DEVICE

BULLETIN

MEDICAL DEVICES AGENCY

Management and Use of IVD Point of Care Test Devices

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The Medical Devices Agency helps safeguard public health by working with users, manufacturers and lawmakers to ensure that medical devices meet appropriate standards of safety, quality and performance and that they comply with the relevant Directives of the European Union.

Our primary responsibility is to ensure that medical devices achieve their fullest potential to help healthcare professionals give patients and other users the high standard of care they have a right to expect.

The Medical Devices Agency is an Executive Agency of the Department of Health

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1. EXECUTIVE SUMMARY

The aim of this bulletin is to provide advice and guidance on the management and use of point of care testing (POCT) *in vitro* diagnostics devices (IVDs) including:

- the importance of identifying a clinical need before a decision is made to introduce POCT;
- clinical governance issues relating to the setting up and management of POCT;
- the need for local hospital pathology laboratory involvement in all aspects of a POCT service;
- the need for training, updating and monitoring of all staff involved in the POCT service;
- quality issues including:
  - accreditation by an external certification body;
  - the need for an appropriate quality control procedure;
  - membership of an External Quality Assessment Scheme (where available);
- the importance of health and safety;
- the need for standard operating procedures (SOPs) and for regular reviews and updates when necessary.

1.1 Who this document is for

This bulletin is written for people involved in the management and use of point of care testing (POCT) services in primary and secondary care including managerial, scientific, technical, clinical and nursing staff. While many of the issues addressed are more relevant to the performance of POCT in a hospital environment, the principles are equally applicable to their use in outpatient clinics, community care and GP practices.

This bulletin is not written for people who use self-testing devices at home although it may be useful to healthcare professionals involved in advising them. It should be of particular interest to:

- all healthcare professionals performing POCT;
- trust chief executives;
- medical directors;
- directors of nursing;
- directors of quality;
- leads for clinical governance and clinical governance general managers;
- clinical directors of laboratories and laboratory managers;
- chief executives and managers of primary care groups and trusts;
- general practitioners;
- pharmacists;
- nurse practitioners;
- POCT co-ordinators;
- healthcare scientists;
- ambulance trusts.

2. INTRODUCTION

Recent years have seen a rapid growth in the use of POCT, largely as a result of technological advances such as new developments in solid phase chemistry and the integration of microprocessors resulting in miniaturisation of equipment[1]. Consequently the latest POCT devices are generally more reliable and less prone to error than previous generations. However, despite improvements in technology, the successful implementation of POCT is still dependent on the effective organisation and management of staff[2].

Users of POCT should have a sound understanding of the relevant analytical principles, and of issues such as quality assurance (QA), interpretation of test results, limitations to use and liability issues. It is therefore important that users of POCT should have access to clear guidance on these and other issues relating to the management of POCT.

Guidelines for POCT have been produced by a number of organisations[3-9]. These include the guidelines issued by the Joint Working Group (JWG) on Quality Assurance to assist health service managers and staff in the procurement, installation use and monitoring of devices for performing tests on blood, urine and stools[10].

The purpose of this bulletin is to review and draw together the main points from these existing guidelines in order to provide a check-list of questions that potential users of POCT will need to consider when implementing and managing POCT. This document is intended to complement existing guidance provided in MDA DB2002(02)[11] on the management of *in vitro* diagnostic medical devices.

For the purpose of this document, POCT is defined as any analytical test performed for a patient by a healthcare professional outside the conventional laboratory setting. Other terms commonly used to describe POCT include:

- near patient testing (NPT)
- bedside testing
- extra-laboratory testing
- disseminated laboratory testing

2.1 Potential sites for point of care testing

Secondary care (in hospital)

- accident and emergency departments
- intensive treatment units
- operating theatres
- coagulation clinics
- renal units
- liver units
- diabetic clinics
- hospital wards
- out-patient departments
- occupational health departments
- ambulance trusts

Primary care

- GP surgeries
- community clinics
- health centres
- industrial medical centres
- pharmacies
- anticoagulation clinics

Some examples of POCT devices:

- blood glucose meters
- bilirubinometers
- urinalysis test strips
- electrolyte analysers
- coagulometers
- analysers and kits for HbA_{1c}
- rapid test kits for infectious disease markers
- blood gas analysers
- cardiac enzyme analysers

Systems can be categorised as:

- **non-instrumental systems;** disposable systems or devices. These vary from reagent test strips for a single analyte to sophisticated multi-analyte reagent strips incorporating procedural controls
- **small analysers;** usually ‘hand-or palm-held’ devices, such as blood glucose meters, although they vary in size
- **desk top analysers** are larger and includes systems designed for use in clinics or small laboratory

3. BEFORE IMPLEMENTATION OF A POCT SERVICE

This section deals with issues and questions that need to be considered before deciding whether to adopt a POCT option. The principles outlined here are equally applicable to existing POCT services.

This section covers some aspects of purchasing that may influence the safety, quality and performance of the devices, however, it does not attempt to address wider issues of best procurement practice, such as regulations implementing EU purchasing requirements, financial evaluations and purchasing specifications. Advice on such matters should be sought from the NHS Purchasing and Supply Agency (PaSA) (See Appendix 2).

3.1 Role of the local hospital pathology laboratory

The local hospital pathology laboratory can play a supportive role in providing advice on a range of issues including the purchase of devices, training, interpretation of results, troubleshooting, quality control, quality assessment and health and safety[12]. There should therefore be close liaison between users and the local hospital pathology laboratory on all issues relating to POCT. Wherever possible this liaison should be formally defined by a Service Level Agreement (SLA) defining the range of services, operational details and the responsibilities of the central laboratory and the POCT user [9].

3.2 Identifying the need for POCT

Before deciding whether to implement POCT it is essential for potential users to establish a clinical need. This should be based on establishing that the perceived need is valid and that meeting it will be clinically effective. Users should also keep under review the continuing clinical need for POCT. The following questions should help in assessing the clinical need for POCT:

Identifying a need – questions to consider [6,7,10]

- Which group(s) of patients need testing and what test(s) need to be performed?
- How is the service currently provided and does it adequately meet the clinical need?
- If clinical need has not been met, what has been done to try to rectify the problem?
- Is access to a laboratory service difficult for patients with conditions requiring frequent monitoring? Has this been discussed with the laboratory?
- Will POCT enable more rapid/effective diagnosis or treatment?
- Can you provide evidence that POCT will provide a measurable clinical and economic benefit?
- Will POCT provide a cost-efective alterative to laboratory testing ?

3.3 Choosing the right equipment

Once a need has been established, the next step is to identify the most suitable device. Accuracy and imprecision of results, robustness of device and traceability of results all need to be evaluated before acquisition; the local hospital pathology laboratory should be able to help with this evaluation. The following questions need to be considered.

What equipment will meet your needs[6,7] - questions to consider

- What is the expected workload?
- Who is going to use the equipment?
- What level of analytical accuracy and imprecision is required for the service?
- Where will the equipment and consumables be sited?
- Do you have adequate space in which to carry out POCT?
- Are appropriate services available e.g. power, water, refrigeration?
- Has the equipment been evaluated by an external professional organisation e.g MDA?
- Are the results comparable to those of the local hospital pathology laboratory?
- What are the limitations of the equipment?
- Will the POCT service work satisfactorily with existing data handling systems and IT infrastructure?
- Has consideration been given to Health and Safety issues such as the safe disposal of clinical waste and sharps?

Users and managers of POCT should consider the possible benefits of equipment standardisation, such as cost-effectiveness for capital purchases and consumables (larger discounts), benefits for staff training (when staff move around wards etc) and also for those staff (lab staff generally) who support the equipment.

(Infomation on the regulation of POCT devices is provided in Appendix 1.)

3.4 Preparing a business case

Once the need and equipment have been identified, a business case must be produced.

The business case should demonstrate the clinical and economic benefits (such as potential savings made in consulting, nursing, management and patient time) of POCT together with details of all the financial costs of providing a POCT service. These may include:

Capital costs

- initial purchase cost
- accessories e.g. centrifuges and incubators
- provision of a safe environment e.g. health and safety improvements
- site alterations to accommodate POCT e.g. operator and storage space
- depreciation
- interfacing with information management systems

Other fixed costs

- routine and preventative maintenance e.g. external service contracts with manufacturers
- internal quality control material and participation in external quality assessment scheme.
- accreditation scheme compliance e.g. CPA (UK) Ltd

Variable costs

- consumables
- record keeping e.g. data-handling system
- waste disposal
- cleaning

Professional costs

- staff training
- management of the POCT programme
- indemnity insurance and legal liability
- operator time
- laboratory support

3.5 Clinical governance

Clinical governance is an essential part of any POCT service.
The purpose of clinical governance is to ensure that patients receive the highest quality of NHS care possible. It covers the organisation's systems and processes for monitoring and improving services, including [13]:

- consultation and patient involvement
- clinical risk management
- clinical audit
- research and effectiveness
- staffing and staff management
- education, training and continuing personal and professional development
- use of information to support clinical governance and healthcare delivery.

It shall be noted that the appropriate use of POCT as an alternative to laboratory testing should be considered as a clinical governance issue and subject to examination of clinical effectiveness[10]. Such considerations may best be achieved through the setting up of a POCT committee (see section 4.1).

The government's white paper, A First Class Service, defines clinical governance as: "A framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish."

3.6 Potential advantages and disadvantages of POCT [14,15]

Users should be aware of some of the potential advantages and disadvantages of POCT before accepting the need for POCT. Examples of potential advantages and disadvantages include the following:

Advantages

- Improved turnaround time – mainly by shortening the pre and post-analytical steps.
- Potential for better monitoring of certain conditions and where frequent testing is desirable.
- Smaller sample and reagent volumes – POCT methods may be less clinically invasive.
- Advantageous in remote areas where access to a laboratory is limited.
- POCT may offer an easier to access service e.g. for the elderly
- Economic – although POCT is generally more expensive than laboratory testing, it may offer wider economic benefits with a reduced number of clinic visits, reduced length of stay in hospital and fewer hospital admissions.
- Greater patient involvement in their own care.

Disadvantages

- Unnecessary duplication of equipment.
- Tests performed by staff with non-analytical background – who will interpret the result and detect erroneous results?
- The availability of an array of tests may tempt users to perform unnecessary or inappropriate testing.
- Data recording may be complex and less robust – less recording of results in patient records.
- Incompatibility with laboratory results – reference ranges and results may differ from the laboratory's, thus making comparisons difficult.
- Without the economies of scale that come from centralised laboratory testing, POCT can be expensive.

4. MANAGEMENT AND ORGANISATION OF POCT

4.1 Responsibility and accountability

There will be many people involved in the creation, implementation and management of a POCT service. It is vital that an appropriate senior professional is identified to act as a 'POCT co-ordinator' and given the authority and overall responsibility for the service at the beginning of the development process. This individual will have responsibility for both the results that are generated and the correct use of the devices, which generate those results.

Managers of POCT should also be aware of their responsibility for clinical governance [16,17] and of the medico-legal implications of an erroneous result. Liability under the Consumer Protection Act (1987) [18] will only remain with the manufacturer or supplier if the user can demonstrate that POCT equipment has been used in strict accordance with the manufacturer's instructions.

Lines of accountability should be clearly written into local policies and procedures and should cover the following areas:

- training
- instructions for use
- standard operating procedures
- health and safety
- quality assurance
- maintenance
- accreditation
- record keeping
- adverse incident reporting

Responsibility and accountability - questions to consider

- Who will take responsibility for interpreting and acting upon results?
- How will the service quality be maintained?
- Does the management structure include designated deputies capable of assuming the necessary responsibilities?
- Is a laboratory able and willing to provide the necessary support for the POCT service, including interpretation of results? If so, is this supported by a Service Level Agreement with the laboratory?

In addition to the appointment of a POCT co-ordinator, the establishment of a multidisciplinary POCT committee to oversee POCT in the hospital setting is also recommended. All stakeholders should be represented in the POCT committee including the laboratory, clinicians, nursing staff, pharmacists and diabetic specialist nurses. If POCT extends to the community a representative from primary care is also recommended[19].

The role of the POCT committee may include the following:

- to determine if POCT is justified at a particular location. This would include a clear demonstration of increased clinical effectiveness;
- to establish a system for the continuing audit and assessment of POCT;
- to ensure that no POCT device is used in the hospital unless it has passed through the POCT committee;
- to set up a quality hierarchy to ensure that there is a direct link between the person performing the analysis and the POCT committee;
- to establish the presence of a link nurse at ward level;
- to include representatives from primary care and the community where necessary;
- to ensure that users are trained and certified in the use of POCT devices and that they are fully aware of all contra-indications and limitations;
- to ensure that internal quality control (IQC) and external quality assessment (EQA) schemes are employed effectively.

4.2 Training

Only staff whose training and competence has been established and recorded should be permitted to carry out POCT.

MDA Safety Notice SN 9616 ‘Extra-Laboratory Use of Blood Glucose Meters and Test Strips: Contra-Indications, Training and Advice to the Users’ (1996) [20].

Training should include:

- basic principles of the measurement
- demonstration of the proper use of the equipment in accordance with the manufacturer's specification
- demonstration of the consequences of improper use
- instruction in sample collection, including health and safety aspects
- instruction in the importance of complete documentation of all data produced
- appropriate calibration and quality control techniques
- practical experience of the procedures, including a series of analyses that satisfy the instructor that the trainee is competent.

Training - questions to consider

- Who is able to provide the necessary support for staff training?
- Does the hospital laboratory or manufacturer offer a comprehensive training programme for the device(s)?
- Is the POCT site willing and able to release staff for the appropriate length of time to complete training?
- Has a training manual been prepared?
- Does the training manual identify operator dependent steps?
- Who will be responsible for compiling a certification programme in order to assess staff competence?
- Is there a Continuing Professional Development (CPD) programme for the staff delivering the service?
- How will the requirement for training updates be carried out and how will it be assessed?

4.3 Instructions for use

All staff performing POCT must be familiar with the manufacturers' instructions for use, with particular reference to:

- the intended purpose of the device
- performance characteristics
- interpretation of results
- limitations for use
- sampling requirements including sample type
- storage of reagents and samples
- expiry dates
- quality assurance procedures
- health and safety issues.

Case study
A known diabetic was admitted to a hospital Accident & Emergency Department exhibiting signs and symptoms of diabetic ketoacidosis. The patient's blood glucose was measured at the point of care using a blood glucose meter. A separate sample sent to the hospital laboratory gave a markedly different result. As insulin treatment of diabetic ketoacidosis is titrated against blood glucose concentrations, the hospital complained to MDA about the performance of the ward based meter.

A review of the manufacturers' instructions for the meter revealed a number of contra-indications for use of which the users were unaware. These included diabetic ketoacidosis.

In all cases users should be aware of the manufacturers' instructions and any contra-indications for use. Such information should be incorporated into training of all staff involved in extra-laboratory blood glucose measurement. This information was published as MDA Safety Notice SN 9616 'Extra-Laboratory Use of Blood Glucose Meters and Test Strips: Contra-Indications, Training and Advice to the Users' [20].

Users should note that in this case, the device itself was not faulty, but used contrary to the manufacturer's recommendations. In such situations MDA does not seek to apportion blame to the user but to advise others on how to avoid similar problems.

4.4 Standard operating procedures (SOPs)

There must be a SOP in place wherever POCT is performed.

It is essential that any standard operating procedures (SOPs) that give instructions for use exactly reproduce the manufacturer's instructions for use and that all existing copies are updated as appropriate.

SOPs - questions to consider

- Have SOPs been produced and written in accordance with a recognised quality standard?
- Have the manufacturer's instructions been included in these procedures?
- Are SOPs regularly reviewed to ensure that they follow the current version of the manufacturer's instructions?
- Do the SOPs contain information on actions to be taken on the basis of the result?
- Do the SOPs contain information on actions to be taken in the event of a fault or instrument breakdown, including the reporting of adverse incidents to the Medical Devices Agency?

4.5 Health and safety

POCT users and managers must recognise the potential hazards of handling and disposing of body fluids and sharps outside of a laboratory setting.

Health & safety - questions to consider
• Will provision of the POCT service comply with existing health and safety policy? • Who will be responsible for ensuring that staff are aware of the current legislation and guidance, including the medico-legal implications of transmission of infection due to lack of safe specimen handling or spillage?

The Department of Health, the Health and Safety Executive and the British Medical Association have issued guidance on the safe handling and disposal of sharps and clinical waste [21-26], which users and managers should be aware of.

4.6 Quality assurance (QA)[27]

Quality assurance is an essential component of POCT and includes all the measures taken to ensure that investigations are reliable. These will include:

- correct identification of patient
- appropriate test selection
- obtaining a satisfactory specimen
- analysing it and recording the results promptly and correctly
- interpreting the result accurately
- taking appropriate action
- documenting all procedures for reference.

Quality assurance also encompasses proper training and review of overall performance. Two components of quality assurance, internal quality control and external quality assessment, can help ensure reliable results, but only if they are applied rigorously.

The local hospital laboratory should be consulted for advice on QA.

4.7 Internal quality control (IQC)

This is a means of checking that patient results are reliable before they are issued. The analysis of an appropriate control material (often supplied by the manufacturer of the POCT device) before analysing a set of specimens can provide reassurance that the system is working correctly. It is essential that the results of QC be recorded appropriately. Readers should note that some POCT devices incorporate electrical or optical checks, which form part of IQC.

IQC – questions to consider

- Is there a procedure in place to ensure that internal QC is performed at an appropriate frequency and that the results are recorded appropriately and in accordance with manufacturers' recommendations?
- Is the manufacturer of the POCT device or the hospital laboratory able to provide appropriate QC material?
- Is the POCT manufacturer or hospital laboratory able to provide support to ensure that any results outside of acceptance limits are investigated?
- Is there a procedure in place for acceptance testing for both single use devices and instrumentation?
- Are there guidelines in place that define responsibilities for interpretation of results?
- Are there procedures in place to deal with QC results that fall outside the specified limits for the QC material being used?

Acceptance testing [28]

Acceptance testing involves testing to check that the device or new batch of consumables is working properly and is within acceptable controls . This can provide an invaluable quality control measure before dispatch to testing sites.

4.8 External quality assessment (EQA)

EQA involves the analysis of samples with unknown values from an external source. Results are then subject to peer group assessment and statistical analysis to compare results across different sites. EQA schemes may be operated by the manufacturer or by dedicated EQA providers. The hospital laboratory should be able to recommend an appropriate EQA provider or may be able to act in this capacity itself in relation to POCT in the hospital and primary care settings.

Users of POCT have a duty to participate in an EQA scheme and perform adequately as part of clinical governance.

EQA - questions to consider

- Is the central laboratory able to provide or recommend appropriate EQA schemes for the POCT service?
- Who will be responsible for co-ordination of the EQA programme within the POCT service?
- Are there procedures in place to ensure that specimens are analysed appropriately and results are returned to the scheme provider and also recorded as for IQC?
- Who will review EQA performance?
- Who will provide the necessary support in the event of inadequate performance in an EQA scheme?
- Is the local hospital pathology laboratory able to provide an alternative EQA tool, such as 'parallel testing' if enrolment on an external scheme is impracticable?

Parallel testing

Parallel testing of a patient sample may be carried out at the POCT site and in the laboratory to provide a QA tool. This needs to be well planned and the comparative data recorded and scrutinised. It has the advantage of using patient samples which avoids possible matrix effects of control material but has the disadvantage of requiring more blood, which might be collected differently to that normally used for the POCT device. POCT managers also need to take into account possible ethical considerations (including patient consent and confidentiality) when planning parallel testing.

4.9 Maintenance

Planned preventative maintenance should follow manufacturer's guidance on procedures and staff training. It is essential for the safe and effective use of POCT devices. If this is not practicable for some reason, the manufacturer should approve changes, preferably before purchase.

Maintenance - questions to consider

- Who will provide support for preventative maintenance training and 'troubleshooting'?
- Has a maintenance logbook been prepared for each device used in the POCT service?
- Does the maintenance logbook include a record of all faults and repairs?
- Are procedures in place to ensure that weekly and monthly maintenance checks are performed and that reagent records are kept?
- Is there a procedure in place, which defines when and how the manufacturer should be contacted in the event of a technical problem or breakdown?

4.10 Accreditation

Accreditation is an external audit of the ability to provide a laboratory service of high quality. By declaring a defined standard of practice, and having this independently confirmed, pathology departments are able to attain a hallmark of performance and offer reassurance to users of their service. In the UK, Clinical Pathology Accreditation (UK) Ltd (CPA) provides a means by which this can be achieved.

CPA (UK) Ltd does not currently have a specific standard for POCT but will include in its inspection and assessment any facilities in a hospital for which the laboratory is responsible.

It is recommended that any site providing a POCT service should submit itself to an accreditation procedure, such as that provided by CPA (UK) Ltd. Users and managers of POCT should either contact CPA(UK) Ltd (see Appendix 2) directly or consult their local hospital pathology laboratory.

4.11 Record keeping

It is essential that accurate records are maintained for POCT devices. This includes the recording of patient results and ensuring that the continuity of the patient records is maintained.

Record keeping - questions to consider

- Are operator ID and patient ID properly recorded?
- Is there a procedure in place to ensure that laboratory staff are able to access QA/QC results?
- Is there a procedure in place to ensure that a record is kept of the batch numbers of the test kits used, including date opened and use-by dates for all reagents?
- Have arrangements been made with the hospital laboratory to provide support to ensure that abnormal results and out of limit results are confirmed and if necessary, referred to the relevant pathology consultant?
- Are the results expressed in the same stated units as used by the hospital laboratory? (eg S.I. units)
- Are staff aware of the confidentiality aspects of patient results?
- How are results stored within the POCT system and for how long?
- If there are computer records how are they stored and backed up?
- Is there a procedure in place to ensure that results are both returned to the clinician and placed in the patients' notes in a written format (with their POCT source identified), with appropriate reference ranges for the POCT device?
- Are results that are stored on computer systems password protected?

4.12 Information technology [29]

There are many areas to consider with regard to POCT and information technology, particularly the connecting of POCT devices to external data systems such as management workstations and laboratory information systems. Work on preparing a series of standards for connecting POCT devices across the healthcare sector is currently being carried out by an organisation called the Connectivity Industry Consortium (CIC). Further information on the work of this group can be found on their website at http://www.poccic.org

4.13 Adverse incident reporting

The Medical Devices Agency is responsible for investigating adverse incidents associated with all medical devices including those used in POCT.

- The first Safety Notice issued by MDA each year is entitled 'Reporting Adverse Incidents Relating To Medical Devices'. This notice requires healthcare managers to establish a system to ensure incident reports are submitted to the MDA. It also acts as an annual reminder of the need to submit such reports to the MDA's Adverse Incident Centre [30].
- An adverse incident is any incident that produces, or has the potential to produce, unwanted effects involving the safety of patients, users and

others. Adverse incidents in POCT devices may arise from shortcomings in the device, its operating instructions, user practices or conditions of use. Unwanted effects may include misdiagnosis or inappropriate treatment.

- Standard Operating Procedures should clearly document the requirement to report adverse incidents to MDA.
- A copy of an adverse incident report form is provided at Appendix 3. Incidents may also be reported via the MDA's website at: http://www.medical-devices.gov.uk

5. CONCLUSIONS

- A clinical need must be identified before the implementation of a POCT service.
- The local hospital laboratory should, where possible, be involved in the management of POCT services.
- Lines of accountability for POCT management must be clear.
- Managers of POCT services must be aware of their responsibilities under clinical governance.
- Arrangements for training, management, QA/QC, Health and Safety Policy and the use of SOPs must be made and reviewed at frequent specified intervals.
- Assessment of the service by an external accreditation body is recommended.
- POCT equipment should have been evaluated by an independent body.
- Adverse incidents must be reported to the Medical Devices Agency.
- Clear comprehensive record keeping and documentation is vital.
- Everyone involved in POCT should know what to do in the event of any abnormal result or unsatisfactory QC result.

6. GLOSSARY

Accuracy
Accuracy is a measure of agreement between a measured value and its true value. This can sometimes be determined by using reference methods and referance meterials.

CE mark
The CE mark means that a manufacturer is satisfied that his product conforms with the relevant essential requirements of a European Directive and that it is fit for its intended purpose.

Clinical effectiveness
For individuals, this means the degree to which a treatment achieves the health improvement for a patient that it is designed to achieve. For whole organisations, it means the degree to which the organisation is ensuring that 'best practice' is used wherever possible[12].

Imprecision
The term imprecision is a measure of how close together are the results of repeted measurments of the same sample.

***In vitro* diagnostic medical device (IVD)**
For the purposes of this document we are using the definition of an IVD as stated in the *In Vitro* Diagnostic Medical Device Regulations (Statutory Instrument 2000 No 1315 ISBN 0110992601).

"*in vitro* diagnostic medical device" means a medical device which

(a) is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination; and
(b) is intended by the manufacturer to be used *in vitro* for the examination of specimens including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information -

(i) concerning a physiological or pathological state,
(ii) concerning a congenital abnormality,
(iii) to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients, or
(iv) to monitor therapeutic measures,

and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for *in vitro* diagnostic examination.

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27. Bevan VM, Bullock DG, Haeney M, Dhell J. The application of near patient testing to microbiology. *Communicable Disease and Public Health*. 1999; **2 (1)**: 14-21.

28. MDA DB9801 – Medical devices and equipment management for hospital and community-based organisations. January 1998.

29. Jones RG. Informatics in Point-of-Care-Testing. **In:** Price, C.P, Hicks, J.M., eds. *Point of Care Testing*. American Association of Clinical Chemistry Press, 1999; 175-195.

30. MDA Safety Notice SN2002(01) January 2002: Medical devices – reporting adverse incidents and disseminating safety warnings.

Further Reading.

Martin A Crook. Handbook of Near-Patient-Testing. Greenwich Medical Media Ltd 1999.

MDA publications that give further information about the Agency's role and responsibilities include:

- MDA Corporate Plan 2000 - 2005
- MDA Safeguarding Public Health
- MDA DB 2002(01) Adverse Incident Reports 2001
- MDA SN 2002(01) Reporting Adverse Incidents Relating to Medical Devices January 2002

Copies of MDA notices and publications are available from Medical Devices Agency, Hannibal House, Elephant & Castle, London, SE1 6TQ. E-mail: mail@medical-devices.gov.uk

APPENDIX 1 REGULATION OF POCT DEVICES

Most of the equipment used for POCT will be regulated by the European *In Vitro* Diagnostic Medical Devices Directive. This Directive is intended to ensure that: there is free trade in *in vitro* diagnostic medical devices (IVDs) throughout the European Community and that IVDs are safe and fit for their intended purpose, as defined by the manufacturer of the device.

The Directive, which was transposed into UK law on 7 June 2000 will come fully into force on 7 December 2003 following a three and half year transition period. During the transition period manufacturers may choose whether to comply with the Directive or with existing national regulations. After the end of the transition period manufacturers will not be permitted to place IVDs on the market within the European Community unless they comply with the Directive.

In order to comply, manufacturers of POCT devices will have to satisfy the essential requirements of the Directive. These aim to ensure that; devices will not compromise the health and safety of patients and users; devices are designed and manufactured to achieve the performance specified by the manufacturer for the stated medical purpose.

Devices that meet the relevant essential requirements of the Directive will carry a CE mark to denote compliance.

Key points for POCT managers are:

- The regulations apply to manufacturers of IVDs and not users.
- Between now and December 2003 CE marked IVDs will begin to appear on the market.
- A CE mark denotes that a device has met the essential requirements of the Directive. One aspect that is not necessarily demanded by the Directive is demonstration of clinical utility. It is therefore for the purchaser to assess whether the IVD, CE marked or not, is clinically useful.
- The manufacturers of IVDs will need to maintain a systematic procedure to review post-production experiences and implement any necessary corrective actions, and to maintain a "vigilance system" to notify the regulatory authorities of any incident that results, or could have resulted, in death or serious injury, or in a systematic recall of a device in order to prevent death or serious injury.

- The MDA will continue to operate a voluntary evaluation programme for certain POCT devices, with the object of providing unbiased comparable information for potential purchasers.
- The MDA will continue to operate a user reporting system for adverse incidents. For CE-marked devices there will, in addition, be a legal requirement for manufacturers to report to the appropriate competent authority (in the UK this is the Medical Devices Agency) incidents that fall under vigilance reporting as defined in the regulations.
- Further information and copies of bulletins and guidance documents can be obtained by leaving a message on (020) 7972 8203 (24 hour answer phone).

Detailed enquires:

Medical Devices Agency
11th Floor
Hannibal House
Elephant & Castle
London SE1 6TQ

Tel: 020 7972 8300
Fax: 020 7972 8112
Email: era@medical.devices.gov.uk

APPENDIX 2 CONTACTS

Clinical Pathology Accreditation (UK) Ltd
45 Rutland Park
Botanical Gardens
Sheffield
S10 2PB

CHI website
http://www.chi.nhs.uk/eng/index.shtml

HTA website
http://www.hta.nhsweb.nhs.uk/

NHS Purchansing and Supply Agency (PaSA)
For information on procurement guidance and support for POCT device procurement please contact PaSA on:

Tel: 0118 980 8832
Fax: 0118 980 8650
Email: through website at nww.pasa.nhs.uk/dme

NHS Purchasing and Supply Agency
Diagnostic Medical Equipment Team
Premier House
60 Caversham Road
Reading
RG1 7EB

The NHS Purchasing and Supply Agency is an executive Agency of the Department of Health. The Agency is responsible for ensuring that the NHS makes the most effective use of its resources by getting the best value for money possible when purchasing goods and services. The ultimate target is to release money that could be better spent on patient care by achieving purchasing savings and improving supply performance across the NHS.

APPENDIX 3 ADVERSE INCIDENT REPORT FORM

ADVERSE INCIDENT REPORT FORM – *IN VITRO* DIAGNOSTIC MEDICAL DEVICES

Please tick (✔) the appropriate boxes

Origin of report

Hospital / Institution.....
Address.....
Laboratory.....
Reporter.....
Position.....
Telephone number.....
Consultant-in-charge (if known).....
Local reference number (if available).....

This report confirms a telephone report ❑ a fax report ❑ neither ❑

Device description (tick one box only)

❑ Clinical Chemistry	❑ Microbiology	❑ Self/Home Testing
❑ Haematology	❑ Cytopathology/Histopathology	❑ Genetic Testing
❑ Immunology	❑ Extra-Lab Testing	❑ Specimen Receptacle

1. Product

❑ Test kit - Colorimetric	❑ Instrumentation/ Software	❑ Calibrators
❑ Test kit - Immunoassay		❑ Reagent
❑ Test kit - Other	❑ QC Materials	❑ Reagent strip

2. Details of device - Instrumentation

Product Name			
Model			
Manufacturer	Telephone no:		
Supplier	Telephone no:		
Serial No		Approximate age	

Is there a CE mark? Yes ❑ No ❑

DISTRIBUTION

This Device Bulletin should be brought to the attention of all professional staff with responsibility for management and use of all in vitro diagnostic medical devices (IVDs) used in point of care testing (POCT. This will include all healthcare professionals performing POCT, both in primary and secondary care; managers of scientific and technical staff in all disciplines of pathology and MDA liaison officers, for onward distribution (see page 4 for further information on distribution).

ENQUIRIES

Enquiries regarding the content of the device bulletin should be addressed to:

Mr Martin Glasspool or Ms Andrea Molyneaux
Medical Devices Agency
Hannibal House
Elephant & Castle
London SE1 6TQ

Tel: 020 7972 8174/8119 respectively
Fax: 020 7972 8106
Email: martin.glasspool@doh.gsi.gov.uk Email: andrea.molyneaux@doh.gsi.gov.uk

HOW TO OBTAIN COPIES

Copies of this Device Bulletin are free to health and social care providers and may be obtained on written request from:

Department of Health
PO Box 777
London
SE1 6XH

Tel: 08701 555 455 Fax: 01623 724 524 Email: doh@prologistics.co.uk

Quoting reference MDA DB2002(03)

Otherwise, copies of the bulletin at a charge of £25 per copy may be obtained from:

Medical Devices Agency
Business Services
Hannibal House
Elephant & Castle
London
SE1 6TQ Fax: 020 7972 8124 Tel: 020 7972 8360

Our website lists all current Device Bulletins and safety warnings: http://www.medical-devices.gov.uk

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