

Buyers' guide

Point-of-care testing for cholesterol measurement

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Point-of-care testing (POCT)

Point-of-care or near-patient testing (NPT), is testing at or near the patient rather than in the traditional central laboratory, bringing testing closer to the primary point of contact. Point-of-care systems, in general, use relatively small volumes of capillary whole blood directly from a fingerstick. Test results are rapidly available with the potential to affect immediate patient management [1-3], thereby improving outcome. Point-of-care testing is primarily performed by non-laboratory personnel in diverse locations that include the patient's bedside [4], out-patient clinics, primary care, retail pharmacies, ambulances and patients' homes.

Traditional, centralised laboratory testing requires the transport of patients or specimens for analysis using well-established and sometimes lengthy procedures [5]. This increases the turnaround time for results being reported to clinicians and other relevant healthcare professionals. Lord Carter of Coles reports in his review of NHS Pathology Services [6] that locating test equipment near to the patient produces a faster result which can be valuable to the patient:

- In life threatening situations, or
- for the long term management of their condition where it informs the consultation process, or
- where they have a heightened concern about their test outcome.

Lord Carter also recommends that pathology services should work with the community based services, including primary care trusts, to develop new care pathways and advise them on the appropriate use of POCT and provide any necessary support [7].

Point-of-care cholesterol testing systems encompass hand held devices and compact desktop analysers. They utilise disposable, dry-reagent technology to measure total cholesterol in a small sample of whole blood. Some of these systems are capable of measuring other lipids such as high density lipoprotein (HDL) cholesterol, triglycerides, low density lipoprotein (LDL) cholesterol and associated analytes.

CVD risk factor assessment and cholesterol

Cardiovascular disease (CVD) is the main cause of death in the UK. CVD risk includes the risks from coronary heart disease (CHD), stroke, transient ischaemic attacks, peripheral arterial disease, type 2 diabetes and chronic kidney disease. In 2005, 124,000 deaths in England and Wales were attributed to CVD of which 39,000 were in people under the age of 75 years [8]. The Government is committed to reducing the death rate from coronary heart disease, stroke and related diseases in people under the age of 75 by at least 40% by 2010 [9].

Major risk factors associated with cardiovascular disease are broadly classified into those that are non-modifiable or modifiable [10-12]. Non-modifiable risk factors are age, male gender, post-menopausal females, having a family history of CHD and ethnicity. Modifiable risk factors are abnormal lipid levels, high blood pressure, diabetes, metabolic syndrome and lifestyle (smoking, diet, obesity, lack of physical exercise, alcohol and / or stress). Blood cholesterol has a log-linear relationship to the risk of CHD and is a key modifiable risk factor [8].

Seventy percent of cholesterol is produced naturally by the body and the rest absorbed from the diet. It is vital for normal body functions and levels less than 5.2 mmol/L are considered desirable. Triglycerides are obtained from the diet or made in the body from excess calories and converted to fat for storage. Triglyceride levels greater than 1.7 mmol/L increase the risk of CVD. Lipoproteins transport cholesterol and triglycerides through the bloodstream. The two main lipoproteins are:

- HDL is referred to as 'good' cholesterol because it helps to remove cholesterol from arteries, reducing the risk of atherosclerosis. An HDL level greater than or equal to 1.0 mmol/L in men and greater than or equal to 1.2 mmol/L in women confers a protective effect [10, 13], whereas a low HDL can indicate the presence of other atherogenic risk factors.
- LDL is referred to as 'bad' cholesterol, because in excess, it is deposited onto the inner wall of arteries causing a harmful build-up and accelerating atherosclerosis, raising the risk of heart attack and stroke. A level greater than 4.0 mmol/L is considered abnormal [10].

National guidance

The Department of Health's NHS Health Check for vascular risk assessment and management programme [14] supports the Government initiative to reduce the number of deaths due to cardiovascular disease. This is a national initiative, delivered in primary care and the community, targeting individuals between the ages of 40 to 74 years who do not have pre-existing vascular disease. The document outlines best practice guidance to commissioners on delivering the programme. It highlights the parameters for risk assessment, including screening tests for total cholesterol and HDL cholesterol, which are required to determine an individual's risk score based on the Framingham and QRISK[®]2 models.

The National Institute for Health and Clinical Excellence (NICE) guidelines CG067, for lipid modification [8] set out a systematic strategy for the primary prevention of CVD in people aged 40 to 74, prioritised on the basis of their estimated CVD risk before a full formal risk assessment. Cholesterol screening is only one factor in the assessment of cardiovascular risk, which provides an opportunity to identify at risk individuals for further investigations.

Review of the literature

The databases Medline, Embase, Web of Science, British Nursing Index, Cochrane and CINAHL were searched for the following terms:

Point of care test* **OR** point-of-care test* **OR** POCT **OR** Near patient test* **OR** near-patient test* **OR** NPT **AND**

Laboratory **AND**

Cholesterol **OR** HDL* **OR** LDL* **OR** lipid*

Searches were limited to these terms appearing in the title, abstract or keywords and to papers available in English. The literature search was conducted for papers published between 1988 and 2009 as some products included in this buyersguide have been available for point-of-care lipid measurement for over 20 years. The references provided information on early studies that are still relevant.

In summary, the papers reviewed reported that POCT is performed extensively by healthcare personnel from various backgrounds whose main role is in providing clinical services. They are unlikely to be familiar with laboratory analytical procedures and precautions such as quality control testing, patient preparation, specimen collection, measurement, and instrument maintenance and troubleshooting. However, with appropriate training reliable results can be produced. The papers reviewed are summarised in table 1.

Table 1: Important characteristics of laboratory and point-of-care testing**Laboratory testing**

Hospital laboratories are accredited; comply with good practice guidelines and quality assurance procedures to achieve high levels of accuracy and precision [3, 15, 16].

Tests are performed by certified, trained healthcare professionals [16]. Results are interpreted and diagnosed correctly, highlighting any patients requiring further investigations [17].

Laboratory results are electronically transferred into patients' medical records via the laboratory and hospital information systems [18].

Large scale laboratory testing incurs minimal cost per test [5, 15].

Point-of-care testing

POC tests are minimally invasive as the majority only require a small blood sample collected from a fingerstick with minimal or no sample preparation [19].

The rapid availability of results leads to improved therapeutic turnaround time [20, 21] with quicker intervention and rapid changes in delivery of care [1-3, 5, 15, 22].

There is no requirement to transport specimens to a central laboratory [19] thereby reducing result turnaround time and transport costs.

Testing in the presence of the patient improves patient compliance, adherence to treatment and therapeutic control [4, 23].

Provides greater convenience for patients with fewer repeat visits to GP leading to greater satisfaction and patient centred treatment [4, 22-24].

Overall healthcare costs can be reduced with fewer unnecessary hospital admissions, reduced length of hospital stay and optimised drug treatment [4, 23].

Point-of-care analysers with reduced number of operator dependent steps which are easy to use can produce reliable results when used by appropriately trained non-technical operators [19, 25] whose competency is verified by annual accreditation [15, 26].

Scope of report

This guide reviews all commercially available lipid measurement systems for point-of-care total cholesterol and / or HDL cholesterol testing. It includes technical, operational, economic and purchasing considerations that are important when selecting a suitable system and highlights those devices suitable for the NHS health checks programme.

Over the counter, single use disposable total cholesterol measurement kits for self testing are also available through retail pharmacies or online. These are not within the scope of this buyers' guide.

For sale in the UK and European Union (EU), point-of-care testing systems are required to conform to the IVD directive 98/79/EC [27] and IS standard BS EN IS 22870 on quality and competence [28]. The Medicines and Healthcare products Regulatory Agency (MHRA) has published guidance on issues related to point-of-care cholesterol testing and the use of point-of-care devices [29-32]. Specific guidelines covering point-of-care cholesterol measurements conducted in retail pharmacies have been produced by the Royal Pharmaceutical Society [33]. Professional bodies such as the Royal College of Pathologists / Association of Clinical Biochemists and Institute of Biomedical Science have also produced guidelines [34, 35].

Lipid measuring systems

Point-of-care lipid measuring systems include hand held meters and compact desktop analysers capable of measuring multiple analytes on whole blood, plasma or serum collected from a fingerstick (capillary) or venous blood sample. They utilise reflectance or biosensor technology with single-use, disposable dry reagent test strips, rotors or cassettes.

Analytes are measured either individually or as multiple tests e.g. a full lipid profile that includes total cholesterol, HDL cholesterol and triglyceride (The market review highlights this. Page number 23). Calculated parameters such as total cholesterol / HDL cholesterol ratio and calculated LDL are also available with some systems.

Measurements are achieved by applying a sample to the chemically active area of the test strip, cassette or rotor. Responses from the reaction after a specific time are converted into a concentration and displayed on the analyser.

Point-of-care lipid measuring systems typically incorporate the following features:

- a display window
- reagent port for insertion of test strip, cassette or rotor
- power supply via mains electricity or batteries
- automatic internal electronic checks ensure optimal operation of the system
- warning messages or audible signals to highlight procedural or analytical errors
- built in memory for storing results
- data port or infra red window for downloading results using the relevant software
- automatic shutdown or standby to conserve power.

Units of measurement

Units of measurement for lipid systems in the UK should be set to mmol/L. Operators should check the units displayed and be aware that total cholesterol results expressed in mg/dL are higher by a factor of 38.7 than results expressed in mmol/L. BS EN IS 14971 states that manufacturers should protect against unintentional change of essential parameters, such as units of measurement+ [36].

Reagents

For optimal performance, the test strips, cassettes or rotors should be stored at the recommended temperatures and humidity, in the original packaging containing a desiccant. They should only be removed for use once all meter and patient preparations have been completed. Dry reagent test strips, cassettes or rotors have a shelf life of approximately two years and the expiry date is printed on the packaging. Individually foil-wrapped test strips remain viable to the stated expiry date, whilst test strip canisters, once opened, have a reduced shelf life of approximately 90 days.

Measurement principle

Lipid testing at point-of-care and in laboratories is based on enzymatic methodologies. The measurement principle of total cholesterol and the HDL sub fraction utilises the same enzymes: cholesterol esterase, cholesterol oxidase and peroxidase. The end point produces either a coloured dye or electrochemical response with intensity proportional to the total cholesterol or HDL cholesterol in the sample. However, prior to its measurement HDL cholesterol requires an initial step to precipitate the LDL fractions and chylomicrons.

Triglyceride measurements utilise the enzymes cholesterol esterase, glycerol kinase, glycerol phosphate oxidase and a peroxidase. As with the total or HDL cholesterol measurement the end point is a chromogen or electrochemical response that is proportional to the triglyceride in the sample.

Standardisation of results

For sale within the EU, the IVD directive [27] requires the manufacturer to demonstrate traceability of results to measurement procedures of a higher metrological order. The classification of vascular risk requires accurate and reliable cholesterol measurement systems. CDC Cholesterol Reference Method Laboratory Network (CRMLN) certification indicates that clinical laboratories and manufactures are standardised in accordance with the National Reference System for cholesterol protocols using fresh patient specimens [37]. However, traceability of any system or its components to the National Reference System for cholesterol does not guarantee the accuracy of results obtained by the end user.

Minimum proficiency standards that meet the NCEP performance criteria [38] for lipid measurement are shown in table 2.

Table 2: Proficiency standards that meet the NCEP performance criteria

	Accuracy	Imprecision (CV %)*	Total allowable error
Total cholesterol	less than or equal to $\pm 3.0\%$	less than or equal to 3.0%	less than or equal to 8.9%
HDL cholesterol	less than or equal to $\pm 5.0\%$	less than or equal to 4.0% at HDL of ≥ 1.1 mmol/L	less than or equal to 13%
Triglyceride	$\pm 5.0\%$	less than or equal to 5.0%	less than or equal to 15%
LDL cholesterol	less than or equal to $\pm 4.0\%$	less than or equal to 4.0%	less than or equal to 12%

Notes: *CV = coefficient of variation; \geq greater than or equal to

Lot-specific calibration

Reagents from different production lots can vary in their performance. This variation is minimised by inputting lot-specific calibration information into the analyser's memory for calculating the results. The calibration information is entered via a code key, a calibration electrode, a bar-coded calibration strip or is achieved automatically upon insertion of the test strip, cassette or rotor into the analyser (see market review page 23).

Quality assurance

Quality processes require the operator to understand the importance of obtaining the correct result on the right patient and ensuring that it is acted upon. Sufficient time should be allocated to perform all necessary quality procedures.

Quality assurance measures in point-of-care testing encompass training and the overall assessment of analytical performance, including pre- and post-analytical processes [39, 40]. The Department of Health, with the UK Accreditation Service, is developing a mandatory accreditation system for point-of-care testing in order to improve the quality of the service [7, 41]. The three main elements of the work are accreditation, competence and development of learning materials. As part of clinical governance it is necessary to implement reliable quality assurance processes and practices that include internal quality control (IQC) and external quality assessment (EQA) schemes.

IQC

Internal quality control is designed to monitor and detect errors in the testing procedure and provides real time reassurance to the operator that the reagents and meter or analyser are working correctly. However, it does not measure the operator's sample collection and sample handling technique. The frequency of performing quality control depends on the level of testing done and should be specified in the standard operating procedure.

Quality control materials may be provided by the manufacturer with system and lot specific result ranges provided. They have a shelf life of approximately 12 months and the expiry date is printed on the packaging. Once opened, the shelf life is reduced to approximately 14 days, but not beyond the expiry date. Once opened, they may also require refrigeration.

EQA schemes

EQA schemes compare results between multiple sites to provide valuable information on performance and systematic analytical bias. They are retrospective and, unlike internal quality control, not in real time. EQA schemes work by individual sites analysing identical specimens and the results compared across all sites. To allow remedial action to be taken, relevant and prompt feedback must be given.

Operators of point-of-care testing for cholesterol measurement are strongly encouraged to enrol in the external quality assessment scheme for extra-laboratory cholesterol organised either by Birmingham Quality POCT EQA Service for Lipids (formerly Wolfson EQA Laboratory; www.birminghamquality.org.uk or www.uknegas.org.uk) or the WEQAS EQA Scheme for POCT Lipids (www.weqas.com). Such services may provide valuable additional information collating performance data from a group of testing sites, e.g. within a PCT. Enrolment in an EQA scheme may be provided by some manufacturers as part of their purchasing package.

Sources of errors

Point-of-care testing has been used for over 25 years in both the clinical and home environments. These early systems could be error prone but improvements have been made with time. Point-of-care testing systems available now are easier to use, with automated features that minimise the number of operator dependent steps [18, 42, 43]. Point-of-care systems are capable of achieving high levels of accuracy and precision with adequate training that includes proper sample collection and handling techniques [24, 25, 44]. Inappropriate specimen collection and processing can invalidate results regardless of the quality, accuracy and precision of the system.

Point-of-care systems are mainly used by non-laboratory personnel who may not fully understand the influence of physiological and analytical factors on the final result. For example, physiological differences produce a capillary blood total cholesterol result which is quoted as 7% higher than in a venous sample [45]. Also, plasma concentrations of total cholesterol are 4.7 % lower than in a serum sample [45, 46].

Point-of-care testing uses methodologies that are different to those in laboratory analysers and as such test limitations and interferences can vary significantly. Understanding the importance of various physiological factors and their influence on lipid measurements is essential. The influences are listed in table 3 below. The adoption of standardised protocols will ensure consistency of the test procedure and minimise or reduce errors associated with the pre-analytical, analytical and post-analytical influences on lipid results.

Table 3: Physiological, pre-analytical, analytical and post-analytical influences on lipid measurement

	Influence	Outcome
Physiological	Lifestyle	Individuals should maintain their normal diet, alcohol intake (a major determinant of triglyceride concentration), smoking and exercise habits prior to testing [47].
	Fasting Status	Fasting is not essential for total and HDL cholesterol measurements [10, 11, 47]. However, fasting for at least 12 hours is necessary prior to triglyceride measurement as food increases transient triglyceride levels by approximately 50%.
	Illness	Cholesterol levels are lowered during illness or stress and following a heart attack. Testing should be delayed for at least 2 to 3 months after a major illness and for 2 weeks after a minor illness [10, 45, 48].
	Pregnancy	Cholesterol levels are high during pregnancy and testing should be delayed for at least 3 months after the birth [45, 48].
	Intra-individual biological variation	The average variation in total cholesterol is 6.1% and can be as high as 11 % [38, 49, 50]. The average variation in HDL cholesterol is 7.4%, triglyceride 22.6% and LDL cholesterol 9.5% [50].
	Seasonal variation	Total cholesterol levels are higher in the autumn and winter months than during the spring and summer [47, 51].
	Drugs	Cholesterol levels are elevated by certain drugs such as steroids, beta blockers, vitamin D, and oral contraceptives [47].

Table 3: Physiological, pre-analytical, analytical and post-analytical influences on lipid measurement (continued)

	Influence	Outcome
Pre-analytical	Anticoagulant	Blood samples for lipid measurements should be collected into anticoagulated tubes following the manufacturer's instructions. Generally, lithium heparin is recommended as it produces a small variation of <1% between plasma and serum samples [45, 47].
	Sample collection technique	Blood collected from a fingerstick should be free flowing. Excessive squeezing may cause haemodilution or haemoconcentration of the sample leading to poor results. Lipid concentrations are raised by approximately 15% with change in posture from supine to standing or with prolonged tourniquet time. Blood samples should be collected after the individual has been sitting for at least 5, preferably 15, minutes and with a tourniquet time of less than 1 minute [47, 48].
	Contaminants	Effective hand washing to remove soaps and creams that may contain lanolin, which consists of fatty acids and cholesterol that can falsely raise cholesterol levels [52]. The alcohol present in sterile wipes should be wiped away to remove it from the skin.
	Reagents	The reagents in the test strip, cassettes or rotors are sensitive to extremes of temperature, humidity and light [53].
Analytical	Haematocrit	Haematocrit variations result in an imbalance in the plasma water available for the chemical reaction that can give erroneous results [54].
	Lot-specific calibration code	Use of an incorrect calibration code may result in incorrect results.
	Insufficient sample	Adequate volumes of blood are required as insufficient samples will give falsely low results [55].
Post-analytical	Transcription errors	Errors resulting from transferring results into patients' notes.
	Misclassification	A false positive or false negative result may result in failure to treat appropriately or require further testing and follow-up.
	Failure to act on the result	To avoid wasting resources, results should be acted upon following interpretation by appropriately qualified staff [29].

Facilities and resources

Cholesterol screening is to be offered as part of the NHS Health Check programme [14] in locations as diverse as GP practices, retail pharmacies or health screening clinics. Facilities for these services must take into account the provision of:

- trained, qualified staff to conduct the cholesterol measurement and / or risk assessment
- adequate bench space to accommodate the analyser and associated equipment in a secure location with sufficient power supply, if required
- refrigeration space for some point-of-care cholesterol reagents
- sufficient time to set-up the analyser including carrying out maintenance and quality control procedures (IQC, EQA)
- sufficient time to conduct the test
- hand washing facilities and adequate seating for testing
- privacy for consultation
- IT facilities to electronically record patients results
- consumables such as gloves, alcohol wipes, lancing devices, sharps bins, gauze, plasters
- sufficient time to order reagents and consumables
- a centrifuge, where required, to separate blood samples.

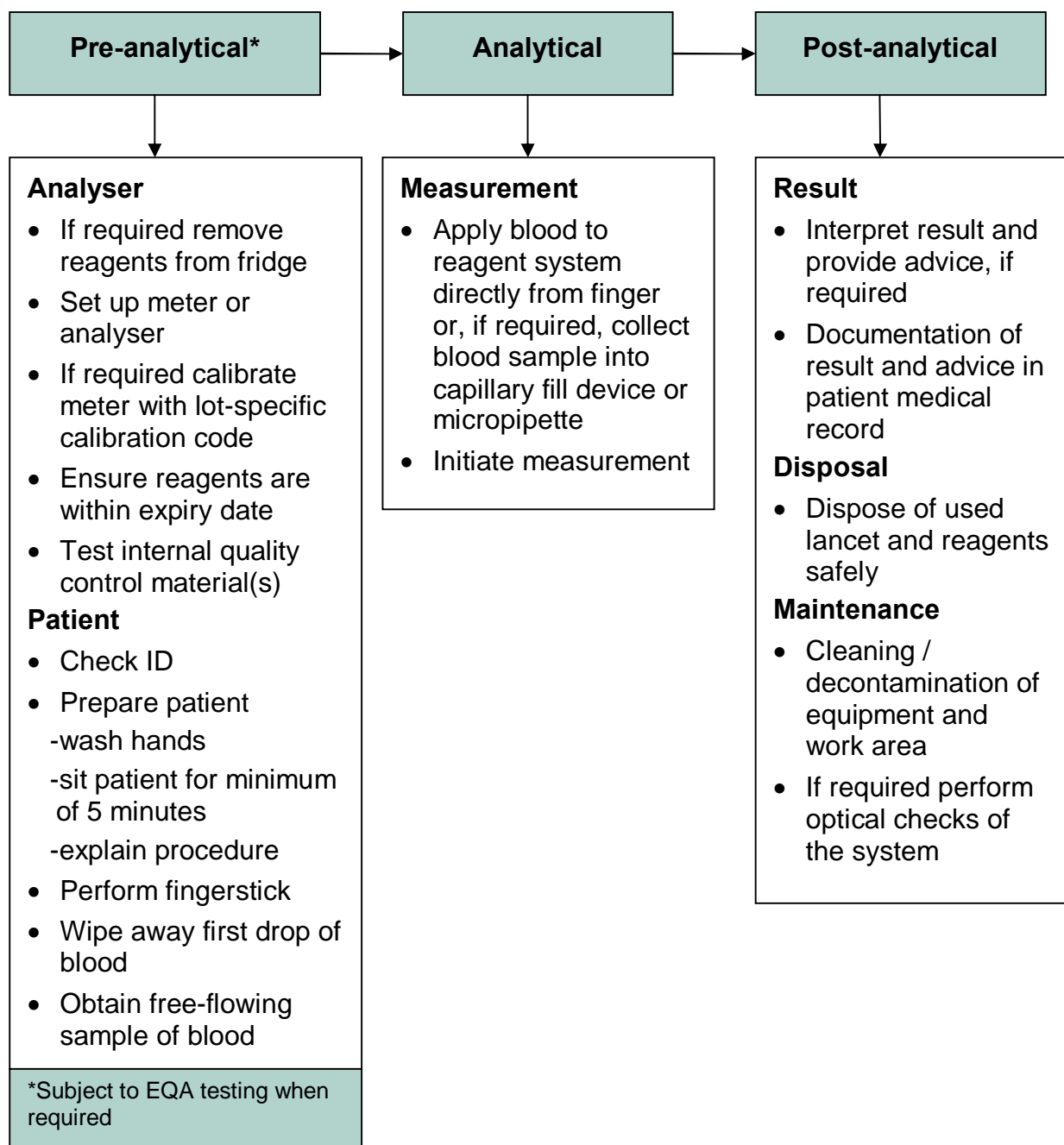
Work flow

Once the initial set-up and quality control of the system has been performed, depending on the system used, the actual lipid measurement takes between 30 seconds and 12 minutes. To facilitate workflow, the analyser, reagents and other consumables should be easily accessible. The location of equipment and sharps bins must ensure that safety is not compromised. The following consumables are also required:

- alcohol wipes to clean the patient's finger
- gauze to wipe the initial drop of blood and stem blood flow
- plasters
- a sharps bin for the disposal of contaminated sharps
- yellow bags for clinical waste disposal
- quality control materials
- decontamination materials
- spare batteries (if required).

The level of initial set-up and maintenance required will depend on whether the system selected is a meter or compact analyser. However, the workflow will be similar and can be divided into pre-analytical, analytical and post-analytical stages, each consisting of short, multiple sequential steps (figure 1).

Figure 1: Work flowchart of steps involved in lipid measurement



Analyser selection

The selection of the most suitable point-of-care cholesterol testing system is complex as independent studies on analytical performance may not be readily available. High levels of accuracy, precision and clinical acceptability should be the main focus of the selection process. However, this can be a difficult process and independent advice and guidance should be sought from the local clinical laboratory services [29-32].

In addition, to reduce the risk of obtaining incorrect results with systems used by non-laboratory operators, they should have a minimal number of complex manoeuvres and safety features to minimise risk to the operator and patient. Automatic checks by the system to highlight procedural or analytical errors via warning messages or audible signals are desirable. Ideally, systems should be capable of prompting the user to perform the required internal quality control measurement and automatically prevent patient testing if target values are not achieved. Medical Device Alerts or hazard notices also provide invaluable information regarding hazards in the use of the system selected.

A major operator-dependent step inherent to all analytical systems using capillary blood is obtaining a sufficient volume of free flowing blood. Unlike blood glucose meters, POCT lipid systems require fairly large volumes of blood of up to 120 μL . Sample application may also require an accurate, defined sample volume to be applied using either a fixed volume pipette or capillary blood collection tubes.

For use in POCT, liquid control materials for IQC are preferable to lyophilised control materials that require reconstitution. If reconstituted incorrectly, the IQC may suggest an apparent problem that does not exist.

Manufacturers and distributors should be well established to guarantee a continuous high level of service, supplies and support. They should be able to offer batch reservation and long term reagent storage if required. Terms of the contract should include negotiation on the duration, number of meters, reagents and QC materials as well as future upgrades and enhancements and any additional training required as a consequence.

Training

Point-of-care testing within a hospital is part of the laboratory accreditation process that verifies technical competence [28]. Currently there is no formal accreditation for POCT conducted in the community, but it should be recognised that to comply with clinical governance, the facilities and the staff training should be formalised and competency monitored [56]. Clinical governance ensures that the POCT is clinically effective and minimises the risk to the patient.

Consistent, well documented training conducted by a competent trainer is essential in POCT as it is performed extensively by non-laboratory personnel from various healthcare backgrounds who may test infrequently [24, 25, 57]. Staff must [4, 25, 56, 58]:

- be competent, with certification to indicate the standard of training and competence achieved
- correctly carry out patient preparation, specimen collection and sample measurement (figure 1)
- carry out and document internal quality control and external quality assessment procedures
- perform necessary maintenance and ensure that it is well documented
- be capable of troubleshooting and contacting the manufacturer for technical help if required
- adhere to and understand infection control protocols.

A standard operating procedure (SOP) for carrying out point-of-care lipid measurements should be available to the user. It should include the manufacturer's instructions for use, warranty information and contact details for troubleshooting and reporting of faults. Any additional support and troubleshooting advice should be sought from the local clinical laboratory services [29].

Safety

Operators of POCT systems should be aware of potential hazards, including those identified in safety advice from the MHRA, the manufacturer or other relevant bodies. They should be aware of the importance of device-related adverse incidents; be capable of recognising when a device is not working properly and follow the appropriate procedures for reporting incidents to the MHRA (www.mhra.gov.uk).

Safety in the use of a cholesterol system also applies to the proper use of accessories and following correct procedures outlined in the SOP. For example, patients and operators may be at risk of infection from a contaminated system. All blood samples and external quality assessment and control materials should be treated as potential biohazards. Suitable infection control and decontamination procedures should be implemented by staff handling such samples and they should have the necessary immunisations against hepatitis B.

Needlestick injury from contaminated sharps can transmit infection. In multiple patient environments a single-use, disposable lancing device with automatic retraction of the needle, or a non-disposable multiple-patient system should be used

to minimise the risks associated with contaminated lancets. CEP has produced a buyersguide for lancing systems that is available on www.pasa.nhs.uk/cep [59] and the MHRA has issued guidance relating to the safe use of lancing devices and the risks associated with inappropriate use [60, 61].

Consumables such as used gloves, tissues, strips or cassettes contaminated with blood must be disposed of in clinical waste bags. However, sharps such as lancing devices, capillary collection devices or tips must be discarded in a sharps bin.

Maintenance

Sufficient time should be allocated to carry out regular maintenance and servicing and if required troubleshooting. Input can be sought from the local hospital point-of-care co-ordinators to maintain, support and manage all relevant activities, including IT support and infection control.

Data management

Connectivity is the ability of a system or device to connect with other systems or devices to allow data transfer, such as to the hospital or laboratory information systems. Connectivity is increasingly incorporated for auditing patient pathways and the Clinical Governance and NHS Litigation Authority guidelines [62] advocate connectivity to help reduce errors and improve staff compliance. Point-of-care test results are often recorded manually, which increases the risk of transcriptional errors and omissions from patient records.

Setting up the devices to connect to other devices should comply with the POCT-2P Standards of the Clinical and Laboratory Standards Institute (ISO 11073-90101), which stipulates that *“connectivity should be easy to use and share a common interface and data manager system with all other point-of-care-testing devices. It should be bi-directional to allow downloading of additional information from the Hospital Information System”* [63].

Cardiovascular disease cost the NHS £14.4 billion in 2006. However, the cost to the UK economy is estimated to be closer to £30.7 billion a year, if loss in productivity due to illness and informal care costs are taken into consideration [64]. As part of the NHS Health Check [14] initiative, £250 million annually has been allocated for cardiovascular risk assessment screening in primary care [65]. Cholesterol is a key modifiable risk factor and both total cholesterol and HDL cholesterol levels are required to calculate an individual's overall CVD risk [14]. The Department of Health publication *Economic Modelling for Vascular Checks* estimates the average cost for a basic vascular check as £23.70, which includes staff time and laboratory tests for cholesterol (£4.20), fasting blood glucose and creatinine [66].

The cost of conducting point-of-care cholesterol testing is the sum of several components. Indirect costs for space, heating, electricity and waste disposal services are considered to be part of the existing infrastructure. Purchase costs are generally negotiable with suppliers and special NHS or volume related discounts may apply. Direct costs such as capital equipment, reagents, labour, quality assurance, additional consumables, maintenance and training are the major considerations.

Capital equipment

The purchase cost (excluding VAT) of these systems range from £75 to £13,490 and should be considered over the lifetime of the system (see market review). All instruments are supplied with at least a one year manufacturer's warranty. Additional warranties or service contracts can be purchased separately. Data management of patient results may require the purchase of a printer, software and data cable.

The purchase of a refrigerator may be necessary for reagent storage or a centrifuge if plasma or serum samples are required (see market review).

Reagents

Reagent costs will depend on whether the analyte is measured individually, or as a multi-analyte test panel which allows measurement of total cholesterol and HDL cholesterol levels simultaneously. This may help to reduce overall testing time, but this format is not available with all systems.

Labour

In point-of-care testing the major labour cost is staff time for conducting the test and will depend on the grade of healthcare professionals involved. Instrument set-up, maintenance, quality control and ordering consumables will add to the labour costs.

Quality assurance

Internal quality control requires the purchase of suitable materials from the manufacturer. It must also include the cost of reagents for conducting the tests. Usually two levels of control materials are purchased that have a limited shelf life

once opened of approximately 10 to 30 days. An additional cost to consider is enrolment in an EQA scheme, such as Birmingham Quality POCT EQA Service for Lipids or WEQAS EQA scheme for POCT Lipids.

Additional consumables

Sample collection and application require additional consumables such as gloves, alcohol swabs, gauze, lancets, capillary tubes or pipette and pipette tips. Consideration should be given to the cost of replacement batteries throughout the expected product life expectancy.

Training and maintenance

Costs associated with the training and accreditation of staff must be considered. There are also additional costs in conducting regular maintenance and quality procedures.

Cost effectiveness

A small number of studies have examined the costs of point-of-care cholesterol testing in primary care settings in the UK [67, 68]. They are limited in scope with very little evidence available to demonstrate cost effectiveness and from which to draw any conclusions regarding economic outcomes.

However, although point-of-care tests are more expensive than conventional laboratory tests [5, 6, 69,] major cost savings are mainly made in other departments further along the patient care pathway [6]. Some studies suggest that POCT may improve patient outcome in disease management, increase quality-adjusted life years produce wider economic benefits. The earlier detection and treatment of disease, reduction in clinic visits and treatment costs may lead to an overall reduction in healthcare costs [5, 69 - 71].

Purchasing procedures

The Trust Operational Purchasing Procedures Manual provides details of the procurement process [72]. European Union procurement rules apply to public bodies, including the NHS, for all contracts worth more than £90,319 (from January 1st 2008) [73] (appendix 2). The purpose of these rules is to open up the public procurement market and ensure the free movement of goods and services within the EU. In the majority of cases, a competition is required and decisions should be based on best value.

NHS Supply Chain (NHS SC) offers national contracts or framework agreements for some products, goods and services. However, at present there is no framework agreement for POCT cholesterol systems. Use of these agreements is not compulsory and NHS organisations may opt to follow local procedures.

Purchasing considerations

Considerations should be given to the technical and operational specifications, additional services, number, type and duration of tests required and length of contract period (if applicable). Advice should be sought from local laboratory services. It is necessary to consider both local and national acquisition policies, whole of life costing and purchasing options. The main purchasing option is outright purchase but leasing may be an option.

Sustainable procurement

The UK Government launched its current strategy for sustainable development, *Securing the Future* [74] in March 2005. The strategy describes four priorities in progressing sustainable development:

- sustainable production and consumption - working towards achieving more with less
- natural resource protection and environmental enhancement - protecting the natural resources and habitats upon which we depend
- sustainable communities - creating places where people want to live and work, now and in the future
- climate change and energy - confronting a significant global threat.

The strategy highlights the key role of public procurement in delivering sustainability.

This section identifies relevant sustainability issues and provides some guidance on how these can be incorporated into procurement decision making processes.

Sustainable development in point-of-care cholesterol testing systems

Manufacturers were surveyed as part of this report to obtain sustainability information on these devices. It is clear from their responses that this is an issue that they are only just beginning to consider. The major sustainability considerations for lipid POCT are: materials used in manufacture, consumables required, packaging, and disposal of materials, consumables and packaging. The information obtained from the manufacturers in the sustainability survey is presented in Appendix 3.

Materials

High levels of plastic are used in the manufacture of medical devices and associated consumables. The type of plastic used could have an impact on product sustainability which can be minimised by use of biodegradable plastics, recyclate or natural products from sustainably managed sources. The European directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) [75] will not apply to medical devices until 2012. Minimisation of such substances ahead of regulation enforcement is seen as advantageous and some suppliers are already compliant with the RoHS regulations (appendix 3).

Power supply and energy demand

Point-of care testing cholesterol systems are mains powered or use batteries. The energy demand is relatively low, especially where units are not in constant use, operate at room temperature and have power saving features. Rechargeable batteries are not recommended by some manufacturers (appendix 3).

Noise levels

All POCT cholesterol systems comply with recommended noise exposure limits specified by the Health and Safety Executive [76] with most systems producing minimal audible noise output (appendix 3).

Waste disposal

The majority of packaging consists of cardboard and plastic from recycled waste materials or virgin materials derived from renewable sources. Most uncontaminated paper and cardboard packaging is recyclable, although some plastics are not.

Consumable waste is predominantly used test strips, cassettes or rotors and other single use items that are contaminated. They must be treated as a bio-hazard and disposed of in appropriate clinical waste containers.

End of life disposal

Consideration should be given to the likely financial and environmental costs of disposal at the end of the product's life. Where appropriate, suppliers of equipment placed on the market after the 13th August 2005 should be able to demonstrate compliance with the UK Waste Electrical and Electronic Equipment (WEEE) regulations (2006) [77]. The WEEE regulations place responsibility for financing the cost of collection and disposal on the producer. Electrical and electronic equipment is exempt from the WEEE regulations where it is deemed to be contaminated at the point at which the equipment is scheduled for disposal by the final user. However, if it is subsequently decontaminated such that it no longer poses an infection risk, it is again covered by the WEEE regulations, and there may be potential to dispose of the unit through the normal WEEE recovery channels.

Batteries contain toxic materials and should be treated as hazardous waste for the purposes of disposal, in line with existing regulatory control measures and sustainable disposal practices [78, 79].

A random, non-fasting, cholesterol test is required under the NHS Health checks vascular risk assessment programme [14]. However, the Framingham and QRISK^{®2} risk calculators require both total and HDL cholesterol measurements. Table 5 lists the systems that are available in the UK for point-of-care cholesterol measurement (see suppliers contact details in appendix 1).

Table 5: POCT cholesterol measurement systems that support the NHS Health Check vascular risk assessment

	Total cholesterol	HDL cholesterol	Calculated total cholesterol / HDL cholesterol ratio
Accutrend Plus	✓	✗	✗
BeneCheck PLUS	✓	✗	✗
CardioChek PA	✓	✓	✓
Cholestech LDX	✓	✓	✓
Piccolo xpress	✓	✓	✓
Reflotron Plus	✓	✓*	✗

Note:

*Using serum or EDTA plasma

- Accutrend Plus (formerly known as the Accutrend GCT) - meter launched in the UK in 2002, uses same test strips as the Accutrend GCT (1989)
- BeneCheck PLUS - launched in the UK in 2009
- CardioChek PA - launched in the UK in 2003
- Cholestech LDX - launched in the UK in 1994
- Piccolo xpress (formerly known as the Piccolo) - launched in the UK in 2006, Piccolo available since 1996
- Reflotron Plus - first launched in the UK in 1982. Reflotron Plus is the sixth version and uses the same total cholesterol test strips as used with the original Reflotron.

The specifications of the first four smaller systems are shown in table 6, and the two desktop analysers in table 7. The advantages and disadvantages of each system and published comparison studies against laboratory reference methods (where available) are outlined in table 8.

Market review

Table 6: Small POCT Cholesterol systems specifications




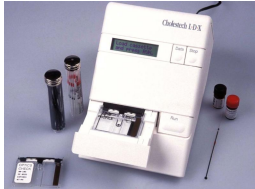
	Accutrend Plus	BeneCheck PLUS	CardioChek PA	Cholestech LDX
				
Technology	Reflectance	Reflectance	Reflectance	Reflectance
CRMLN* certified system	✗	✗	✓	✓
Tests available	Individual tests for: total cholesterol triglyceride glucose lactate	Individual tests for: total cholesterol glucose uric acid	Total cholesterol, HDL cholesterol and triglyceride OR Total cholesterol, HDL cholesterol and glucose OR HDL cholesterol, triglyceride and glucose OR Individual tests for: total cholesterol HDL cholesterol triglyceride direct LDL glucose ketones creatinine	Total cholesterol, HDL cholesterol OR Total cholesterol, HDL cholesterol and glucose OR Total cholesterol, HDL cholesterol, LDL cholesterol and triglyceride OR Total cholesterol, HDL cholesterol, LDL cholesterol triglyceride and glucose OR Direct LDL OR ALT and AST OR hs-CRP

Table 6: Small POCT Cholesterol systems specifications (continued)

	Accutrend Plus	BeneCheck PLUS	CardioChek PA	Cholestech LDX
List price (excl VAT)	£199	£75	£479	£950 without printer
Reagent price (excl VAT)	£49.00 / 25 test strips in a canister	£18.90 / 10 test strips in a canister	£106.37 / 25 dual test strips for total cholesterol and HDL cholesterol £67.20 / 15 triple panel test strips (total cholesterol, HDL and glucose)	£76.45 / 10 individually wrapped total cholesterol and HDL cholesterol cassettes £85.00 / 10 individually wrapped cassettes for total cholesterol, HDL cholesterol and glucose
Reagent storage	Room temperature	Room temperature	Room temperature	Room temperature 30 days, 2 - 8 °C up to expiry date
Analytical range (mmol/L)				
Total cholesterol	3.88 . 7.76	2.6 - 10.3	2.59 . 10.36	2.58 - 12.92
HDL-cholesterol	-----	-----	0.39 . 2.59	0.39 - 2.59
Triglyceride	0.80 - 6.86	-----	0.56 . 5.65	0.51 . 7.34
Direct LDL	-----	-----	1.30 . 5.18	-----
Lot-specific calibration	Manually insert and remove barcoded strip	Manually insert and remove calibration electrode	Manually inserting memo chip into slot	Automatic. Encoded on test cassette magnetic strip.
Sample type	Capillary blood	Capillary blood	Capillary or venous blood	Capillary or venous blood, plasma or serum
Sample volume (µL)	15 . 40	0.3	15 - 40	35
Sample application	Hanging drop of blood applied to test area	Capillary fill test strips	Using capillary blood collector or pipette	Lithium heparin coated capillary tube and plunger
Measurement time	3 minutes	30 seconds	Approximately 2 minutes	5 minutes
Haematocrit range (%)	30 to 55	Up to 55	30 . 45	Up to 52

Table 6: Small POCT Cholesterol systems specifications (continued)

	Accutrend Plus	BeneCheck PLUS	CardioChek PA	Cholestech LDX
Memory	100 results	360 results	200 results (30 per analyte)	Last result only
Operating temperature (°C)	18 - 30	10 - 40	18 - 35	20 - 30
Power supply	4 x 1.5v AAA	1 x 3v lithium battery (CR2032)	2 x 1.5v AAA	9v mains adaptor. Battery pack (5 hours rechargeable)
Dimension (cm)	8.1 x 15.4 x 3.0	6.0 x 2.0 x 9.0	7.6 x 14.0 x 2.5	12.7 x 12.7 x 22.9
Weight	140 g	45 g	122 g	1 kg
Additional features	-----	RS 232 link for data transfer	Optional printer available.	Optional printer available

Note: *Cholesterol Reference Method Laboratory Network (see page 8)

Table 7: Desktop POCT cholesterol analysers' specifications



	Piccolo xpress	Reflotron Plus
		
Technology	Photometric	Reflectance
CRMLN* certified system	✓	✗
Tests available	Lipid panel - total cholesterol, HDL cholesterol and triglyceride OR Lipid panel plus ALT, AST and glucose OR Other test panels	Individual tests for: total cholesterol HDL cholesterol triglyceride Plus 17 other parameters including liver and renal function
List price (excl VAT)	£13,490	£3600
Reagent price (excl VAT)	£106.40 / 10 single-use centrifugal reagent rotors	£29.10 / 30 test strips in canister total cholesterol £35.40 / 30 test strips for HDL cholesterol £30.90 / 30 test strips for triglyceride
Reagent storage	Refrigerate at 2 . 8 °C	Room temperature
Analytical range (mmol/L)		
Total cholesterol	0.52 . 13.5	2.59 . 12.9
HDL-cholesterol	0.39 . 2.59	0.26 . 2.59
Triglyceride	0.23 . 5.65	0.80 . 6.86
Direct LDL	-----	-----

Table 7: Desktop POCT cholesterol analysers' specifications (continued)

	Piccolo xpress	Reflotron Plus
Lot-specific calibration	None	Automatic. Encoded on back of test strip
Sample type	Lithium heparinised venous whole blood, plasma or serum	Capillary or venous whole blood, plasma or serum. HDL cholesterol plasma samples
Sample volume (µL)	100 -120	30 per test
Sample application	Fill sample chamber to mark	Using fixed volume pipette
Measurement time	12 minutes	2 to 3 minutes per individual test
Haematocrit range (%)	Up to 60	Up to 55
Memory	5000 patients and QC results	60 with date, time and ID
Operating temp (°C)	15 - 32	15 - 34
Power supply	Mains adaptor or 15v battery	Mains adaptor
Dimension (cm)	15.2 x 20.3 x 32.4	30.0 x 35.0 x 21.0
Weight	5.1 kg	5.3 kg
Additional feature	Integral printer, touch screen, USB connectors	Integral printer for operator and patient identification and results

Note: *Cholesterol Reference Method Laboratory Network (see page 8)

Table 8: Additional features of POCT cholesterol systems

Accutrend Plus - Roche

Advantages

- Lot number on the test strip is congruent with the stored code preventing use of mismatched test strip and lot code.
- Test recognition eliminates the need to recalibrate for each separate analyte even when measured consecutively.
- Capillary blood sample applied directly onto test strip.
- Reagent test strips are stored at room temperature.



Disadvantages

- Does not measure HDL cholesterol.
- Insufficient sample may give an inappropriately low result.
- Test strip housing and test strip guide require cleaning.
- Each analyte is measured individually which may involve more than one fingerstick or require blood collection into an anticoagulated sample tube which delay the clotting process for a short time (approximately 5 minutes).
- The lot-specific calibration code strip must be kept separately from the reagent test strip as it may impair quality of test strips.

Performance claims

Published studies [80, 81]

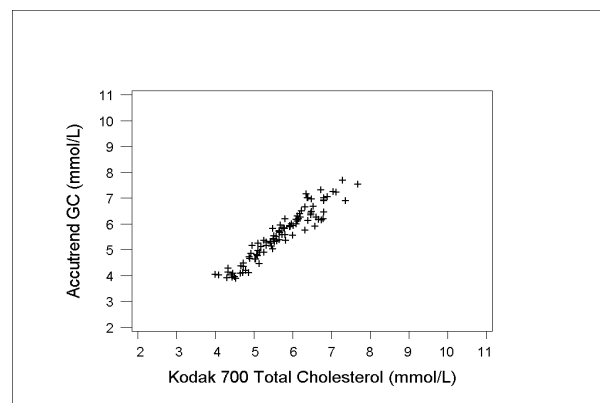
Independent evaluation report [55]

The report is still valid as the same test strips used with the Accutrend Plus were used with the Accutrend GC meter.

The graph shows the correlation obtained on the 98 results within the analytical range of 3.9 to 7.8 mmol/L.

The correlation coefficient was 0.95 and regression statistics gave a slope of 1.13, with an intercept of -0.75 ($y = 1.13x - 0.75$). The imprecision was 5% to 6%.

Correlation of total cholesterol results from 98 patients specimens using Accutrend GC and the Kodak 700 analyser



Manufacturer's data:

N = 168, correlation coefficient = 0.956, $y = 0.94x + 0.22$.

Table 8: Additional features of POCT cholesterol systems (continued)

BeneCheck PLUS- General Life Biotechnology Ltd

Advantages

- Very small sample volume of 0.5 µL.
- Capillary fill action draws blood automatically into the measurement chamber.
- 30 second measurement time.
- Reagents stored at room temperature.

Disadvantages

- Does not measure HDL cholesterol or triglyceride.
- Each test has to be conducted individually.
- Lot-specific calibration required. Incorrect results may be obtained if meter is calibrated incorrectly.



Performance claims

Published studies - no published studies were found through literature search.

Independent evaluation report - no independent evaluation report available.

Manufacturer's data:

Total cholesterol: N = 120, correlation coefficient = 0.93, regression - $y = 0.96x + 0.19$. Imprecision was between 4.9 and 6.9 %.

Table 8: Additional features of POCT cholesterol systems (continued)

CardioChek PA- Polymer Technology Systems Inc

Advantages

- Reagents stored at room temperature.
- Single sample application of 30 µL provides a total and HDL cholesterol and calculated TC/ HDL cholesterol ratio in approximately 120 seconds.



Disadvantages

- Lot-specific calibration information requires input into the meter's memory using a code chip. Incorrect results may be obtained if meter is calibrated incorrectly.
- Code chip will need to be swapped to that for the analyte being measured.
- Avoid storing or using the analyser in direct light, such as sunlight, spotlight, under a lamp or by a window. The manufacturer states that direct light may adversely affect test results.
- Sample is applied to the test strip using either anticoagulated capillary tubes or non-anticoagulated plastic pastette pipettes. Sample application must be performed quickly to minimise the risk of the sample clotting and producing incorrect results when using non-anticoagulated plastic pipette.
- Test strip housing and test strip guide require cleaning.

Performance claims

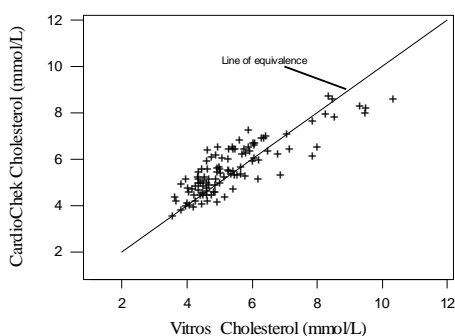
According to PTS the test strip production for the CardioChek PA test strips has been improved. However, an entirely new architecture and chemistry for HDL has been introduced since 2003. There is no independent evaluation data on the new production test strips

Published studies . [80, 82 - 84]

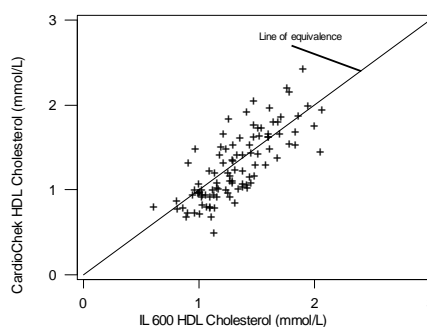
Independent evaluation report [85]

Correlation of total cholesterol results from 106 patients' specimens using CardioChek PA and the Vitros 950 analyser

Correlation of HDL cholesterol results from 101 patients' specimens using CardioChek PA and the IL 600 analyser



The graph shows the correlation obtained on 106 results. The correlation coefficient was 0.86 and regression statistics gave a slope of 0.72, with an intercept of 1.76 ($y = 0.72x + 1.76$). The imprecision was around 12%.



The graph shows the correlation obtained on 101 results. The correlation coefficient was 0.77 and regression statistics gave a slope of 1.02, with an intercept of -0.06 ($y = 1.02x - 0.06$). The imprecision was between 15% and 24%.

Manufacturer's data:

Total cholesterol: N = 20, $y = 0.83x + 0.51$. HDL cholesterol: N = 20, $y = 0.75x + 0.03$.

Table 8: Additional features of POCT cholesterol systems (continued)

Cholestech LDX - Inverness Medical UK

Advantages

- No calibration required.
- Single sample application of 35 µl provides a full lipid profile eg total and HDL cholesterol, triglyceride and calculated LDL and VLDL, TC / HDL-cholesterol ratio and Framingham cardiac risk score.

Disadvantages

- A defined volume of blood applied to the sample chamber using heparinised capillary tubes with plunger or fixed volume pipette.
- Extended storage up to expiry date requires refrigeration of test cassettes. However, they are can be stored at room temperature for one month.
- EQA measurements are conduct as a serum sample. Once completed, the analyser set up must be changed back to blood sample testing.

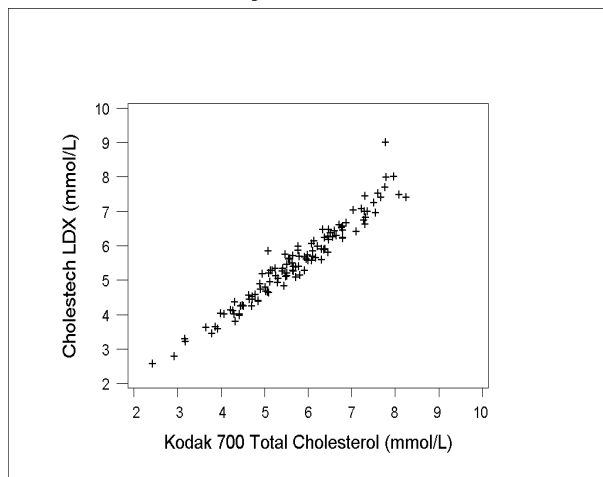


Performance claims

Published studies - [82 - 84, 86 - 94]

Independent evaluation report [95]

Correlation of total cholesterol results from 119 patients' specimens using Cholestech LDX and the Kodak 700 analyser



The graph shows the correlation obtained on the 119 results.

The correlation coefficient was 0.97 and regression statistics gave a slope of 0.95, with an intercept of 0.11 ($y = 0.95x + 0.11$).

The imprecision was around 5%

Manufacturer's data:

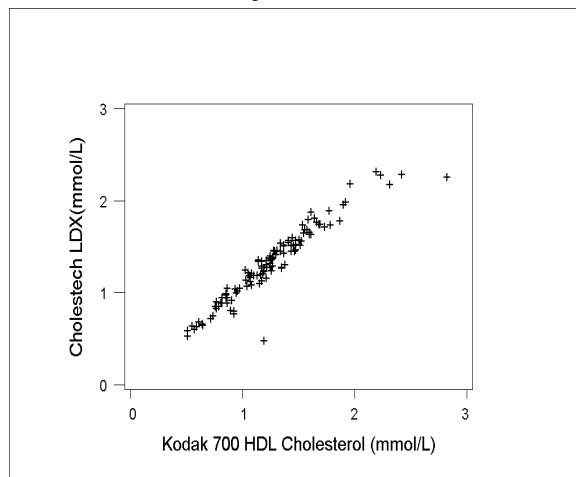
Total cholesterol

N = 40, correlation coefficient = 0.97

$y = 0.98x + 0.062$

Imprecision CVs 2.5 % and 2.4 %

Correlation of HDL cholesterol results from 119 patients' specimens using Cholestech LDX and the Kodak 700 analyser



The graph shows the correlation obtained on the 119 results.

The correlation coefficient was 0.95 and regression statistics gave a slope of 0.93, with an intercept of +0.16 ($y = 0.93x + 0.16$).

The imprecision was between 5 and 10%

HDL cholesterol

N = 40, correlation coefficient = 0.95

$y = 0.897x + 0.006$

Imprecision CVs 3.4 % and 4.8 %

Table 8: Additional features of POCT cholesterol systems (continued)

Piccolo xpress – Abaxis Inc

Advantages

- No calibration required, self-calibrates with each test run.
- Rotors can be used straight from the fridge.
- Degree of sample haemolysis, icterus and lipaemia are indicated for each set of results.
- Built in quality control. Intelligent QC system checks the analyser, the reagent disc and sample during each run to verify correct electronic and chemistry performance. It automatically suppresses the result(s) if it detects uncharacteristic performance.
- Single sample application of 120 µL provides a full lipid profile eg total and HDL cholesterol and calculated LDL and VLDL, TC / HDL-cholesterol ratio and Framingham cardiac risk score.



Disadvantages

- Approximately 100 µL of heparinised blood, plasma or serum sample has to be applied to test chamber using either a fixed volume pipette or other transfer device.
- Lyophilised QC material requires accurate reconstitution with distilled water. Requires refrigeration and is stable for 10 days. The distributor will reconstitute control, aliquot material and distribute five aliquots weekly.
- Refrigerator space required for rotors storage and control materials.

Performance claims

Published studies - no published studies were found through literature search for the Piccolo xpress. However, the following studies evaluate the Piccolo using the same reagent system [96- 98].

Independent evaluation report - no independent evaluation report available.

Manufacturer’s data:

Total cholesterol

N = 174, correlation coefficient = 0.997
 $y = 1.079x - 0.44$
 Imprecision CVs 1.3 % and 1.5 %

HDL cholesterol

N = 166, correlation coefficient = 0.965
 $y = 0.851x + 0.21$
 Imprecision CVs 2.6 % and 3.5 %

Table 8: Additional features of POCT cholesterol systems (continued)

Reflotron Plus – Roche

Advantages

- No calibration as information coded on back of each individual test strip.
- Test strips stored at room temperature.
- Calculates LDL cholesterol, total cholesterol/HDL cholesterol ratio, creatinine clearance and Framingham cardiac risk score.



Disadvantages

- HDL cholesterol can only be measured using plasma or serum samples. This will require a centrifuge for separation of the blood sample.
- Capillary blood sample would need to be collected into a sample tube containing an anticoagulant.
- Skill is required in using fixed volume pipette and correct application of blood to test strip.
- Each test is conducted one at a time thereby extending the measurement time.
- Lyophilised QC materials require accurate reconstitution with distilled water. Requires refrigeration and is stable for 10 days.

Performance claims

Published studies . [81, 89, 99-102]

Independent evaluation report . [103]

Total cholesterol (serum samples) N = 100, correlation coefficient = 0.97,
y = 1.04x - 0.05.

HDL cholesterol was not evaluated at the time of the evaluation report in 1989

Manufacturer's data

Total cholesterol

No data provided

HDL cholesterol (EDTA plasma):

N = 116; correlation coefficient = 0.989

y = 1.017x - 0.094

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BHR Pharmaceuticals Ltd

Inverness Medical UK

Miller Medical Supplies

Point of Care Testing Ltd

Roche Diagnostics UK

Accuracy	A measure of the agreement in the result obtained compared to a true result with a laboratory reference method.
Atherogenic	The formation of fat deposits on the inner lining of blood vessels
Atherosclerosis	The progressive narrowing and hardening of the arteries over time due to aging, high cholesterol, high blood pressure, smoking, diabetes and family history for atherosclerotic disease.
Bias	Bias represents the magnitude of the systematic error of a system - either negative or positive.
Biosensor	Biosensors use an enzyme and other mediator to detect measure or analyse chemicals. The chemical reaction produces a small electric current which is proportional to the concentration in the sample. Metallic contacts carry the current from the reagent area, along the strip and to the instrument where a result is displayed. The biosensor reagent section with blood is not inserted into the body of the meter hence reducing the risk of meter contamination.
Chylomicrons	Chylomicrons are triglyceride-rich lipoproteins formed in the intestine from dietary fat and appear in the blood after a fat-containing meal.
Coefficient of variation (CV)	The coefficient of variation represents the ratio of the standard deviation to the mean, expressed as a percentage. It helps when comparing the degree of variation between data sets which have differing mean value.
Coronary artery disease (CAD)	Is a condition in which plaque builds up inside the coronary arteries which supply the heart muscle with oxygen-rich blood.
Framingham	A risk assessment tool that uses information from the Framingham Heart Study to predict a person's chance of having a heart attack in the next 10 years. This tool is designed for adults aged 20 and older who do not have heart disease or diabetes.
Haematocrit	Haematocrit is a measure of the percentage of a blood sample that consists of red blood cells. It is measured after the blood has been centrifuged and the cells compacted. The haematocrit range over which the cholesterol measurements should be made are quoted in the manufacturers instructions for use.
Imprecision	A measure of the variation in results obtained repeatedly on an identical sample and expressed as standard deviation or coefficient of variation. High standard deviation and coefficient of variation values indicate that the system is imprecise.
Lipoproteins	Lipoproteins transport cholesterol and triglycerides through the bloodstream. There are five major types of lipoproteins which are classified according to their density - chylomicrons, very low density lipoprotein (VLDL), low density lipoprotein (LDL), high density lipoprotein (HDL) and lipoprotein subclasses.
Medical Device Alerts	Adverse incidents relating to the use of a medical device must be reported to the Medicines and Healthcare products Regulatory Agency at www.mhra.gov.uk .

QRISK^{®2}	<p>The QRISK^{®2} algorithm was developed by doctors and academics working in the National Health Service. It is based on routinely collected data from GPs across the UK.</p> <p>This calculator works out the risk of having a heart attack or stroke over the next ten years in individuals who do not already have a diagnosis of heart disease or stroke.</p>
Reflectance meter	<p>Reflectance meters measure the light reflected from the coloured test strip and convert the signal into analyte concentration.</p>
Standard deviation (SD)	<p>SD is a measure of the spread of the data. A low standard deviation will arise when the data points are clustered together around the mean; whereas high standard deviation occurs when the data are widely spread about the mean.</p>
Total allowable error	<p>Is a combination of bias and imprecision, which reflects how far a system gives results away from the true values.</p>
Very low density lipoproteins (VLDL)	<p>Triglyceride-rich lipoproteins but contain 10. 15 percent of the total serum cholesterol. VLDL is produced by the liver and is a precursor of LDL; some forms of VLDL, particularly VLDL remnants, appear to promote atherosclerosis, similar to LDL.</p>

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108. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsProcurement/DH_4109316

UK distributor	Address	Manufacturer
BHR Pharmaceuticals Ltd	41 Centenary Business Centre Hammond Close, Nuneaton Warwickshire CV11 6RY Tel: 0870 0349 606 www.bhr.co.uk	Polymer Technology Systems Inc
Inverness Medical UK	Pepper Road Hazel Grove Stockport Cheshire SK7 5BW Tel: 0161 483 5884 www.invmeduk.com	Inverness Medical UK
Miller Medical Supplies	Phoenix House Turner St Newport South Wales NP19 7BA Tel: 01633 213366 www.millermedicalsupplies.com	General Life Biotechnology Ltd
Point of Care Testing Ltd	Units 1 . 7 Arbroath Business Centre Dens Road Arbroath Angus DD11 1RS Tel: 01241 439020 www.poct.co.uk	Abaxis Inc
Roche Diagnostics UK	Charles Avenue Burgess Hill West Sussex RH15 9RY Tel: 01444 256000 www.accu-chek.co.uk	Roche

Lease options

National frameworks are in place for operating leases to help the NHS procure leases more cost efficiently and effectively. Further details are available from the PASA website [104].

EU procedures

The Public Sector Directive (2004/18/EC) has been transposed into UK law via the following statutory instruments:

- the Public Contracts Regulations SI 2006 No.5 (the regulations)
- the Utilities Contracts Regulations SI 2006 No. 6 (not relevant to this guide).

The regulations apply to contracts worth more than £90,319 (from January 1st 2008) [73] over their whole life, and specify the procedures to be followed for public sector contracting, including adherence to strict timetables, requirements for advertising, invitation to tender and the award of contract. Organisations undertaking a procurement exercise covered by the regulations must give all suppliers an equal opportunity to express an interest in tendering for the contract by placing a contract notice in the Official Journal of the European Union (OJEU).

At all stages of the procurement process, the purchaser must be demonstrably fair, as any decision made can be challenged by the unsuccessful suppliers.

Establishing a procurement strategy

To achieve a successful outcome, decisions need to be made on:

- whether an existing contract/agreement can be used
- the need to consider sustainable development issues
- whether EU directives apply
- the type and form of contract
- sourcing potential suppliers
- duration of contract and opportunity to review/extend
- payment schedules
- how to minimise any risks with the chosen strategy, including supplier appraisal and evaluation/clarification of suppliers' bids.

Preparing a business case

A business case should be drafted and approved before conducting any procurement exercise. Further guidance on preparing business cases is available from the Office of Government Commerce [105] and an illustrative example is provided in the *NHS PASA Operational Purchasing Procedures Manual*, Procedure 1-01 [106].

The EU tendering exercise

EU procurements usually take between 4 and 6 months to complete. This needs to be taken into account in the planning stages. The length of the exercise depends on the chosen procedure (open or restricted). Further information is available from the Department of Health [107].

The procurement panel

A multidisciplinary team should be selected to guide the purchase. Representatives from clinical, user, technical, estates and financial areas should be considered.

Identifying potential suppliers

Criteria for supplier selection must be established. A pre-qualification questionnaire, seeking background information (eg on the skills and experience of the service engineers) may be employed as an initial screen to exclude unsuitable suppliers.

Evaluation criteria

Performance specifications should be derived from local operational requirements, and agreed by the procurement panel. They will form the basis for assessing the adequacy of suppliers' technical specifications, provided in response to the technical specification questionnaire.

It is important to have agreed on the performance specifications of the product as they will be used in the adjudication against company specifications.

Requests for features which are supplier-specific are not permitted under the regulations. Very specific features which are not supported by operational requirements are also not allowed.

Award of contract

Following award of the contract to the successful supplier; unsuccessful suppliers may need to be debriefed. This is at the supplier's request.

Buyers must be aware of the Alcatel procedure (see the *Trust Operational Purchasing Procedures Manual* [72], Procedure No.T-08, section 6 - *Mandatory Standstill Period*).

For more information on procurement please refer to the Department of Health Website [108].

Appendix 3: Sustainable development

Table 5: Point-of-care cholesterol testing systems – sustainable development issues

		Accutrend Plus	BeneCheck PLUS	CardioChek PA	Cholestech LDX	Piccolo xpress	Reflotron Plus
Power supply		4 x 1.5v AAA batteries	1 x 3v lithium battery (CR2032)	2 x 1.5v AAA batteries	9v mains adaptor. Rechargeable battery pack	Mains adaptor or 15v battery	Mains adaptor
Approximate energy use:	Operation	25.92 W	Negligible	Not known	Not known	32.0 - 50.3 W	9.6 W***
	Standby	None, automatic switch off after 2 minutes of non-use	None, automatic switch off after 5 minutes of non-use	None, automatic switch off after 3 minutes of non-use	None, automatic switch off after 10 minutes of non-use	Screen saver mode	Switches to standby (1.7 W)
Power saving features:		Automatic switch off, LED & LCD display	Automatic switch off, LCD display	Automatic switch off	Automatic switch off	Screen saver mode	LED & LCD display
Audible noise output (dBA):	Operation	0	0	0*	0**	65 dBA	43.9 dBA
	Standby	0	0	0	0	60 dBA	41.5 dBA
Percentage of recyclate used in:	Analyser	0 %	30 %	Not known	Not known	Not known	0 %
	Consumables	0 %	0 %	0 % for strips	Not known	10 %	0 %
	Packaging	Not known	> 70 %	0 %	Not known	0 %	Not known
Product lifespan (years):		10	5	5	10	16	Indefinite
RoHS compliance:		Yes	Not known	Yes	By 2012	Applies to some components	No. Product defined before RoHS was in place

Note: *Will make a humming noise when batteries are running low and need to be replaced. **Except when tray opens/closes. ***Uses 14 W during printing. NA . not applicable.

Buyers' guide: Point-of-care testing for cholesterol measurement

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