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Guidance for supervisors and operators of point-of-care testing (POCT) devices

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems.*

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Due to the ease of use and rapidness of point-of-care-testing (POCT), POCT equipment is widely used as a tool for making decisions related to the health, management or care needs of patients. Such decisions can include admission to hospital, evacuation to more appropriate care environments and directed patient management. There can also be significant civil and/or legal implications that arise from POCT such as cessation or termination of employment, family court rulings or revocation of bail or parole.

The availability of simple-to-use point of care equipment has led to continuous development in POCT, examples include testing for diabetes management, blood clotting factors, infectious disease markers, haemoglobin, white blood cell counts, pregnancy tests, cardiac markers, illicit drug use and performance enhancing chemical testing.

Whilst examinations of a patient's body fluids, excreta and tissues have been performed traditionally in the controlled and regulated environment of a medical laboratory, globally, POCT is increasingly being performed outside of a traditional laboratory setting and by operators without medical laboratory support.

Circumstances where POCT testing can occur include but are not limited to hospitals, medical practices, pharmacies, paramedics, long-term care facilities, outreach clinics in remote and rural settings, in emergency and natural disasters and community settings such as law enforcement, workplace health and safety, sporting facilities, academia, the military and public areas such as shopping centres.

As POCT results can be used to make important decisions about patients, it is vital that the equipment works properly to yield the correct results and that the operators are trained and competent. This requires that a quality testing structure is provided by supervisors and made available to the operators.

Testing should be of benefit to the patient being tested, if the testing is not performed within a defined quality testing structure then incorrect results can have a negative effect on the patient in terms of health outcomes or punitive action taken.

This document has been written in easy to understand language. Its purpose is to provide supervisors and operators of POCT services guidance for assessing the appropriateness of proposed POCT, test and equipment selection, as well as skill requirements for technical performance and result interpretation that will ensure that the reliability, quality and interpretation of the results produced is of a quality appropriate to the intended use.

It is recommended that manufacturers and their distributors draw this this document to the attention of purchasers of POCT equipment and encourage them to follow this document.

NOTE 1 The Annexes provide detailed information and add context that is not included in the main body of this document. Therefore, to appreciate this document fully the reader is encouraged to ensure the relevant annexes are read in conjunction with main body of this document.

NOTE 2 It is presupposed that procedures are developed in accordance with statutory and regulatory requirements.

NOTE 3 In some sections readers of this document are referred to medical laboratory professionals. Medical laboratory professionals with the required competence to offer advice can be found in laboratories adhering to international standards including ISO 15189, *Medical laboratories — Requirements for Quality and Competence* and ISO 22870, *Point-of-care testing (POCT) — Requirements for quality and competence.*

Guidance for supervisors and operators of point-of-care testing (POCT) devices

1 Scope

This document gives guidance for supervisors and operators of point-of-care testing (POCT) services where POCT is performed without medical laboratory training, supervision or support. It includes the key components that should be considered to provide safe and reliable POCT results.

Self-testing is excluded from this document.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
analyte
item that is being measured, tested or calculated

EXAMPLE Glucose, troponin, concaine, HIV antibodies.

3.2
biological reference interval
reference range
normal range
normal value
specified interval of the distribution of values taken from a biological reference population

Note 1 to entry: A reference interval is composed of the values or range for an *analyte* (3.1) that are expected for a “healthy person”. They are sometimes called "normal" values. Whilst “normal” ranges can give an indication about the wellbeing of a *patient* (3.10), things which should be considered are that a result within the “normal” range does not necessarily mean the *patient* (3.10) is healthy, or a result outside of the “normal” range does not necessarily mean the *patient* (3.10) is unhealthy. It is also important to note that “normal ranges” can differ from *equipment* (3.6) to *equipment* (3.6) and population to population.

Note 2 to entry: In some cases, such as drugs of abuse testing the normal value should be negative or not detected.

[SOURCE: ISO 15189:2012, 3.4, modified — NOTE 1 to NOTE 4 have been deleted and Note 1 to entry has been added.]

3.3
clinical handover
patient handover
handover
transfer of professional responsibility and accountability for some or all aspects of care for a *patient* (3.10) to another person or professional group on a temporary or permanent basis

Note 1 to entry: Transferring all or part of a *patient's* (3.10) care between healthcare providers or locations is a high-risk situation and a failure in clinical handover is a major source in preventable *patient* (3.10) harm.

Note 2 to entry: Effective clinical handover, which is structured and standardised, can reduce communication errors and improve *patient* (3.10) safety.

Note 3 to entry: A simple example of clinical handover is ensuring critical result notification to an appropriate person is performed in a timely manner to minimise harm to the *patient* (3.10).

3.4
competence
demonstrated ability to apply knowledge and skills to produce an accurate POCT result

[SOURCE: ISO 15189:2012, 3.5, modified — "to produce an accurate POCT result" has been added and "NOTE" has been deleted.]

3.5
critical results
results outside defined limits which may indicate a life-threatening situation and require immediate notification of the referring doctor

3.6
equipment
any device or apparatus which can be used to perform a *POCT* (3.11)

Note 1 to entry: Examples include simple colour changing urine test strips for glucose to more complex electronic hand held or bench top analysers such as glucometers, lipid analysers and alcoholmeters.

Note 2 to entry: For the purposes of this document equipment includes any reagents or consumables required to perform the test.

3.7
external quality assessment (EQA)
proficiency testing (PT)
process where *samples* (3.13) of known values are tested periodically and the results are not known to the operator at the time of testing

Note 1 to entry: The results obtained are then compared against others testing the same *sample* (3.13) with the same *POCT* (3.11) *equipment* (3.6) type giving the participant the ability to evaluate their performance against others.

Note 2 to entry: Commercially available EQA programmes are recommended but are not always available. Where these are not available manufacturers and/or laboratories may be able to offer assistance with *sample* (3.13) exchange programs.

3.8
interference factors
a substance or process which falsely alters a test result

Note 1 to entry: Interference can be significant.

Note 2 to entry: Interfering substances can be endogenous (substances found naturally in the *patient* (3.10) *sample* (3.13) such as lipids, proteins, antibodies) or exogenous (substances not naturally found in the patient's sample such as drugs, poisons or medications).

Note 3 to entry: The most common interfering factors are haemolysis (the rupturing of red blood cells and the release of their contents into surrounding fluid (e.g. blood plasma/serum), hyperbilirubinemia (a yellow or green pigmentation of the blood plasma/serum due to high bilirubin) and lipaemia (an abnormally high concentration of lipids in the blood, characteristically the blood plasma can appear white or milky in colour due to the presence of fat).

Note 4 to entry: The type of collection tube can also cause test interference as these often contain additive components.

3.9
internal quality control (IQC)
quality control (QC)
internal procedure which monitors the testing process to decide if the system is working correctly and gives confidence that the results are reliable enough to be released

Note 1 to entry: IQC *samples* (3.13) have known quantities of the *analyte* (3.1) being tested. The result obtained is expected to be close to the known value and within an acceptable range. Where results fall outside the acceptable range action to rectify the issue needs to occur before *patients* (3.10) are tested.

3.10
patient
individual undergoing *POCT* (3.11)

Note 1 to entry: For this document the term patient has been used for consistency.

Note 2 to entry: It should be noted that an individual who undergoes *POCT* (3.11) may not have an ongoing disease and therefore may not be a patient as such. They can be clients or employees being tested for reasons other than to receive medical care, such as community screening, pre-employment testing or assessing the use of performance-enhancing drugs or chemicals.

3.11
point-of-care testing
POCT
near-patient testing
testing that is performed near or at the site of a *patient* (3.10)

3.12
point of care testing service provider
POCT service provider
individual or organisation responsible for providing *POCT* (3.11)

3.13
sample
primary sample
specimen
discrete portion of a body fluid (e.g. blood, urine, saliva), breath, hair or tissue taken from the human body for *POCT* (3.11) which is assumed to represent the whole patient

Note 1 to entry: In some countries, the terms “specimen” or “primary sample’ are used instead of sample. For the purpose of this document the terms “sample”, “primary sample” and “specimen” should be considered interchangeable

Note 2 to entry: The source of blood samples (whether arterial, venous or capillary) is another important consideration as POCT results for capillary specimens may differ from arterial, venous values for certain tests and in certain circumstances.

3.14
urgent results
results needed for the care management of a patient within a minimal time period

3.15
validation
process of establishing the performance characteristics and limitations of *POCT* (3.11) *equipment* (3.6) and the identification of the influences which can change these characteristics and to what extent

Note 1 to entry: Which *analytes* (3.1) it can measure and in which *sample* (3.13) type (blood arterial, venous or capillary), plasma, urine) in the presence of which *interferences* (3.8) are important considerations.

Note 2 to entry: The process for confirming that a method is fit for purpose (is appropriate for its intended use).

3.16
verification
process of demonstrating the performance criteria to which the method has been validated have been met by the *POCT Service provider* (3.12) prior to introducing into routine use

4 Personnel

4.1 Supervisor

There shall be an appointed person(s) (supervisor) who has the authority and takes responsibility for, the quality of the service and is competent to supervise the testing provided.

The supervisor is responsible for the quality, timeliness, accuracy and safe delivery of the POCT which includes hazard analysis (See 9.2.5).

The supervisor shall define the roles and responsibilities of POCT operators.

The supervisor shall ensure implementation of the following:

— selection of appropriate tests in consultation with a medical professional, when indicated;

— maintaining privacy, safety and confidentiality of personal information and test results of patients undergoing testing;

— availability of appropriate result interpretation;

— access to advisory services;

— confirmatory testing and/or referral for appropriate or necessary additional testing;

— selection of suitable testing equipment;

— identification and adherence to applicable guidelines;

— performance and review of quality control with corrective actions;

— establishment and maintenance of internal instructions or processes;

— operator training and competency assessment;

— appropriate environment for testing;

— inventory control management processes;

— appropriate and effective clinical handover; and

— appropriate biosafety and infection control procedures.

The supervisor shall ensure procedures are in place and appropriate for the POCT service provided and that operators adhere to all instructions and procedures relating to POCT.

The supervisor should ensure there is access to medical experts and medical laboratory professionals to provide consultation as needed.

4.2 Operators

4.2.1 General

There shall be an appointed person(s) (operator) who has been trained and has demonstrated the competence required to perform testing. A supervisor may also be an operator.

4.2.2 Training

An operator training program shall be implemented that

— describes the key aspects of the testing process including:

  — the intent of the testing process;

  — its essential steps; and

  — the significance of each step;

— ensures the operators can produce reliable results;

— describes the requirements for use of internal quality control and external quality assessment programs and ensure they are used (if available); and

— states the importance of following policies, procedures and instructions for use.

All operators are required to have successfully completed the training program.

The training program shall be updated when changes to the testing service occur (e.g. new equipment or procedure is introduced) and operators shall be trained to the new processes.

The training program shall be evaluated periodically for effectiveness.

NOTE Aspects of the testing process to consider in training programs are described in Annex A.

4.2.3 Competence

Operators shall be assessed for competence after training and before being allowed to perform testing.

Operators not deemed competent shall not perform any testing until they have been retrained and deemed competent.

The competence of operators shall be reassessed at planned intervals. The interval for competence reassessment should be based on the following:

— test volume and frequency;

— frequency of individual operator involvement in testing;

— complexity of testing (degree of difficulty);

— quality assessment data (e.g. more errors can require more frequent training and a search for root cause).

Where patient testing does not occur immediately after competence has been granted the POCT service should consider a reasonable timeframe whereby the operator is still deemed competent to test and competence reassessment does not need to occur. After this time, however, the operator should be reassessed for competence.

Generally low volume or less frequent testing requires more frequent competency assessment.

The volume and frequency of tests and the frequency of operator involvement in POCT can determine an operator's ability to remain competent. The complexity of the POCT can influence this as more complex tests are often more difficult to perform correctly, especially when performed rarely. Therefore, planned reassessment intervals should take into account how often and how many POCT an operator performs i.e. 1 test, 10 tests, 100 tests performed daily, weekly, monthly or yearly in conjunction with the degree of difficulty of the POCT. Each competency assessment needs to be recorded against a predetermined set of realistic and measurable targets as defined by the supervisor.

When operators are deemed not competent after training, the training program should be evaluated and improved as necessary.

NOTE Aspects of the testing process to consider in competence assessment programs are described in Annex A.

5 Point-of-care testing equipment selection

Selection of POCT equipment shall be based on:

— scope and purpose of the POCT Service;

— performance specifications of the equipment;

— reliability of the equipment when used;

— needs of those to be tested;

— other third party needs e.g. employer request; and

— local and national regulatory requirements.

Whilst POCT equipment may not meet every desirable attribute that has been identified, the equipment that is the most appropriate for a given testing scenario should be considered fit-for-purpose.

Lack of understanding of the testing requirements can result in selection of equipment that is not fit-for-purpose. Selection of inappropriate equipment can impact patient safety.

Before equipment is purchased and testing is implemented, the POCT equipment shall be approved by the supervisor as being fit-for-purpose.

NOTE Annex B provides advice for selecting POCT equipment that is fit-for-purpose.

6 Point-of-care testing process management

6.1 General

The testing process consists of three stages: pre-testing, testing and post-testing.

Pre-testing includes all activities performed up to the point of performing the test.

Testing includes using the patient sample and POCT equipment to generate a test result.

Post-testing includes review, interpretation and reporting of results as well as disposal of residual samples, collection equipment and restoring the testing environment and equipment to its pre-testing stage.

All three stages contribute to the quality of the test results.

6.2 Pre-testing stage

6.2.1 General

The majority and often most serious errors (e.g. misidentified patient, insufficient sample, unsuitable sample, improper sample handling) occur in the pretesting stage. If errors occur in this stage, the reliability and accuracy of test results are affected no matter how good the testing or post-testing processes are.

Testing on the wrong patient will always mean the wrong result is produced. As such the wrong treatment might be provided to the wrong patient or a patient can miss the treatment needed causing harm.

6.2.2 Planning and development of the POCT service

The planning and development of the POCT service shall consider

— the reasons for testing including potential outcomes to those being tested;

— what patient population is the POCT service directed toward;

— who is eligible to be tested;

— the criteria for selecting appropriate testing methods, equipment and the tests to be provided;

— who can request the test;

— who can receive test results;

— personnel resources;

— appropriate methods to assure the POCT service is performing as expected;

— evaluation of failures and their consequences to patients and POCT service;

— requirements for quality including internal quality control and external quality assessment;

— storage of equipment, reagents and consumables; and

— regulatory requirements.

Medical and/or Medical laboratory professionals should be available to provide consultation and advice.

6.2.3 Suitable testing environment

A testing environment shall be available which is suitable for POCT. Such an environment shall provide safety for patients and operators, suitable accommodation and sufficient space for testing operations and privacy to maintain patient confidentiality according to ethical and cultural considerations.

6.2.4 Availability and adequacy of test consumables

6.2.4.1 General

Test consumables shall be available and adequate for the test to be performed. This includes sample collection devices, test tubes, test strips or test cards as well as reagents, labels and writing instruments to label samples.

Availability of extra consumables could be appropriate in case of contamination or loss of supplies while POCT is being performed.

All consumables shall be handled in accordance with manufacturers recommendations.

6.2.4.2 Collection devices

The correct use of sample collection devices is critical to providing the correct result and these devices shall always be used according to manufacturer's instruction.

In all cases where blood is used as the sample type, single use devices, such as needles or lancets, shall be used and the needle appropriately sheathed (shielded) with needle protection and discarded after the single use.

If blood collection supplementary equipment such as tube holders and tourniquets are reused, thorough disinfection procedures shall be employed to reduce the chance of cross-contamination.

6.2.5 POCT equipment readiness for use

6.2.5.1 General

Equipment shall be confirmed to be functional and set up appropriately prior to patient testing.

Equipment shall have undergone and passed the prescribed quality control at the site of testing and where applicable, have sufficient electrical or battery power to complete testing.

The temperature of the testing environment shall not fall outside the temperature range recommended for the POCT equipment by the manufacturer.

Additional environmental conditions prescribed by the manufacturer shall also be verified as being met.

6.2.5.2 Validation of POCT equipment

Validation of POCT equipment shall be performed before the equipment is introduced into the testing environment to establish the performance specifications. Where the manufacturer has performed validation users may rely on the manufacturer's validation and need only perform verification.

Where the equipment or test is modified or is developed In-house by the user, or is used in clinical settings which have not been validated by the manufacturer, validation shall be performed.

NOTE 1 Regulations in some countries have prohibited the modification of equipment or tests by the user of POCT. It is presupposed that procedures are developed in accordance with statutory and regulatory requirements.

NOTE 2 Annex B gives more information on validation.

6.2.5.3 Verification of POCT equipment

Verification shall be performed before the equipment is introduced into the testing environment to confirm that the operators can achieve the same test performance in their testing environment, as has been attained in the manufacturer's validation.

NOTE Annex B gives more information on verification.

6.2.5.4 Calibration of POCT equipment

When required, POCT equipment shall be calibrated according to the manufacturer's instructions using the calibrator recommended by the manufacturer.

NOTE Annex B gives more information on calibration.

6.2.5.5 Preventive maintenance of POCT equipment

A program of preventive maintenance of the POCT equipment shall be developed considering the complexity of the equipment and the manufacturer's instructions. Preventive maintenance can require external servicing by the manufacturer.

6.2.6 Patient consent and counselling

6.2.6.1 General

Patients shall be given information to enable them to understand the risks, benefits and possible outcomes of the POCT to be performed. Plain language shall be used to convey information to a level the patient can understand.

6.2.6.2 Patient consent

The patient (or where appropriate their legal guardian) shall consent to testing before the sample is collected. For most routine POCT consent can be inferred/ implied when the patient presents for testing and willingly submits to the sample being collected and tested.

NOTE Inferred/Implied consent is consent that is not expressly granted by a person, but rather implicitly granted by a person's actions and the facts and circumstances of the situation (or in some cases, by a person's silence or inaction).

Patients should be given the opportunity to refuse POCT prior to sample collection.

In emergency situations, such as an unconscious patient, consent might not be possible, under these circumstances it is acceptable to carry out necessary POCT, provided they are in the patient's best interest.

A greater level of consent, known as informed consent, could be required. It is presupposed that procedures are developed in accordance with statutory and regulatory requirements.

Where required, informed consent should be obtained by the operator to ensure the patient understands the facts, implications, and consequences of the POCT.

Informed consent should be required for POCT that can have profound impact on the patient (e.g. drug testing or infectious disease testing).

To allow informed consent to be obtained, information should be made available to the patient that includes an explanation of the POCT to be performed in plain language the patient can understand.

A formal record that informed consent has been obtained should be kept.

6.2.6.3 Patient counselling

Where appropriate the patient should be counselled about the test, including the likelihood of false positive and false negative results and the process for confirming results where appropriate.

The POCT operator will not always be the most appropriate person to provide detailed information regarding the test. In such cases a medical laboratory professional and/or the person requesting the test should be available to provide advice. In addition, written instructions (as well as graphical education materials designed for patients) can be used to support verbal communication.

6.2.7 Verification of the Patient's identity

Before initiating POCT the patient shall have their identity unequivocally verified by the POCT operator. Procedures for verifying a patient's identity shall be established and available to the operator.

Failure to identify the patient correctly can lead to serious patient harm and/or adverse consequences.

6.2.8 Sample collection requirements

Operators shall ensure all samples collected meet the manufacturer's sample collection requirements. Deviations from these requirements can lead to incorrect results as POCT equipment is validated against specific sample collection requirements.

The time between sample collection and testing shall not exceed that allowed by the manufacturer of the POCT equipment as some tests become invalid if excessive time is taken between collection and testing.

6.2.9 Factors interfering with testing

Operators shall understand that the presence of certain substances or conditions (interference factors), such as medications or diet, could impact test results.

This information should also be included in information provided to patients in order that they understand that factors such as medications or diet are important to disclose to the operator.

NOTE Advice on these factors and their impact on results can be obtained from medical laboratory professionals.

6.3 Testing stage

6.3.1 General

All POCT equipment requires regular quality control testing to be performed to ensure POCT equipment is working properly and that results are accurate and reliable.

6.3.2 Internal quality control

An IQC program shall be designed based on the manufacturer's instructions. IQC materials with expected values at clinically important levels i.e. close to the reference ranges or cut-offs shall be tested, wherever possible.

IQC shall be tested at a frequency that is based on the stability of the POCT and the risk of harm to the patient from an erroneous result.

Documented criteria for the acceptance and failure of IQC shall be available to operators.

IQC shall be reviewed at the time of testing to confirm that the test is performing as expected and as needed for basing decisions on test results.

IQC failure requires immediate corrective action before patient testing is performed.

NOTE Annex D provides more information on IQC.

6.3.3 External quality assessment

In addition, where available, EQA should also be performed periodically. Where EQA is not available an alternative approach should be sought.

NOTE Annex D provides more information on EQA.

6.3.4 Performing the test

6.3.4.1 General

Testing shall only be performed if it is within the scope of what the service is designed to deliver.

POCT equipment shall only be used according to the intended use and exactly as specified by the manufacturer.

Instructions for performing the test shall be available to operators in the testing area.

These instructions shall identify the critical aspects of all testing stages to ensure testing is performed consistently. These can include Standard operating procedures (SOPs), manufacturer's instructions for use, site-specific instructions or quick reference guides.

Each test performed shall be traceable to a patient, records of quality control, operator ID and, where applicable, lot numbers of consumables.

Testing procedures shall have the intent to ensure safety of operators and patients.

POCT performed outside of established instructions can lead to inconsistent and unreliable results and pose a risk to patients. Risks include giving wrong results, which could lead to incorrect or inappropriate decisions being made in relation to the health, management or care needs of patients.

There can also be legal implications for the POCT service provider as a result of incorrect POCT results being produced.

6.3.4.2 Performing the test in the presence of the patient

Performing the test in the presence of the patient is preferable and can serve as additional safeguard to ensure that the correct test results are matched to the right patient.

6.3.4.3 Processing one sample at a time

Only one patient sample at a time should be processed and tested to prevent sample mix-ups.

6.3.4.4 Sample identification

If testing does not occur immediately or if more than one sample is collected from different patients, samples shall be labelled. This shall occur in the presence of the patient.

Unique identifiers to ensure traceability to the patient from whom they were collected shall be used to identify samples.

6.3.4.5 Reading the result

Where timing is critical to the test result, a timer should be available to, and used by, operators at the testing site. Using timing intervals prescribed by the manufacturer before reading the test result is critical and shall be followed.

Reading test results before the manufacturer's recommended time interval has passed can cause invalid or false negative results due to incomplete reaction of patient sample and reagents.

Reading a test after the manufacturer's recommended time interval has passed can lead to false positive results due to overdevelopment of colour, false negative results due to fading of the reaction or colour, invalid results when the reaction moves beyond a visible area.

6.3.5 Identification and resolution of problems

Identification of recurrent errors or trends during the testing stage can be used to improve the POCT service. Errors that should be recorded and tracked include:

— POCT equipment failures;

— IQC and EQA failures; and

— Defective collection devices.

Medical laboratory professionals should be consulted wherever possible to provide practical ongoing advice that includes answering such questions as:

— Is the equipment or test working?

— Is the reagent working?

— Is the user performing the test properly?

— How do I know when it isn't working and how do I fix it?

Alternatively, the manufacturer of the POCT equipment could offer advice for troubleshooting problems with the equipment or recommend suitable professionals to offer advice.

6.4 Post-testing stage

6.4.1 Result recipients

All test results shall be reported to a person identified as appropriate to receive the results. A person appropriate to receive test results could be

— the person who requested the test;

— the patient who has been tested; or

— another person as appropriate.

In many countries, results are reported directly to the patient who has been tested. National regulations and/or requirements could apply which dictate to whom a result can be provided. It is presupposed that procedures are developed in accordance with statutory and regulatory requirements.

Medical and/or social consequences around the result itself could exclude providing results directly to the patient being tested.

For example, receiving a result for an infectious disease such as HIV can have both medical and social consequences. The POCT service provider should consider the testing they provide and the impact the results could have on a patient. If appropriate, the operator should be able to provide pre and post testing counselling when the result is reported directly to the patient or direct the patient for appropriate clinical consultation.

6.4.2 Result interpretation

Where the operator is competent to do so, an interpretation of the test result may be included with the test result. Where available any interpretation of test results shall be made according to the manufacturer's instructions.

Medical laboratory professionals should be consulted as needed to provide advice regarding result interpretation.

Physicians should be consulted to provide advice on clinical consultation and referrals.

6.4.3 Result reporting

6.4.3.1 General

Test results should be reported without undue delay and with necessary detail to enable appropriate care management where relevant and should include the following where possible:

— a unique combination of identifiers to link the result to the patient;

— date and time of collection and testing;

— the test result with measurement units and reference interval or decision point;

— interpretation of test results where appropriate; and

— advice on how to access follow up care.

Operators shall ensure that results have been communicated to and understood correctly by the recipient.

When results are reported verbally, this should include a process whereby the person receiving the result repeats what has been communicated to them by the operator, including what advice or instruction they have received. Whenever possible results provided verbally should be followed by a written report.

6.4.3.2 Results which pose significant risk to patients and need immediate action

On occasion POCT results can indicate a significant risk or life-threatening situation to the patient. Such results require immediate notification to a healthcare professional or where this is not possible the patient advised to seek urgent medical attention.

The POCT service shall clearly define results which are deemed to pose significant risk to patients, where possible this should be in consultation with medical laboratory professionals.

Instructions for what action is required when such as result is obtained shall be available to operators.

Where such results are obtained effective clinical handover is critical to the health outcome of the patient.

Some tests always require immediate reporting of the result irrespective of whether it is within biological reference interval or outside biological reference interval. One such example is a cardiac troponin test.

6.4.4 Handling and disposal

All samples, collection devices (e.g. needles), reagents and kits shall be handled and disposed of safely.

It is presupposed that procedures are developed in accordance with statutory and regulatory requirements.

6.4.5 Cleaning of POCT equipment

POCT equipment shall be cleaned following manufacturer's instructions and when the equipment is obviously contaminated with body fluids.

6.5 External audits of the POCT service

External audits of the POCT service by peers, consultants, medical laboratory professionals or an external body e.g. national or international Accreditation Body should be considered to evaluate testing practices and to identify opportunities for improvement.

7 Information management considerations

7.1 General

The complexity of information management (IM) required to support the POCT service needs to be "fit-for-purpose" and should not be overly complex or costly.

The level of IM support chosen should equate directly to the needs of the service.

Whatever IM solution is used, the confidentiality of patient information and test results shall never be compromised.

Complex POCT services should consider the use of IM software systems that offer integrated records and assay performance management options.

These IM software systems should be able to integrate different POCT equipment, identify operators, track equipment errors, test performance and maintenance routines and allow supervisors real time visibility of the performance of the POCT service.

POCT equipment suppliers and medical laboratory professionals can offer advice on these IM software systems.

7.2 Confidentiality and security

Equipment often have built-in security measures to prevent access to unapproved operators. The use of operator "log-in" security is the most common security measure. Where these measures are not available, other forms of security shall be considered.

Security measures shall be employed to ensure only authorised operators use equipment.

Testing information shall be kept confidential and secure at all times.

Where appropriate cybersecurity (the protection of internet connected systems) shall be considered.

The security of confidential information and results is of vital importance. Computer equipment shall be protected against viruses, corruption of data and unauthorised access.

8 Documentation and record keeping

8.1 Documents

The POCT service shall document its procedures to the extent necessary to ensure the consistent application of its POCT activities and the validity of the results.

Any activity that requires consistency in the way it is performed should be documented.

These documents shall be controlled to ensure only the latest authorised document is in use.

8.2 Records and Records management

8.2.1 General

Records do not provide instructions.

Records can be produced and kept in any form or type of medium e.g. hard copy paper records or electronic records.

8.2.2 Requirements for managing records

There shall be a system for the retrieval of information and preservation of data if kept.

The requirements for recording information are the same for both manual and electronic systems.

If data is transferred electronically, regular checks of the integrity of the data shall be performed.

8.2.3 Correction of records

Original records (e.g. reports) shall not be altered, obscured, concealed or deleted and are retained as required.

Original records can be amended creating a new record known as a corrected record e.g. corrected or amended report. Corrected records are also kept as required.

When an error in a record is identified e.g. an incorrect POCT result, a process for error correction shall be available. The corrected record shall be clearly identifiable as a revision and the time and date of the change recorded. Where the results are significantly different the original and corrected result should both be reported to ensure the change is identified and actioned. The person making the change shall also be traceable.

Where the revision potentially impacts significantly on a patient outcome, the user of the POCT service shall be advised of the revision as soon as possible.

8.2.4 Storage of records

POCT services operate in different ways and for different reasons. Many POCT services keep records of the testing activities they perform which allows them to produce evidence of that record at a later time.

However, in other POCT settings records of testing activities such as the patient record and/or patient result is not kept. In these cases, the patient/client is given the result directly and no patient data is kept at the testing site.

The POCT service shall determine which records should be kept and for how long.

Statutory and regulatory requirements can require certain records to be kept for a defined time period and it is presupposed that procedures are developed in accordance with statutory and regulatory requirements.

NOTE Examples of Documents and Records are listed in Annex C.

9 Health and safety consideration

9.1 General

Health and safety applies to all areas of the work place, including provision of POCT services.

A named person shall be responsible for all aspects of health and safety.

Health and safety procedures shall be included in the operators training program.

Advice on health and safety can be sought from the equipment manufacturers, local healthcare providers and local, regional and national authorities.

NOTE Special consideration should be made where infants and children are being tested to ensure their safety.

9.2 Infection prevention and control (biosafety)

9.2.1 General

POCT deals with human material and with sharps, which pose a risk of transmission of blood borne pathogens.

9.2.2 Use of sharps

Sharps shall only be used once and disposed of in a secure container. Sharps with built in safety features should always be used.

Incorrect use of lancet devices (sharps) can increase the risk of infection, so these should be selected in consultation with the equipment manufacturers.

The POCT service shall implement a prophylaxis procedure or a post accidental procedure in the event of needle stick injury occurring.

9.2.3 Personal protection

Gloves, eye protection e.g. glasses, eye wash and other protective equipment should be provided as well as appropriate disinfectant to clean the work area and to deal with spills, including on the POCT equipment.

Latex allergy should be considered by providing non-latex gloves where appropriate.

A facility to clean hands, such as a sink or an appropriate disinfectant hand gel, is required to minimise the risk of infection.

9.2.4 Disposal of waste

The requirements for safe handling and disposal of clinical waste shall be considered subject to local, regional and national regulations. In addition, the environmental impact of clinical waste should be minimized.

9.2.5 Hazard analysis

Identification and mitigation of possible hazards should be undertaken when using the POCT device. These could include batteries swelling causing fire risk and spillage from clinical waste damaging electrical circuit ports.

9.3 Other health and safety considerations

A risk assessment of the health and safety of patients, operators and supervisors shall be performed prior to commencement of the POCT service. Any identified risk shall be minimised to the extent possible.

The risk assessment should include consumables, POCT equipment and collection devices. In addition, the testing infrastructure required such as electrical supply and water requirements should be considered.

Insufficient or poorly applied health and safety procedures can have serious medical and/or legal repercussions.

Statutory and regulatory health and safety regulations and/or requirements could apply and it is presupposed that procedures are developed in accordance with statutory and regulatory requirements

NOTE Annex E provides further information on Infection prevention and control (Biosafety).

Annex A
(normative)

Training and competence of operators

A.1 General

Testing operators shall receive appropriate training in the theory and technical performance of the test(s) to be performed and have satisfactorily demonstrated required knowledge and technical competence prior to performing patient tests.

A training manual shall be made available to testing operators. The training manual should identify the topics to be addressed by the training programme, and adequately describe the specific knowledge and technical skill elements required to be assessed within each topic.

The method of provision of each training element, and how the knowledge and technical competence of the trainee is assessed, should be indicated.

A pass rate for competence assessment shall be set. Testing operators shall undergo periodic reassessment of competency.

The following is a list of topics that should be included in a training and competency program.

A.2 Training:

a) an understanding of the test(s) to be performed;

b) the purpose of the test;

c) the limitations of the test (including how long the cartridge or strip can be outside its primary and secondary packing and still give a reliable test result);

d) the type of sample able to be tested (including Patients, IQC and EQA samples);

e) the measurement units the POCT equipment reports;

f) the performance characteristics of the POCT equipment, such as:

   — accuracy, or trueness of the result

   — imprecision of the measurement for quantitative results

   — sensitivity or true positive rate

   — the specificity or true negative rate for qualitative results

g) common interference factors;

h) pre-test considerations;

   — appropriateness of test requests

   — test frequency

   — suitability of person to be tested including their safety and preparation for the test

   — sample collection and suitable sample containers

- appropriate identification of patients to be tested
- the unique identification of each sample
- appropriate preparation of patients e.g. fasting for glucose test

i) performing the test;
- how to store the reagent or kits
- details of interference factors affecting results
- how to conduct a test
- what do error messages mean and what action to take to rectify them
- recognition of improbable results and actions to take
- recording test results

j) ensuring correctness (internal and external quality checks);
- storage and preparation of quality control material
- frequency of quality control testing and recording these results
- acceptance/rejection criteria and actions

k) reporting results;
- applicable reference intervals and clinical decision values
- measurement units
- standard interpretative comments
- hard copy and electronic reports (if applicable)
- critical and urgent results and actions to be taken

l) instrument or equipment maintenance;
- routine maintenance
- equipment troubleshooting
- calibration if necessary
- follow manufacturer's instructions

m) health and safety;
- infection control and biosafety,
- handling of blood spills and sharps
- biological waste management

n) privacy and confidentiality requirements;

o) understanding of ethical standards of practice; and

p) cleaning of equipment.

A.3 Competence assessment

As part of a competency assessment the operator should be asked to:

a) demonstrate knowledge and understanding of the procedures for the testing being undertaken;

b) perform tests following the manufacturers' instructions and/or instruction for use, including quality control checks, operating environment and reagent storage;

c) demonstrate safe and accurate result reporting and interpretation;

d) demonstrate an understanding of quality assurance activities such as IQC, EQA/PT and test failures;

e) perform maintenance and troubleshoot faulty equipment;

f) explain reporting requirements; and

g) detect erroneous results and explain what action is to be taken.

Annex B
(normative)

POCT Equipment and selecting the most appropriate test

B.1 Fit-for-purpose assessment of POCT equipment

B.1.1 General

Medical laboratory professionals should be consulted for advice on the selection process.

Before equipment is purchased and testing commences key criteria regarding equipment requirements and whether the equipment is "fit-for-purpose" shall be established.

The equipment used shall be fit for the purpose intended in each particular POCT scenario.

In some cases, the purpose for testing can require a highly complex piece of equipment that is very precise and accurate. In other cases, a simple screening "rule out" test, which is easier to use, less expensive and more portable could be more appropriate. This is often termed "fit for purpose".

The following section offers some simple rules and advice to help with the selection of testing equipment which will be "fit-for-purpose" and which will aid in selecting the right equipment, for the right test, for the right reason.

To determine whether equipment is "fit-for-purpose," important equipment characteristics shall be established. Some equipment characteristics will be more important than others depending on the scope and purpose of the POCT service and these should direct the supervisor in the selection of equipment. When considering equipment characteristics, cost should never outweigh the well-being of the patient being tested.

The following should be considered when equipment is being purchased:

— an assessment of the need for the test and the outcomes expected from providing the test;

— performance characteristics of the equipment such as:

  — accuracy, or trueness (see B.1.2.2) of the result, and imprecision of the measurement for quantitative results

  — sensitivity or true positive rate, and the specificity or true negative rate for qualitative results

— troubleshooting capabilities including the availability of external support if required;

— projected workload and capacity of selected equipment to meet demand;

— consumables and paperwork including refrigerator/freezer space required for consumables;

— ease of use (i.e., user-friendly for operators, this will include the level of technical support required and provided by the manufacturer or distributor and whether special training required to operate the equipment);

— maintenance requirements, including cleaning of equipment;

— sample type required (i.e., requirements for preparation of sample type samples which require processing prior to testing such as centrifugation, dilution or extraction can complicate the testing process and not be appropriate in some situations;);

— sample volume (i.e., sample requirements for the test);

— expiry date of consumables (i.e., performing sufficient tests to ensure that consumables will be used before expiry);

— results comparability with local laboratory if applicable is important if a combination of laboratory and POCT results will be used to assess the same patient;

— connectivity (i.e. transfer of results electronically to records);

— barcode capability for patients, operators and consumables;

— portability (i.e. need to move testing equipment, portability is sufficient for testing needs) If the equipment needs to be highly portable and/or needs to be moved manually and is heavy or bulky it may not be "fit-for-purpose";

— durability including damage incurred due to dropping of equipment and contamination of instrument with bodily fluids that affects use;

— availability of appropriate quality control materials;

— availability of appropriate external quality assessment programs;

— warranty for the equipment;

— service contracts (i.e. access to ongoing service and support, terms of the contract?);

— affordability both for initial outlay and of running costs (including maintenance contracts, consumables, quality control, quality assessment materials and connectivity costs);

— provision of training and/or training materials by the supplier;

— reliability of supply;

— the testing environment the equipment needs to operate in such as temperature, humidity, lighting and electricity, If a equipment is sensitive to extreme environmental conditions or requires a permanent mains power supply and will not operate well if the testing is to be performed in such extreme conditions or with no access to mains electricity then it may not be "fit-for-purpose";

— length of time to obtain a result;

— the length of time samples are stable before testing;

— how biological waste is to be safely discarded after testing;

— information management compatibility, e.g. equipment, middleware and information system data transfer is compatible; and

— access to follow-up or supplementary testing as required.

In order to select the most appropriate test, method comparison of different devices should be considered, if possible.

B.1.2 Analytical performance

B.1.2.1 General

Analytical performance is the consideration of a number of key criteria or components which when evaluated give the POCT service provider an indication of how well the proposed equipment will or has performed and whether the equipment is suitable for the users' needs and "fit for purpose".

These should include such things as

— the results reading too high or low;

— the equipment giving erratic results; and

— nonlinear testing (the results tailing off at the high or low ends giving unreliable results);

In technical terms, these criteria include

— accuracy/bias;

— precision;

— linearity;

— total analytical error;

— limit of detection;

— limit of quantification;

— trueness;

— interference factors; and

— traceability.

B.1.2.2 Equipment characteristics

Equipment characteristics which should be considered include:

a) Accuracy

The closeness of single estimate to the true value. Accuracy is determined by both bias and imprecision.

b) Bias

A quantitative term describing the difference between the average of measurements made on the same object and its true value.

Bias is described a positive or negative. Positive bias is where the results are reading higher than the true value. Negative bias is where the results are reading lower than the true value.

c) Imprecision

The amount of variability when measuring the same sample more than once.

d) Limit of detection (LoD),

The lowest quantity of a substance that can be distinguished from the absence of that substance (a blank value) within a stated confidence limit.

e) Limit of quantification (LoQ)

The lowest concentration at which the analyte can not only be reliably detected but at which some predefined goals for bias and imprecision are met. The LoQ can be equivalent to the LoD or it could be at a higher concentration.

f) Linearity

A property of a calibrated test that can be graphically represented as a straight-line relationship between the values reported by the test and the true concentrations of the analyte. F Linearity

testing should be performed for devices to assure limit of detection; therefore, when test value obtained is outside the device's detection limit, the highest or the lowest detection limit value set forth, shall be chosen instead of the test value obtained. For example: test value is 10 mmol/L and lowest limit of linearity/detection level is 12 mmol/L. The test result reported shall be <12 mmol/L.

g) Precision

The closeness of two or more measurements to each other on the same sample "getting the same measurement each time".

h) Predictive value for qualitative tests

Positive and negative predictive values are normally used for tests where the results typically are binary (positive/negative, present/absent). They are the proportions of positive and negative results that are true positive and true negative results. Therefore, positive predictive value (true positive) is when a positive result is obtained, and the analyte is actually present. Negative predictive value (true negative) is when a negative result is obtained, and the analyte is not present. Such examples are HIV and other infectious disease testing or Pregnancy testing where the result is either Negative, Positive or equivocal (a grey zone where the result is not clear cut and should be repeated at a later date or by a more sensitive test).

i) Qualitative testing

Whether a particular analyte is present in the sample. Usually reported as Positive/Negative, Present/Absent. Qualitative tests can be used for screening (drug testing) and diagnostically (infectious diseases, pregnancy).

j) Quantitative testing

How much (the quantity) of an analyte is present in the sample. Quantitative tests give a value which is usually checked against a cut off (drug test confirmations, troponin), target (cholesterol, HbA1c) or reference interval (glucose).

k) Reporting of results

POCT equipment provides results which are qualitative, semi-quantitative or quantitative. It is important to determine which type of result is best suited to the testing scenario.

l) Semi-quantitative testing

Tests that yield a result such as "less than 5", "between 5 and 20" or "greater than 20".

m) Sensitivity

The ability of a test to correctly identify those with the disease (true positive rate).

n) Specificity

The ability of a test to correctly identify those without the disease (true negative rate).

o) Total analytical error

Combination of imprecision and average bias. Can be used as a useful calculation to assess test quality and to set goals.

p) Traceability

Traceability is the attribute of a measurement result where the result can be related to a reference through a documented unbroken chain of calibrations.

The benefit of traceability in POCT is to ensure the same analyte is being measured which should give comparable/equivalent measurement results across different POCT equipment.

q) Trueness

Is the closeness of the average value of multiple estimates to the true (target or reference) value and is expressed as bias. Perfect trueness is the absence of bias.

B.1.3 Applying the important equipment characteristics

Once the important equipment characteristics have been established, the test equipment and methodology shall be fully evaluated against them.

— The equipment characteristics need to be prioritised from the most to least important to determine which equipment best fits the POCT service's needs. In some circumstances, none of the equipment available will meet all or any of the important characteristics established. In these circumstances, consideration should be given to whether testing should even be started. However, where testing is still considered essential, prioritising the requirements will still be useful.

— Some manufacturers validate equipment extensively and under different operating environments, some only validate the equipment to a minimum in ideal situations. The extent of the manufacturers' validation should therefore be considered as part of the purchasing process.

B.2 Validation and/or verification of methods and equipment

B.2.1 General

Validation and/or verification of methods and equipment shall be performed prior to introduction into the testing environment to the degree possible.

B.2.2 Validation of POCT equipment and tests

Validation of POCT equipment and tests is usually extensive and performed by the manufacturer and defines the best performance possible i.e. the most accurate and most reliable results each test can achieve. Validation is often complex and can be expensive.

It is important that the extent of the validation demonstrates the accuracy and reliability which is "fit for purpose".

It should be noted that the extent of manufacturers validation processes varies. The extent of this validation is important and needs to be understood by the POCT supervisor. Some manufacturers will validate equipment recognising different testing and environmental conditions. However, some manufacturers perform validation in tightly controlled laboratory environments by operators who are expert in the use of this equipment. While this provides an indication of the equipment's best performance it will likely not reflect how the equipment is used in the provision of POCT.

Different operators may perform POCT under different and sometimes extreme test environmental conditions. Ideally POCT equipment should be validated to reflect the different test environments likely to be encountered when the POCT service commences. Extreme heat or cold, humidity, dust, frequent relocation and "bumping" of equipment can have a detrimental effect on POCT equipment's reliability and accuracy and the performance of the test. The POCT service provider should discuss with the manufacturer the implications of their likely testing conditions and how these might affect the POCT equipment.

— Where equipment and tests have been sourced from a commercial manufacturer or supplier it can be expected that the validation of the equipment will have been performed by the manufacturer and need not be repeated. As such the performance characteristics of the device will be available from the manufacturer. However, some verification shall be performed by the testing operator (see B.2.2)

— Where the manufacturer has not validated equipment, validation needs to be performed by the user of the equipment prior to use. This can be difficult and expensive to achieve. In such cases a different equipment option should be considered.

— Where equipment is used outside of the manufacturers' instructions for use or specifications, the use will likely not be validated, and incorrect results can be produced. In such cases, equipment used outside of its validated use would require the operator to validate the changes, however minor. This can be difficult and expensive to achieve and should be avoided.

As a minimum validation studies performed on all new devices should include accuracy, precision, linearity and comparative testing with other devices.

B.2.3 Verification of POCT equipment and tests

Verification is a process less extensive than validation and aims to confirm that the operators of the POCT equipment can achieve the accuracy and reliability levels obtained during validation, or at least achieve the accuracy and reliability that is "fit for purpose".

Verification of the equipment attempts to demonstrate that the operator meets the expected performance claims documented by the manufacturer but under the operator's own conditions e.g. testing by the operators at the POCT location. It should be as extensive as necessary but will be linked to the complexity of the equipment used and the potential different environmental conditions likely to be encountered e.g. extreme heat, dust.

A statistically significant number of samples should be used in the evaluation process and these should cover the clinically important levels for the intended use of the assay.

NOTE The generally accepted statistically significant number of samples is 20 (N=20) by statisticians.

The accuracy and precision shall be determined for methods that provide a quantitative result.

For qualitative and semi-quantitative methods concordance studies with existing validated methods should be performed.

For quantitative methods running IQC samples with known values across a range of concentrations provides an estimation of accuracy.

Running the same IQC sample multiple times provides an estimation of precision at that specific concentration.

Pooled patient's samples and sample exchanges are also a potential source of samples that can aid in verification studies. In some cases, the POCT manufacturer equipment or a medical laboratory could provide access to suitable samples.

B.3 Calibration of POCT equipment

Equipment calibration is an important step in the verification of equipment and helps to ensure a correct result is produced consistently. Calibration adjusts the equipment to an expected value. IQC should be performed after any calibration to identify any changes to the measuring system. Where available and applicable, all equipment shall be calibrated according to the manufacturer's instructions. Typically, the manufacturer supplies the relevant calibrators to be used with their equipment. Where the manufacturer does not supply relevant calibrators, other sources need to be investigated, this can be difficult to achieve, and the use of such equipment should be avoided.

NOTE Not all equipment needs to be calibrated which could simplify its use. Conversely some equipment could need to be sent away for calibration that could be costly and disrupt the POCT service. These are important factors to consider.

B.4 POCT equipment and in Vitro diagnostics (IVD) regulation

In many countries, POCT equipment has to be evaluated and approved by an *in Vitro* diagnostics (IVD) regulator before it can be sold in that jurisdiction. This process can provide useful information and give some assurance that the equipment is of a certain quality.

Annex C
(informative)

Documents and Records

C.1 Documents

A document is a piece of written, printed, or electronic material that provides information or describes how a process should be carried out. These are typically Policies, SOPs and Instructions for Use.

Documents are subject to periodic review and amendment and adequate document control is essential.

NOTE Document control means all documents are approved by the supervisor and ensures all operators have the same instructions available for performing the testing in the same way at any given time.

Procedures and activities that should be documented are as follows:

— how the selection and procurement of equipment, consumables, IQC and EQA and reagents occurs;

— how training and competency assessments are performed;

— how routine and non-routine maintenance procedures are performed.

— policies, procedures and instructions for use;

— how and to whom results are reported;

— a list of urgent and critical results and how these are to be reported and to whom;

— how to dispose of waste;

— product labelling; and

— how documents are controlled.

C.2 Records

A record is a permanent piece of evidence about a past process or activity (such as a POCT result).

Records that should be kept include:

— staff training and competency assessments;

— internal quality control and external quality assessment results;

— testing results;

— time and date of testing;

— adverse event reporting;

— inventory of reagents and controls;

— verification and or validation of the method to be used;

— risk assessments and audits;

— error logs;

— complaints and compliments;
— equipment maintenance records;
— equipment service records;
— temperature logs where required;
— location where testing is performed;
— identity of the person performing the testing
— name of the equipment used to perform the test
— lot number of the POCT equipment and reagents; and
— expiration date of the POCT reagents.