESR measurement by any technique usually in use by group practice in 1987	Same (Same)	Same	Impact – effectiveness Effect of method to improve NPT performance by standardising equipment and written instructions [Uncontrolled pre/post design, with consequent difficulty in attributing the origin of any effects observed]	NFA	(i) Test performance (vs laboratory method): 1987 r = 0.83 1988 r = 0.97 (ii) Repeatability (between practices): mean CVs calculated for each group. Difference between 1987 and 1988 using the Rank Sum Test was statistically significant (p = 0.003) (iii) Repeatability (within practice): mean CVs calculated for each group. Difference between 1987 and 1988 using the Signed Rank Test statistically significant (p = 0.04)
None	Haematology/ D-dimer									No articles scoring above 4 in initial quality assessment were located
Erickson 1993 (0077)	Clinical chemistry/ desktop analysers/ chemistry profiles	i-STAT Portable Clinical Analyser (PCA) (i-STAT Corporation, USA) for Na, K, Cl, urea (U), glucose and Hct	Laboratory technician (Same)	Hospital laboratory (USA)	Same	Same (Same)	Same	Repeatability (n = 60 for each of 2 controls tested twice a day for 30 days over a period of 65 days)	No detail	CVs (%) for controls A; B Na = 0.64; 0.50: K = 1.38; 1.45 Cl = 1.02; 0.79 U (old) = 4.87; 4.74: U (new) = 3.34; 3.4 glucose = 4.39; 4.84

continued

Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Erickson 1993 (0077)	Clinical chemistry/ desktop analysers/ chemistry profiles	i-STAT PCA (i-STAT Corporation, USA) for Na, K, Cl, U, glucose and Hct	Nursing staff; training not mentioned (Same)	Hospital emergency dept (USA)	Same	Same (Same)	Same	Repeatability (n = 23 for each of 2 controls; tested once a day for 23 days)	No detail	CVs (%) for controls A; B Na = 0.46; 0.89: K = 1.06; 1.29 Cl = 2.76; 0.69 U (old) = 5.90; 4.59 U (new) = 6.12; 2.54 glucose = 5.06; 5.19
Erickson 1993 (0077)	Clinical chemistry/ desktop analysers/ chemistry profiles	i-STAT PCA (i-STAT Corporation, USA) for Na, K, Cl, U, glucose and Hct	Nursing staff; training not mentioned (Same)	Hospital emergency dept (USA)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 82, patients presenting to the emergency dept)	4	CCs: Na = 0.979: K = 0.993 Cl = 0.954: U = 0.994 glucose = 0.987: Hct = 0.974
Erickson 1993 (0077)	Clinical chemistry/ desktop analysers/ chemistry profiles	i-STAT PCA (i-STAT Corporation, USA) for Na, K, Cl, U, glucose and Hct	Laboratory technician (Same)	Hospital laboratory (USA)	Central laboratory measurements: Ektachem 700XRC (Eastman Kodak Co., Rochester, NY) for routine chemistry; Coulter S+IV counter (Coulter Electronics, Miami, FL) for Hct	Same (Same)	Same	Test performance (n = 142, 82 patients presenting to the emergency dept and 60 patients presenting for routine phlebotomy)	4	Mean (SD) of differences: Na < 130 (n = 4): 1.00 (2.16) Na > 130 (n = 139): 1.37 (1.36) K 3.1–5.3 (n =141): 0.08 (0.08) Cl < 90 (n = 2): 1.00 (4.24) Cl 90–115 (n = 139):1.91(2.06) Cl > 115 (n = 2): –0.5 (2.12) U < 7 (n = 89): –0.22 (0.38) U 7–18 (n = 39): –0.25 (0.76) U > 18 (n = 15): –0.69 (1.6) glucose < 3.9 (n = 4): 0.1 (0.24) glucose 3.9–6.7 (n = 83): 0.01 (0.29) glucose 6.7–11.1 (n = 39): –0.04 (0.42) glucose > 11.1 (n = 17): 0.52 (1.35) Hct < 0.35 (n = 24): 0.03 (0.03) Hct 0.35–0.5 (n = 110): 0.04 (0.02) Hct > 0.50 (n = 3): 0.04 (0.03)
Tsai 1994 (0142)	Clinical chemistry/ desktop analysers/ chemistry profiles	i-STAT PCA (i-STAT Corporation, USA) for Na, K, Cl, U, glucose and Hct	Single research assistant (Read by single research assistant; PCA results not made available to clinical carers)	Hospital emergency dept (USA)	Chem7 (Na, K, Cl, CO_2, BUN, glucose, creatine) + CBC (FBC)	Laboratory technician (Read by laboratory technician, interpreted by clinicians in emergency dept)	Hospital laboratory	Impact – effectiveness Effect of PCA on turn-round time and whether any change would lead to changes in times and decisions to admit/ discharge/treat. Estimate of effect on cost also attempted [Effect of NPT assessed indirectly with inadequate control. Design open to much bias]	NFA	59/210 patients' course of care was felt to have been altered, in physician's opinion by chemistry results. Of these, it was felt that more rapidly available results would have led to earlier intervention in 40 cases, no effect in 15, indeterminable effect 4. Mean turnround time for PCA was 8 min vs mean of 59 min for central laboratory

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Sands 1995 (0800)	Clinical chemistry/ desktop analysers/ chemistry profiles	i-STAT PCA (i-STAT Corporation, USA) for Na, K, Cl, U, glucose and Hct	Research assistant (Same)	Hospital emergency dept (USA)	Same	Same (Same)	Same	Repeatability day-to-day quality control with 2 control solutions (n = 82 samples of each control solution)	No detail	CVs (%) for controls A; B Na = 0.6; 0.5: K = 1.2; 1.8 Cl = 1.2; 1.1: U = 13.2; 2.6 glucose = 4.0; 4.8
Sands 1995 (0800)	Clinical chemistry/ desktop analysers/ chemistry profiles	i-STAT PCA (i-STAT Corporation, USA) for Na, K, Cl, U, glucose and Hct	Research assistant (Same)	Hospital emergency dept (USA)	Ektachem 700XRC (Eastman Kodak Co., Rochester, NY) or Beckman CX-3 (Beckman Instruments, CA) for routine chemistry; Coulter S+IV counter (Coulter Electronics, Miami, FL) for Hct; NOVA StatProfile-6 Analyzer (Nova Biomedical, USA) for MEPs (Na, K, Cl, Ca and glucose)	Laboratory technician (Same)	Hospital laboratory	Test performance (n = ?960 patients attending emergency department when blood test (Na, K, Cl, BUN, glucose or Hct) ordered from central laboratory and the research assistant was available to analyse blood)	5	Mean (95% range) of difference of i-STAT PCA vs central laboratory value Na [n = 688] = –0.2 (–6–+3) K [n = 676] = –0.17 (–0.07–+0.2) Cl [n = 683] = +0.46 (–1.5–+1.0) U [n = 654] = +0.36 (–1.07–+1.78) glucose [n = 608] = +0.47 (–0.66–+1.65) Hct [n = 841] = +4.48 (–0.5–+7.5)
Sands 1995 (0800)	Clinical chemistry/ desktop analysers/ chemistry profiles	i-STAT PCA (i-STAT Corporation, USA) for Na, K, Cl, U, glucose and Hct	Research assistant (Research assistant; PCA results not made available to clinical carers)	Hospital emergency dept (USA)	Ektachem 700XRC (Eastman Kodak Co, NY) or Beckman CX-3 (Beckman Instruments, CA) for routine chemistry; Coulter S+IV counter (Coulter Electronics, Miami, FL) for Hct; NOVA StatProfile-6 Analyzer (Nova Biomedical, USA) for MEPs (Na, K, Cl, Ca and glucose)	Laboratory technician (Read by laboratory technician, interpreted by clinicians in emergency dept)	Hospital laboratory	Impact – effectiveness Effect of PCA on turnround time and whether any change would lead to changes in times and decisions to admit/discharge/treat. [Effect of NPT assessed indirectly, with inadequate control. Design open to considerable bias]	NFA	103/960 patients' admission/ discharge was felt to have been altered, in physicians' opinion by at least one test result. 91/960 patients' treatment was felt to have been altered by at least one test result. 166/960 patients' admission/discharge/treatment was felt to have been altered, by at least one test result. Mean speed of turnround was 31 min faster for PCA
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Reflotron (Boehringer Mannheim Canada): glucose, cholesterol, triglycerides, GGT	Laboratory technician (Same)	Hospital laboratory (Canada)	Same	Same (Same)	Same	Repeatability (n = minimum of 15 of low and high manufacturer's control samples)	No detail	CVs (%): glucose = 1.8; cholesterol = 3.4 triglycerides = 2.7; GGT = 3.0 Mean = 2.7

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Reflotron (Boehringer Mannheim Canada): glucose, cholesterol, triglycerides, GGT	17 nurses trained by a trained technician (Same)	Hospital out-patient dept (mock out-patient clinic) (Canada)	Same	Same (Same)	Same	Repeatability (n = minimum of 15 of low and high manufacturer's control samples)	No detail	CVs (%); glucose = 4.3; cholesterol = 4.4 triglycerides = 3.0; GGT = 2.8 Mean = 3.7
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Reflotron (Boehringer Mannheim Canada): glucose, cholesterol, triglycerides, GGT	17 nurses trained by a trained technician (Same)	Hospital out-patient dept (mock out-patient clinic) (Canada)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 68 blood, serum or plasma samples)	3	No of results differing by 10% from results obtained by hospital technician = 2/68 (2.9%)
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Reflotron (Boehringer Mannheim Canada): glucose, cholesterol, triglycerides, GGT	14 physicians trained by a trained technician (Same)	Hospital ICU (mock ICU) (Canada)	Same	Same (Same)	Same	Repeatability (n = minimum of 15 of low and high manufacturer's control samples)	No detail	CVs (%) glucose = 4.7; cholesterol = 4.6 triglycerides = 4.8; GGT = 6.6 Mean = 5.2
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Reflotron (Boehringer Mannheim Canada): glucose, cholesterol, triglycerides, GGT	14 physicians trained by a trained technician (Same)	Hospital ICU (mock ICU) (Canada)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 75 blood, serum or plasma samples)	3	No of results differing by 10% from results obtained by hospital technician = 13/75 (17.3%)
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Reflotron (Boehringer Mannheim Canada): glucose, cholesterol, triglycerides, GGT	12 medical office staff (secretaries/ clerks/ computer operators) trained by a technician (Same)	Primary care (mock physician's office) (Canada)	Same	Same (Same)	Same	Repeatability (n = minimum of 15 of low and high manufacturer's control samples)	No detail	CVs (%): glucose = 3.4; cholesterol = 3.0 triglycerides = 3.4; GGT = 6.9 Mean = 4.2
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Reflotron (Boehringer Mannheim Canada): glucose, cholesterol, triglycerides, GGT	12 medical office staff trained by a technician (Same)	Primary care (mock physician's office) (Canada)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 56 blood, serum or plasma samples)	3	No of results differing by 10% from results obtained by hospital technician = 4/56 (7.1%)
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Seralyser (Ames Division, Miles Laboratories, Elkhart, IND) for CK, glucose, K, AST	Laboratory technician (Same)	Hospital laboratory (Canada)	Same	Same (Same)	Same	Repeatability (n = minimum of 15 of low and high manufacturer's control samples)	No detail	CVs (%): CK = 5.8; glucose = 4.0 K = 5.9; AST = 5.1 Mean = 5.2
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Seralyser (Ames Division, Miles Laboratories, Elkhart, IND) for CK, glucose, K, AST	17 nurses trained by a trained technician (Same)	Hospital out-patient clinic (mock out-patient clinic) (Canada)	Same	Same (Same)	Same	Repeatability (n = minimum of 15 of low and high manufacturer's control samples)	No detail	CVs (%): CK = 8.4; glucose = 4.1 K = 5.1; AST = 14.1 Mean = 9.4

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Seralyser (Ames Division, Miles Laboratories, Elkhart, IND) for CK, glucose, K, AST	17 nurses trained by a trained technician (Same)	Hospital out-patient clinic (mock out-patient clinic) (Canada)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 68 blood, serum or plasma samples)	3	No of results differing by 10% from results obtained by hospital technician = 16/68 (23.5%)
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Seralyser (Ames Division, Miles Laboratories, Elkhart, IND) for CK, glucose, K, AST	14 physicians trained by a trained technician (Same)	Hospital ICU (mock ICU) (Canada)	Same	Same (Same)	Same	Repeatability (n = minimum of 15 of low and high manufacturer's control samples)	No detail	CVs (%): CK = 17.8; glucose = 6.4; K = 7.0; AST = 9.2; Mean = 10.1
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Seralyser (Ames Division, Miles Laboratories, Elkhart, IND) for CK, glucose, K, AST	14 physicians trained by a trained technician (Same)	Hospital ICU (mock ICU) (Canada)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 100 blood, serum or plasma samples)	3	No of results differing by 10% from results obtained by hospital technician = 44/100 (44%)
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Seralyser (Ames Division, Miles Laboratories, Elkhart, IND) for CK, glucose, K, AST	12 medical office staff (secretaries/ clerks/computer operators) trained by a trained technician (Same)	Primary care (mock physicians office) (Canada)	Same	Same (Same)	Same	Repeatability (n = minimum of 15 of low and high manufacturer's control samples)	No detail	CVs (%) CK = 14.1; glucose = 12.8; K =8.8; AST = 19.9 Mean = 13.9
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Seralyser (Ames Division, Miles Laboratories, Elkhart, IND) for CK, glucose, K, AST	12 medical office staff trained by a trained technician (Same)	Primary care (mock physicians office) (Canada)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 84 blood, serum or plasma samples)	3	No of results differing by 10% from results obtained by hospital technician = 35/84 (41.7%)
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Vision (Abbott Laboratories, Chicago, IL) for glucose, U, cholesterol, triglycerides, alk phosphatase, urate	Laboratory technician (Same)	Hospital laboratory (Canada)	Same	Same (Same)	Same	Repeatability (n = minimum of 15 of low and high manufacturer's control samples)	No detail	CVs (%): glucose = 1.5; U = 2.8; cholesterol = 1.3; triglycerides = 2.5; alk phosphatase = 2.0; uric acid = 2.0; Mean = 2.0
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Vision (Abbott Laboratories, Chicago, IL) for glucose, U, cholesterol, triglycerides, alk phosphatase, urate	17 nurses trained by a trained technician (Same)	Hospital out-patient clinic (mock out-patient clinic) (Canada)	Same	Same (Same)	Same	Repeatability (n = minimum of 15 of low and high manufacturer's control samples)	No detail	CVs (%): glucose = 1.8; U = 2.2; cholesterol = 1.8; triglycerides = 1.5; alk phosphatase = 1.8; uric acid = 2.2; Mean = 1.9

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Vision (Abbott Laboratories, Chicago, IL) for glucose, U, cholesterol, triglycerides, alk phosphatase, urate	17 nurses trained by a trained technician (Same)	Hospital out-patient clinic (mock out-patient clinic) (Canada)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 108 blood, serum or plasma samples)	3	No of results differing by 10% from those obtained by hospital technician = 0/108 (0%)
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Vision (Abbott Laboratories, Chicago, IL) for glucose, U, cholesterol, triglycerides, alk phosphatase, urate	14 physicians trained by a trained technician (Same)	Hospital ICU (mock ICU) (Canada)	Same	Same (Same)	Same	Repeatability (n = minimum of 15 of low and high manufacturer's control samples)	No detail	CVs (%): glucose = 2.8 U = 3.4; cholesterol = 3.3; triglycerides = 4.6; alk phosphatase = 2.4; uric acid = 2.6; Mean = 3.2
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Vision (Abbott Laboratories, Chicago, IL) for glucose, U, cholesterol, triglycerides, alk phosphatase, urate	14 physicians trained by a trained technician (Same)	Hospital ICU (mock ICU) (Canada)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 108 blood, serum or plasma samples)	3	No of results differing by 10% from those obtained by hospital technician = 0/108 (0%)
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Vision (Abbott Laboratories, Chicago, IL) for glucose, U, cholesterol, triglycerides, alk phosphatase, urate	12 medical office staff (secretaries/ clerks/computer operators) trained by a technician (Same)	Primary care (mock physicians office) (Canada)	Same	Same (Same)	Same	Repeatability (n = minimum of 15 of low and high manufacturer's control samples)	No detail	CVs (%): glucose = 1.7; U = 2.2; cholesterol = 1.9; triglycerides = 4.0; alk phosphatase = 2.6; uric acid = 2.9 Mean = 2.5
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	Vision (Abbott Laboratories, Chicago, IL) for glucose, U, cholesterol, triglycerides, alk phosphatase, urate	12 medical office personnel trained by a trained technician (Same)	Primary care (mock physicians office) (Canada)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 108 blood, serum or plasma samples)	3	No of results differing by 10% from those obtained by hospital technician = 2/108 (1.8%)
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	DT-60 (Eastman Kodak, Rochester, NY) for Na, K, glucose, amylase, urate, CK	Laboratory technician (Same)	Hospital laboratory (Canada)	Same	Same (Same)	Same	Repeatability (n = minimum of 15 low and high manufacturer's control samples)	No detail	CVs (%): Na = 1.9; K = 1.0; glucose = 1.2; amylase = 4.3; urate = 0.9; CK = 6.9 Mean = 2.7
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	DT-60 (Eastman Kodak, Rochester, NY) for Na, K, glucose, amylase, urate, CK	17 nurses trained by a trained technician (Same)	Hospital out-patient clinic (mock out-patient clinic) (Canada)	Same	Same (Same)	Same	Repeatability (n = minimum of 15 low and high manufacturer's control samples)	No detail	CVs (%): Na = 2.9; K = 3.8; glucose = 3.7; amylase = 12.2; urate = 4.9; CK = 13.5 Mean = 6.8

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	DT-60 (Eastman Kodak, Rochester, NY) for Na, K, glucose, amylase, urate, CK	17 nurses trained by a trained technician (Same)	Hospital out-patient clinic (mock out-patient clinic) (Canada)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 108, blood, serum or plasma samples)	3	No of results differing by 10% from those obtained by hospital technician = 18/108 (16.7%)
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	DT-60 (Eastman Kodak, Rochester, NY) for Na, K, glucose, amylase, urate, CK	14 physicians trained by a trained technician (Same)	Hospital ICU (mock ICU) (Canada)	Same	Same (Same)	Same	Repeatability (n = minimum of 15 low and high manufacturer's control samples)	No detail	CVs (%): Na = 2.7; K = 4.2; glucose = 3.6; amylase = 13.0; urate = 4.2; CK = 8.4 Mean = 4.3
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	DT-60 (Eastman Kodak, Rochester, NY) for Na, K, glucose, amylase, urate, CK	14 physicians trained by a trained technician (Same)	Hospital ICU (mock ICU) (Canada)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 104, blood, serum or plasma samples)	3	No of results differing by 10% from those obtained by hospital technician = 19/104 (18.3%)
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	DT-60 (Eastman Kodak, Rochester, NY) for Na, K, glucose, amylase, urate, CK	12 medical office staff (secretaries/ clerks/computer operators) trained by a technician (Same)	Primary care (mock physicians office) (Canada)	Same	Same (Same)	Same	Repeatability (n = minimum of 15 low and high manufacturer's control samples)	No detail	CVs (%): Na = 1.7; K = 1.8; glucose = 4.2; amylase = 8.8; urate = 3.7; CK = 15.2 Mean = 5.9
Nanji 1988 (0248 & 0709)	Clinical chemistry/ desktop analysers/ chemistry profiles	DT-60 (Eastman Kodak, Rochester, NY) for Na, K, glucose, amylase, urate, CK	12 medical office staff trained by a technician (Same)	Primary care (mock physicians office) (Canada)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 106, blood, serum or plasma samples)	3	No of results differing by 10% from those obtained by hospital technician = 22/106 (20.7%)
Cobbaert 1994 (0704)	Clinical chemistry/ lipids/profiles	Cholestech LDX (Cholestech Corp, USA) for total cholesterol, HDL-cholesterol, triacylglycerols	Laboratory technician (Same)	Hospital laboratory (The Netherlands)	Same	Same (Same)	Same	Repeatability within-day variation (n = 10, analyses each of 2 control solutions (Precinorm and Seronorm) on 3 days consecutively, each day considered separately)	No detail	Range of CVs (%): Precinorm: cholesterol = 2.0–4.7; HDL-cholesterol = 3.4–5.5; triacylglycerol = 2.1–4.8 Seronorm: cholesterol = 2.2–3.8; triacylglycerol = 2.9–5.4
Cobbaert 1994 (0704)	Clinical chemistry/ lipids/profiles	Cholestech LDX (Cholestech Corp, USA) for total cholesterol, HDL-cholesterol, triacylglycerols	Laboratory technician (Same)	Hospital laboratory (The Netherlands)	Same	Same (Same)	Same	Repeatability day-to-day variation (n = 11, analyses of control solutions (Precinorm and Seronorm))	No detail	CVs given for both Cholestech LDX and reference method However, impossible to identify which values refer to which test

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Cobbaert 1994 (0704)	Clinical chemistry/ lipids/profiles	Cholestech LDX (Cholestech Corp, USA) for total cholesterol, HDL-cholesterol, triacylglycerols	Laboratory technician (Same)	Hospital laboratory (The Netherlands)	Cholesterol: (a) Manual; Abell-Kendall technique; (b) Semi-automated (CHOD-PAP) HDL-cholesterol: photungstic acid/ $MgCl_2$ precipitation of non-HDL, then CHOD-PAP; Triacylglycerols: Bucolo/David UV method (Chem I analyser – Technicon Inc, NY)	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 43, cohort of non-fasting blood samples obtained from attendees at lipid clinic; participants selected to give an appropriate range of cholesterol values)	3	CCs (r) (range using 4 different reagent lots): cholesterol = 0.985–0.994; HDL-cholesterol = 0.981–0.989; triacylglycerol = 0.990–0.996
Koch 1987 (0844)	Clinical chemistry/ lipids/cholesterol	Abbott Vision Analyser (Abbott Laboratories, N Chicago, IL)	Single trained technician, initially instructed by manufacturers rep. (Laboratory technician)	Hospital laboratory (USA)	Same	Same (Same)	Same	Repeatability total imprecision (n = 27, runs of 3 CDC reference samples and 3 commercial lipid control solutions (Fisher Scientific Co, Pittsburgh, PA))	No detail	CVs (%): CDC LPH-4 (2500 mg/l) = 1.5; CDC no 45 (3490 mg/l) = 1.9; CDC no 48 (1510 mg/l) = 1.8; Fisher normal = 2.5; Fisher abnormal = 4.3; Fisher elevated lipid = 1.6
Koch 1987 (0844)	Clinical chemistry/ lipids/cholesterol	Abbott Vision Analyser (Abbott Laboratories, N Chicago, IL)	Single trained technician, initially instructed by manufacturers rep. (Laboratory technician)	Hospital laboratory (USA)	Same	Same (Same)	Same	Repeatability within-run and between-run (n = 27, duplicate runs of CDC reference sample LPH-4 (2500 mg/l))	No detail	Mean = 2448.4 mg/l SD total = 43.0 mg/l SD within-run = 34.2 mg/l SD between-run = 26.1 mg/l
Koch 1987 (0844)	Clinical chemistry/ lipids/cholesterol	Abbott Vision Analyser (Abbott Laboratories, N Chicago, IL)	Single trained technician, instructed by manufacturers rep. (Laboratory technician)	Hospital laboratory (USA)	Blind assessment by CDC, Atlanta, using cholesterol reference method	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 109, volunteer medical students, employees and selected out-patients between March and June 1986)	4	CCs: (i) serum, r = 0.99 (ii) venous plasma, r = 0.98 (iii) fingerstick, r = 0.98 (iv) venous whole blood, r = 0.99

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Koch 1987 (0844)	Clinical chemistry/ lipids/cholesterol	Ames Seralyzer (Ames Division, Miles Laboratories Inc, Elkhart, IND)	Single trained technician, initially instructed by manufacturers rep. (Laboratory technician)	Hospital laboratory (USA)	Same	Same (Same)	Same	Repeatability – total imprecision: (n = 27, runs of 3 CDC reference samples and 3 commercial lipid control solutions (Fisher Scientific Co, Pittsburgh, PA))	No detail	CVs (%): CDC LPH-4 (2500 mg/l) = 4.5 CDC no 45 (3490 mg/l) = 3.9 CDC no 48 (1510 mg/l) = 3.9 Fisher normal = 5.6 Fisher abnormal = 7.1 Fisher elevated lipid = 4.1
Koch 1987 (0844)	Clinical chemistry/ lipids/cholesterol	Ames Seralyzer (Ames Division, Miles Laboratories Inc, Elkhart, IND)	Single trained technician (Laboratory technician)	Hospital laboratory (USA)	Same	Same (Same)	Same	Repeatability – within-run and between-run: (n = 27, duplicate runs of CDC reference sample LPH-4 (2500 mg/l))	No detail	Mean = 2542.1 mg/l SD total = 85.5 mg/l SD within-run = 57.2 mg/l SD between-run = 63.5 mg/l
Koch 1987 (0844)	Clinical chemistry/ lipids/cholesterol	Ames Seralyzer (Ames Division, Miles Laboratories Inc, Elkhart, IND)	Single trained technician, instructed by manufacturers rep. (Laboratory technician)	Hospital laboratory (USA)	Blind assessment by CDC, Atlanta, using cholesterol reference method	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 109, volunteer medical students, employees and selected outpatients between March and June 1986)	4	CCs: (i) serum, r = 0.96 (ii) venous plasma, r = 0.95 (iii) fingerstick = N/A (iv) venous whole blood = N/A
Koch 1987 (0844)	Clinical chemistry/ lipids/cholesterol	BMD Reflotron (Boehringer Mannheim Diagnostics Division, USA)	Single trained technician, initially instructed by manufacturers rep. (Laboratory technician)	Hospital laboratory (USA)	Same	Same (Same)	Same	Repeatability – total imprecision: (n = 27, runs of 3 CDC reference samples and 3 commercial lipid control solutions (Fisher Scientific Co, Pittsburgh, PA))	No detail	CVs (%): CDC LPH-4 (2500 mg/l) = 2.3 CDC no 45 (3490 mg/l) = 3.4 CDC no 48 (1510 mg/l) = 3.8 Fisher normal = 2.7 Fisher abnormal = N/A Fisher elevated lipid = 3.1
Koch 1987 (0844)	Clinical chemistry/ lipids/cholesterol	BMD Reflotron (Boehringer Mannheim Diagnostics Division, USA)	Single trained technician, instructed by manufacturers rep. (Laboratory technician)	Hospital laboratory (USA)	Same	Same (Same)	Same	Repeatability – within-run and between-run: (n = 27, duplicate runs of CDC reference sample LPH-4 (2500 mg/l))	No detail	Mean = 2435.9 mg/l SD total = 50.0 mg/l SD within-run = 40.7 mg/l SD between-run = 28.9 mg/l
Koch 1987 (0844)	Clinical chemistry/ lipids/cholesterol	BMD Reflotron (Boehringer Mannheim Diagnostics Division, USA)	Single trained technician, instructed by manufacturers rep. (Laboratory technician)	Hospital laboratory (USA)	Blind assessment by CDC, Atlanta, using cholesterol reference method	Laboratory technician (Same)	Hospital laboratory	Test performance: (n = 109, volunteer medical students, employees and selected out-patients between March and June 1986)	4	CCs: (i) serum, r = 0.97 (ii) venous plasma, r = 0.95 (iii) fingerstick, r = 0.95 (iv) venous whole blood, r = 0.96

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Koch 1987 (0844)	Clinical chemistry/ lipids/cholesterol	Chrometrics Cholesterol Test System (Chrometrics Laboratories Inc, USA)	Single trained technician, initially instructed by manufacturers rep. (Laboratory technician)	Hospital laboratory (USA)	Same	Same (Same)	Same	Repeatability – total imprecision (n = 27, runs of 3 CDC reference samples and 3 commercial lipid control solutions (Fisher Scientific Co, Pittsburgh, PA))	No detail	CVs (%): CDC LPH-4 (2500 mg/l) = 2.3; CDC no 45 (3490 mg/l) = 2.8; CDC no 48 (1510 mg/l) = 2.4; Fisher normal = 2.2; Fisher abnormal = 3.3; Fisher elevated lipid = 2.5
Koch 1987 (0844)	Clinical chemistry/ lipids/cholesterol	Chrometrics Cholesterol Test System (Chrometrics Laboratories Inc, USA)	Single trained technician, instructed by manufacturers rep. (Laboratory technician)	Hospital laboratory (USA)	Same	Same (Same)	Same	Repeatability – within-run and between-run (n = 27, duplicate runs of CDC reference sample LPH-4 (2500 mg/l))	No detail	Mean = 2448.4 mg/l; SD total = 57.4 mg/l; SD within-run = 45.0 mg/l; SD between-run = 35.7 mg/l
Koch 1987 (0844)	Clinical chemistry/ lipids/cholesterol	Chrometrics Cholesterol Test System (Chrometrics Laboratories Inc, USA)	Single trained technician, instructed by manufacturers rep. (Laboratory technician)	Hospital laboratory (USA)	Blind assessment by CDC, Atlanta, using cholesterol reference method	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 109, volunteer medical students, employees and selected out-patients between March and June 1986)	4	CCs: (i) serum, r = 0.98; (ii) venous plasma, r = 0.97; (iii) fingerstick, r = 0.98; (iv) venous whole blood, r = 0.98
Koch 1987 (0844)	Clinical chemistry/ lipids/cholesterol	Kodak DT-60 (Eastman Kodak Co, Rochester, NY)	Single trained technician, initially instructed by manufacturers rep. (Laboratory technician)	Hospital laboratory (USA)	Same	Same (Same)	Same	Repeatability – total imprecision (n = 27, runs of 3 CDC reference samples and 3 commercial lipid control solutions (Fisher Scientific Co, Pittsburgh, PA))	No detail	CVs (%): CDC LPH-4 (2500 mg/l) = 2.0; CDC no 45 (3490 mg/l) = 1.6; CDC no 48 (1510 mg/l) = 2.2; Fisher normal = 2.0; Fisher abnormal = 4.3; Fisher elevated lipid = 1.3
Koch 1987 (0844)	Clinical chemistry/ lipids/cholesterol	Kodak DT-60 (Eastman Kodak Co, Rochester, NY)	Single trained technician (Laboratory technician)	Hospital laboratory (USA)	Same	Same (Same)	Same	Repeatability – within-run and between-run (n = 27, duplicate runs of CDC reference sample LPH-4 (2500 mg/l))	No detail	Mean = 2448.4 mg/l; SD total = 48.0 mg/l; SD within-run = 39.3 mg/l; SD between-run = 27.6 mg/l
Koch 1987 (0844)	Clinical chemistry/ lipids/cholesterol	Kodak DT-60 (Eastman Kodak Co, Rochester, NY)	Single trained technician, instructed by manufacturers rep. (Laboratory technician)	Hospital laboratory (USA)	Blind assessment by CDC, Atlanta, using cholesterol reference method	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 109, volunteer medical students, employees and selected out-patients between March and June 1986)	4	CCs: (i) serum, r = 0.99; (ii) venous plasma, r = 0.99; (iii) fingerstick = N/A; (iv) venous whole blood = N/A

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Phillips 1988 (0845)	Clinical chemistry/ lipids/cholesterol	Reflotron dry-chemistry system for cholesterol (Boehringer-Mannheim, W Germany)	Specially trained operator (Same)	?Hospital out-patient dept (Australia)	Same	Same (Same)	Same	Repeatability – day-to-day variation (n = 80, volunteers' duplicate fingerprick samples 1 day apart) [Will include an element of biological variability]	6	Mean (SD) cholesterol: Day 1 = 5.38 (1.17) mmol/l Day 2 = 5.30 (1.14) mmol/l Mean difference = 0.079 mmol/l; SD 0.045; paired *t*-test $t = 1.77$, difference not significant CC: $r^2 = 0.935$
Phillips 1988 (0845)	Clinical chemistry/ lipids/cholesterol	Reflotron dry-chemistry system for cholesterol (Boehringer-Mannheim, W Germany)	Specially trained operator (Same)	?Hospital out-patient dept (Australia)	Hitachi 705 analyser (Hitachi, Japan) by means of cholesterol esterase/cholesterol oxidase/peroxidase monotest (Boehringer-Mannheim) cholesterol method based on (a) Single run – day 1 (b) Average of 2 runs on days 1 & 2	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 80, volunteers' fingerprick samples)	6	(a) Mean difference of Hitachi – Reflotron (single) in mmol/l: Mean = 0.22; SD = 0.30; Range = +0.74– –0.81 (b) Mean difference of Hitachi – Reflotron (mean of two): Mean = 0.258; SD = 0.27; CC: $r^2 = 0.945$
Rayman 1988 (0544)	Diabetes/ blood glucose	Glucose-oxidase reagent strips (BM-stix)	'Skilled operator' ?laboratory technician (Same)	Hospital laboratory (UK)	Same	Same (Same)	Same	Repeatability (n = 20, replicate readings of 3 venous heparinised samples with high, medium and low glucose values)	No detail	Mean value (mmol/l) and CV: High = 22.8 (4.1%) Med = 10.5 (2.4%) Low = 3.6 (4.3%)
Rayman 1988 (0544)	Diabetes/ blood glucose	Wiping device to improve performance of glucose-oxidase reagent strips (BM-stix)	'Skilled operator' ?laboratory technician (Same)	Hospital laboratory (UK)	Same	Same (Same)	Same	Repeatability (n = 20, replicate readings of 3 venous heparinised samples with high, medium and low glucose values)	No detail	Mean value (mmol/l) and CV: High = 22.3 (3.8%) Med = 10.6 (2.6%) Low = 3.4 (3.9%)
Rayman 1988 (0544)	Diabetes/ blood glucose	Glucose-oxidase reagent strips (BM-stix)	Hospital nurses used to using BM-stix (n = 78) (Same)	Hospital ward (UK)	Same (immediately after 'test')	'Skilled operator' ?laboratory technician (Same)	Same	Test performance (n = 84, fingerprick samples from diabetic in-patients; 11 of 84 strips uninterpretable and excluded)	4	CC, r = 0.91 28% of 73 interpretable results differed from standard by more than 20%

continued

Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Rayman 1988 (0544)	Diabetes/ blood glucose	Wiping device to improve performance of glucose-oxidase reagent strips (BM-stix)	Hospital nurses used to using BM-stix (n = 78) given demo. of use (Same)	Hospital ward (UK)	Glucose-oxidase reagent strips (BM-stix) (immediately before 'test')	'Skilled operator' ?laboratory technician (Same)	Same	Test performance (n = 84, fingerprick samples from diabetic in-patients; 1 of 84 strips uninterpretable and excluded)	3	CC, r = 0.99 0% of 83 interpretable results differed from standard by more than 20%
Rayman 1988 (0544)	Diabetes/ blood glucose	Glucose-oxidase reagent strips (BM-stix)	Hospital nurses given instruction in prior 2 weeks (Same)	Hospital ward (UK)	Venous blood samples in fluoride tube analysed for plasma glucose using a reference laboratory method ('Synchron AS 4', Beckman Instruments)	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 60, duplicate samples taken within 10 min of each other with no food consumption from diabetic in-patients)	4	CC, r = 0.72 51% of 60 results differed from standard by more than 20%
Rayman 1988 (0544)	Diabetes/ blood glucose	Wiping device to improve performance of glucose-oxidase reagent strips (BM-stix)	Hospital nurses given instruction in prior 2 weeks on proper use of BM-stix, plus 2 days to familiarise with wiping device (Same)	Hospital ward (UK)	Venous blood samples in fluoride tube analysed for plasma glucose using a reference laboratory method ('Synchron AS 4', Beckman Instruments)	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 60, duplicate samples taken within 10 min of each other from in-patients with diabetes with no food consumption)	4	CC, r = 0.96 10% of 60 differed from standard by more than 20%
Pope 1993 (1148)	Diabetes/ HbA1c	Ames DCA 2000 (Bayer Diagnostics Ltd, Basingstoke, UK)	Laboratory technician (Same)	?Hospital laboratory (UK)	Same	Same (Same)	Same	Repeatability (n = 12, 6 each of high (13%) and low (5.2%) manufacturer's control samples)	No detail	CVs: Low = 1.6% High = 2.4% ['Typical laboratory values' given as 5% & 2.5%, respectively]
Pope 1993 (1148)	Diabetes/ HbA1c	Ames DCA 2000 (Bayer Diagnostics Ltd, Basingstoke, UK)	Laboratory technician (Same)	?Hospital out-patient dept (UK)	DIAMAT HPLC system (BIO RAD Laboratories, Hemel Hempstead, UK)	Laboratory technician (Same)	?Hospital laboratory	Test performance (n = 48, consecutive patients with IDDM & NIDDM attending general diabetic out-patients clinic)	4	Mean difference HbA1c [DCA 2000 – DIAMAT] = -0.69% 95% CI = –1.42–+0.04%
Pope 1993 (1148)	Diabetes/ HbA1c	Ames DCA 2000 (Bayer Diagnostics Ltd, Basingstoke, UK)	4 medical or nursing staff given 15 min training (Same)	Hospital out-patient dept (UK)	Same	Same (Same)	Same	Repeatability (n = 10, samples, 5 of each high and low control)	No detail	CVs for each operator for each control < 3.4%

continued

Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Pope 1993 (1148)	Diabetes/ HbA1c	Ames DCA 2000 (Bayer Diagnostics Ltd, Basingstoke, UK)	Medical staff given 15 min training (?n = 1) (Same)	Hospital out-patient dept (child diabetes) (UK)	DIAMAT HPLC system (BIO RAD Laboratories, Hemel Hempstead, UK)	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 19, IDDM)	6	Mean difference HbA1c [DCA 2000 – DIAMAT] = –0.93% 95%CI = –1.93–+0.07%
Pope 1993 (1148)	Diabetes/ HbA1c	Ames DCA 2000 (Bayer Diagnostics Ltd, Basingstoke, UK)	Medical staff given 15 min training (?n = 1) (Same)	Hospital out-patient dept (obstetric) (UK)	DIAMAT HPLC system (BIO RAD Laboratories, Hemel Hempstead, UK)	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 24, IDDM and gestational DM)	6	Mean difference HbA1c [DCA 2000 – DIAMAT] = –0.29% 95%CI = –1.09–+0.51%
Pope 1993 (1148)	Diabetes/ HbA1c	Ames DCA 2000 (Bayer Diagnostics Ltd, Basingstoke, UK)	Nursing staff given 15 min training (?n = 2) (Same)	?Hospital out-patient dept (GP clinic) (UK)	DIAMAT HPLC system (BIO RAD Laboratories, Hemel Hempstead, UK)	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 15, NIDDM)	6	Mean difference HbA1c [DCA 2000 – DIAMAT] = –0.77% 95%CI = –1.30–0.24%
Pope 1993 (1148)	Diabetes/ HbA1c	Ames DCA 2000 (Bayer Diagnostics Ltd, Basingstoke, UK)	4 medical or nursing staff given 15 min training (Same)	Hospital out-patient dept (UK)	None	None (Same)	None	Impact – acceptability and effectiveness Ease of use (n = 4), and perceived impact (n = 18, cases selected at random from the obstetric and GP clinics). Methods vague	NFA [Great potential for bias]	All operators found DCA 2000 easy to use; sample result time (9 min) too long for busy clinics NPT result influenced management in 9/18 cases
Kouri 1994 (0828)	Diabetes/urine microalbumin concentration/ nephelometry	Urinary albumin concentration by nephelometry (Behring Nephelometric Analyser, Behringwerke, Marburg, Germany)	Laboratory technician (Same)	Hospital laboratory (Finland)	Same	Same (Same)	Same	Repeatability (n = 10, repetitions of 2 control samples)	No detail	CVs: Control A (4.9 mg/l) = 13% Control B (65.5 mg/l) = 1.3%
Kouri 1994 (0828)	Diabetes/urine microalbumin concentration/ nephelometry	Urinary albumin concentration by nephelometry (Behring Nephelometric Analyser, Behringwerke, Marburg, Germany)	Laboratory technician (Same)	Hospital laboratory (Finland)	Urinary albumin excretion rate calculated from urinary albumin concentration (as measured), urine volume and collection times	Same (Same)	Same	Test performance (n = 206, consecutive out-patients with type I & II diabetes; cases of macroalbuminuria (positive dipstick test) excluded (n = 32); collection times > 11 h excluded (n = 15); remaining cohort = 159)	4	r = 0.869 Defining microalbuminuria as > 20 µg/min, for cut-off micro-albumin urine concentration = 20 mg/l *Sensitivity = 86%; Specificity = 96%* Defining microalbuminuria as 15 µg/min, for cut-off micro-albumin urine concentration = 20 mg/l *Sensitivity = 67%; Specificity = 96%*

continued

Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
de Grauw 1995 (1108)	Diabetes/urine microalbumin concentration/ nephelometry	Single measurement of immunological nephelometric measurements (Hyland-Disc 120)	Laboratory technician (Same)	Hospital laboratory (The Netherlands)	Same	Same (Same)	Same	Repeatability (n = 401 patients with type II diabetes (not on insulin within 1 y of diagnosis) under control of GP from 10 practices. First morning samples collected on 3 consecutive days; stored at 4 °C; brought to practice on day 3. Samples positive for nitrite/protein excluded (n = 86) leaving 317. Results from each of the 3 samples compared)	No detail	Difference from mean (SD) for each sample: 0–9.9 mg/l (n = 174) S1 0.02 (1.3); S2 0.00 (1.2); S3 –0.03 (1.4). 10–19.9 mg/l (n = 77) S1 2.1 (6.2); S2 –1.5 (4.2); S3 –0.5 (5.1). 20–49.9 mg/l (n = 48) S1 0.4 (9.6); S2 –0.6 (10.2); S3 0.3 (10.8). 50–99.9 mg/l (n = 5) S1 –4.9 (8.9); S2 –9.5 (5.9); S3 11.5 (8.3). 100–300 mg/l (n = 13) S1 23.5 (71.2); S2 –15.2 (62.8); S3 –8.3 (44.9).
de Grauw 1995 (1108)	Diabetes/urine microalbumin concentration/ dipstick	Micral (Boehringer Mannheim, Germany) using threshold > 20 mg/l	GPs and practice assistants (Same)	Primary care (The Netherlands)	Immunological nephelometric measurements (Hyland-Disc 120) (a) single measurement (b) average of 3 measurements	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 401, patients with type II diabetes under control of GP from 10 practices. First morning samples collected on 3 consecutive days; stored at 4 °C; brought to practice on day 3. Samples positive for nitrite/protein excluded (n = 86) leaving 317)	4	(a) Standard > 20 mg/l (single) Sensitivity/Specificity, 67/93% PPV, 74%; NPV, 90%; LR+, 9.6; LR–, 0.35 b) Standard > 20 mg/l (average) Sensitivity, 45/65 = 69% Specificity, 228/252 = 90% ROC curve AUC = 0.84 (max = 1.0); 95% CI = 0.78–0.90
Kouri 1994 (0828)	Diabetes/urine microalbumin concentration/ dipstick	NycoCard U-Albumin (Nycomed, Norway) using threshold > 10 mg/l or > 20 mg/l	Laboratory technician (Same)	Hospital laboratory (Finland)	Urinary albumin concentration by nephelometry (Behring Nephelometric Analyser, Behringwerke, Marburg, Germany)	Same (Same)	Same	Test performance (n = 206, consecutive out-patients with type I & II diabetes.; cases of macroalbuminuria (positive dipstick test) excluded (n = 32); collection times > 11 h excluded (n = 15); remaining cohort, 159)	4	Fraction of dipstick results exceeding 10 mg/l in each NycoCard category: 0 = 0/80; 10 = 11/40; 20 = 21/23; 40 = 14/14; 80 = 2/2

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Kouri 1994 (0828)	Diabetes/urine microalbumin concentration/ dipstick	Micral (Boehringer Mannheim, Germany) using threshold > 10 mg/l or > 20 mg/l	Laboratory technician (Same)	Hospital laboratory (Finland)	Urinary albumin concentration by nephelometry (Behring Nephelometric Analyser, Behringwerke, Marburg, Germany)	Same (Same)	Same	Test performance (n = 206, consecutive out-patients with type I & II diabetes; cases of macroalbuminuria (positive dipstick test) excluded (n = 32); collection times > 11 h excluded (n = 15); remaining cohort; 159)	4	Fraction of dipstick results exceeding 10 mg/l in each Micral category: 0 = 0/93; 10 = 12/30; 20 = 18/18; 50 = 16/16; 100 = 2/2
Kouri 1994 (0828)	Diabetes/urine microalbumin concentration/ dipstick	NycoCard U-Albumin (Nycomed, Norway) using threshold > 10 mg/l or > 20 mg/l	Laboratory technician (Same)	Hospital laboratory (Finland)	Urinary albumin excretion rate calculated from urinary albumin concentration by nephelometry (Behring Nephelometric Analyser, Behringwerke, Marburg, Germany) and urine volume/ collection times	Same (Same)	Same	Test performance (n = 206, consecutive out-patients with type I & II diabetes; cases of macroalbuminuria (positive dipstick test) excluded (n = 32); collection times > 11 h excluded (n = 15); remaining cohort, 159)	4	Defining microalbuminuria as > 15 µg/min: (i) 10 mg/l cut-off PPV = 38%; NPV = 100% (ii) 20 mg/l cut-off PPV = 62%; NPV = 95% Defining microalbuminuria as > 20 µg/min: (i) 10 mg/l cut-off PPV = 28%; NPV = 100% (ii) 20 mg/l cut-off PPV = 51%; NPV = 98%
Kouri 1994 (0828)	Diabetes/urine microalbumin concentration/ dipstick	Micral (Boehringer Mannheim, Germany) using threshold > 10 mg/l or > 20 mg/l	Laboratory technician (Same)	Hospital laboratory (Finland)	Urinary albumin excretion rate calculated from urinary albumin concentration by nephelometry (Behring Nephelometric Analyser, Behringwerke, Marburg, Germany) and urine volume/ collection times	Same (Same)	Same	Test performance (n = 206, consecutive out-patients with type I & II diabetes; cases of macroalbuminuria (positive dipstick test) excluded (n = 32); collection times > 11 h excluded (n = 15); remaining cohort, 159)	4	Defining microalbuminuria as > 15 µg/min: (i) 10 mg/l cut-off PPV = 44%; NPV = 99% (ii) 20 mg/l cut-off PPV = 72%; NPV = 97%. Defining microalbuminuria as > 20 µg/min: (i) 10 mg/l cut-off PPV = 33%; NPV = 100% (ii) 20 mg/l cut-off PPV = 61%; NPV = 100%
Andersen 1992 (0210)	Microbiology/ Group A β haemolytic streptococci	Phadirect Strep A (Pharmacia Biosystems AS, Denmark); coagglutination test	GP (n = 2) (Same)	Primary care (Denmark)	Culture of charcoal-impregnated cotton-tipped wooden swab on 5% defibrinated horse blood–agar plates and chocolate agar plates, incubated aerobically for 18–24 h at 37 °C	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 105, consecutive patients presenting with a sore throat as the primary reason for presentation)	6	Sensitivity, 68% (95% CI, 48–84%) Specificity, 97% (95% CI, 91–100%) PPV, 90% (95% CI, 70–99%) NPV, 89% (95% CI, 81–95%)

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		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Wright 1987 (0241)	Microbiology/ Group A β haemolytic streptococci	Culturette Brand 10-Minute Group A Strep ID (Marion Scientific, Kansas City, Missouri) streptococcal agglutination test	5 nurses who had received 2 training sessions from the manufacturer (Same)	Primary care; family practice office (USA)	5% sheep blood–agar cultures incubated in O_2- limited, CO_2- increased atmosphere for 24–36 h at 37 °C	Same (Practice residents; checking and sub-culture in different cases	Same	Test performance (n = 104, consecutive patients with pharyngitis)	5	Sensitivity, *38%*; Specificity, *95%* PPV, 69%; NPV, 84%
True 1986 (0247)	Microbiology/ Group A β haemolytic streptococci	Culturette Brand 10-Minute Group A ID test (Culturette II, Marion Scientific, Kansas City, Missouri)	3 family physicians – on research team (Residents & physicians (n = 34))	Primary care; family practice office (USA)	5% sheep blood–agar cultures incubated in 5% CO_2 atmosphere for 18–24 h at 35 °C	Single laboratory technician (Same)	?Primary care; (family practice office)	Test performance (n = approx 280 individuals presenting to family practice with symptoms suggestive of pharyngitis, for whom throat culture was ordered)	5	Sensitivity, *82%*; Specificity, *92%* PPV, 76%; NPV, 94%
True 1986 (0247)	Microbiology/ Group A β haemolytic streptococci	Culturette Brand 10-Minute Group A ID test (Culturette II, Marion Scientific, Kansas City, Missouri)	3 family physicians – on research team (Residents & physicians (n = 34))	Primary care; family practice office (USA)	None	None (Same)	None	Impact – effectiveness Effect of NPT on (i) ordering of throat culture (ii) symptomatic treatment, no antibiotics (iii) antibiotics prescribed before test result known (iv) antibiotics prescribed when test result positive (v) antibiotic prescription given, to be filled only if culture result positive [Design = pre/post, hence difficulty attributing any change due to NPT. Bias from retrospective collection of pre-data; likelihood that data abstracters not blind to period to which notes related]	NFA	(i) Throat culture Before, 98%; After, 99% (ii) Symptomatic treatment Before, 58%; After, 63% (iii) Antibiotics before test results known Before, 27%; After, 9% (iv) Antibiotics only when test results known Before, 10%; After, 26% (v) Antibiotic prescription only if culture positive Before, 6%; After, 2%. Changes statistically significant ($p < 0.001$)

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Wegner 1992 (1191)	Microbiology/ Group A β haemolytic streptococci	Culturette Brand 10-Minute Group A Strep ID (Marion Scientific, Kansas City, Missouri)	Nurse/nurse analyst with instruction (Same)	Primary care – community office (USA)	Culture: (i) SXT blood–agar plate incubated anaerobically (ii) 5% sheep blood trypticase soy agar plates incubated aerobically. Colony count: 1 & 2 days. Typed with Gp A identification latex reagent	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 176, consecutive out-patients with symptoms suggestive of streptococcal pharyngitis, all from one of five participating practices)	5	Sensitivity = 31% Sensitivity varies with number of colonies grown on culture
Wegner 1992 (1191)	Microbiology/ Group A β haemolytic streptococci	Testpack Strep A (Abbott Laboratories, N Chicago, IL)	Nurse/nurse analyst with instruction (Same)	Primary care – community office (USA)	Culture: (i) SXT blood–agar plate incubated anaerobically (ii) 5% sheep blood trypticase soy agar plates incubated aerobically. Colony count at 1 & 2 days. Typed with Gp A identification latex reagent	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 186, consecutive out-patients with symptoms suggestive of streptococcal pharyngitis, all from one of five participating practices)	5	Sensitivity = 36% Sensitivity varies with number of colonies grown on culture
Wegner 1992 (1191)	Microbiology/ Group A β haemolytic streptococci	Reveal (Wellcome Diagnostics, Research Triangle Park, NC)	Nurse/nurse analyst with instruction (Same)	Primary care – community office (USA)	Culture: (i) SXT (ii) 5% sheep blood trypticase soy agar plates incubated aerobically	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 127, consecutive out-patients with symptoms suggestive of streptococcal pharyngitis, all from one of five participating practices)	5	Sensitivity = 44% Sensitivity varies with number of colonies grown on culture
Wegner 1992 (1191)	Microbiology/ Group A β haemolytic streptococci	Ventrescreen Strep A (Ventrex Laboratories, Portland, Maine)	Nurse/nurse analyst with instruction (Same)	Primary care – community office (USA)	Culture: (i) SXT (ii) 5% sheep blood trypticase soy agar plates incubated aerobically	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 143, consecutive out-patients with symptoms suggestive of streptococcal pharyngitis, all from one of five participating practices)	5	Sensitivity = 50% Sensitivity varies with number of colonies grown on culture

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Wegner 1992 (1191)	Microbiology/ Group A β haemolytic streptococci	Cards	Nurse/nurse analyst with instruction (Same)	Primary care – community office (USA)	Culture: (i) SXT (ii) 5% sheep blood trypticase soy agar plates incubated aerobically	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 123, consecutive out-patients with symptoms suggestive of streptococcal pharyngitis, all from one of five participating practices)	5	Sensitivity = 47%. Sensitivity varies with number of colonies grown on culture
None	Microbiology/ C trachomatis									No articles scoring above 4 in initial quality assessment were located
Ditchburn 1990 (0555)	Microbiology/ urine testing/ inspection	Appearance (clear/cloudy)	GPs in a single rural practice (Same)	Primary care (UK)	Bacterial culture by hospital laboratory. Colony counts > 10^5 per ml were taken as positive	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 325, consecutive midstream urine samples, taken in response to a range of 'relevant symptoms')	4	For cloudy appearance (n = 237): Sensitivity, 85%; Specificity, 60% PPV, 61%; NPV, 84%
Ditchburn 1990 (0555)	Microbiology/ urine testing/ inspection	Smell (none/strong)	GPs in a single rural practice (Same)	Primary care (UK)	Bacterial culture by hospital laboratory. Colony counts > 10^5 per ml were taken as positive	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 325, consecutive midstream urine samples, taken in response to a range of 'relevant symptoms')	4	For strong smell (n = 266): Sensitivity, 22%; Specificity, 96% PPV, 76%; NPV, 67%
Ditchburn 1990 (0555)	Microbiology/ urine testing/ dipstick/leucocyte esterase	Nephurtest plus leuco (Mannheim-Boehringer)	GPs in a single rural practice (Same)	Primary care (UK)	Bacterial culture by hospital laboratory. Colony counts of > 10^5 per ml were taken as positive	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 325, consecutive midstream urine samples, taken in response to a range of 'relevant symptoms')	4	For leucotest positive (n = 229): Sensitivity, 89%; Specificity, 68% PPV, 66%; NPV, 90%
Winkens 1995 (1192)	Microbiology/ urine testing/ dipstick/leucocyte esterase	Nephur test plus leuco (Boehringer Mannheim, Almere, The Netherlands)	16 GPs in 12 practices (Same)	Primary care (The Netherlands)	Bacterial culture: 0.03 ml urine on 7% sheep blood agar/ McConkey agar. Urine infection if > 10^5 per ml bacteria (Kass' criteria). Samples with > 2 bacteria types considered contaminated	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 1388, urine samples on patients presenting with dysuria, impeded painful micturition (strangury), frequency, and urgency. 77 samples considered contaminated, leaving 1311)	6	For any positive result: Sensitivity, 87%; Specificity, 29% LR+, 1.2; LR–, 0.4 (Comparative results in laboratory conditions from other studies: Sensitivity, 72%; Specificity, 77% LR+, 3.1; LR–, 0.4)

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Winkens 1995 (1192)	Microbiology/ urine testing/ dipstick/leucocyte esterase	Nephur test plus leuco (Boehringer Mannheim, Almere, The Netherlands)	16 GPs in 12 practices (Same)	Primary care (The Netherlands)	Same	GPs from a different practice (Same)	Same	Repeatability – between-practice variation of measure of test performance (practices where n > 100 urine samples collected on patients presenting with dysuria, impeded painful micturition (strangury), frequency, and urgency)	NFA	LR+ or LR–: GP1: LR+, 1.0; LR–, 0.5 GP2: LR+, 1.4; LR–, 0.6 GP3: LR+, 1.3; LR–, 0.4 GP4: LR+, 1.6; LR–, 0.1 GP5: LR+, 1.1; LR–, 0.3 Rest: LR+, 1.3: LR–, 0.4 (Biological variability and random variation could account for observed differences)
Ditchburn 1990 (0555)	Microbiology/ urine testing/ dipstick/nitrite	Nephurtest plus leuco (Boehringer Mannheim)	GPs in a single rural practice (Same)	Primary care (UK)	Bacterial culture by hospital laboratory. Colony counts of > 10^5 per ml were taken as positive	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 325, consecutive midstream urine samples, taken in response to a range of 'relevant symptoms')	4	For nitrite positive, (n = 266): Sensitivity, 57%; Specificity, 96% PPV, 89%; NPV, 79%
Winkens 1995 (1192)	Microbiology/ urine testing/ dipstick/nitrite	Nephur test plus leuco (Boehringer Mannheim, Almere, The Netherlands)	16 GPs in 12 practices (Same)	Primary care (The Netherlands)	Bacterial culture: 0.03 ml urine on 7% sheep blood/ McConkey agar. Urine infection if > 10^5 per ml bacteria (Kass' criteria). Samples with > 2 types of bacteria considered contaminated	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 1388, urine samples from patients presenting with dysuria, impeded painful micturition (strangury), frequency, and urgency. 77 samples considered contaminated, leaving 1311)	6	For any positive result: Sensitivity, 66%; Specificity, 75% LR+, 2.6; LR–, 0.5 (Comparative results in laboratory conditions from other studies: Sensitivity, 55%; Specificity, 99% LR+, 55; LR–, 0.5)
Winkens 1995 (1192)	Microbiology/ urine testing/ dipstick/nitrite	Nephur test plus leuco (Boehringer Mannheim, Almere, The Netherlands)	16 GPs in 12 practices (Same)	Primary care (The Netherlands)	Same	GPs from a different practice (Same)	Same	Repeatability – between-practice variation of measure of test performance (practices where n > 100 urine samples collected from patients presenting with dysuria, impeded painful micturition (strangury), frequency, and urgency)	NFA	LR+ or LR–: GP1: LR+ 2.3; LR–, 0.4 GP2: LR+, 3.0; LR–, 0.5 GP3: LR+, 9.4; LR–, 0.4 GP4: LR+, 1.8; LR–, 0.4 GP5: LR+, 2.7; LR–, 0.6 Rest: LR+, 3.1; LR–, 0.5 (Biological variability and random variation could account for observed differences)

continued

Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Ditchburn 1990 (0555)	Microbiology/ urine testing/ dipstick/red cells	Nephurtest plus leuco (Boehringer Mannheim)	GPs in a single rural practice (Same)	Primary care (UK)	Bacterial culture by hospital laboratory. Colony counts of $>10^5$ per ml were taken as positive	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 325, consecutive midstream urine samples, taken in response to a range of 'relevant symptoms')	4	For blood positive (n = 266): Sensitivity, 76%; Specificity, 62% PPV, 55%; NPV, 81%
Winkens 1995 (1192)	Microbiology/ urine testing/ dipstick/red cells	Nephur test plus leuco (Boehringer Mannheim, Almere, The Netherlands)	16 GPs in 12 practices (Same)	Primary care (The Netherlands)	Bacterial culture on 7% sheep blood/ McConkey agar. Urine infection if $> 10^5$ per ml. Samples with > 2 types of bacteria considered contaminated	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 1388, urine samples from patients presenting with dysuria, strangury, frequency, and urgency. 77 samples considered contaminated, leaving 1311)	6	For any positive result: Sensitivity, 66%; Specificity, 50% LR+, 1.3; LR–, 0.7 (Comparative results in laboratory conditions from other studies: Sensitivity, 53%; Specificity, 91% LR+, 5.9; LR–, 0.5)
Winkens 1995 (1192)	Microbiology/ urine testing/ dipstick/red cells	Nephur test plus leuco (Boehringer Mannheim, Almere, The Netherlands)	16 GPs in 12 practices (Same)	Primary care (The Netherlands)	Same	GPs from a different practice (Same)	Same	Repeatability: between-practice variation of measure of test performance (practices where n > 100 urine samples collected from patients presenting with dysuria, strangury, frequency, and urgency)	NFA	LR+ or LR–: GP1: LR+, 1.2; LR–, 0.7 GP2: LR+, 1.2; LR–, 0.9 GP3: LR+, 1.1; LR–, 0.7 GP4: LR+, 2.0; LR–, 0.5 GP5: LR+, 1.0; LR–, 1.0 Rest: LR+, 1.6; LR–, 0.6 (Biological variability and random variation could account for observed differences)
Ditchburn 1990 (0555)	Microbiology/ urine testing/ microscopy/ white cells	Per low-power field	GPs in a single rural practice (Same)	Primary care (UK)	Bacterial culture by hospital laboratory. Colony counts of $> 10^5$ per ml were taken as positive	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 325, consecutive midstream urine samples, taken in response to a range of relevant symptoms')	4	For > 18 cells per low power field (n = 237): Sensitivity, 95%; Specificity, 76% PPV, 74%; NPV, 95%
Ditchburn 1990 (0555)	Microbiology/ urine testing/ microscopy/ white cells	Cytometer count	GPs in a single rural practice (Same)	Primary care (UK)	Bacterial culture by hospital laboratory. Colony counts of $> 10^5$ per ml taken as positive	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 325, consecutive midstream samples, taken in response to a range of 'relevant symptoms')	4	For > 20 per mm^3 (n = 184): Sensitivity, 95%; Specificity, 81% PPV, 77%; NPV, 96%

continued

Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Winkens 1995 (1192)	Microbiology/ urine testing/ microscopy/ white cells	Microscopy of sediment from spun fresh urine to determine leucocytes (≥ 5 per field)	16 GPs in 12 practices (Same)	Primary care (The Netherlands)	Bacterial culture on 7% sheep blood/ McConkey agar. Infection if > 10^5 per ml. Urine with > 2 bacteria types considered contaminated	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 1388, urine samples from patients presenting with dysuria, strangury, frequency, and urgency. 77 samples considered contaminated, leaving 1311)	6	For ≥ 5 white blood cells per field: Sensitivity, 91%; Specificity, 27% LR+, 1.2; LR–, 0.3 (Comparative results in laboratory conditions from other studies: Sensitivity, 77%; Specificity, 92% LR+, 9.6; LR–, 0.3)
Winkens 1995 (1192)	Microbiology/ urine testing/ microscopy/ white cells	Microscopy of sediment from spun fresh urine to determine leucocytes (≥ 5 per field)	16 GPs in 12 practices (Same)	Primary care (The Netherlands)	Same	GPs from a different practice (Same)	Same	Repeatability – between-practice variation of test performance (practices where n > 100 urine samples collected from patients presenting with dysuria, strangury, frequency, and urgency)	NFA	GP1: LR+, 1.2; LR–, 0.2 GP2: LR+, 1.1; LR–, 0.4 GP3: LR+, 1.4; LR–, 0.2 GP4: LR+, 2.1; LR–, 0.2 GP5: LR+, 1.1; LR–, 0.2 Rest: LR+, 1.3; LR–, 0.5 (NB: Effect of biological and random variation)
Winkens 1995 (1192)	Microbiology/ urine testing/ microscopy/ red cells	Microscopy of sediment from spun fresh urine to determine red blood cells (≥ 5 per field)	16 GPs in 12 practices (Same)	Primary care (The Netherlands)	Bacterial culture on 7% sheep blood/ McConkey agar. Infection if > 10^5 per ml. Urine with > 2 bacteria types considered contaminated	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 1388, urine samples from patients presenting with dysuria, strangury, frequency, and urgency. 77 samples considered contaminated, leaving 1311)	6	For ≥ 5 red blood cells per field: Sensitivity, 45%; Specificity, 65% LR+, 1.3; LR–, 0.8 (Comparative results in laboratory conditions from other studies: Sensitivity, 59%; Specificity, 74% LR+, 2.3; LR–, 0.6)
Winkens 1995 (1192)	Microbiology/ urine testing/ microscopy/ red cells	Microscopy of sediment from spun fresh urine to determine red blood cells (≥ 5 per field)	16 GPs in 12 practices (Same)	Primary care (The Netherlands)	Same	GPs from a different practice (Same)	Same	Repeatability – between-practice variation of test performance (practices where n > 100 urine samples collected from patients presenting with dysuria, strangury, frequency, and urgency)	NFA	GP1: LR+, 1.4; LR–, 0.7 GP2: LR+, 1.0; LR–, 1.0 GP3: LR+, 1.0; LR–, 1.0 GP4: LR+, 2.3; LR–, 0.8 GP5: LR+, 1.2; LR–, 0.5 Rest: LR+, 1.3; LR–, 0.9 (NB: Effect of biological and random variation)
Winkens 1995 (1192)	Microbiology/ urine testing/ microscopy/ bacteria	Microscopy of sediment from spun fresh urine to determine bacteria (≥ 20 per field)	16 GPs in 12 practices (Same)	Primary care (The Netherlands)	Bacterial culture on 7% sheep blood/ McConkey agar. Infection if > 10^5 per ml. Urine with > 2 bacteria types considered contaminated	Laboratory technician (Same)	Hospital laboratory	Test performance (n = 1388, urine samples from patients presenting with dysuria, strangury, frequency, and urgency. 77 samples contaminated, leaving 1311)	6	For ≥ 20 bacteria per field: Sensitivity, 47%; Specificity, 81% LR+, 2.5; LR–, 0.7 (Comparative results in laboratory from other studies: Sensitivity, 85%; Specificity, 99% LR+, 85; LR–, 0.2)

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Winkens 1995 (1192)	Microbiology/ urine testing/ microscopy/ bacteria	Microscopy of sediment from spun fresh urine to determine bacteria (≥ 20 per field)	16 GPs in 12 practices (Same)	Primary care (The Netherlands)	Same	GPs from a different practice (Same)	Same	Repeatability – between-practice variation of test performance (practices where n > 100 urine samples collected from patients presenting with dysuria, strangury, frequency, and urgency)	NFA	GP1: LR+, 2.8; LR–, 0.6 GP2: LR+, 3.4; LR–, 0.7 GP3: LR+, 4.5; LR–, 0.9 GP4: LR+, 8.7; LR–, 0.7 GP5: LR+, 3.1; LR–, 0.6 Rest: LR+, 2.2; LR–, 0.7 (NB: Effect of biological and random variation)
None	Microbiology/ HIV									No articles scoring above 4 in initial quality assessment were located
None	Microbiology/ Epstein-Barr virus									No articles scoring above 4 in initial quality assessment were located
None	Cancer screening/ faecal occult blood									No articles scoring above 4 in initial quality assessment were located
Messing 1987 (0260)	Cancer screening/ haematuria/ dipstick	Urine dipstick testing (make unspecified). Haematuria ≥ 'trace'	Laboratory technician (Same)	Hospital laboratory (USA)	Microscopy of spun urine for red blood cells	Same (Same)	Same	Test performance (n = 176, consecutive adult attenders of urology clinic providing urine specimens)	3	> 2 red blood cells per high power field Sensitivity, 6/66 *(91%)* Specificity, 109/110 *(99%)* PPV, 60/61 *(98%)* NPV, 109/115 *(95%)*
Messing 1987 (0260)	Cancer screening/ haematuria/ dipstick	Urine dipstick testing (make unspecified) for screening of serious treatable disease of urological tract. Haematuria ≥ 'trace' Testing: Daily for first 5 days, then weekly, but not first urine of day OR after vigorous sexual activity. If any test positive, twice further that day and then daily	General public (Same)	Home (USA)	History, examination, microscopic urinalysis, urine culture, FBC, serum creatinine, IVP (later renal US and retro-grade pyelography), cystoscopy, bladder lavage cytology	Urologist (Same)	Hospital	Test performance (n = 626 men > 50 y who met eligibility criteria (see below). 231 self-tested for at least 3 months; 200 refusals; 93 uncontact-able; 102 tested for less than 3 months). Eligibility criteria: No Hx of unevaluated haematuria in last 2 y; No known existing medical conditions giving rise to haematuria; No recent urological instrumentation; No prior/existing urological cancers; Judged by primary care physician as unable to comply	3	23/231 had haematuria at least once; 4 not evaluated clinically; 16 had identifiable cause of haematuria; 10 required immediate treatment (8 surgical; 2 medical) (Results open to work-up bias; any false negative results would not be identified)

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 1: Employing inhibition of haemagglutination	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 3%; Specificity, 100% High dose "hook" – Y Interference from: Protein – N; Blood – N
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 2: Employing inhibition of haemagglutination	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of human hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 16%; Specificity, 97% High dose "hook" – Y Interference from: Protein – N; Blood – N
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 3: Employing inhibition of haemagglutination	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 63%; Specificity, 100% High dose "hook" – N/A Interference from: Protein – N/A; Blood – N/A
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 4: Employing inhibition of haemagglutination	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 43%; Specificity, 97% High dose "hook" – Y Interference from: Protein – Y; Blood – Y
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 5: Employing inhibition of haemagglutination	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 53%; Specificity, 100% High dose "hook" – Y Interference from: Protein – N; Blood – N
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 6: Employing inhibition of haemagglutination	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 70%; Specificity, 100% High dose "hook" – N Interference from: Protein – N; Blood – Y
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 7: Employing inhibition of haemagglutination	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 60%; Specificity, 100% High dose "hook" – Y Interference from: Protein – N; Blood – N
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 8: Employing inhibition of haemagglutination	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 53%; Specificity, 100% High dose "hook" – Y Interference from: Protein – N; Blood – N
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 9: Employing agglutination	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 100%; Specificity, 100% High dose "hook" – N Interference from: Protein – N; Blood – N

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Daviaud 1993 (0008)	Pregnancy/ home test kits/ home test kits	Kit 10: Employing immuno-chromatography	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 100%; Specificity, 90% High dose "hook" – N Interference from: Protein – N; Blood – N
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 11: Employing immuno-chromatography	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 100%; Specificity, 100% High dose "hook" – N Interference from: Protein – N; Blood – N
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 12: Employing immuno-chromatography	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 100%; Specificity, 100% High dose "hook" – N Interference from: Protein – Y; Blood – Y
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 13: Employing immuno-enzymology	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 93%; Specificity, 90% High dose "hook" – N Interference from: Protein – Y; Blood – Y
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 14: Employing immuno-enzymology	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 100%; Specificity, 100% High dose "hook" – N Interference from: Protein – N; Blood – N
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 15: Employing immuno-enzymology	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 100%; Specificity, 100% High dose "hook" – N Interference from: Protein – N; Blood – N
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 16: Employing immuno-enzymology	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 83%; Specificity, 20% High dose "hook" – N/A Interference from: Protein – N/A; Blood – N/A
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 17: Employing immuno-enzymology	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 100%; Specificity, 100% High dose "hook" – N Interference from: Protein – Y; Blood – N
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 18: Employing immuno-enzymology	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 90%; Specificity, 100% High dose "hook" – N Interference from: Protein – N; Blood – N

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 19: Employing immuno-enzymology	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 100%; Specificity, 100% High dose "hook" – N Interference from: Protein – N; Blood – N
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 20: Employing immuno-enzymology	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 43%; Specificity, 53% High dose "hook" – N Interference from: Protein – N; Blood – N
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 21: Employing immuno-enzymology	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 87%; Specificity, 93% High dose "hook" – N Interference from: Protein – N; Blood – Y
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 22: Employing immuno-enzymology	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 100%; Specificity, 100% High dose "hook" – N Interference from: Protein – N; Blood – N
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 23: Employing immuno-enzymology	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 100%; Specificity, 100% High dose "hook" – N Interference from: Protein – N; Blood – N
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 24: Employing immuno-enzymology	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 100%; Specificity, 100% High dose "hook" – N Interference from: Protein – N; Blood – N
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 25: Employing immuno-enzymology	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 40%; Specificity, 100% High dose "hook" – N Interference from: Protein – N/A; Blood – N/A
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 26: Employing immuno-enzymology	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 100%; Specificity, 100% High dose "hook" – N Interference from: Protein – N; Blood – N
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 27: Employing immuno-enzymology	Laboratory technician (Same)	Hospital laboratory (France)	Range of control solutions with known concentrations of hCG	N/A (N/A)	N/A	Test performance	4	Sensitivity, 100%; Specificity, 100% High dose "hook" – N Interference from: Protein – N; Blood – N

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 9: Employing agglutination	Lay-women (Same)	Home (France)	Range of control solutions; known concentrations of hCG; U– negative; U+ at detection limit; U++ twice detection limit	N/A (N/A)	N/A	Test performance (n = 58 assays)	5	Specificity, 93.7%; Sensitivity: U++, 35.5%; U+, 19.2% NPV, 0.91 (assuming previous, 10%); 0.54 (assuming previous, 50%)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 9: Employing agglutination	Lay-women (Same)	Home (France)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (?n = 58 assays)	6	Concordance: κ value (95% CI) U++, 0.37 (0.00–0.74) U+, 0.15 (0.00–0.61)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 11: Employing immuno-chromatography	Lay-women (Same)	Home (France)	Range of control solutions; known concentrations of hCG; U– negative; U+ at detection limit; U++ twice detection limit	N/A (N/A)	N/A	Test performance (n = 58 assays)	5	Specificity, 100%; Sensitivity: U++, 100%; U+, 92.9% NPV, 0.99 (assuming previous, 10%); 0.93 (assuming previous, 50%)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 11: Employing immuno-chromatography	Lay-women (Same)	Home (France)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (?n = 58 assays)	6	Concordance: κ value (95% CI) U++, 1.00 (1.00) U+, 0.90 (0.76–1.00)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 12: Employing immuno-chromatography	Lay-women (Same)	Home (France)	Range of control solutions; known concentrations of hCG; U– negative; U+ at detection limit; U++ twice detection limit	N/A (N/A)	N/A	Test performance (n = 58 assays)	5	Specificity, 100%; Sensitivity: U++, 46.7%; U+, 13.8% NPV, 0.91 (assuming previous, 10%); 0.54 (assuming previous 50%)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 12: Employing immuno-chromatography	Lay-women (Same)	Home (France)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (?n = 58 assays)	6	Concordance: κ value (95% CI) U++, 0.47 (0.13–0.80) U+, 0.11 (0.00–0.60)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 14: Employing immuno-enzymology	Lay-women (Same)	Home (France)	Range of control solutions; known concentrations of hCG; U– negative; U+ at detection limit; U++ twice detection limit	N/A (N/A)	N/A	Test performance (n = 58 assays)	5	Specificity, 91.7%; Sensitivity: U++, 20%; U+, 0% NPV, 0.89 (assuming previous, 10%); 0.48 (assuming previous, 50%)

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Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 14: Employing immuno-enzymology	Lay-women (Same)	Home (France)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (?n = 58 assays)	6	Concordance: κ value (95% CI) U++, 0.18 (0.00–0.73) U+, 0.00 (0.00–0.64)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 15: Employing immuno-enzymology	Lay-women (Same)	Home (France)	Range of control solutions; known concentrations of hCG; U–, negative; U+ at detection limit; U++, twice detection limit	N/A (N/A)	N/A	Test performance (n = 58 assays)	5	Specificity, 92.9%; Sensitivity: U++, 93.3%; U+, 100% NPV, 1.0 (assuming previous, 10%); 1.0 (assuming previous, 50%)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 15: Employing immuno-enzymology	Lay-women (Same)	Home (France)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (?n = 58 assays)	6	Concordance: κ value (95% CI) U++, 0.86 (0.68–1.00) U+, 0.95 (0.84–1.00)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 19: Employing immuno-enzymology	Lay-women (Same)	Home (France)	Range of control solutions; known concentrations of hCG; U–, negative; U+, at detection limit; U++, twice detection limit	N/A (N/A)	N/A	Test performance (n = 58 assays)	5	Specificity, 100%; Sensitivity: U++, 92.8%; U+, 51.7% NPV, 0.95 (assuming previous 10%); 0.67 (assuming previous, 50%)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 19: Employing immuno-enzymology	Lay-women (Same)	Home (France)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (?n = 58 assays)	6	Concordance: κ value (95% CI) U++, 0.93 (0.80–1.00) U+, 0.43 (0.16–0.71)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 22: Employing immuno-enzymology	Lay-women (Same)	Home (France)	Range of control solutions; known concentrations of hCG; U–, negative; U+, at detection limit; U++, twice detection limit	N/A (N/A)	N/A	Test performance (n = 58 assays)	5	Specificity, 76.9%; Sensitivity: U++, 31.2%; U+, 33.3% NPV, 0.91 (assuming previous, 10%), 0.54 (assuming previous, 50%)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 22: Employing immuno-enzymology	Lay-women (Same)	Home (France)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (?n = 58 assays)	6	Concordance: κ value (95% CI) U++, 0.10 (0.00–0.55) U+, 0.12 (0.00–0.54)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 23: Employing immuno-enzymology	Lay-women (Same)	Home (France)	Range of control solutions; known concentrations of hCG; U–, negative; U+, at detection limit; U++, twice detection limit	N/A (N/A)	N/A	Test performance (n = 58 assays)	5	Specificity, 86.7%; Sensitivity: U++, 37.5%; U+, 22.2% NPV, 0.91 (assuming previous, 10%), 0.53 (assuming previous, 50%)

continued

Author Year (Study no)	Area and target of test	Test package characteristics			Comparator characteristics			Study type and details	Quality score	Results
		Name	Operator (Interpreter)	Setting	Name	Operator (Interpreter)	Setting			
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 23: Employing immuno-enzymology	Lay-women (Same)	Home (France)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (?n = 58 assays)	6	Concordance: κ value (95% CI) U++, 0.35 (0.00–0.75) U+, 0.18 (0.00–0.63)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 24: Employing immuno-enzymology	Lay-women (Same)	Home (France)	Range of control solutions; known concentrations of hCG; U–, negative; U+, at detection limit; U++, twice detection limit	N/A (N/A)	N/A	Test performance (n = 58 assays)	5	Specificity, 100%; Sensitivity: U++, 85.7%; U+, 70% NPV, 0.97 (assuming previous, 10%); 0.77 (assuming previous, 50%)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 24: Employing immuno-enzymology	Lay-women (Same)	Home (France)	Same	Laboratory technician Same)	Hospital laboratory	Test performance (?n = 58 assays)	6	Concordance: κ value (95% CI) U++, 0.93 (0.53–1.00) U+, 0.69 (0.47–0.90)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 26: Employing immuno-enzymology	Lay-women (Same)	Home (France)	Range of control solutions; known concentrations of hCG; U–, negative; U+, at detection limit; U++, twice detection limit	N/A (N/A)	N/A	Test performance (n = 58 assays)	5	Specificity, 100%; Sensitivity: U++, 93.8%; U+, 53.6% NPV, 0.95 (assuming previous, 10%); 0.68 (assuming previous, 50%)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 26: Employing immuno-enzymology	Lay-women (Same)	Home (France)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (?n = 58 assays)	6	Concordance: κ value (95% CI) U++, 0.93 (0.80–1.00) U+, 0.51 (0.23–0.78)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 27: Employing immuno-enzymology	Lay-women (Same)	Home (France)	Range of control solutions; known concentrations of hCG; U–, negative; U+, at detection limit; U++, twice detection limit	N/A (N/A)	N/A	Test performance (n = 58 assays)	5	Specificity, 85.7%; Sensitivity: U++, 20%; U+, 6.9% NPV, 0.89 (assuming previous, 10%); 0.48 (assuming previous; 50%)
Daviaud 1993 (0008)	Pregnancy/ home test kits	Kit 27: Employing immuno-enzymology	Lay-women (Same)	Home (France)	Same	Laboratory technician (Same)	Hospital laboratory	Test performance (?n = 58 assays)	6	Concordance: κ value (95% CI) U++, 0.22 (0.00–0.53) U+, 0.04 (0.00–0.60)
None	Other/cardiac troponin T									No articles scoring above 4 in initial quality assessment were located
None	Other/drugs of abuse									No articles scoring above 4 in initial quality assessment were located
None	Other/allergy screening									No articles scoring above 4 in initial quality assessment were located

Appendix 3

Summary lists of available NPTs

Contents

A Clinical chemistry

A1 General chemistry – desktop analysers

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
General chemistry: Small analysers – multiple tests (some include haemoglobin)									
Reflotron 2000	amylase bilirubin total cholesterol CK creatinine GGT glucose AST ALT HDL cholesterol Hb potassium triglycerides U urate	serum plasma whole blood	quantitative	Boehringer Mannheim	£4617 test: £0.93–£1.91	analyser and dry chemistry reagent strips	yes	++	STD 89/27 STD 90/31 MDD 92/04
Spotchem * In development	albumin amylase bilirubin total cholesterol CK creatinine GGT glucose AST ALT HDL cholesterol triglycerides U urate LDH Hb*	serum plasma whole blood*	quantitative	Kyoto Daiichi Kagaku dist: Biomen	£10,000 test: £0.81–£2.20 multiple profile strip: £3.04	dry chemistry strips (auto pipetting)	yes	++	MDD 92/08
Spotchem SE-1510	sodium potassium chloride (simult.)	whole blood plasma serum	quantitative	Kyoto Daiichi Kagaku dist: Biomen		potentiometric: multiple ISE slide	yes	++	

continued

A1 General chemistry – desktop analysers *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
General chemistry: Small analysers – multiple tests (some include haemoglobin) contd									
Seralyser III	glucose creatinine CK U urate total cholesterol Hb AST triglycerides total bilirubin potassium ALT TDM: carbamazine	plasma serum	quantitative	Bayer Diagnostics	£3500 cost/test: general £0.30 enzymes £0.60 drugs £1.50 (instrument no longer available)	dry reagent strips	yes	++	yes
Coletrig 2	total cholesterol triglycerides	whole blood	quantitative	Callegari (Italy)		dry reagent strip			++
Accutrend GC	glucose total cholesterol	whole blood	quantitative	Boehringer Mannheim	£149 cholesterol: £1.59 glucose: £0.27	dry reagent strip	yes	+	
Stat-Site	paracetamol HBD **Future:** theophylline; glucose; Hb; total bilirubin	whole blood serum plasma	quantitative	GDS Diagnostics		dry reagent card		++	
Cholestech LDX	total cholesterol HDL cholesterol triglycerides glucose Ca total chol/HDL chol ratio LDL cholesterol VLDL cholesterol **In development:** PSA; HbA1c LDL cholesterol; LPA	whole blood	quantitative	Cholestech dist: Diagnostic Testing† dist: Biomen‡	£1599† £3954‡ tests: chol/HDL chol £5.39† £10.00‡ lipid profile: £6.69† £14.90‡	dry phase cassette, up to 4 simultaneous assays	yes	+	MDA 95/23 yes

continued

A1 General chemistry – desktop analysers *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
General chemistry: Small analysers – multiple tests (some include haemoglobin) contd									
Piccolo	ALT albumin alk.phosphatase amylase Ca total cholesterol creatinine glucose potassium total bilirubin total protein U	whole blood plasma serum	quantitative	Abaxis dist: Diagnostic Testing	£7995 general health panel: £12.10 primary health panel: £10.00	single use centrifugal reagent rotor containing diluent and reagents for a panel of tests	yes	+	
First 4	CK CK–mB myoglobin	whole blood	quantitative	First Medical		centrifugal blood separation, fluorescence immunoassay			
i-STAT	sodium potassium chloride pH P_{CO_2} P_{O_2} U glucose Hct **Calculated:** Hb; T_{CO_2}; HCO_3; base excess	whole blood	quantitative	i-STAT dist: Hewlett Packard (USA)	US $4500 glucose: US $3.00 7 different tests: US $9.00	test cartidges in hand-held unit. Each cartridge dedicated to a panel of up to 6 tests. Microelectrodes made on silicon chips. Each coated with a sensitive film such as an ion selective membrane, or an enzyme layer. Integral calibrant in the test cartridge	yes	+	
Chemalab	glucose triglycerides Hb Hct erythrocytes	whole blood	quantitative	Trio Diagnostics dist: Lifeline (UK)	meter: £360 test: £1.19	liquid reagent-filled cuvette		++	
Minilab * In development	Hb* erythrocytes* bilirubin glucose U total cholesterol HDL cholesterol	whole blood* plasma	quantitative	Bayer Diagnostics	£500 cost/test is similar to the Seralyser (instrument is no longer available)	liquid reagent-filled cuvettes		++	STD 89/66

continued

A1 General chemistry – desktop analysers *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
General chemistry: Small analysers – multiple tests (some include haemoglobin) contd									
Pharmalab	cholesterol glucose triglycerides Hb Hct erythrocytes	whole blood	quantitative	Callegari (Italy)		pre-filled liquid cuvettes		++	
Clin-check	total cholesterol Hct Hb erythrocytes glucose triglycerides urate total bilirubin HDL cholesterol creatinine total protein	whole blood " " " " " serum " " " "	quantitative	Lifeline (UK)	£650 tests: £0.87–£1.19	pre-filled liquid cuvettes	yes	++	
Miniphotometer LMN18-P	alcohol total cholesterol erythrocytes glucose Hct Hb lactate triglycerides bilirubin Ca HDL cholesterol LDL cholesterol iron total protein urate	whole blood " " " " " " " serum or plasma " " " " " "	quantitative	Dr. Bruno Lange GmbH (Germany) dist: BodyCare Products	£1790	pre-filled liquid cuvettes		++	
Opti 1	pH P_{CO_2} P_{O_2} **Calculated:** base excess; O_2 sat.; HCO_3; T_{CO_2}; O_2CT	whole blood	quantitative	AVL Scientific dist: AVL Medical Instruments (UK)	£7000	single use, reagent-filled cartridge operating by optical fluorescence	yes	++	

continued

A1 General chemistry – desktop analysers *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
General chemistry: Small analysers – multiple tests (some include haemoglobin) contd									
IRMA (blood gas cartridge)	pH Pco_2 Po_2 **Calculated:** base excess; O_2 sat.; HCO_3; Tco_2	whole blood	quantitative	Diametrics Medical		disposable credit card-sized cartridge	yes	++	
IRMA (electrolyte cartridge)	potassium sodium ionised Ca	whole blood	quantitative	Diametrics Medical		disposable credit card-sized cartridge	yes	++	
Stat Pal	pH Pco_2 Po_2	whole blood	quantitative	PPG Industries					
Gem Stat	pH Pco_2 Po_2 sodium potassium ionised Ca Hct **Calculated:** base excess; O_2 sat.; HCO_3; Tco_2	whole blood	quantitative	Mallinckrodt Sensor Systems		self-contained disposable electrode and reagent cartridge	yes	++	
Spotlyte	sodium potassium chloride	whole blood serum plasma urine	quantitative	dist: Biomen	£5785	ion specific electrode (ISE)	yes	++	
Easylyte	sodium potassium	whole blood serum plasma urine	quantitative	Medica dist:YSI	£3545	ISE with plug-in reagent pack	yes	++	
Easylyte PLUS	sodium potassium chloride	whole blood serum plasma urine	quantitative	Medica dist:YSI	£3945	ISE with plug-in reagent pack	yes	++	

continued

A1 General chemistry – desktop analysers *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
General chemistry: Small analysers – multiple tests (some include haemoglobin) contd									
Pearl Electrolyte Screener	sodium potassium	whole blood serum	quantitative	Analyser/Industries dist: Croft-Greiner Instruments		ISE			
Easylyte Lithium	sodium potassium lithium	whole blood serum plasma urine	quantitative	Medica dist:YSI	£4445	ISE with plug-in reagent pack	yes	++	
DuPont Analyser	sodium potassium lithium	whole blood serum plasma urine	quantitative	DuPont dist: Bio Stat Diagnostics		flow-through ISE		++	
Easylyte Calcium	sodium potassium ionised calcium pH	whole blood serum plasma urine	quantitative	Medica dist:YSI	£4945	ISE with plug-in reagent pack	yes	++	
Ionetics 540 electrolyte analyser	sodium potasium chloride lithium ionised calcium pH	whole blood serum plasma	quantitative	Ionetics dist:Allerayde	£4995	ISE; up to 4 analytes simultaneously		++	
ILyte	sodium potassium chloride	whole blood serum plasma; urine	quantitative	dist: Instrumentation Laboratory (UK)	£4000	ISE	yes	++	
ILyte	sodium potassium lithium	whole blood serum plasma; urine	quantitative	dist: Instrumentation Laboratory (UK)	£4500	ISE	yes	++	
ILyte	sodium potassium	whole blood serum; plasma; urine	quantitative	dist: Instrumentation Laboratory (UK)	£3500	ISE	yes	++	
ILyte	sodium potassium ionised calcium pH	whole blood serum plasma urine	quantitative	dist: Instrumentation Laboratory (UK)	£4500	ISE	yes	++	

continued

A1 General chemistry – desktop analysers *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
General chemistry: Small analysers – single test (for glucose meters, see A3 – diabetes) (for cholesterol meters, see A4 – lipids)									
Stat K	potassium	whole blood serum plasma	quantitative	PDX Technologies		single use, self-calibrating potassium sensor	yes		
Pearl lithium screening	lithium	whole blood serum	quantitative	Analyser/Industries dist: Croft-Greiner Instruments		ISE			
Advanced Micro Osmometer (3MO *plus*)	osmolality	serum plasma urine	quantitative	Vitech Scientific			yes	+++	
Bilitron elvi 444	total bilirubin	serum plasma	quantitative	Elvilogos (Italy)		direct spectrophotometry		++	
Accusport	lactate	whole blood	quantitative	Boehringer Mannheim	meter: £221 strips: £0.98	dry phase strips	yes		
Ammonia Checker II	ammonia	whole blood	quantitative	dist: Biomen	meter: £760 strips: £4.97	dry phase strips			
DCA 2000	HbA1C	whole blood	quantitative	Bayer Diagnostics	£2500	cassette, inhibition of latex agglutation	yes	+	
Various analytes: Small analysers – non-invasive technology									
Nonin Onyx	SpO_2	(blood)	quantitative	Nonin Medical		self-contained finger pulse oximetry		+	
Nonin 8500	SpO_2	(blood)	quantitative	Nonin Medical		hand-held pulse oximeter		+	
Futrex-5000	% body fat		quantitative	Futrex Inc. dist:YSI		non-invasive near-IR spectroscopy		++	
Biodynamics Model 310	% body fat basal metabolic rate total body water		quantitative	Biodynamics (USA)		whole body bioimpedence		++	
Bedfont Micro Smokerlyzer **Bedfont Mini Smokerlyzer**	carbon monoxide	breath	quantitative	Bedfont Technical Instruments	£375 £499	electrochemical sensor		++	

continued

A1 General chemistry – desktop analysers *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Various analytes: Small analysers – non-invasive technology contd									
Bedfont EC60 hydrogen monitor	hydrogen	breath	quantitative	Bedfont Technical Instruments	£950	electrochemical sensor		++	
Alcolmeter S300	alcohol	breath	semi-quantitative	Lion Laboratories	£688	electrochemical sensor	yes	+	
Futrex 9000	glucose U bilirubin Hb	(blood)	quantitative	Futrex		near-IR scanning through the finger		++	
General chemistry: Large desktop analysers (some include haemoglobin)									
Vision	glucose U potassium total cholesterol triglycerides sodium urate creatinine AST ALT alk.phosphatase theophylline potassium CK amylase total bilirubin Hb CRP GGT phenytoin Ca HDL cholesterol LDH total protein albumin thyroxine HbA1c prothrombin	whole blood serum plasma	quantitative	Abbott Diagnostics	£14,707 test: £1.90–£2.50	wet chemistries in self-contained disposable cassettes	yes	++	STD 89/27 STD 90/31

continued

A1 General chemistry – desktop analysers *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
General chemistry: Large desktop analysers (some include haemoglobin) contd									
Vitros DT60 II **(Ektachem DT chemistry system)**	ammonia amylase total cholesterol creatinine glucose Hb HDL magnesium phosphate total bilirubin neonatal bilirubin total protein triglycerides U urate lactate	serum plasma whole blood	quantitative	Johnson & Johnson Clinical Diagnostics dist: Shield Diagnostics	£5718 slides: £0.75–£2.56	dry chemistry slides	yes	+++	MDD 90/42
Vitros DTSCII **(Ektachem DT chemistry system)**	CO_2 chloride potassium sodium	serum plasma	quantitative	Johnson & Johnson Clinical Diagnostics dist: Shield Diagnostics	£3327 £0.82–£0.93	dry chemistry slides	yes	+++	yes
Vitros DTE II **(Ektachem DT chemistry system)** * In development	alk.phosphatase ALT AST Ca CK CK–mB GGT LDH theophylline lipase albumin cholinesterase iron creatinine*	serum plasma urine*	quantitative	Johnson & Johnson Clinical Diagnostics dist: Shield Diagnostics	£2204 £0.93–£1.66	dry chemistry slides	yes	+++	yes

continued

A1 General chemistry – desktop analysers *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
General chemistry: Large desktop analysers (some include haemoglobin) contd									
PROCHEM	albumin; glucose U; potassium total cholesterol; triglycerides; Na; urate creatinine; AST; ALT; alk.phosphatase; K; CK; amylase; total bilirubin; GGT; Ca; HDL cholesterol; LDH; total protein; apolipoprotein A1; apolipoprotein B; bicarbonate; direct bilirubin; chloride; CK–mB; Fe; lipase; Mg; phosphate	serum plasma	quantitative	PrismaSystems	£8995 pre-filled liquid cassettes 1–15 simultaneous tests £1.10–£4.06	pre-filled liquid cassettes 1–15 simultaneous tests	yes	+++	
LISA	21 chemistries 4 electrolytes 2 coagulation tests		quantitative	DataChem					
Analyst	alk.phosphatase; GGT; AST; ALT; amylase; U; total protein; glucose; Ca; chloride; triglycerides; urate; creatinine; bilirubin; HDL cholesterol; LDL cholesterol; VLDL cholesterol; theophylline	serum plasma	quantitative	Dupont dist: Bio Stat Diagnostics	£9214 14 chemistry rotor: £6.15 lipid profile rotor: £4.27 glucose-II rotor: £1.65	sealed rotor, simultaneous or single test	yes	++	

continued

A1 General chemistry – desktop analysers *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
General chemistry: Large desktop analysers (some include haemoglobin) contd									
EASY ST * In development	40 tests: general clinical chemistry: drugs PT Hb*	serum plasma whole blood*	quantitative	EM Diagnostic Systems dist: BDH Diagnostics	£15,000 (1990 price) test: £0.15–£2.50	disposable cuvettes containing dry powder reagents, with automatic fluid delivery	yes	++	MDD 90/42
Omni I (range of analysers with an increasing repertoire including electrolytes and co-oximetry)	pH P_{CO_2} P_{O_2} **Calculated:** base excess O_2 saturation bicarbonate T_{CO_2} O_2 content Hb/Hct	whole blood	quantitative	dist: AVL Medical Instruments (UK) Ltd	£16,000	single use, reagent-filled cartridge operating by optical fluorescence	yes	++	
Gem Premier	pH; P_{CO_2}; P_{O_2}; Na; K; ionised Ca; Hct **Calculated:** base excess; O_2 saturation; HCO_3;T_{CO_2}	whole blood	quantitative	Mallinckrodt Sensor Systems		self-contained disposable electrode and reagent cartridge	yes	++	
Range of blood gas analysers with varying test combinations including electrolytes and co-oximetry	Measured parameters: pH/P_{CO_2}/P_{O_2}; Na/K; ionised Ca; glucose; lactate; Hct; Hb	whole blood	quantitative	Radiometer (UK) Ciba-Corning Instrumentation Laboratory Nova Biomedical (dist: Biomen) Omni (dist: AVL Scientific)					

A2 Chemistry – Urinalysis

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
General chemistry: Examples of strips or tablets for single tests (for further details of glucose, ketones and microalbumin, see A3 diabetes)									
Ictotest	bilirubin	urine	semi-quantitative	Bayer Diagnostics	£0.20	colorimetric reagent tablet	no	+	
Albustix	protein	urine	semi-quantitative	Bayer Diagnostics	£0.06 (on drug tariff)	reagent strip	no	+	
Albym-Test	protein	urine	semi-quantitative	Boehringer Mannheim	£0.06 (on drug tariff)	reagent strip	no	+	
Diabur Test 5000	glucose	urine	semi-quantitative	Boehringer Mannheim	£0.05 (on drug tariff)	enzyme reagent dipstick	no	+	
Ketur Test	ketones	urine	semi-quantitative	Boehringer Mannheim	£0.04 (on drug tariff)	reagent dipstick	no	+	
Nycocard	microalbumin	urine	semi-quantitative	Nycomed (UK)		flow-through immunoassay	yes (integral procedural control)		
General chemistry: Example of a strip for a multiple test combination (for full details, see B2 microbiology urinalysis)									
Combur-10 Test	specific gravity; pH; leucocytes; nitrite; protein; glucose; ketones; urobilinogen; bilirubin; blood	urine	semi-quantitative	Boehringer-Mannheim			no	+	
Chemistry: Special tests – example of a strip for screening for drugs of abuse (for full details see A6 drug screening)									
AccuSign	cocaine; THC (cannabis/marijuana); amphetamine; metamphetamine; barbiturates; opiate; phencyclidine; benzodiazepines; methadone; tricyclic anti-depressants	urine	qualitative	PBM Princeton BioMeditech (USA)	test: US $2.00	flow-along inmmunoassay	yes (integral procedural control)	+	
	2-drug panel: e.g. cocaine/THC				US $4.50				
	3-drug panel: e.g. benzodiazepines; barbiturates; PCP				US $7.10				
	4-drug panel: cocaine/THC/opiates amphetamine or metamphetamine				US $10.00				

continued

A2 Chemistry – Urinalysis *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Chemistry: Special tests – examples of strips for ovulation prediction and pregnancy (for full details, see A7 fertility and pregnancy)									
OvuKit	LH	urine	semi-quantitative	Quidel dist: Diagen		dipstick enzyme immunoassay using immobilised antibody. Sequential incubation with liquid reagents	yes (integral procedural control)	++	
Osom Test Strip	hCG	urine	qualitative	Wyntek Diagnostics (USA)		visual flow-along immunoassay	yes (integral procedural control)	+	

A3 Chemistry – Diabetes

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Diabetes: Non-instrumental – urinalysis									
Clinitest	glucose	urine	semi-quantitative	Bayer Diagnostics	£0.05 (on drug tariff)	reagent tablet	no	+	
Clinistix					£0.08 (on drug tariff)	enzyme reagent dipstick			
Diastix					£0.07 (on drug tariff)	enzyme reagent dipstick			
Diabur Test 5000	glucose	urine	semi-quantitative	Boehringer Mannheim	£0.05 (on drug tariff)	enzyme reagent dipstick	no	+	
Medi-Test Glucose	glucose	urine	semi-quantitative	BHR Pharmaceuticals	£0.05 (on drug tariff)	enzyme reagent dipstick	no	+	
Acetest	ketones	urine	semi-quantitative	Bayer Diagnostics	£0.03 (on drug tariff)	reagent tablet	no	+	
Ketostix					£0.05 (on drug tariff)	non-enzyme reagent dipstick			
Ketur Test	ketones	urine	semi-quantitative	Boehringer Mannheim	£0.04 (on drug tariff)	reagent dipstick	no	+	
Keto-Diastix	glucose ketones	urine	semi-quantitative	Bayer Diagnostics	£0.11	combination reagent dipstick	no	+	yes
Micro-bumintest	microalbumin	urine	semi-quantitative	Bayer Diagnostics	£0.13	reagent dipstick	no	+	
QuickDot	microalbumin	urine	semi-quantitative	Diatechnician Diagnostics		flow-through enzyme immunoassay	yes	++	
Nycocard U-albumin	microalbumin	urine	semi-quantitative	Nycomed (UK) (discontinued))		flow-through immunoassay	yes (integral procedure control)	+	yes
Micral-Test II	microalbumin	urine	semi-quantitative	Boehringer Mannheim	£1.18	immunoassay reagent strip	no	+	yes

continued

A3 Chemistry – Diabetes *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Diabetes: Non-instrumental – urinalysis contd									
Multistix GP **Multistix10SG** **Multistix 8SG** **Multistix SG** **N-Multistix SG** **Labstix SG** **(see page 212)**	multiple test combinations that include glucose/ketones	urine	semi-quantitative	Bayer Diagnostics	£0.33 £0.34 £0.29 £0.29 £0.34 £0.25	reagent strip	no	+	
Clinitek 50 **Clinitek 100**	instruments for measuring the above	urine	quantitative	Bayer Diagnostics	£1500	semi-automated reflectance spectrophotometry		+	
Labstix; Bili-stix; **N-labstix; Uristix** **Hema-combistix** **(see page 212)**	multiple test combinations that include glucose/ ketones	urine	semi-quantitative	Bayer Diagnostics	£0.26; £0.29 £0.29; £0.16 £0.30	reagent strip	no	+	
BM-Test GP **Keto-Diabur-Test 5000** **BM-Test 3** **BM-Test 4** **BM-Hopitest** **BM-Test 5L** **Nephur-Test+leuco** **BM-Test 7** **BM-Test 8** **(see page 212)**	multiple test combinations that include glucose/ketones	urine	semi-quantitative	Boehringer Mannheim	£0.09 £0.10 (on drug tariff) £0.09 £0.13 £0.13 £0.14 £0.22 £0.16 £0.22	visual reagent strip	no	+	yes
Combur-Test **N-Combur Test** **Combur-4 Test** **Combur-5 Test+leuco** **Combur-6 Test+leuco** **Combur-8 Test** **Combur-9 Test** **Combur-10 Test** **Ecur-Test** **Ecur-4 Test** **L-Combur-5 Test** **Nephur-Test** **Nephur-Test+leuco** **Nephur-7 Test** **Ratio Test** **(see page 213)**	multiple test combinations that include glucose/ketones	urine	semi-quantitative	Boehringer Mannheim		reagent strip	no	+	
Miditron Junior	Combur-10 tests	urine	semi-quantitative	Boehringer Mannheim		semi-automated urine test strip analyser			

continued

A3 Chemistry – Diabetes *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Diabetes: Non-instrumental – blood glucose									
BM Test 1-44	glucose	blood	semi-quantitative	Boehringer Mannheim	£0.28 (on drug tariff)	twin-pad visual reagent strip	no	++	yes
Dextrostix	glucose	blood	semi-quantitative	Bayer Daiagnostics	£0.28 (on drug tariff)	single-pad visual reagent strip	no	++	yes
Glucostix	glucose	blood	semi-quantitative	Bayer Diagnostics	£0.28 (on drug tariff)	twin-pad visual reagent strip	no	++	yes
Hypoguard GA	glucose	blood	semi-quantitative	Hypoguard (UK)	£0.25 (on drug tariff)	twin-pad visual reagent strip	no	++	
Hypoguard Supreme	glucose	blood	semi-quantitative	Hypoguard (UK)	£0.26 (on drug tariff)	single-pad visual reagent strip	no	++	
Biocare Glucose VT	glucose	blood	semi-quantitative	Biocare International	£0.17 (on drug tariff)	single-pad visual reagent strip	no	++	MDD 93/43
Medi-Test Glycaemie C	glucose	blood	semi-quantitative	BHR Pharmaceuticals	£0.26 (on drug tariff)	twin-pad visual reagent strip	no	+	
Diabetes: Small analysers – blood glucose									
Accutrend (BM Accutest test strip) Accutrend DM (data management system)	glucose	whole blood	quantitative	Boehringer Mannheim	meter: £34 strip: £0.27 (on drug tariff) dm system: £149	colorimetric non-wipe strip technology	yes	++	MDD 93/25 MDD 94/15
Accutrend Mini	glucose	whole blood	quantitative	Boehringer Mannheim					MDD 94/22
Accutrend alpha (BM Accutest test strip)	glucose	whole blood	quantitative	Boehringer Mannheim	meter: £29	colorimetric non-wipe strip technology	yes	++	MDA 96/20
Accutrend GC	glucose (cholesterol)	whole blood	quantitative	Boehringer Mannheim	meter: £149 glucose strip: £0.27 (on drug tariff)	colorimetric non-wipe strip technology	yes	++	MDA 95/11
Reflolux S (II/IIM) (BM 1-44 test strip) (BM 20-800 test strip) (Chemstrip bG test strip)	glucose	whole blood	quantitative	Boehringer Mannheim (1984)	meter: £29 strip: £0.28 (on drug tariff)	colorimetric wipe strip technology	yes	+++	MDD 93/25 yes
Reflocheck	glucose	whole blood	quantitative	Boehringer Mannheim		colorimetric wipe strip technology	yes	+++	
Reflomat (Reflotest test strip)	glucose	whole blood	quantitative	Boehringer Mannheim (1978)		colorimetric wipe strip technology	yes	+++	yes

continued

A3 Chemistry – Diabetes *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Diabetes: Small analysers – blood glucose contd									
Glucometer 4 (Glucotide test strip)	glucose	whole blood	quantitative	Bayer Diagnostics	£35 strip: £0.26 (on drug tariff)	colorimetric non-wipe strip technology	yes	++	MDA 94/67
Glucometer GX (Glucostix test strip)	glucose	whole blood	quantitative	Bayer Diagnostics	(discontinued) strip: £0.28 (on drug tariff)	colorimetric wipe strip technology	yes	+++	MDD 93/25
Eyetone (Dextrostrix test strip)	glucose	whole blood	quantitative	Bayer Diagnostics Ames (1978)	(discontinued)	colorimetric wipe strip technology	yes	+++	yes
Glucocheck (Dextrostix test strip)	glucose	whole blood	quantitative	Medistron (1980)		colorimetric wipe strip technology	yes	+++	yes
One-Touch II (One Touch test strip)	glucose	whole blood	quantitative	Lifescan	meter: £49 strip: £0.27 (on drug tariff)	colorimetric non-wipe strip technology	yes	+	MDD 93/18
One Touch Basic (One Touch test strip)	glucose	whole blood	quantitative	Lifescan	meter: £33 (on drug tariff)	colorimetric non-wipe strip technology	yes	+	
Glucoscan	glucose	whole blood	quantitative	Lifescan		colorimetric strip technology	yes		yes
Glycotronic C	glucose	whole blood	quantitative	BHR Pharmaceuticals	meter £31	colorimetric non-wipe strip technology	yes	+	MDA 92/21 yes
Hypoguard GA (GA test strip)	glucose	whole blood	quantitative	Hypoguard dist: Hypoguard (UK) Lifeline UK	 meter: £20 strip: £0.24 (on drug tariff) meter: £43.50 strip: £0.35	colorimetric wipe strip technology	yes	+++	MDD 93/25

continued

A3 Chemistry – Diabetes *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Diabetes: Small analysers – blood glucose contd									
Hypoguard Supreme	glucose	whole blood	quantitative	Hypoguard dist: Hypoguard (UK)	meter: £29.50 strip: £0 25	colorimetric non-wipe strip technology	yes	++	MDD 93/25 MDD 93/45
Hypocount	glucose	whole blood	quantitative	Hypoguard (1980)		colorimetric wipe strip technology	yes	+++	yes
CheckMate	glucose	whole blood	quantitative	Cascade Medical (USA)		colorimetric non-wipe strip technology	yes	++	MDA 95/31
HemoCue-B glucose (micro-cuvette) **Analyser with data management**	glucose	whole blood	quantitative	HemoCue	£625 cuvette: £0.65 £975	self-filling reagent micro-cuvette	yes	+	MDD 91/45 yes
ExacTech (Exactech test strip)	glucose	whole blood	quantitative	MediSense	card sensor: £24 strip: £0.27 (on drug tariff)	electrode-based biosensor (non-wipe)	yes	+	MDD 93/25 yes
MediSense (card and pen sensor) (MediSense G2 sensor electrode) (companion 2) **Precision Link (data management system)**	glucose	whole blood	quantitative	MediSense	sensor: £35 sensor electrodes: £0.26 (on drug tariff) £99	electrode-based biosensor (non-wipe)	yes	+	MDD 94/49 MDD 93/25
Satellite G	glucose	whole blood	quantitative	MediSense		electrode-based biosensor (non-wipe)	yes	+	MDD 93/25
SensorLink (Sensor Link test electrode)	glucose	whole blood	quantitative	MediSense	£650 test electrode: £0.27	electrode-based biosensor (non-wipe)	yes	++	MDA 96/13
Precision Q.I.D. (microflow electrode)	glucose	whole blood	quantitative	MediSense		3-electrode biosensor (non-wipe)	yes	+	
GLUCOCARD (glucocard strip)	glucose	whole blood	quantitative	Kyoto Daiichi Kagaku (Japan) dist: Biomen		self-filling electrode-based biosensor (non-wipe)	yes	+	

continued

A3 Chemistry – Diabetes *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Diabetes: Small analysers – blood glucose contd									
Accu-Chek Advantage (advantage test strip)	glucose	whole blood	quantitative	Boehringer Mannheim		electrode-based biosensor (non-wipe)	yes	+	
Sensimac	glucose	whole blood	quantitative	Metertech (Taiwan) dist: Imaco		electrode-based biosensor (non-wipe)	yes	+	
Biotrack	glucose (total cholesterol) (Hb)	whole blood	quantitative	Biotrack (Ciba-Corning Diagnostics)		disposable cartridges containing capillary tracks leading to dry reagents. 3 simultaneous colorimetric assays	yes	+	yes
Diabetes: Small analysers – non-invasive technology									
Diasensor 1000	glucose	(blood)	quantitative	Diasense (USA) dist: Diasense (UK)	£5000	infra-red scanning absorption of forearm		++	
Futrex 9000	glucose (U; Hb; bilirubin)	(blood)	quantitative	Futrex Inc. dist: Hi-Care Health Products		near-IR scanning through finger		++	
Diabetes: Small analysers – HbA1c									
DCA 2000	HbA1c	whole blood	quantitative	Bayer Diagnostics	£2500	cassette, inhibition of latex agglutation	yes	+	yes
Diabetes: Small analysers – multiple tests									
Reflotron 2000 (see page 170)	15 general tests including glucose	whole blood serum plasma	quantitative	Boehringer Mannheim	£4617 test: £0.93–£1.91	analyser and dry chemistry reagent strips	yes	++	yes
Spotchem (see page 170)	17 general tests including glucose	serum plasma	quantitative	Kyoto Daiichi Kagaku dist: Biomen	£10,000 test: £0.81–£2.20 multiple profile strip: £3.04	dry chemistry strips (auto pipetting)	yes	++	

continued

A3 Chemistry – Diabetes *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Diabetes: Small analysers – multiple tests contd									
Seralyser III (see page 171)	14 general tests including glucose	serum plasma	quantitative	Bayer Diagnostics	(discontinued)	dry reagent strips	yes	++	
Cholestech LDX (see page 171) * In development	9 chemistry tests including glucose HbA1c *	whole blood	quantitative	Cholestech dist: Diagnostic Testing† dist: Biomen‡	 £1599† £3954‡	dry phase cassette, up to 4 simultaneous assays	yes	+	
Piccolo (see page 172)	12 chemistry tests including glucose	whole blood (plasma or serum)	quantitative	Abaxis dist: Diagnostic Testing	£7995 general health panel: £12.10 primary health panel: £10.00	single use centrifugal reagent rotor containing diluent and reagents for a panel of tests	yes	+	
i-STAT (see page 172)	8 chemistry tests including glucose	whole blood	quantitative	i-Stat		microelectrode test cartidges in hand-held unit. Each cartridge dedicated to a panel of upto 6 tests. Electrode coated with an ion selective membrane, or enzyme layer. Integral calibrant in the test cartridge.	yes	+	
Chemalab (see page 172)	6 chemistry tests including glucose	whole blood	quantitative	Trio Diagnostics dist: Lifeline (UK)	meter: £360 test: £1.19	liquid reagent-filled cuvette		++	
Minilab (see page 172)	7 general tests including glucose	plasma	quantitative	Bayer Diagnostics	(discontinued)	liquid reagent-filled cuvette			
Pharmalab (see page 173)	6 general tests including glucose	whole blood	quantitative	Callegari (Italy)		pre-filled liquid cuvettes		++	
Clin-check (see page 173)	11 tests including glucose	serum	quantitative	dist: Lifeline (UK)	£650 tests: £0.87–£1.19	pre-filled liquid cuvettes	yes	++	
Miniphotometer (see page 173)	15 general tests including glucose	whole blood	quantitative	Dr. Bruno Lange dist: Bodycare Products	 £1790	pre-filled liquid cuvettes		++	

continued

A3 Chemistry – Diabetes *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Diabetes: Large desktop analysers – multiple tests									
Vision **(see page 177)**	28 general tests including glucose	whole blood serum plasma	quantitative	Abbott Diagnostics	£14,707 test: £1.90–£2.50	wet chemistries in disposable cassettes	yes	++	yes
Vitros DT60 II (Ektachem DT chemistry system) **(see page 178)**	16 general tests including glucose	whole blood serum or plasma	quantitative	Johnson & Johnson Clinical Diagnostics dist: Shield Diagnostics	£5718 slides: £0.75–£2.56	dry chemistry slides	yes	+++	yes
PROCHEM **(see page 179)**	30 general tests including glucose	serum plasma	quantitative	PrismaSystems	£8995 pre-filled liquid cassettes 1–15 simultaneous tests: £1.10–£4.06	pre-filled liquid cassettes. 1–15 simultaneous tests	yes	+++	
LISA **(see page 179)**	27 general tests including glucose		quantitative	DataChem					
Analyst **(see page 179)**	18 general tests including glucose	serum plasma	quantitative	Dupont dist: Bio-Stat Diagnostics	£9214 glucose-II rotor: £1.65	sealed rotor, simultaneous or single test	yes	++	
EASY ST **(see page 180)**	40 general tests including glucose	serum plasma	quantitative	EM Diagnostic Systems dist: BDH Diagnostics	£15,000 (1990) test: £0.15–£2.50	disposable cuvettes containing dry powder reagents, with automatic fluid delivery	yes	++	yes

A4 Chemistry – lipids

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Lipids: Non-instrumental									
Accutest Cholesterol	total cholesterol	whole blood	semi-quantitative	Jant Pharmacal (USA)		colorimetric enzyme reagent pad	no	++	
Accumeter **Boots Home Cholesterol Test**	total cholesterol	whole blood	quantitative	Chemtrak (USA) dist: Boots	 £8	combined blood filtration and paper impregnated enzyme system. Visual reading of colorimetric strip length	yes	++	MDD 93/39
Lipids: Small analysers									
Biolip	total cholesterol	whole blood	quantitative	Callegari (Italy)		dry phase strip			
Lipotrend	total cholesterol	whole blood	quantitative	Boehringer Mannheim		dry phase strips	yes		MDD 92/60
Chemachol	total cholesterol	whole blood	quantitative	Trio Diagnostics dist: Lifeline (UK)	 meter: £360 test: £1.19	liquid reagent-filled cuvette	yes	++	
Coletrig 2	total cholesterol triglycerides	whole blood	quantitative	Callegari (Italy)		dry reagent strip		++	
Accutrend GC	total cholesterol (glucose)	whole blood	quantitative	Boehringer Mannheim	£149 cholesterol: £1.59 glucose: £0.27	dry reagent strip	yes	+	MDA 95/11
Cholestech LDX	total cholesterol HDL cholesterol triglycerides total cholesterol: HDL chol ratio LDL cholesterol VLDL cholesterol (glucose) **In development:** direct LDL cholesterol lipoprotein	whole blood	quantitative	Cholestech dist: Diagnostic Testing† dist: Biomen‡ lipid profile:	 £1599† £3954‡ tests: chol/HDL £5.39† £10.00‡ £6.69† £14.90‡	dry phase cassette, up to 4 simultaneous assays	yes	+	MDA 95/23
Quickread	total cholesterol HDL cholesterol triglycerides	whole blood serum	quantitative	Photest Diagnostic	£425 (1991) test: £1.30	erythrocyte removal by agglutination reagent. Colorimetric measurement after reaction with dry reagent tablets	yes	++	MDD 91/08

continued

A4 Chemistry – lipids *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Lipids: Small analysers contd									
Reflotron 2000 (see page 170)	15 tests including: total cholesterol HDL cholesterol triglycerides (glucose)	whole blood serum plasma	quantitative	Boehringer Mannheim	£4617 test: £0.93–£1.91	analyser and dry chemistry reagent strips	yes	++	yes
Spotchem (see page 170)	17 tests including: total cholesterol HDL cholesterol triglycerides (glucose)	serum plasma	quantitative	Kyoto Daiichi Kagaku dist: Biomen	£10,000 test: £0.81–£2.20 multiple profile strip: £3.04	dry chemistry strips (auto pipetting)	yes	++	
Seralyser III (see page 171)	14 tests including: total cholesterol triglycerides (glucose)	plasma serum	quantitative	Bayer Diagnostics	(discontinued)	dry reagent strips	yes	++	
Minilab (see page 172)	7 tests including: total cholesterol HDL cholesterol triglycerides (glucose)	plasma	quantitative	Bayer Diagnostics	(discontinued)	liquid reagent-filled cuvette			
Pharmalab (see page 173)	6 tests including: total cholesterol triglycerides (glucose)	whole blood	quantitative	Callegari (Italy)		pre-filled liquid cuvettes		++	
Clin-check (see page 173)	11 tests including total cholesterol HDL cholesterol triglycerides (glucose)	serum	quantitative	Lifeline (UK)	£650 tests: £0.87–£1.19	pre-filled liquid cuvettes	yes	++	

continued

A4 Chemistry – lipids *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Lipids: Small analysers contd									
Miniphotometer (see page 173)	15 tests including: total cholesterol HDL cholesterol LDL cholesterol triglycerides (glucose)	whole blood serum or plasma	quantitative	Dr. Bruno Lange dist: Bodycare Products	£1790	pre-filled liquid cuvettes		++	
Chrometrics Cholesterol Test System	total cholesterol HDL cholesterol triglycerides (glucose)	plasma	quantitative	Chrometrics Laboratories (USA)		colorimetric monitoring of disposable reagent-filled cuvettes	yes	+++	yes
Biotrack	total cholesterol (glucose) (Hb)	whole blood	quantitative	Biotrack (Ciba-Corning Diagnostics)		disposable cartridges containing capillary tracks leading to dry reagents; 3 simultaneous colorimetric assays	yes	+	yes
Lipids: Large desktop analysers									
Vision (see page 177)	28 tests including: total cholesterol triglycerides HDL cholesterol (glucose)	whole blood serum plasma	quantitative	Abbott Diagnostics	£14,707 test: £1.90–£2.50	wet chemistries in disposable cassettes	yes	++	yes
Vitros DT60 II (Ektachem DT chemistry system (see page 178)	16 tests including: total cholesterol HDL cholesterol triglycerides (glucose)	whole blood serum plasma	quantitative	Johnson & Johnson Clinical Diagnostics dist: Shield Diagnostics	£5718 slides: £0.75–£2.56	dry chemistry slides	yes	+++	yes
PROCHEM (see page 179)	31 tests including: total cholesterol triglycerides HDL cholesterol apolipoprotein A1 apolipoprotein B (glucose)	serum plasma	quantitative	PrismaSystems	£8995 pre-filled liquid cassettes 1–15 simultaneous tests: £1.10–£4.06	pre-filled liquid cassettes; 1–15 simultaneous tests	yes	+++	

continued

A4 Chemistry – lipids *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Lipids: Large desktop analysers contd									
Analyst (see page 179)	18 tests including: HDL cholesterol LDL cholesterol VLDL cholesterol triglycerides (glucose)	serum plasma	quantitative	Dupont dist: Bio-Stat Diagnostics	£9214 14 chemistry rotor: £6.15 lipid profile rotor: £4.27 glucose-II rotor: £1.65	sealed rotor, simultaneous or single test	yes	++	
EASY ST (see page 180)	40 tests including: total cholesterol triglycerides	serum plasma whole blood	quantitative	EM Diagnostic Systems dist: BDH Diagnostics	?£15,000 test: £0.15–£2.50	disposable cuvettes containing dry powder reagents, with automatic fluid delivery	yes	++	yes

A5 Cardiac screening

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Cardiac screening: Non-instrumental									
CK–MB-Check-II	CK–mB		qualitative	Veda Laboratories (France)		flow-along immunoassay	yes (integral procedural control)	+	
Tandem Icon QSR	CK–mB	serum	qualitative	Hybritech (Europe)		flow-through immunoassay	yes (integral procedural control)	++	
MGL-Check I	myoglobin	serum	qualitative	Veda Laboratories (France)		flow-along immunoassay	yes (integral procedural control)	+	
Trop T	troponin T	whole blood	qualitative	Boehringer Mannheim	£9.99	flow-along immunoassay	yes (integral procedural control)	+	
Cardiac Status	anti-streptokinase	whole blood	qualitative	Spectral Diagnostics dist: Brownes (UK)					

continued

A5 Cardiac screening *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Cardiac screening: Non-instrumental contd									
VEDA LAB	myglobin CK–mB	serum	qualitative	Veda Laboratories (France)		flow-along immunoassay	yes (integral procedural control)	+	
Point-of-Care	myoglobin CK–mB myosin light chains troponin I streptokinase antibodies 2 test panel: CK–mB myoglobin 4 test panel: CK–mB myoglobin myosin light chains troponin I	whole blood plasma/ serum	quantitative	Spectral Diagnostics dist: Brownes (UK)	£13.50	flow-along immunoassay	yes (integral procedural control)	+	
LifeSign MI	myoglobin CK–mB myosin light chains troponin I streptokinase antibodies 2 test panel: CK–mB myoglobin 4 test panel: CK–mB myoglobin myosin light chains troponin I	plasma/ serum	quantitative	PBM Princeton (USA) BioMeditech Corporation (USA) dist: Dako dist: Cambridge Life Sciences		flow-along immunoassay	yes (integral procedural control)	+	

continued

A5 Cardiac screening *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Cardiac screening: Small analysers									
First 4	CK CK–mB myoglobin	whole blood	quantitative	First Medical		centrifugal blood separation, fluorescence immunoassay			
Reflotron 2000 (see page 170)	15 tests including: CK;AST	whole blood serum plasma	quantitative	Boehringer Mannheim	£4617 test: £0.93–£1.91	analyser and dry chemistry reagent strips	yes	++	yes
Spotchem (see page 170)	17 tests including: CK LDH AST	serum plasma	quantitative	Kyoto Daiichi Kagaku dist: Biomen	£10,000 test: £0.81–£2.20 multiple profile strip: £3.04	dry chemistry strips (auto pipetting)	yes	++	
Seralyser III (see page 171)	14 tests including: CK;AST	serum plasma	quantitative	Bayer Diagnostics	(discontinued)	dry reagent strips	yes	++	
Cardiac screening: Large desktop analysers									
Vision (see page 177)	28 tests including: CK;AST	whole blood serum plasma	quantitative	Abbott Diagnostics	£14,707 test: £1.90–£2.50	wet chemistries in disposable cassettes	yes	++	yes
Vitros DTE II (Ektachem DT chemistry system) (see page 178)	14 tests including: CK CK–mB LDH AST	serum plasma	quantitative	Johnson & Johnson Clinical Diagnostics dist: Shield Diagnostics	£2204 £0.93–£1.66	dry chemistry slides	yes	+++	yes
PROCHEM (see page 179)	31 tests including: CK CK–mB LDH AST	serum plasma	quantitative	PrismaSystems	£8995 pre-filled liquid cassettes 1–15 simultaneous tests: £1.10–£4.06	pre-filled liquid cassettes; 1–15 simultaneous tests	yes	+++	

A6 Screening for drugs of abuse and therapeutic drug monitoring

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Drugs of abuse screening: Non-instrumental									
Q.E.D.A350	alcohol	saliva	quantitative	Enzymatics (USA) dist: Cambridge Diagnostics Services	£2.00	visually assessed disposable device	yes	++	MDA 95/22
AlcoSure	alcohol	saliva	semi-quantitative	dist: Cambridge Life Sciences		paper test strip with immobilised enzyme reagents. Visual assessment of colorimetric endpoint		++	
AbuSign	cocaine;THC amphetamine barbiturate opiate/morphine metamphetamine PCP; benzodiazepine drug panel	urine	qualitative			flow-along immunoassay	yes (integral procedural control)	+	
FRONTLINE (* In development)	cocaine; cannabis opiates amphetamines* benzodiazepines* methadone*	urine	qualitative	Boehringer Mannheim	£4.50	flow-along immunoassay dipstick	yes (integral procedural control)	+	
Bionike A/Q	cocaine cannabinoids amphetamine metamphetamine barbiturates morphine (opiate/heroine/morphine) benzodiazepine methadone	urine	qualitative	dist: Gamidor	£2.00	flow-along immunoassay	yes (integral procedural control)	+	
E-Z Screen	cocaine; cannabinoid amphetamines barbiturates; opiate drug panel: cannabinoid/ cocaine/opiates drug panel: cannabinoid/cocaine	urine	qualitative	dist: Shield Diagnostics	£3.25 £7.75	flow-along immunoassay	yes (integral procedural control)	+	

continued

A6 Screening for drugs of abuse and therapeutic drug monitoring *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Drugs of abuse screening: Non-instrumental contd									
Accutest	cocaine THC (cannabinoids) amphetamine metamphetamine opiates/heroin/ morphine	urine	qualitative	JANT Pharmacal (USA)		flow-along immunoassay strip or platform format	yes (integral procedural control)	+	
First Check Panel 4	panel: marijuana (THC) morphine/opiates cocaine amphetamines	urine	qualitative	Worldwide Medical (USA)		flow-along immunoassay		+	
OnTrak TesTcup	panel: cocaine morphine THC	urine	qualitative	Roche Diagnostic Systems dist: Brownes (UK)	£15.00 £7.75	flow-along immunoassay integrated collection and testing device	yes (integral procedural control)	+	
AccuSign	cocaine THC (cannabis/ marijuana) amphetamine metamphetamine barbiturates opiate PCP benzodiazepines methadone tricyclic anti-depressants	urine	qualitative	PBM Princeton BioMeditech (USA)	single test: US $2.00	flow-along immunoassay	yes (integral procedural control)	+	
	2-drug panel: e.g. cocaine/THC				US $4.50				
	3-drug panel: e.g. benzodiazepines barbiturates PCP				US $7.10				
	4-drug panel: cocaine/THC/opiates amphetamine or metamphetamine				US $10.00				

continued

A6 Screening for drugs of abuse and therapeutic drug monitoring *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Drugs of abuse screening: Non-instrumental contd									
VisualineII	cocaine morphine marijuana PCP metamphetamine	urine	qualitative	Hanson Hong Biomedical		flow-along immunoassay	yes (integral procedural control)	+	
Easy Card	amphetamine metamphetamine cannabinoids cocaine, morphine	urine	qualitative	dist: Lifeline (UK)	£2.85/single test	flow-along immunoassay		+	
ToxiQuick	opiates cannabinoids cocaine amphetamine benzodiazepines methadone barbiturates (and metabolites)	urine	qualitative	Cambridge Life Sciences	£2.50/single test	visual flow-along immunoassay	yes (integral procedural control)	+	
Abuscreen Ontrak	cocaine, THC methadone amphetamine barbiturates PCP benzodiazepines	urine	qualitative	Roche Diagnostic Systems		latex agglutination with viewing track detection	yes (integral procedural control)	++	
Fingerprint-DOA	simultaneous detection of: amphetamine cocaine, opiates PCP cannabinoids	urine saliva	qualitative	Fingerprint Biotek		flow-through immunoassay with personal identification by fingerprint	yes (integral procedural control)		
Triage	PCP benzodiazopines cocaine amphetamine/ metamphetamine tetrahydrocannabinol opiates barbiturates methadone	urine	qualitative	Biosite Diagnostics dist: Merck	 £29.80 for test panel	simultaneous multiple flow across immunoassay. Ascend Multi Immunno Assay	yes (integral procedural control)	++	

continued

A6 Screening for drugs of abuse and therapeutic drug monitoring *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Therapeutic drug monitoring: Non-instrumental									
Accumeter	theophylline	whole blood serum plasma	quantitative	Chemtrak		flow-along immunoassay with visual height reading	yes (integral procedural control)	++	
Acculevel	theophylline phenobarbital phenytoin carbamazapine	whole blood	quantitative	dist: Syva (UK)	(discontinued)	flow-along immuno-chromatography	yes	++	
Therapeutic drug monitoring: Small analysers									
Stat-Site	paracetamol **Future:** theophylline	whole blood serum plasma	quantitative	GDS Diagnostics		dry reagent card		++	
Biotrack 516	theophylline carbamazepine theophenytoin	whole blood	quantitative	Ciba Corning		single-use test cartridge; competitive latex-based immuno-assay with turbidimetric endpoint		++	yes
Seralyser III **(see page 171)**	carbamazepine	serum plasma	quantitative	Bayer Diagnostics	(discontinued)	dry reagent strips	yes	++	
Therapeutic drug monitoring: Large desktop analysers									
Vision **(see page 177)**	29 tests including: phenytoin theophylline	whole blood serum plasma	quantitative	Abbott Diagnostics	£14,707 test: £1.90–£2.50	wet chemistries in disposable cassettes	yes	++	yes
Vitros DTE II **(see page 178)**	14 tests including: theophylline	serum plasma	quantitative	Johnson & Johnson Clinical Diagnostics dist: Shield Diagnostics	£2204 £0.93–£1.66	dry chemistry slides	yes	+++	yes
Analyst **(see page 179)**	18 tests including: theophylline	serum plasma	quantitative	Dupont dist: Bio-Stat Diagnostics	£9214	sealed rotor, simultaneous or single test	yes	++	
EASY ST **(see page 180)**	40 tests including drugs	serum plasma	quantitative	EM Diagnostic Systems dist: BDH Diagnostics	£15,000 (1990) test: £0.15–£2.50	disposable cuvettes containing dry powder reagents, with automatic fluid delivery	yes	++	yes

A7 Fertility and pregnancy

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Fertility: Non-instrumental – ovulation prediction									
Bioself	female fertility indicator: (basal body temp.)	non-invasive	qualitative	dist: Royce Laboratories		microcomputer controlled thermometer measurement of basal body temp. throughout menstrual cycle	+		
OvuKit	LH	urine	semi-quantitative	Quidel dist: Digen		OTC dipstick enzyme immunoassay using immobilised antibody; sequential incubation with liquid reagents	yes (integral procedural control)	++	
Clearplan One Step (home ovulation test)	LH	urine	semi-quantitative	Unipath	£11.80 (box of 5)	one step flow-along immunoassay with mid-stream urine collection and antibody coated blue latex particles on porous media	yes (integral procedural control)	+	
SAS One-Step Ovulation	LH	urine	qualitative	SA Scientific dist: Brownes (UK)	£2.50	flow-along immunoassay	yes (integral procedural control)	+	
Conceive ovulation predictor	LH	urine	semi-quantitative	Quidel dist: Digen		platform, flow-along immunoassay	yes (integral procedural control)	+	
OvuQuick (self test)	LH	urine	semi-quantitative	Quidel		flow-through colorimetrically monitored enzyme immunoassay	yes (integral procedural control)	++	
VEDA LAB	LH	urine	qualitative	Veda Laboratories (France)		flow-along inmmunoassay	yes (integral procedural control)	+	
Ovutime	LH	urine	qualitative	Ortho Diagnostics		dipstick enzyme immunoassay using immobilised antibody; sequential incubation with liquid reagents	yes (integral procedural control)	++	yes
OvuSTICK	LH	urine	qualitative	Monoclonal Antibodies (USA)		dipstick enzyme immunoassay using immobilised antibody; sequential incubation with liquid reagents	yes (integral procedural control)	++	yes
Fertility status – Small analysers									
SQA Sperm Quality Analyser	sperm cell conc. sperm % motility % normomorphology	semen	quantitative	dist: Merck	£2000 test profile: £2.00			++	
FertilitySCORE	OTC male fertility test: sperm activity	semen	quantitative	Fertipro dist: Microm (UK)	kit: £25	tube based; visual redox reaction		++	

continued

A7 Fertility and pregnancy *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Pregnancy testing: Non-instrumental									
TestPack Plus hCG Urine	hCG	urine	qualitative	Abbott Diagnostics	£3	flow-along immunoassay	yes (integral procedural control)	+	
TestPack Plus hCG Combo		urine serum			£6				
Clearblue Onestep (home step)	hCG	urine	qualitative	Unipath	£6.50 (double test)	one step flow-along immunoassay with mid-stream urine collection and antibody-coated blue latex particles on porous media	yes (integral procedural control)	+	
Clearview HCGII	hCG	urine	qualitative	Unipath	£1.86	flow-along immunoassay	yes (integral procedural control)	+	
Clearview HCGDUO					£3				
Tandem Icon II HCG	hCG	urine	semi-quantitative	Hybritech		flow-through colorimetrically monitored enzyme immunoassay	yes (integral procedural control)	++	
				dist: Brownes	£2.20				
Tandem Icon II HCG (serum/urine)	hCG	serum urine	semi-quantitative	Hybritech (Europe)		flow-through colorimetrically monitored enzyme immunoassay	yes (integral procedural control)	++	
				dist: Brownes (UK)	£2.80				
Osom Test Strip	hCG	urine	qualitative	Wyntek Diagnostics (USA)		visual flow-along immunoassay	yes (integral procedural control)	+	
Fertitex Mono	hCG	urine	qualitative	Bio-Stat Diagnostics		latex slide agglutination test	yes (integral procedural control)	++	
Fertitex Duo									
SAS Direct hCG									
Insta Test Onestep hCG Combo		serum or urine							
One-step Generation	hCG	urine	qualitative	Veda Laboratories (France)		flow-through immunoassay	yes (integral procedural control)	++	
Tandem Icon	hCG	serum	semi-quantative	Hybritech (Europe)		flow-through immunoassay	yes (integral procedural control)	++	

continued

A7 Fertility and pregnancy *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Pregnancy testing: Non-instrumental contd									
SureCell	hCG	urine	qualitative	Kodak Clinical Products		flow-through immunoassay	yes (integral procedural control)	++	
SureCheck **STAT-PAK** **FASTEST one step**	hCG	urine serum urine	qualitative	Chembio Diagnostic Systems (USA)		flow-along sandwich immunoassay	yes (integral procedural control)	+	
Conceive **Quick Vue Onestep (urine)** **Quick View Onestep (hCG-Combo)**	hCG	urine serum urine	qualitative	Quidel dist: Digen		flow-along immunoassay	yes (integral procedural control)	+	
Concise Plus	hCG	urine	qualitative	Rapid Diagnostic Technologies		flow-along sandwich immunoassay	yes (integral procedural control)	+	
SAS serum/urine	hCG	serum urine	qualitative	SA Scientific		flow-along sandwich immunoassay	yes (integral procedural control)	+	
Auratek	hCG	urine, plasma, serum	qualitative	Organon Teknika		flow-along sandwich immunoassay	yes (integral procedural control)	+	
Immuno/hCG detector **Immuno/hCG detector Stix**	hCG	urine	qualitative	Immunostics (USA)		flow-along immunoassay	yes (integral procedural control)	+	
Contrast hCG	hCG	urine serum	qualitative	Medix Biotech (USA)		flow-along immunoassay	yes (integral procedural control)	+	
SAS-1	FSH	urine	qualitative	SA Scientific		flow-along sandwich immunoassay	yes (integral procedural control)	+	
VEDA LAB	FSH, hCG, prolactin	urine	qualitative	Veda Laboratories (France)		flow-along inmmunoassay	yes (integral procedural control)	+	
Fertility test strips: Instrumental – contraception									
PERSONA	FSH oestrone-3-glucuronide	urine	semi-qualitative	Unipath	Instrument: £49.95 One month test strip: £9.95	disposable dipstick immunoassay with hand-held reader with ovum and sperm survival times	yes (integral procedural control)	+	

A8 Cancer screening

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Cancer screening: Non-instrumental – faecal occult blood									
Hemacheck	blood	faeces	semi-quantitative	Bayer Diagnostics	£0.45	colorimetric peroxidase activity	yes	+	
Hemdetect	blood	faeces	qualitative	Dipro Diagnostic Products dist: Autogen Bioclear (UK)		colorimetric peroxidase activity	yes	+	
Haemoccult	blood	faeces	qualitative	YSI dist: Smith Kline Diagnostics	 £0.45	colorimetric peroxidase activity	yes	+	yes
Hema Screen	blood	faeces	qualitative	Biostat Diagnostics	£0.38	colorimetric peroxidase activity	yes	+	
Ez Detect	blood	feaces	qualitative	Biomerica dist: Allerayde Diagenics	 £6.00	colorimetric peroxidase activity; home test with no specimen handling	yes	+	
Hexagon OBTI	human Hb	faeces	qualitative	Biostat Diagnostics	£3.54	visual immuno-chromatography	yes	+	
FOBT	human Hb and transferrin	faeces	qualitative	Mizuho		visual simultaneous immuno-chromatography	yes	+	
SAS	human Hb	faeces	qualitative	SA Scientific (USA) dist: Brownes (UK)	 £2.07	visual immuno-chromatography	yes	+	
JANT fecal occult blood (Hb test)	human Hb	faeces	qualitative	Jant Pharmacal (USA)		visual immuno-chromatography	yes	+	
Flexsure	human Hb	faeces	qualitative	SmithKline Diagnostics (USA)		visual immuno-chromatography	yes	+	
BioSign Hemo	human Hb	faeces	qualitative	Dako dist: CambridgeLife Sciences		visual immuno-chromatography	yes	+	

continued

A8 Cancer screening *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Cancer screening: Non-instrumental – various									
Accutest	alpha fetoprotein	serum or plasma	qualitative	Jant Pharmacal (USA)		flow-along immunoassay	yes (integral procedural control)		
VEDA LAB	PSA	serum	qualitative	Veda Laboratories (France)		flow-along inmmunoassay	yes (integral procedural control)	+	
BTA	basement membrane proteins (tumour marker for bladder cancer)	urine		Bard Diagnostic-Sciences (USA)					
BTA TRAK BTA Stat	bladder tumour antigen	urine	qualitative	Bard Diagnostic Sciences (USA)		flow-along immunoassay	yes (integral procedural control)	+	

A9 Allergy testing

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Allergy testing: Non-instrumental									
QuickVue one step allergy screen	IgE antibodies to 5 indoor allergens	blood	qualitative	Quidel dist: Allerayde		flow-along immunoassay	yes (integral procedural control)	+	yes
Quidel Allergen Screens	IgE antibodies to 10 common inhalants	blood serum	qualitative	Quidel dist: Allerayde	£12.50	colorimetric enzyme immunoassay, using dipstick technology	yes (integral pos. and neg. controls)	++	
	IgE antibodies to 10 food allergens				£12.50				
	IgE antibodies to venoms (yellow jacket and honey bee)				£8.50				
MAST CLA Allergen Specific IgE Assay	IgE antibodies to multiple allergens	serum	semi-quantitative	Mast Immunosystems dist: Micon (UK)		chemiluminescence; photographic monitoring of ELISA in cassette containing multiple cellulose threads with bound allergen	yes (integral pos. and neg. controls)	++	

continued

A9 Allergy testing *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Allergy testing: Non-instrumental									
MAST CLA	IgE antibodies to up to 36 allergens	serum	semi-quantitative	Mast Immunosystems dist: Micon (UK)		IgE binding to specific bound allergens measured by chemiluminescence with meter detection	yes (integral pos. and neg. controls)	++	
QuickDot	IgE	serum	semi-quantitative	Diatech Diagnostics					
VEDA LAB	total IgE			Veda Laboratories (France)					

A10 TSH Screening

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
TSH – Check 1	TSH adult > 5 µIU/l paediatric > 15 µIU/l	whole blood serum plasma	semi-quantitative	Veda Laboratories		flow-along, 10 minute immunoassay using diluent	yes (integral procedural control)	++	

B MICROBIOLOGY (this section includes virology and parasitology)

B1 Infectious diseases

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Microbiology: Non-instrumental – HIV									
DoubleCheck HIV-1/HIV-2	antibodies to HIV-1 and HIV-2	serum plasma	qualitative	Orgenics (Israel)		combination of flow-through and flow-along immunoassay	yes (integral procedural control)	+	
SeroCard HIV-1/HIV-2	antibodies to HIV-1 and HIV-2	whole blood serum, plasma	qualitative	Trinity Biotech dist: Incstar		membrane-based ELISA with bi-directional lateral chromatography	yes (integral procedural control)	++	
TestPack HIV-1 /HIV-2	antibodies to HIV-1 and HIV-2	serum plasma	qualitative	Abbott Diagnostics	£8.15	flow-through colorimetrically monitored enzyme immunoassay	yes (integral procedural control)	++	
Capillus	antibodies to HIV-1 and HIV-2	whole blood serum, plasma	qualitative	Cambridge Biotech Alpha Laboratories		latex agglutination test in a capillary slide with viewing window			
HIVSAV 1+2 Rapid Serotest	antibodies to HIV-1 and HIV-2	serum plasma	qualitative	Savyon Diagnostics dist: Omni-Triage Medical		flow-through gold labelled immunoassay	no	++	
Rapid	antibodies to HIV-1 and HIV-2	serum plasma	qualitative	Metachem Diagnostics Clonatec		flow-through enzyme immunoassay		++	
HIV-RIT	antibodies to HIV-1 and HIV-2	whole blood serum, plasma	qualitative	Oxymedyca (USA)		lateral flow immuno-chromatography	yes (integral procedural control)	+	
SalivaCard HIV-1/HIV-2	antibodies to HIV-1 and HIV-2	saliva	qualitative	Trinity Biotech dist: Incstar		membrane-based ELISA with bi-directional lateral chromatography	yes (integral procedural control)	++	
Genie	antibodies to HIV-1	serum	qualitative	Genetic Systems (USA)		flow-through enzyme immunoassay	yes (integral procedural control)	++	yes
Microbiology: Non-instrumental – Hepatitis B (HB)									
Hepator HBs Ag	HB surface antigen	serum plasma	qualitative	Bionike dist: Gamidor	£2.50	flow-along colloidal gold-based immunoassay	yes (integral procedural control)	+	
Hepator HBs Ab	antibody to HB surface antigen	serum plasma	qualitative	Bionike dist. Gamidor	£2.75	flow-along colloidal gold-based immunoassay	yes (integral procedural control)	+	
Hepator HBe Ag	HBe antigen	serum plasma	qualitative	Bionike dist: Gamidor	£3.00	flow-along colloidal gold-based immunoassay	yes (integral procedural control)	+	
Hepator HBe Ab	antibody to HBe antigen	serum plasma	qualitative	Bionike dist: Gamidor	£3.12	flow-along colloidal gold-based immunoassay	yes (integral procedural control)	+	
Hepator HBc Ab	antibody to HB core antigen	serum plasma	qualitative	Bionike dist: Gamidor	£3.12	flow-along colloidal gold-based immunoassay	yes (integral procedural control)	+	

continued

B1 Infectious diseases *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Microbiology: Non-instrumental – Hepatitis B (HB) contd									
Hepator HBc Ab IgM (Bionike Advanced)	IgM antibody to HB core antigen	serum plasma	qualitative	Bionike dist: Gamidor	£3.00	flow-along colloidal gold-based immunoassay	yes (integral procedural control)	+	
VEDA LAB	HB surface antigen	serum plasma	qualitative	Veda Laboratories (France)		flow-along immunoassay			
Immuno/hepa-trax	HB surface antigen	serum plasma	qualitative	Immunostics (USA)		flow-along immunoassay	yes (integral procedural control)	+	
FASTEST one test	HB surface antigen	serum plasma	qualitative	Chembio Diagnostic Systems (USA)		flow-along immunoassay	yes (integral procedural control)	+	
Microbiology: Non-instrumental – **H. pylori**									
FlexPack HP	antibodies to *H. pylori*	serum	qualitative	SmithKline Diagnostics (Flexsure) dist: Abbott Diagnostics	£9.55	reverse flow immunochromatography	yes (integral procedural control)	++	
QuickVue	antibodies to *H. pylori*	whole blood	quantitative	Quidel dist: Allerayde	£9.00	flow-along immunoassay	yes (integral procedural control)	+	
BioSign H. Pylori WB	antibodies to *H. pylori*	whole blood	quantitative	Princeton BioMeditech (USA) dist: Dako dist: Cambridge Life Sciences	$5.50	flow-along immunoassay	yes (integral procedural control)	+	
Accumeter Helicobacter pylori	antibodies to *H. pylori*	whole blood	quantitative	Chemtrak dist: Diagnostic Testing	£7.99	flow-along immunoassay	yes (integral procedural control)	++	
Helisal	antibodies to *H. pylori*	whole blood	qualitative	Cortecs Diagnostics Boehringer Mannheim (Germany)		flow-through enzyme immunoassay	yes (integral procedural control)	++	
Accumeter H. pylori	antibodies to *H. pylori*	whole blood	qualitative	Chemtrak	£15.00	flow-along immunoassay	yes (integral procedural control	+	
ImmunoCard H. Pylori	antibodies to *H. pylori*	serum or plasma	qualitative	Meridian Diagnostics		membrane-based ELISA with bi-directional lateral chromatography	yes (integral procedural control)	++	
Biocard H. Pylori	antibodies to *H. pylori*	whole blood	qualitative	Ani Biotech		flow-along immunoassay	yes (integral procedural control	+	

continued

B1 Infectious diseases *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Microbiology: Non-instrumental – **Streptococcus A/B**									
Clearview Strep A	*streptococcus* group A antigens	throat swab	qualitative	Unipath	£1.78	extraction followed by flow-along one step immunoassay	yes (integral procedural control)	++	
Contrast Strep A	*streptococcus* group A antigens	throat swab	qualitative	Genzyme Diagnostics (USA)		swab extraction followed by flow-through colorimetric enzyme immunoassay	yes (integral procedural control)	+	
Icon Strep A	*streptococcus* group A antigens	throat swab	qualitative	Hybritech dist: Brownes (UK)	 £3.75	swab extraction followed by flow-through colorimetric enzyme immunoassay	yes (integral procedural control)	++	
SureCell	*streptococcus* group A antigens		qualitative	Kodak Clinical Products		flow-through enzyme immunometric assay	yes (integral procedural control)	++	
Smart	*streptococcus* group A antigens	swab	qualitative	Rohm Pharma		flow-through immunoassay after swab extraction	yes (integral procedural control)	++	
OSOM Strep A	*streptococcus* group A antigens	throat swab or culture colonies	qualitative	Wyntek Diagnostics		dipstick immunochromatography	yes (integral procedural control)	+	
ImmunoCard Strep A	*streptococcus* group A antigens	throat swab	qualitative	Meridian Diagnostics		membrane-based ELISA with bi-directional lateral chromatography	yes (integral procedural control)	++	
FAStrep A	*streptococcus* group A antigens		qualitative	Medix Biotech (USA)		flow-along immunoassay	yes (integral procedural control)	++	
FASTEST one step	*streptococcus* group A antigens		qualitative	Chembio Diagnostic Systems (USA)		flow-along immunoassay			
PathoDx	*streptococcus* group A antigens	throat swab	qualitative	Diagnostic Products (USA)		swab extraction followed by latex agglutination		++	yes
Phadirect Strep.A	*streptococcus* group A antigens	throat swab	qualitative	Pharmacia Biosystems		swab extraction followed by latex agglutination		++	yes
TestPack Strep A	*streptococcus* group A antigens	throat swab	qualitative	Abbott Diagnostics		swab followed by flow-through colorimetrically monitored enzyme immunoassay	yes (integral procedural control)	++	yes
Respiralex	*streptococcus* group A antigens	throat swab	qualitative			swab extraction followed by latex agglutination		++	yes
Culturette Brand 10-Min Group A Strep ID	*streptococcus* group A antigens	throat swab	qualitative	Marion Scientific (USA)		swab extraction followed by latex agglutination	yes (integral procedural control)	++	yes

continued

B1 Infectious diseases *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Microbiology: Non-instrumental – **Streptococcus A/B** *contd*									
Reveal	*streptococcus* group A antigens	throat swab	qualitative	Wellcome Diagnostics			yes (integral procedural control)	++	yes
Ventrescreen Strep A	*streptococcus* group A antigens	throat swab	qualitative	Ventrex Laboratories (USA)			yes (integral procedural control)	++	yes
Directogen Strep A	*streptococcus* group A antigens	throat swab	qualitative	Becton Dickinson Diagnostics dist: Gamidor		swab extraction with immunoassay	yes (integral procedural control)	++	
QuickView In-line One-Step Strep A Test	*streptococcus* group A and B antigens	throat swab	qualitative	Quidel dist: Diagen Ltd.		in-line antigen extraction and flow-along immunoassay	yes (integral procedural control)	+	
Icon Strep B	*streptococcus* group B antigens	throat swab	qualitative	Hybritech dist: Brownes (UK)	£5.42	swab extraction followed by flow-through colorimetric enzyme immunoassay	yes (integral procedural control)	++	
VEDA LAB	*streptococcus* group B antigens	throat swab	qualitative	Veda Laboratories (France)		flow-along immunoassay			
Microbiology: Non-instrumental – Chlamydia trachomatis									
SureCell	chlamydia trachomatis antigen	endocervical or urethral swab	qualitative	Kodak Clinical Products		flow-through enzyme immunometric assay	yes (integral procedural control)	++	
FASTEST one step	chlamydia trachomatis antigen	endocervical or urethral swab	qualitative	Chembio Diagnostic Systems (USA)		specimen extraction followed by flow-along immunoassay			
QuickView chlamydia	chlamydia trachomatis antigen	endocervical or urethral swab	qualitative	Quidel dist: Diagen		in-line antigen extraction and flow-along immunoassay	yes (integral procedural control)	+	
TestPack chlamydia	chlamydia trachomatis antigen	endocervical or urethral swab	qualitative	Abbott Diagnostics	£6.10	specimen extraction followed by flow-through colorimetrically monitored enzyme immunoassay	yes (integral procedural control)	++	
Chlamyfast solus	chlamydia trachomatis antigen	genital or occular swab	qualitative	International Mycoplasma		specimen extraction followed by flow-along immunoassay	yes (integral procedural control)	++	
Quickstripe Chlamydia-Ag	chlamydia trachomatis antigen	endocervical or urethral swab, male urine	qualitative	Savyon Diagnostics (Israel) dist: Gamidor		specimen extraction followed by flow-along immunoassay	yes (integral procedural control)	++	
Clearview Chlamydia	chlamydia trachomatis antigen	endocervical or urethral swab, male urine	qualitative	Unipath	£1.78	specimen extraction followed by flow-along immunoassay	yes (integral procedural control)	++	

continued

B1 Infectious diseases *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Microbiology: Non-instrumental – various									
Anda TB IgG	IgG for TB (M. tuberculosis M. avium M. leprae)	serum plasma	qualitative	Anda Biologicals		immuno-chromatography	yes (integral procedural control)	+	
TB STAT-PAK	antibodies to M. tuberculosis	serum	qualitative	Chembio Diagnostic Systems (USA)		flow-along immunoassay	yes (integral procedural control)	++	
TestPack rotavirus	rotavirus antigen	faeces	qualitative	Abbott Diagnostics	£6.75	flow-through colometrically monitored enzyme immunoassay	yes (integral procedural control)	++	
ImmunoCard rotavirus	rotavirus antigen	faeces	qualitative	Meridian Diagnostics		membrane-based ELISA with bi-directional lateral chromatography	yes (integral procedural control)	++	
Clearview IM	heterophile antibodies against infectious mononucleosis	serum plasma	qualitative	Unipath	£1.75	one step flow-along immunoassay	yes (integral procedural control)	+	
ImmunoCard mono	antibodies to mononucleosis	serum plasma	qualitative	Meridian Diagnostics		membrane-based ELISA with bi-directional lateral chromatography	yes (integral procedural control)	++	
Mono-plus	antibodies to mononucleosis	serum plasma	qualitative	Carter-Wallace International (USA)		flow-along immunoassay	yes (integral procedural control)	++	
ImmunoCard Mycoplasma	antobodies to mycoplasma	serum plasma	qualitative	Meridian Diagnostics		membrane-based ELISA with bi-directional lateral chromatography	yes (integral procedural control)	++	
TestPack RSV	respiratory syncytial virus	naso-pharangeal aspirates, washes and swabs	qualitative	Abbott Diagnostics	£6.75	specimen treatment followed by flow-through colometrically monitored enzyme immunoassay	yes (integral procedural control)	++	
Directogen RSV	respiratory syncytial virus	naso-pharangeal aspirates, washes and swabs	qualitative	Becton Dickinson Diagnostics		specimen treatment followed by immunoassay	yes (integral procedural control)	++	
Kodak Surecell Herpes (HSV) Test Kit	herpes 1 and 2 antigens	genital, anal or external swabs	qualitative	Kodak Clinical Products		extraction followed by flow-through immunoassay	yes (integral procedural control)	++	
Kodak Evalusite	periodontal bacterial antigens (3 bacteria)	periodontal scrapings	qualitative	Kodak Clinical Products		flow-through immunoassay	yes (integral procedural control)	++	

continued

B1 Infectious diseases *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Microbiology: Non-instrumental – various contd									
SAS One Step adenovirus	adenovirus antigen	naso-pharangeal, throat and rectal swabs, cell culture	qualitative	SA Scientific		extraction followed by flow-along immunoassay	yes (integral procedural control)	++	
ParaSight F	plasmodium falciparum antigen (malaria)	whole blood	qualitative	Becton Dickinson Diagnostics dist: Gamidor	£3.50	red cell lysis and sequential liquid reagent addition to an antibody coated test strip	yes (integral procedural control)	++	MDA 96/33
Directigen Influenza A kit	influenza A antigen	swab	qualitative	Becton Dickinson Diagnostics dist: Gamidor	£6.35	flow-through liposome immunoassay	yes (integral procedural control)	++	
BioSign Rubella	rubella antibody (IgG/IgM)	serum plasma	qualitative	Princeton Biomedical (USA) dist: Dako dist: Cambridge Life Science	$1.86	flow-along colloidal gold-based immunoassay	yes (integral procedural control)	+	
CMV Scan	CMV	serum or plasma	qualitative	Gamidor		latex agglutination	yes (integral procedural control)	++	
Microbiology: Non-instrumental – general infection									
FloraClear	bacterial vaginosis	vaginal secretion	qualitative	dist: Royce Laboratories		odour development in alkaline environment		++	
UriScreen	bacteruria pyuria haematuria	urine	semi-quantitative	Diatech Diagnostics				++	
Nyococard CRP	CRP	serum whole blood	quantitative	dist: Nycomed (UK)	£1.15 £1.44	flow-through immunoassay			MDD 92/54 yes
Microbiology: Small desktop analysers									
Mini-ves	ESR	whole blood	quantitative	Biomen Diagnostics	£575 tubes: £0.31	automatic sedimentation reading		+	
QuickRead CRP	CRP	whole blood	quantitative	Orion Diagnostica (Finland)		small photometer, cuvettes coated with blood separating reagent, and liquid reagents			
Microscope	various micro-biological and haematological applications	various	qualitative	Olympus		direct microscopy			

B2 Microbiology urinalysis – Multiple test strips (see under diabetes for details of strips specifically for glucose, ketones and microalbumin)

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Multistix GP **Multistix10SG** **Multistix 8SG** **Multistix SG** **N-Multistix SG** **Labstix SG**	multi analytes from: leucocytes nitrites proteins blood glucose bilirubin ketones specific gravity urobilinogen pH	urine	semi-quantitative	Bayer Diagnostics	£0.33 £0.34 £0.29 £0.29 £0.34 £0.25	colorimetric dry reagent strips	no	+	Multistix 8SG: STD 90/39
Clinitek 50 **Clinitek 100**	instruments for measuring Multistix 8 and 10SG test strips	urine	quantitative	Bayer Diagnostics	£1500	semi-automated reflectance spectrophotometry		+	STD 90/39
Labstix	blood	urine	semi-quantitative	Bayer Diagnostics	£0.26	colorimetric dry reagent strips	no	+	
Bili-stix					£0.29				
N-labstix					£0.29				
Uristix					£0.16				
Hema-combistix					£0.30				
Hemastix					£0.25				yes
BM-Test GP **BilugenTest** **Keto-Diabur-Test 5000** **BM-Test 3** **BM-Test 4** **BM-Hopitest** **BM-Test 5L**	glucose, protein bilirubin urobilinogen glucose, ketones pH, protein, glucose nitrite, pH, protein glucose protein, glucose ketones, blood pH, protein, glucose ketones, blood	urine	semi-quantitative	Boehringer Mannheim	£0.09 £0.18 £0.10 (on drug tariff) £0.09 £0.13 £0.13 £0.14	colorimetric dry reagent strips	no	+	

continued

B2 Microbiology urinalysis – Multiple test strips (see under diabetes for details of strips specifically for glucose, ketones and microalbumin) *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
continued									
Nephur-Test+leuco	leucocytes, nitrite pH, protein, glucose blood				£0.22				
BM-Test 7	pH, protein, glucose ketones, uroblinogen bilirubin, blood				£0.16				
BM-Test 8	nitrite, pH, protein glucose, ketones urobilinogen, biliribin blood				£0.22				
BM-Test-LN	leucocytes, nitrite								
Combur-Test	pH, protein	urine	semi-quantitative	Boehringer Mannheim	colorimetric dry reagent strips		no	+	yes
N-Combur-Test	glucose, pH, nitrite protein, glucose								
Combur-4 Test	protein, glucose, urobilinogen, blood								
Combur-5 Test+leuco	leucocytes, nitrite protein, glucose urobilinogen, blood								
Combur-6 Test+leuco	pH, leucocytes nitrite, protein glucose, urobilinogen blood								
Combur-8 Test	pH, nitrite, protein glucose, ketones urobilinogen, bilirubin blood								
Combur-9 Test	pH, leucotes, nitrite protein, glucose, ketones urobilinogen, bilirubin blood								
Combur-10 Test	specific gravity, pH leucocytes, nitrite protein, glucose ketones, urobilinogen bilirubin, blood								

continued

B2 Microbiology urinalysis – Multiple test strips (see under diabetes for details of strips specifically for glucose, ketones and microalbumin) *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
continued									
Miditron Junior	Combur-10 tests								
Cytur-Test	leucocytes								
Ecur-Test	protein glucose blood								
Ecur-4 Test	leucocytes protein glucose blood								
L-Combur 5 Test	pH protein glucose ketones blood								
Nephur-Test	pH nitrite protein glucose blood								
Nephur-Test+leuco	pH leucocytes nitrite protein glucose								
Nephur 7 Test	blood pH leucocytes nitrite protein glucose ketones								
Nitur-Test	blood, nitrite								
Ratio-Test	nitrite								
Sangur-Test	glucose, blood								
URS-9	specific gravity pH, nitrite, protein glucose, ketones urobilinogen bilirubin, blood	urine	qualitative	Teko Diagnostics (USA)		colorimetric dry reagent strips	no	+	

C Haematology

C1 General haematology

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Haematology: Non-instrumental									
Bedside Card	ABO compatibility blood testing	whole blood	qualitative	Diagast dist: Quest Biomedical		impregnated reagent cards		+	
HemoCard Hb S	Hb S	whole blood	qualitative	Isolab (USA)		monoclonol antibody based detection	yes	+	
HemoCard Hb C and Hb E	Hb C and Hb E	whole blood	qualitative	Isolab (USA)		monoclonol antibody based detection	yes	+	
Sickle-STAT	Hb S	whole blood	qualitative	Chembio Diagnostic Systems (USA)		sodium dithionite deoxygenation of Hb S with visual turbidimetric measurement of insoluble product			
Nycocard D-Dimer	D-dimer	plasma	semi-quantitative (quantitative with reader)	Nycomed Pharma dist: Nycomed (UK)	£2.60	flow-though immunoassay with visual comparison of test colour	yes (integral procedural control)		yes
Haematology: Small analysers									
AVL tHb I	Hb	whole blood	quantitative	AVL Medical Instruments		disposable pre-filled cuvette		++	
Hemocue B-Hemoglobin Analyser with Data Management	Hb	whole blood	quantitative	Hemocue	£625 micro-cuvettes: £0.45 £975	self-filling micro-cuvette containing enzyme and colorimetric reagents	yes	+	MDA 95/21
Microspin Centrifuge	Hct	whole blood	quantitative	Bayer Diagnostics		centrifugal analysis followed by visual measurement		+	
Mini-ves	ESR	whole blood	quantitative	Biomen Diagnostics	£575 tubes: £0.31	automatic sedimentation reading		+	
Biotrack	Hb (glucose) (total cholesterol)	whole blood	quantitative	Biotrack (Ciba-Corning Diagnostics)		disposable cartridges containing capillary tracks leading to dry-reagents. 3 simultaneous colorimetric assays	yes	+	yes
QBC Autoread	Hct, Hb, MCHC, platelet count, total WBC, absolute and % granulocyte ratio abs. and % lymphocyte/ monocyte ratio	whole blood	quantitative	Becton Dickinson Diagnostics dist: Gamidor	£7995 QBC capillary tubes: £1.50	capillary blood collected in pre-coated tubes, centrifuged with buffy coat scanning		+++	

continued

C1 General haematology *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Haematology: Small analysers contd									
Chemalab (see page 172)	5 tests including Hb Hct erythrocytes	whole blood	quantitative	Trio Diagnostics dist: Lifeline (UK)	meter: £360 test: £1.19	liquid reagent-filled cuvette		++	
Minilab (see page 172)	7 tests including Hb erythrocytes	whole blood	quantitative	Bayer Diagnostics	(discontinued)	liquid reagent-filled cuvette		++	
Pharmalab (see page 173)	6 tests including Hb Hct erythrocytes	whole blood	quantitative	Callegari (Italy)		pre-filled liquid cuvettes		++	
Reflotron 2000 (see page 170)	15 test including Hb	whole blood	quantitative	Boehringer Mannheim	£4617 test: £0.93–£1.91	analyser and dry chemistry reagent strips	yes	++	yes
Spotchem (see page 170)	17 tests including Hb	whole blood	quantitative	Kyoto Daiichi Kagaku dist: Biomen	£10,000 tests: £0.81–£2.20	dry chemistry strips (auto pipetting)	yes	++	
Seralyser III (see page 171)	14 tests including Hb	whole blood	quantitative	Bayer Diagnostics	(discontinued)	dry reagent strips	yes	++	
Clin-check (see page 173)	11 tests including Hb Hct erythrocytes	whole blood	quantitative	dist: Lifeline (UK)	£650 tests: £0.87–£1.19	pre-filled liquid cuvettes	yes	++	
Miniphotometer LMN18-P (see page 173)	15 tests including Hct Hb erythrocytes	whole blood	quantitative	Dr. Bruno Lange dist: Bodycare Products	£1790	pre-filled liquid cuvettes		++	
Futrex 9000	Hb	non-invasive (blood)	quantitative	Futrex		near-IR scanning through finger		++	

continued

C1 General haematology *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Haematology: Large desktop analysers									
Coulter MD II (8 parameter) **(10 parameter)** **(18 parameter)**	WBC, RBC, Hb, Hct, MCV, MCH, MCHC, platelet count	whole blood	quantitative	Coulter Electronics	£10,000 test: £0.48 £12,500	automatic particle counting technology, and colorimetric Hb	yes	++	
Excell 10	WBC, RBC, RDW,Hb, Hct, MCV, MCH, MCHC, platelet count, MPV	whole blood	quantitative	Danam dist: Diagnostic Testing	£13,915	automatic particle counting technology, and colorimetric Hb	yes	++	
Celltac (8 parameter)	WBC, RBC, Hb, Hct, MCV, MCH, MCHC, platelet count	whole blood	quantitative	Nihon Kohden (Japan) dist: Lifescreen (UK)	£14,100	automatic particle counting technology, and colorimetric Hb	yes	++	
Celltac (2 parameter)	Hb WBC	whole blood	quantitative		£6950				
Vision (see page 177)	28 tests including Hb prothrombin	whole blood plasma	quantitative	Abbott Diagnostics	£14,707 test: £1.90–£2.50	wet chemistries in disposable cassettes	yes	++	yes
Vitros DT60 II (Ektachem DT) chemistry system (see page 178)	16 tests including Hb	whole blood	quantitative	Johnson & Johnson Clinical Diagnostics dist: Shield Diagnostics	£5718 slides: £0.75–£2.56	dry chemistry slides	yes	+++	yes
EASY ST (see page 180)	40 tests including Hb PT	whole blood plasma	quantitative	EM Diagnostic Systems dist: BDH Diagnostics	£15,000 (1990) test: £0.15–£2.50	disposable cuvettes containing dry powder reagents, with automatic fluid delivery	yes	++	yes

C2 Coagulation

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Coagulation: Small analysers									
QBC Fibrinogen	fibrinogen	whole blood	quantitative	Becton Dickinson Diagnostics dist: Gamidor	£465 test: £0.79	centrifugution, incubation and scanning			
Coagucheck PT test (Coagucheck Plus)	PT PT, APTT	whole blood	quantitative	Boehringer Mannheim	£670 PT £2.30	magnetic pulsing of iron oxide particles immobilised on test carrier	yes	+	MDA 96/08 MDA 96/07
CoaguCheck Plus (formerly Biotrack 512)	PT APTT	capillary or venous whole blood	quantitative	Boehringer Mannheim	£1655 PT: £3.96 APTT: £4.80	test cartridge with reagents, mixing and capillary channel; laser beam scattering by erythrocyte movement	yes	+	yes
Coumatrak	PT	capillary blood	quantitative	DuPont Boehringer Mannheim		test cartridge	yes		
ProTime Microcoagulation System	PT	whole blood	quantitative	International Technidyne Corp. (USA)		instrument with disposable reagent cuvette	yes	+	yes
Thrombotrack I	PT, APTT fibrinogen intrinsic and extrinsic coagulation factors	citrated whole blood	quantitative	Nycomed Pharma dist: Nycomed (UK)	 inst. £1260 thrombotest: £0.11–£0.24	manual reagent and sample addition with electromagnetic (steel ball) clot detection		++	STD 89/22
TAS (thrombolytic assessment system)	PT (APTT) heparin management test replaces the ACT streptokinase panel (antibodies to streptokinase and streptokinase/ plasminogen complex inhibitors) lysis onset time	citrated whole blood plasma	quantitative	Cardiovascular Diagnostics dist: Diagnostic Testing	£2500 tests: PT £2.50 APTT £2.95 HMT £2.95 SK £10.80 LOT £6.00	individual magnetically coded dry reagent test cards; unmeasured sample addition, with automatic result reading	yes	+	

continued

C2 Coagulation *contd*

System	Test	Sample type	Method type	Manufacturer, distributor	Cost	Methodology	Quality control	Operator dependency	Reviewed
Coagulation: Small analysers contd									
Hemochron 8000 **Hemochron 801** **Hemochron 401**	test combinations from: ACT, APTT fibrinogen, thrombin time heparin neutralised thrombin time	whole blood	quantitative	International Technidyne Corp. (USA)	£4832 £2702 (2 simultaneous tests: £1.05/test) £1800 (1 test: £1.05)	manual sample addition; bar-coded cuvette with hand held reader, preloaded coagulation test tubes with electromagnetic clot detection	yes	+	
Mobile Haemostasis Unit (Cascade M/M-4 haemostasis analyser and a CoagSpin centrifuge)	PT, APTT thrombins fibrinogens	whole blood	quantitative	dist: Helena Laboratories (UK)		electronic pipetting with computer controlled photo-optic coagulation detection	yes	++	
Amelung KC 1A	PT, fibrinogen intrinsic and extrinsic coagulation factors	whole blood	quantitative	Amelung dist: Brownes (UK)	£1100	manual reagent and sample addition with electromagnetic (steel ball) clot detection	yes	++	
MCL 2 coagulation analyser	PT, APTT thrombin time fibrinogen and factor assays	whole blood	quantitative	Instrumentation Laboratory (UK)	(discontinued)	20 sample and liquid reagent addition with photometric coagulation detection	yes	++	
ThromboTimer	coagulation tests	whole bloood	quantitative	Behnk Elektronik (Germany)		cuvettes with opto-mechanical measuring system	yes		
LISA **(see page 179)**	27 tests including 2 coagulation tests		quantitative	DataChem					

Appendix 4

Products evaluated by the Medical Devices Agency (MDA) and suitable as NPTs

Report No	Title	Cost (£)	Published
MDA/96/07	Boehringer Mannheim CoaguCheck Plus Coagulation Monitor	30	18.3.96
MDA/96/08	Boehringer Mannheim CoaguCheck Coagulation Monitor	60	3.4.96
MDA/96/13	MediSense SensorLink blood glucose sensor	60	11.4.96
MDA/96/20	Boehringer Mannheim Accutrend alpha blood glucose meter	45	22.4.96
MDA/96/33	Becton Dickinson ParaSight F test	30	20.6.96
MDD/94/15	Boehringer Accutrend blood glucose meter	25	
MDD/94/22	Boehringer Accutrend Mini blood glucose meter	30	
MDD/94/49	MediSense Companion 2 blood glucose sensor	30	
MDA/94/67	Bayer Glucometer 4 blood glucose meter	45	
MDA/95/11	Boehringer Mannheim Accutrend GC meter for the determination of blood glucose and cholesterol	45	
MDA/95/21	HemoCue B-Haemoglobin photometer	45	
MDA/95/22	Enzymatics Q.E.D. Saliva Alcohol Test	30	
MDA/95/23	Cholestech LDX lipid analyser	45	
MDA/95/31	Cascade Checkmate Plus blood glucose meter	45	
MDD/92/21	Glycotonic C blood glucose meter	25	
MDD/92/22	Urine reagent strips	35	
MDD/92/54	Nycocard CRP kit	25	
MDD/92/57	Bio-Stat CRP-latex QuickTest	25	
MDD/92/60	Lipotrend C whole blood cholesterol assay system	25	
MDD/93/18	LifeScan One Touch II blood glucose meter	30	
MDD/93/25	Extra-laboratory glucose meters: an assessment of sources of error	35	
MDD/93/36	Uriscreen test for urinary tract infection	25	
MDD/93/37	Uristat test for urinary tract infection	25	
MDD/93/39	Accumeter and Boots cholesterol test kits	30	
MDD/93/40	Becton Dickinson QBC Autoread haematology anlayser	35	
MDD/93/43	Biocare Glucose V visual blood glucose test strips	25	
MDD/93/45	Hypoguard Supreme blood glucose meter	30	
MDD/90/53	Ciba-Corning 288 blood gas analyser	35	
MDD/90/54	Nova Stat Profile 5 blood gas analyser	35	
MDD/91/08	QuikRead whole blood cholesterol assay system	25	

continued

Report No	Title	Cost (£)	Published
MDD/91/45	Hemocue B blood glucose meter	25	
MDD/92/04	Reflotron potassium dry reagent strip	25	
MDD/92/08	Spotchem SP4410 clinical chemistry analyser	25	
STD/89/22	Nycomed Thrombotrack coagulation system	15	
STD/89/27	Abbott Vision and BCL Reflotron analysers (Part 1)	25	
STD/89/66	Ames Minilab plus Micorspin centrifuge	25	
STD/90/20	Cumulative report on 10 coagulometers	100	
STD/90/31	Abbott Vision and BCL Reflotron analysers (Part 2)	25	
STD/90/39	Ames Multistix 8SG and Clinitek 200 urine analyser	25	
MDD/90/42	Kodak Ektachem DT and BDH Easy ST analysers	25	

Evaluation reports published by the MDA are available free of charge to the NHS and are for sale to commercial organisations and other interested parties.

Further information available from:

Orders Department
Room 1207
Medical Devices Agency
Hannibal House
Elephant and Castle
London SE1 6TQ

Enquiries

General enquiries should be directed to the Orders Department:

Tel: 0171 972 8181
Fax: 0171 972 8105

Technical enquiries should be directed to Mr Paul Garden:

Tel: 0171 972 8147
Fax: 0171 972 8105

Appendix 5

Suppliers of medical devices and systems

Abaxis Inc,
1320, Chesapeake Terrace,
Sunnyvale, California,
94089, USA

Abbott Diagnostics Division,
Abbot House, Norden Road,
Maidenhead, Berkshire,
SL6 4XF, UK

Allerayde Ltd,
3, Sanigar Court, Whittle Close,
Newark, Nottinghamshire,
NG24 2BW, UK

Alpha Laboratories Ltd,
40, Parham Drive, Eastleigh,
Hampshire, SO50 4NU, UK

Amelung,
Heinrich Amelung GmbH,
Lehbrinksweg 59-D,
Lemgo, Germany

Analyser/Industries,
Zuiddijkweg 4,
4315 PC Dreischor,
The Netherlands

Ani Biotechnician Oy (Finland),
Temppelikatu 3-5, Helsinki,
00100, Finland

Autogen Bioclear (UK) Ltd,
Butts Farm, Potterne, Nr. Devices,
Wiltshire, SN10 5LR, UK

AVL Medical Instruments
(UK) Ltd,
Unit 24, Whitebridge Industrial
Estate, Whitebridge Lane,
Stone, Staffordshire,
ST15 8LQ, UK

Bard Diagnostic Sciences Inc.,
12277, 134th. Court NE,
Redmond WA, 98052, USA

Bayer Plc (Diagnostics Division),
Bayer House, Strawberry Hill,
Newbury, Berkshire,
RG14 1JA, UK

BDH Diagnostics Ltd,
Broom Road, Poole, Dorset,
BH12 4NN, UK

Becton Dickinson
Diagnostics (France),
5, Chemin des Sources,
Meylan Cedex,
F 38241, France

Bedfont Technical
Instruments Ltd,
Bedfont House, Holywell Lane,
Upchurch, Sittingbourne, Kent,
ME9 7HN, UK

Behnk Elektronik,
Hans-Bockler-Ring 27,
22851 Norderstedt,
Germany

BHR Pharmaceuticals Ltd,
41, Centenary Business Centre,
Hammond Close, Attleborough
Fields, Nuneaton, Warwickshire,
CV11 6RY, UK

Bio-Stat Diagnostics,
Bio-Stat House, Pepper Road,
Hazel Grove, Stockport,
Cheshire, SK7 5BW, UK

Biocare International Inc,
3375, Park Avenue,
Suite 2000A, Wantagh,
New York, 1193, USA

Biodynamics Corporation,
4515, Purdue NE, Seattle WA,
98105, USA

Biomen Ltd,
Pentos House, Falcon Business
Park, Ivanhoe Road,
Finchampstead, Berkshire,
RG40 4QQ, UK

Biomerica,
1533, Monrovia, Newport Beach,
California, 92663, USA

Bionike,
1015, Grandview Drive,
South San Francisco, California,
94080-4910, USA

Biosite Diagnostics,
11030 Roselle Street, San Diego,
California, 92121, USA

Biotrack,
Ciba Corning Diagnostics,
1058, Huff Avenue, Mountain
View, California, 94043, USA

BodyCare Products Ltd,
Unit 9A, Princes Drive
Industrial Estate, Kenilworth,
Warwickshire, CV8 2FD, UK

Boehringer Mannheim (UK)
(Diagnostics & Biochemicals),
Ltd, Bell Lane, Lewes,
East Sussex, BN7 1LG, UK

Boehringer Mannheim
Corporation (USA),
9115 Hague Road, Indianapolis
IN, 46250, USA

Boehringer Mannheim GmbH,
Mannheim, D-68298, Germany

Boots the Chemists,
3, Wilford Road, Nottingham,
Nottinghamshire, NG2 3AA, UK

Brownes (UK),
Pincents Kiln Industrial Park,
Calcot, Reading, Berkshire,
RG13 7SB, UK

Callegari SpA,
PO Box 332, Parma, 43100, Italy

Cambridge Biotech Ltd,
Mervue Industrial Estate,
Mervue, Galway,
Republic of Ireland

Cambridge Diagnostics
Services Ltd,
Horseheath, Cambridge,
CB1 6RG, UK

Cambridge Life Sciences plc,
Cambridge Business Park,
Angel Drove, Ely, Cambridge,
CB7 4DT, UK

Cardiovascular Diagnostics Inc,
Raleigh, North Carolina, USA

Carter-Wallace International,
2, Research Way, Princeton,
New Jersey, 08540, USA

Cascade Medical Inc,
10180, Viking Drive,
Eden Prairie, Minnesota,
55344, USA

Chembio Diagnostic Systems,
3661, Horseblock Road,
Medford, New York,
11763-2221, USA

Chemtrak Inc,
992 E Arques Avenue, Sunnyvale,
California, 94086, USA

Cholestech Corporation,
3347, Investment Boulevard,
Hayward, California,
94545-3877, USA

Chrometrics Laboratories Inc,
808, Busse Highway, Park Ridge,
Illinois, 60068, USA

Ciba Corning Diagnostics
(UK) Ltd,
Colchester Road, Halstead,
Essex, CO9 2DX, UK

Ciba Corning Diagnostics
Corp. (USA),
266, Main St., Olde Medfield
Square, Medfield MA,
02052, USA

Cortecs Diagnostics Ltd,
Technicianbase 1, Newtach
Square, Deeside Industrial Park,
Deeside, Clwyd, CH5 2NT, UK

Coulter Electronics Ltd,
Northwell Drive, Luton,
Bedfordshire, LU3 3RH, UK

Croft-Greiner Instruments Ltd,
Sandbeck Way, Sandbeck Estate,
Wetherby, West Yorkshire,
LS22 4SU, UK

Dako Diagnostics Ltd,
Denmark House, Angel Drove,
Ely, Cambridgeshire,
CB7 4ET, UK

DataChem Inc,
7742, Moller Rd., Indianapolis
IN, 46268, USA

Diagast,
BP9, 59374 Loos,
Cedex, Belgium

Diagnostic Products Corp. (UK),
Glyn Rhonwy, Llanberis,
Gwynedd, LL55 4EL, UK

Diagnostic Products Corp. (USA),
Los Angeles, California, USA

Diagnostic Testing Ltd,
Hawkedon House, Hawkedon,
Bury St Edmunds, Suffolk,
IP29 4NP, UK

Diametrics Medical,
St. Paul, Minneapolis, USA

Diasense (UK) Ltd.,
37, Queen Anne Street, London,
W1M 0JD, UK

Diatech Diagnostics Inc,
90 Windom Street, PO Box 860,
Boston MA, 02134, USA

Digen Ltd,
65, High Street, Wheatley,
Oxford, Oxfordshire,
OX33 1XT, UK

Dipro Diagnostic Products
GESMBH,
A-2355 Wiener Neudorf,
POB 51, Austria

Dr. Bruno Lange GmbH,
Postf 370363, Berlin,
14133, Germany

DuPont (UK) Ltd,
Wedgewood Way, Stevenage,
Hertfordshire, SG1 4QN, UK

Elvilogos Sri,
Via Tolstoy 57, San Giuliano,
Milan, 20098, Italy

EM Diagnostic Systems Inc.,
Gibbstown, New Jersey, USA

Enzymatics Inc.,
Harsham, Philadelphia PA,
19044, USA

EuroMedix-LBS Tara,
Scarsdale Place, Wrights Lane,
London, W8 5SR, UK

Fingerprint Biotek Inc,
2930 Prosperity Ave, Fairfax,
VA 22031, USA

Futrex Inc,
PO Box 2398, Gaithersburg MD,
20886, USA

Gamidor (UK) Ltd.,
Bio Medical Services and
Supplies, 67 Milton Park,
Abingdon, Oxfordshire,
OX14 4RX, UK

GDS Diagnostics,
25235, Leer Drive, Elkhart,
Indiana, 46514, USA

GDS Technology Inc,
Elkart, Indiana, USA

Genzyme Diagnostics,
50 Gibson Drive, Kings Hill,
West Malling, Kent,
ME19 6HG, UK

Hanson Hong Biomedical
(Hong Kong) Co Ltd.,
Flat C7, 6F Winner Centre,
333 Chaiwan Road, Hong Kong

Hanson Hong Biomedical
Co Ltd (Taiwan),
PO Box 234 Naihu,
6f No 81 Chengkung Rd,
Sec 3 Naihu, Taipei,
Taiwan ROC

Helena Laboratories (UK) Ltd,
Seventh Avenue, Team Valley
Trading Estate, Gateshead,
Tyne and Wear, NE11 0LH, UK

HemoCue Ltd,
5, South West Centre,
Archer Road, Sheffield,
S8 0JR, UK

Hewlett-Packard Co. (USA),
Patient Monitoring Division,
3000, Minuteman Road,
Andover, MA, 01810, USA

Hewlett-Packard
GmbH (Germany),
Schickardstrasse 4, PO Box 1427,
Boblingen, 71034, Germany

Hi-Care Health Products Ltd.,
30, Sycamore Road, Amersham,
Buckinghamshire, HP6 5DR, UK

Hybritech Europe SA,
Allee des Noisetiers 12, Liege,
4031, Belgium

Hypoguard (UK) Ltd.,
Dock Lane, Melton, Woodridge,
Suffolk, IP1 1PE, UK

i-Stat Corporation,
303A College Road East,
Princeton, New Jersey,
08536, USA

Imaco GmbH,
Haupstrasse 27f, Ludersdorf,
23923, Germany

Immunostics Inc.,
3505, Sunset Avenue, Ocean,
New Jersey, 07712, USA

Incstar Ltd,
Charles House, Toultley Road,
Wokingham, Berkshire,
RG11 5QN, UK

Instrumentation Laboratory
(UK) Ltd,
Kelvin Close, Birchwood
Science Park, Warrington,
Cheshire, WA3 7PB, UK

International Mycoplasma,
Parc D'Activites,
Allee D'Athenes, Signes,
83870, France

International Technidyne
Corp. (ITC) (USA),
8, Olsen Ave, Edison, New Jersey,
08820, USA

International Technidyne
Corp.(ITC) (UK),
The Hilger Suite,
Westwood Industrial Estate,
Ramsgate Road, Margate,
Kent, CT9 4JL, UK

Ionetics Inc.,
10574, Belcher River,
Fountain Valley, California,
92708, USA

Isolab, N.V.,
Dellingstraat, 34/1, Mechelen,
2800, Belgium

ITC Commercial Group,
Edison, New Jersey, USA

Jant Pharmacal Corporation,
16255, Ventura Boulevard,
Suite 940, Encino, California,
91436, USA

Johnson & Johnson Clinical
Diagnostics Ltd,
62, The Broadway, Amersham,
Buckinghamshire,
HP7 0HJ, UK

Kodak Clinical Diagnostics,
Mandeville House,
62, The Broadway, Amersham,
Buckinghamshire, HP7 0HJ, UK

Kyoto Daiichi Kagaku Co. Ltd.,
57, Nishi, Aketo-Cho,
Higashi-Kujo, Minami-Ku,
Kyoto, 601, Japan

L D Labor Diagnostika,
Industriestr 12, Heiden,
Westfalen, 46359, Germany

Lifeline (UK),
Chessingham Park, Common
Road, Dunnington, York,
YO1 5SE, UK

Lifescan,
1000, Gibraltar Drive, Milpitas,
California, 95035, USA

Lifescreen Ltd.,
Unit 15, The Metro Centre,
Dwight Road, off Tolpits Lane,
Watford, Hertfordshire,
WD1 8SS, UK

Lion Laboratories,
Ty Verlon Industrial Estate,
Barry, Glamorgan, UK

Mallinckrodt Sensor Systems,
1590, Eisenhower Place,
Ann Arbor, Michigan,
48103, USA

Mast Immunosystems,
630, Clyde Court, Mountain
View, California, 94043, USA

Medica,
14, DeAngelo Drive,
Bedford MA, 01730, USA

MediSense Britain Ltd,
PO Box 2159, Coleshill,
Birmingham, B46 1HZ, UK

Medix Biotech Inc,
420 Lincoln Centre Drive,
Foster City, California,
94404, USA

Merck (UK) Ltd.,
Merck House, Seldown Lane,
Poole, Dorset, BH15 1TD, UK

Meridian Diagnostics Inc.,
3471, River Hills Drive,
Cincinnati, Ohio, 45244, USA

Metachem Diagnostics Ltd,
29, Forest Road, Piddington,
Northampton, NN7 2DA, UK

Metertech Inc.,
63-2, Cheng Kong Rd, Sec. 1,
Nankang, Taipei, Taiwan

Micon (UK) Ltd.,
Sycamore House, 1, Woodside
Road, Amersham,
Buckinghamshire, HP6 6AA, UK

Microm (UK),
8, Thame Business Centre,
Wenman Road, Thame,
Oxfordshire, OX9 3XA, UK

Mizuho Inc.,
San Diego, California, USA

Nihon Kohden Corporation,
31-4, 1-chome, Shinjuku-ku,
Tokyo, 161, Japan

Nonin Medical Inc.,
2605, Fernbrook Lane North,
Plymouth, Minneapolis,
55447-4755, USA

Nova Biomedical (USA),
200, Prospect St., Waltham MA,
021544, USA

Nycomed (UK) Ltd.,
2111, Coventry Road, Sheldon,
Birmingham, West Midlands,
B26 3EA, UK

Nycomed Pharma
AS Diagnostics,
PO Box 5912, Majorstua,
Oslo, N-0301, Sweden

Olympus Optical Co UK Ltd,
Biomedical Products
Division, 7, West Links,
Tollgate, Eastleigh, Hampshire,
SO5 3TG, UK

Omni Triage Medical Ltd.,
131, Tranmere Road, London,
SW18 3QP, UK

Organon Teknika Ltd,
Science Park, Milton Road,
Cambridge, CB4 4FL, UK

Orgenics,
POB 360, Yavne, Israel

Orion Diagnostica,
Orion Corporation, PO Box 83,
02101, Espoo, Finland

Ortho Diagnostic Systems Ltd.,
Mandeville House,
62, The Broadway, Amersham,
Buckinghamshire, HP7 0JS, UK

Oxymedica Inc.,
108, Merrick Road, Lynbrook,
New York, 11563, USA

PDX Technologies Inc.,
2260, Townsgate Road, Suite 2,
Westlake Village, California,
91361-2407, USA

PPG Industries,
Biomedical Systems
Division, Sensors E4M,
11077 North Torrey Pines
Road, La Jolla, California,
92037, USA

Princeton BioMeditech
Corporation,
PO Box 7139, Princeton,
New Jersey, 08543, USA

PrismaSystems Corporation,
1721, Black River Boulevard
Suite 200, Rome, New York,
13440, USA

Quest Biomedical,
Suite B, Greville Court,
1665, High Street, Knowle,
West Midlands, B93 0LL, UK

Quidel,
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San Diego, California,
92121, USA

Radiometer Ltd.,
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RH10 2PY, UK

Rapid Diagnostic Technologies,
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San Diego, California,
92121, USA

Roche Diagnostic
Systems Inc. (USA),
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Branchburg, New Jersey,
08876-176, USA

Roche Diagnostics,
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Garden City, Hertfordshire,
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Rohm Pharma GmbH,
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Royce Laboratories Ltd.,
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SA Scientific Inc,
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Savyon Diagnostics Ltd.,
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Shield Diagnostics plc,
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Vitech Scientific,
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Wellcome Diagnostics,
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Worldwide Medical Corp (USA),
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Appendix 6

Search strategies

Medline

Search Terms

1. Near patient (t.w.)
2. Point of care (t.w.)
3. Home testing (t.w.)
4. Set testing (t.w.)
5. 1 or 2 or 3 or 4

1. Exp. decision making, computer-assisted/
2. Exp. decision support techniques/
3. 1 or 2
4. Exp. family practice/
5. 3 and 4
6. Exp. primary health care/
7. 3 and 6
8. 5 or 7

1. Exp. diagnosis, laboratory/
2. Exp. computer communication networks/
3. 1 and 2

1. Exp. physicians' offices/
2. Exp. reagent kits, diagnostic/
3. 1 and 2
4. Office laboratory (t.w.)
5. Exp. primary health care/
6. 4 and 5
7. Exp. family practice/
8. 4 and 7
9. 4 and 1

(t.w. = textword, Exp. = explode term)

BIDS

1. Near patient test*
2. Point of care*
3. Home test*
4. Computer communication network*
5. Computerised decision system*
6. Computerised decision support system*
7. Computer assisted decision*
8. Laboratory rapid transit system*
9. Laboratory service*
10. Communication system*
11. Computerised communication system*
12. Decision support*
13. Diagnostic decision support system*
14. Rapid test*
15. Nycocard*
16. Set test*
17. Decision support technique*
18. Office laboratory*

Each of the above search terms (1–18) was used in conjunction with the following terms:

a. Primary care; b. Family practice; c. General practice; d. Physician* office
(* = truncate word)

Methodological proforma

Main validity scoring instrument

Paper no. .....

Methodology ***Scoring Grid***

	Yes	No	Don't know
1. Was there an independent blind comparison to a reference standard?			
2. Did the sample include an appropriate spectrum of patients?			
3. Was the reference standard performed in all patients?			
4. Were the test methods described sufficiently to permit replication?			
5. Are likelihood ratios quoted?			

Critique

Would the results be reproducible in a primary care setting?
Would the test alter management?
Would the test improve patient care?
Are there any particular requirements or special circumstances for the use of this test?

The detailed review criteria

Area	Test package characteristics	Comparator	Study type and design	Quality score	Results
	Name Op Int Set	**Name Op Int Set**			
Categories reflecting the general area and specific targets of proposed NPT tests.	Characteristics of the NPT test package, as supplied in article **Name** Trade-name, manufacturer and any other relevant details of test apparatus **Operator** Any details of type of person operating apparatus including whether training or instruction received **Interpreter** Any details of type of person interpreting and/or applying test result including whether training or instruction received **Setting** (a) Categorised as: hospital laboratory (including reference laboratories) hospital intensive care (including coronary care) hospital ward hospital out-patient hospital emergency dept primary care (including general practice, family practice office) home (b) Country "?" indicates that, although implied, a detail is not explicitly stated N/A indicates an absence of any detail	Characteristics of the test package with which the NPT package was compared, as supplied in article **Name** **Operator** **Interpreter** **Setting** Details abstracted identical in nature to those for test characteristics. Where "**None**" appears, the study involved no comparison "**Same**" indicates that the comparator characteristic is identical to that in the NPT test package. "**Same**" in all categories invariably indicates that the repeatability/reproducibility of the NPT test package is being measured	Categorised as: * Repeatability * Test performance * Impact – acceptability * Impact – effectiveness * Impact – harm * Impact – efficiency/cost WITH as many additional details of study design as relevant, e.g. no. of samples or patients compared and exclusions from analyses	Score from modified "Reid" checklist (see text for detail) Max = 7 OR Not formally assessed (NFA) with comment on bias OR Insufficient detail to assess validity (No detail)	As expressed in the article Italics indicate where result has been re-calculated from raw data presented

Appendix 7

Members of the external review panel

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