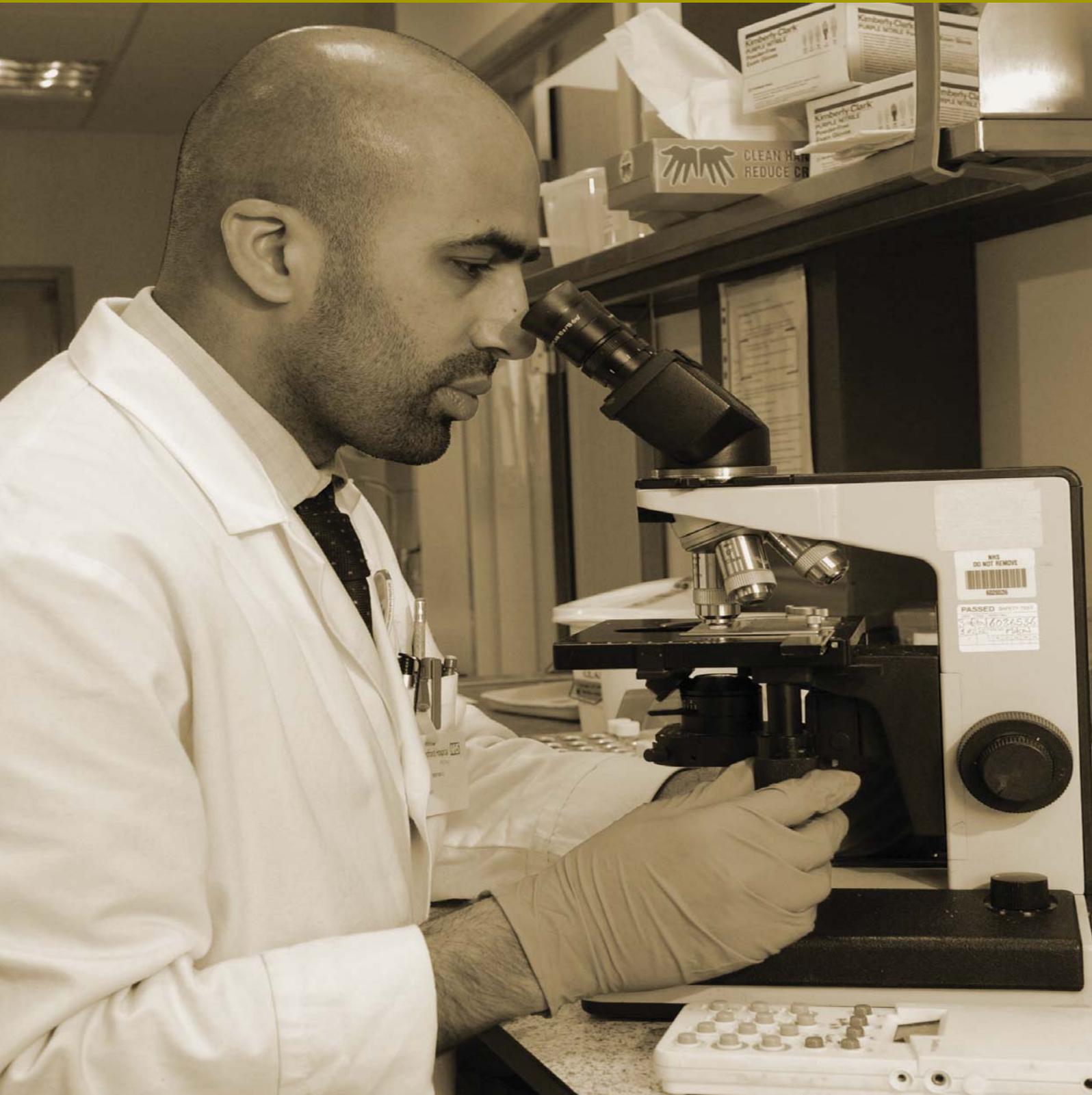




Institute of Biomedical Science

Point of Care Testing (Near-Patient Testing) Guidance on the Involvement of the Clinical Laboratory



IBMS Professional Guidance

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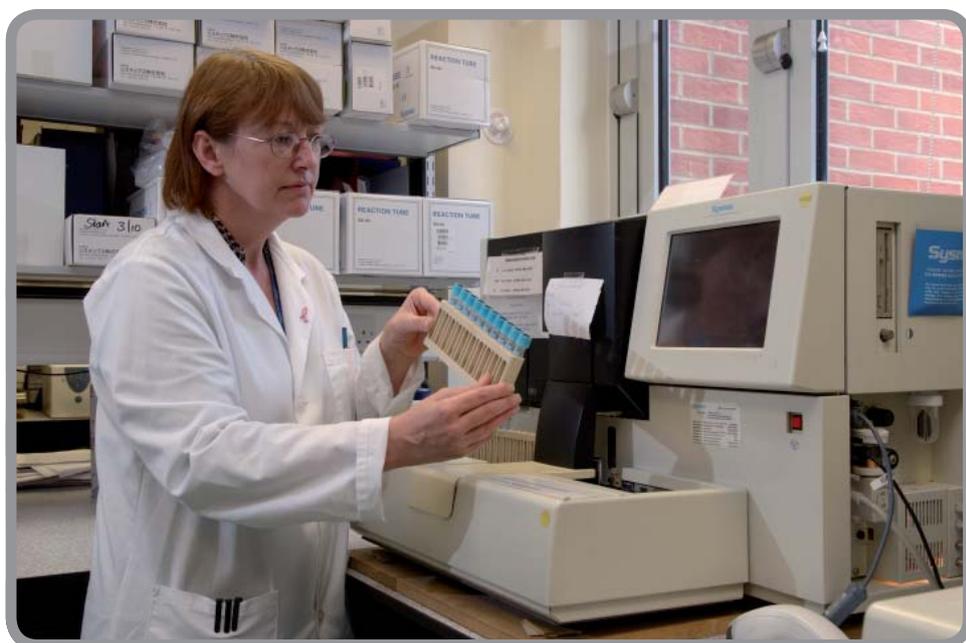
'Near-patient testing' (NPT) and 'Point-of care testing' (POCT) are used synonymously to describe analytical procedures performed for patients by healthcare professionals outside of the conventional laboratory. (The use by patients of home-testing devices is not included.) Advances in technology have led to the development of instruments and kits designed for use in this role and which are able to provide an increasing repertoire of tests. Analytical tests are now available for use in operating theatres, hospital wards, or outpatient departments in the acute sector, in general practice surgeries and in the homes of patients in primary care.

The purpose of this document is to give guidance to all users and potential users on the need for laboratory-based professionals to be closely involved in all aspects of POCT provision. These guidelines complement those issued by the Joint Working Group on Quality Assurance, which Clinical Pathology Accreditation (UK) Ltd endorses, and any department wishing to gain CPA accreditation must comply with them. The crucial role that the laboratory has to play is clearly identified.

Biomedical scientists providing clinical services to patients in healthcare are required to be registered under the Health Professions Order 2001, which stipulates that registrants must be appropriately educated and trained. This statutory provision was made for the protection of patients, and the Institute of Biomedical Science considers that the underlying principles of this legislation should apply to staff performing POCT.

The Institute recognises that POCT can lead to improved patient care. However, it is considered imperative that wherever POCT is operated, it must be monitored and supervised by qualified staff of a clinical laboratory that is accredited by CPA (UK) Ltd. This also complies with the principles of clinical governance related to standards of patient care and the control of clinical risk.

Analytical systems used according to laboratory-approved operating procedures provide clinically acceptable measurements. It is widely recognised, however, that procedural errors generate inaccurate data that can be clinically misleading. There are also concerns about the health and safety consequences of testing done outside the contained environment of the laboratory.



Accordingly, the Institute considers it necessary for POCT to be operated within the framework of a clearly defined policy that recognises the essential role of laboratory-trained personnel. Although analytical environments are variable, precluding strict regulations, general guidelines and recommendations must not be so vague as to be meaningless in practice. An approach that can be varied with local circumstances is to be preferred.

Implementation

Responsibility

The head of the clinical unit or directorate and the head of pathology should establish an initial clinical need for POCT, in consultation with relevant clinicians, that fundamentally will depend on the relevance of the analysis and the efficacy of the analyte(s) for the specific clinical requirement; and the ability of the

laboratory to provide that requirement. When a need has been established, there has to be mutual agreement on:

- the precise responsibility of the laboratory in the management of the service
- the arrangements by which the service is delivered (senior laboratory staff must be involved in establishing the optimum means of provision)
- the financial accountability for purchase and subsequent operation and maintenance of equipment
- the responsibility for training the appropriate non-laboratory staff
- actions to be taken in the event of analytical incompetence or the misuse of equipment.

Responsibility for the maintenance of the service should normally reside with a delegated senior biomedical scientist with postgraduate qualifications such as FIBMS or equivalent. He/she should

be authorised by the head of pathology to act as the trainer and general 'liaison officer'. It is equally important to create a complementary 'liaison person' with the appropriate seniority and authority in each clinical area using POCT. In addition, the appropriate supplier contacts for service and support must be established.

Methods and equipment

A pilot study should be conducted, prior to the implementation of POCT, so that the potential problems can be assessed and training requirements established. Current analytical systems have limitations, so suitability for specific usage must be reviewed and assessed. The required analytical performance and characteristics will be dictated by need. If the same analyte is also to be measured by the laboratory, results (and units) need to be comparable, particularly if principles of measurement are different.

An audit of clinical effectiveness and outcome should be done before and after implementation of the system.

Costs

The overall cost is determined by considering all relevant factors, for example:

- equipment costs – to include capital cost of the equipment and recurring service/maintenance costs
- running costs – to include the cost of reagents, quality control materials and miscellaneous items such as lancets, syringes and needles
- administration costs – to include the cost of staff training, quality assurance procedures, audit, regular

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maintenance and troubleshooting and any other additional resources needed.

Training

The success of POCT depends crucially on the effectiveness of the training of non-laboratory staff. Trainers may need to acquire additional teaching, education and communication skills. The designated trainer is responsible for the routine training of all staff involved. Although direct instruction with a prospective operator is the most effective technique, it is time consuming and expensive and may have to be delegated, eg. as cascade training. Training strategies will require a mechanism for scrutiny and supervision.

A comprehensive training manual should be prepared. (Although a standardised training procedure is effective in principle, allowances should be made to ensure understanding by those with differing educational backgrounds.) Training should ensure:

1. an awareness of pre-analytical factors, including obtaining the correct specimen, the importance of clinical contradictions, sample handling and stability of sample and reagents;
2. a demonstrable expertise in analytical skills, including:

- operation, calibration and routine maintenance, together with, and understanding of, any
- analytical limitations of the instrument;
- a recognition of instrument malfunction and simple troubleshooting techniques;
- principles and procedures of internal quality control and external quality assessment;
- cleaning and decontamination procedures;

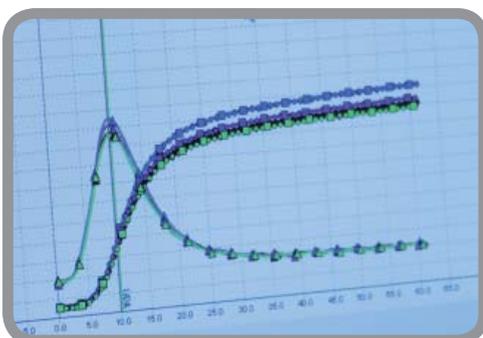
3. an appreciation of the importance of post-analytical factors including accurate documentation of patient data and basic knowledge of the importance of normal and abnormal results.

Certification

Prospective users who are assessed as competent require formal certification. This must contain the following:

- the unique identity of the competent person (an RCN PIN number is ideal for nurses)
- details of the instrument and the test(s) performed
- the dated signature of the trainer, together with the dated signature of the trainee.

This means that an individual is certified as having been satisfactorily trained, but it does not necessarily imply competence. Competence may only be assessed after a suitable period of supervised experience has been acquired (note: if not 'outside the laboratory' then 'on site').



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It is important to recognise that liability for future actions of the operator does not reside with the trainer, as long as the training and documentation can be shown to be satisfactory.

A list of trained users should be kept at the clinical location, and a log must be maintained so that updates or retraining of staff can be identified. Such sessions need to be conducted and recorded:

- on a regular basis, eg. annually
- if a replacement instrument is introduced
- if a problem with a user has been identified with any major revision to the service (or the training itself).

Operation and maintenance

The standard operating procedure (SOP) incorporates the details included in the standard training procedure (STP); which it complements. It must conform to CPA standards with a mechanism for regular revision, and a copy must be retained near the equipment for convenient access. It should provide clear precise instructions on:

- hazard warning and safety information
- normal operating techniques
- contra-indications and limitations of the instrument and technique
- how to perform routine operations such as maintenance and decontamination
- basic troubleshooting if an instrument malfunction is recognised
- the procedure for advice and guidance if a problem is unresolved.

An instrument log, which should be retained for the life of the instrument, is essential. This should contain the instrument serial number and service history and details of problems encountered and resolved, including dates and signatures.

Quality assurance

Medico-legal considerations and the requirements of the Data Protection Act must be borne in mind when establishing the quality procedures. Quality assurance

is thus considered in the widest context. The chronological link between test results, quality control results and instrument status must be retained.

The providers of a service operating from a CPA accredited pathology laboratory have a duty to ensure that the service is carried out within recommended national and/or local quality assurance schemes. The service must comply with any relevant standards that may be required under the *in vitro* diagnostic medical device (IVDD) regulations.

Internal quality control (IQC)

IQC is a system for validating the results before they are issued. This means that the operator must know the acceptable range of results for the QC material. It is important to devise a protocol that will distinguish between instrument malfunction and a procedural error.

1 The 'limits of acceptability' should be displayed by the instrument, together with a protocol for unacceptable results.

2 All trained operators must be involved so that the quality of the analytical team, as well as the instrument, is effectively monitored.

3 The control material must mimic the biological specimen as closely as possible, both physically and chemically, and be handled and analysed in an identical way to the test specimen; it must not receive special treatment.

4 The controls must be analysed regularly, although the frequency will be determined locally; in addition, they must be analysed whenever an unexpected result is achieved or when any instrument malfunction is suspected.

5 Manipulations, such as dilutions or

'Medico-legal considerations and the requirements of the Data Protection Act must be borne in mind when establishing the quality procedures.

reconstitution of lyophilised material, must be performed by laboratory staff who should be responsible for controlling the validity of the material (lot number, expiry date) and maintaining the correct storage conditions.

6 Results must be recorded along with the date and time of analysis, and be accompanied by unique operator identification for scrutiny by the laboratory: They must be retained for any possible enquiry for as long as is practicable or as instructed in the SOP, or should follow the recommendations contained in The Royal College of Pathologists guidance notes called *The Retention and Storage of Pathological Records and Archives*.

External quality assessment (EQA)

EQA involves the analysis of samples received into a clinical area from an external source – this could be from the local laboratory itself, from the manufacturer or from an external body such as a NEQAS. It is a means of validating the results after they are issued, which means that the acceptable range of results is unknown to the operator. These samples should:

- be distributed periodically to the site by the laboratory, which retains the responsibility for ensuring that the sample is representative throughout the POCT service
- be handled and analysed in an identical way to the specimen from a patient
- have their results recorded and retained as for IQC.

Test results

Quality assurance also requires that the recording of analytical data from specimens is satisfactory. There must be a mechanism for recording data from every specimen, which must be identified uniquely by:

- name of patient with registration number or NHS number
- date and time of analysis
- result(s) obtained
- name of operator.

These data must be retained for two calendar years in such a way that

they can be linked with other quality assurance data.

Instrument data

Instrument data should be recorded, and retention times should be linked with quality assurance and patient data if possible. The record comprises calibration details and any details of malfunction.

They complement the instrument log, into which they can be incorporated if practicable.

Health and safety

The following legislation and guidance applies equally to all laboratories and other sites where POCT is performed, irrespective of size or location:

- *Health & Safety at Work etc Act 1974*
- *Consumer Protection Act 1987*
- *Control of Substances Hazardous to Health Regulations 2002*
- *Safe Working and the Prevention of Infection in Clinical Laboratories guidance 1991.*

Hazards and risks

Staff performing NPT must be aware of the microbiological hazards of samples from patients, the chemical hazards of reagents and the physical or electrical hazards of equipment.

Suitable and sufficient risk assessments must be carried out before equipment is commissioned.

Controls

Standard operating procedures must include protocols for:

- routine external and internal decontamination of equipment
- safe disposal of biological material
- safe handling of all specimens and spillages.

Staff must observe the precautions required for safe working practice, eg. the correct use of disposable gloves.

Security

The siting of equipment must be such that unauthorised use is prevented – by



location, coding or password protection – and that safety regulations are not contravened.

Physical security, confidentiality of reports and the legal requirements of the Data Protection Act have to be considered.

Additional reading

The Royal College of Pathologists: *The Retention and Storage of Pathological Records and Archives*. Second edition, 1999.

MDA DB2002(03): Management and Use of Point of Care Test Devices. March 2002.

Joint Working Group on Quality Assurance: *Near to Patient or Point of Care Testing Guidelines*. January 1999. (JWGQA, Diagnostic Services Ltd, Mast House, Derby Road, Liverpool L20 1EA)

Health Services Advisory Committee: Safety in Health Service Laboratories Safe working and the prevention of infection in clinical laboratories. 1991.

In vitro Diagnostic Medical Device Regulations (Statutory Instrument 2000 No 1315 ISBN 0110992601)

IBMS Professional guidance

About this document

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IBMS vision

The Institute of Biomedical Science (IBMS) is the professional body for biomedical scientists in the United Kingdom that also has many overseas members and international links. It aims to promote and develop the wide range of roles in biomedical science to deliver high quality, safe and effective services. It does this by supporting biomedical scientists in their education and training, improving standards of practice, representing the profession and working with organisations. The Institute is also licensed by The Science Council to award the designation 'Chartered Scientist' (CSci) to qualifying IBMS members.

The Institute was founded in 1912 and represents over 19,000 members employed mainly in National Health Service and private laboratories, university and veterinary laboratories, the National Blood Service, Health Protection Agency, Medical Research Council and Department for Environment, Food and Rural Affairs. Other members also work in related commercial fields and in teaching. Most members live and work in the United Kingdom and Ireland but many others are employed overseas.

IBMS roles

- To aid and support the development of biomedical science, both nationally and internationally.
- Develop and influence professional standards of practice to guide biomedical scientists and protect patients.
- Assess competence to practise as Health Professions Council (HPC) registered biomedical scientists.
- Define an appropriate structure of membership and provide benefits of membership.
- Provide personal and professional support for members.
- Represent the interests of biomedical science, provide advice and work with UK government and its devolved administrations, NHS and private healthcare management, media, universities, industry and commercial sector, professional organisations and all other partners.
- Ensure that the education and training of biomedical scientists provide practitioners competent to practice at all levels in healthcare.
- Develop qualifications and diplomas to demonstrate expertise and provide a career pathway.
- To enable members to achieve their potential through career pathways, career long learning and continuing professional development.
- Update and inform biomedical scientists through media, scientific meetings and professional events.
- Promote public awareness of biomedical science.
- Produce scientific and professional publications, guidance and other resources for members.
- Award the designation of Chartered Scientist to qualifying members.
- Fund research and support charitable causes in biomedical science.
- Maintain a historical archive of the Institute and biomedical science profession.

Join IBMS

The Institute offers a package of membership benefits to help biomedical scientists develop their careers and scientific knowledge, and to provide personal and professional support.

Further information on the IBMS, its work and its benefits of membership can be found at www.ibms.org/join.

Institute of Biomedical Science

12 Coldbath Square
London EC1R 5HL

T: +44 (0)20 7713 0214 **F:** +44 (0)20 7837 9658

E: mail@ibms.org **W:** www.ibms.org