New Zealand Best Practice Guidelines

For Point-of-Care Testing

New Zealand Point-of-Care Testing Advisory Group

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FOREWORD

"His urine is sweet, he has diabetes mellitus," said the physician. Long gone are the days when physicians tasted urine to detect glycosuria, one of the earliest applications of near patient testing. Point-of-care-testing (POCT) has come a long way since, and in the 21st century is transforming the topography of laboratory medicine, with far-reaching potential. It has become an indispensable tool that can expand the capacity of limited-resource health services and that can overcome barriers to access healthcare. POCT constantly challenges professionals who endeavour to keep up with its ever-expanding myriad of applications and tests. As we reflect on this, we have to consider the scope of governance that regulates POCT and the appropriateness of its applications.

The New Zealand POCT Advisory Group (NZPOCTAG) was born out of the need for bringing together local knowledge and expertise to consult and console on the challenges faced by POCT services and providers in New Zealand. It recognized a need to heighten awareness of the funders and providers both within and outside of the health sector on the necessity for investment in quality processes and clinical risk management. The NZPOCTAG strives towards bridging the gap between the end user and the expert.

Core membership of the group includes laboratory scientists, managers and pathologists who are all involved in the provision of POCT throughout the country, with representation from the Royal College of Pathologists of Australasia and the New Zealand Institute of Medical Laboratory Scientists. Within 4 years of its establishment in 2009, the NZPOCTAG has realised the need for home-grown nationwide best practice guidelines for POCT.

Solid foundations are essential for establishing a viable POCT framework. The New Zealand Best Practice Guidelines for Point of Care Testing are based on sound international literature and societal guidelines but also draw from local expertise and knowledge of the NZ healthcare needs and environment. This document is written with the intention of helping, guiding and supporting the use of POCT devices and services. The ultimate goal is to secure the safety of the patient, the ultimate benefactor, and ensure appropriate clinical and cost-effective use of POCT. The vision for POCT in NZ is that of a POCT device that is analytically verified, a POC test that is reproducible, accurate and relevant, a POCT result that is safe, beneficial, easily interpretable and seamlessly incorporated in patient-care pathways; and ultimately a POCT service that is governed and managed based on evidence and focused on patient needs.

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PURPOSE

The purpose of these guidelines is to assist all potential users of point-of-care testing (POCT), particularly those healthcare professionals without a laboratory background who are required to perform point of care tests, or who may be interested in implementing POCT in their facility.

SCOPE

There are few randomised controlled trials in point-of-care testing. This document is based on principles of good clinical practice and quality healthcare provision and incorporates the requirements of the following international standards with reference to a number of international point-of-care statements and documents:

- ISO15189:2022 Medical Laboratories – particular requirements for quality and competence
- Australasian Association of Clinical Biochemists: Point of Care Testing Implementation Guide
- Guidelines for Safe and Effective Management and Use of Point of Care Testing (Ireland) 2007
- MHRA Device Bulletin: Management and use of IVD Point of care Test Device DB2010(D2)
- Royal Australasian College of Pathologists Point of Care Testing Position Statement 2013
- Clinical and Laboratory Standards Institute (CLSI) 'POCT04': Essential Tools for Implementation and Management of a Point of Care Testing Program 3rd Edition (2016).
- International Accreditation New Zealand (IANZ) Specific Criteria for Accreditation: Medical Laboratory Testing SC7 6th Edition, August 2025

Principles of these guidelines apply to all POC tests, including transcutaneous measurements, the analysis of expired air, and in-vivo monitoring of physiological parameters. Patient self-testing in the home or community setting is excluded, but there are elements of this guide which may be applicable in this setting.

These Guidelines have been developed in the interests of clinical safety and are also designed to meet the intentions of the Health and Disability Commission (HDC) Code of Health and Disability Services Consumers' Rights Regulation 1996, in particular Right 4 of the Code, which states that consumers have the Right to Services of an Appropriate Standard.

Disclaimer:

The document is intended for guidance purposes only. Therefore, where a particular brand, type or design of technology is mentioned, this is intended to convey meaning by use of an example only, and does not imply specific endorsement of this brand, type or design by the New Zealand Point-of-Care Testing Advisory Group. It is recommended that providers seek advice from an accredited medical laboratory with expertise in POCT when considering implementation of POCT systems.

ABBREVIATIONS AND DEFINITIONS

AACB	Australasian Association for Clinical Biochemistry and Laboratory Medicine
CLSI	Clinical Laboratory Standards Institute
EQA	External Quality Assurance
HDC	Health and Disability Commission
HIS	Hospital Information System
IANZ	International Accreditation New Zealand
ID	Identity
IQC	Internal Quality Control
LIS	Laboratory Information System
NPAAC	National Pathology Accreditation Advisory Council
POCT	Point-of-care testing (or near-patient testing)
QC	Quality Control
QMS	Quality Management System
RCPA	Royal College of Pathologists of Australasia
TEG	Thromboelastograph or Thromboelastography

Pre-analytical	The stage before sample analysis. It contains all the elements that influence the quality of the sample, condition of the device, and consumables. Examples include but not limited to, patient identification, environmental conditions, sample collection technique.
Analytical	Technical procedures which take place during sample analysis
Post-analytical	The stage after analysis. Examples include, but not limited to: display of qualitative reporting, display of quantitative reporting, number of significant figures and decimal places, units, appended comments.
Analyte	The molecule, substance or chemical being measured.
Reference Interval	This denotes the range of expected values for a particular analyte within which 95% of subjects' results will fall. For example, a commonly used reference interval for Sodium ion (Na+) is 135 to 145 mmol/L. Note: the reference interval for a particular analyte may vary between different analysers and may also be affected by time of day, fasting status, age and gender. POCT users are advised to check with the local accredited laboratory as to which reference intervals to use for individual devices.
Critical Limits	These are limits for a particular analyte which may be life threatening or cause significant harm and therefore require quick intervention. For example, a glucose level less than 2.5mmol/L or a potassium level greater than 6.5mmol/L may be considered critical limits. Clinical staff responsible for the care of the patient should be notified if test results

	outside critical limits occur. POCT users are advised to check with the local accredited laboratory as to which values to use for critical limits
Connectivity	The electronic capability to transfer patient results to the patient record.
Accredited laboratory	A medical laboratory accredited against ISO15189:2022.
ISO15189:2022	International Standard for Medical laboratories - Requirements for quality and competence.

INTRODUCTION / OVERVIEW

Point-of-care testing (POCT) involves the performance of an analytical test outside the conventional laboratory, at the site or in the vicinity of, the patient. It is performed in a variety of locations such as, but not limited to, hospital wards, general practice surgeries, health clinics, pharmacies, law enforcement, ambulance services, and also by patients. The range of testing performed can include simple dipstick urinalysis or urine pregnancy tests, or more complex instrumentation such as cardiovascular risk screening, anticoagulant monitoring, and blood gas analysis. POCT is also used where it is not practical to send clinical samples to a conventional laboratory for testing i.e., where tests are performed on whole blood samples without anticoagulant and must be processed within a short time frame after collection e.g. samples for Thromboelastography (TEG).

The use of POCT can result in increased clinical effectiveness and improved outcomes for patients, but this is only true if the result is accurate, reliable, cost effective and able to be acted on in a timely manner. POCT should be seen as complementary to, and not as a replacement for conventional laboratory testing.

The key question which needs to be asked in deciding whether or not to introduce a point-of care testing service is:
"What is the clinical problem which needs to be solved by point-of- care testing which cannot be solved by conventional laboratory testing?"

The question needs to be answered by appropriate engagement with key stakeholders and the POCT governance body.

There are a number of clinical advantages to the provision of POCT and these include:

- Reduced turnaround time
- Reduced therapeutic turnaround time
- Improved monitoring of certain conditions where frequent testing is desirable, for example diabetes and oral anticoagulant monitoring
- Improved convenience and access to service e.g., for elderly patients
- Smaller sample volumes which may be less invasive
- Opportunistic screening of the public for early identification of certain conditions
- Ability to provide laboratory tests in remote locations or outside laboratory hours

- POCT may offer economic benefits in terms of reduced clinic visits, length of hospital stay, hospital admissions, and reduced patient transfers from rural areas.

There are also potential disadvantages which need to be considered, and these include:

- Introducing POCT without adequate investigation of clinical need
- Inaccurate results due to lack of training, expertise, insufficient quality testing and failure to recognise erroneous results, which may cause patient harm
- Problems of comparability of results between different methods (laboratory versus non laboratory)
- Swift action on inaccurate results
- Increased costs due to additional instrumentation, expensive reagents, enrolment in external quality assurance programs and accreditation schemes
- Inadequate documentation of results and reporting
- Increased workload for clinical staff
- The availability of arrays of screening tests which may result in inappropriate testing
- Risks to patients as a result of implementation of non-performing devices or failure to recognise limitations of POCT devices.

To overcome the disadvantages of POCT significant resources are required and so careful consideration should be given to the clinical need before contemplating this type of testing. The advantages of POCT only hold true if the test result provided is accurate and reliable and improves patient outcomes. It is therefore imperative that all POCT is conducted within a framework of quality standards which ensures that the quality of results generated is as close as possible to those performed within an accredited laboratory environment.

REQUIREMENTS FOR POCT PROGRAMMES

Where any POCT services are provided, a system for clinical and managerial governance must be established. This includes a person on site who is designated as responsible and accountable for the service. All POCT devices or technologies should be approved for clinical use by a governance group with executive authority for POCT. Staffing for the POCT service should be proportionate to the level of service in scope, scale and volume.

Appropriate referral criteria should be in place to ensure that where results obtained are unexpected, inconsistent with the clinical picture or outside a defined range, confirmatory testing is performed (methodology of confirmatory testing should be discussed with an accredited medical laboratory) and patients are referred for further medical attention as necessary.

Governance for POCT

The practice of evidence-based medicine is an essential component of Clinical Governance, which also includes risk management, clinical and cost effectiveness, education, training

and continuous professional development of staff, research and audit, and the application of information about patient outcomes. All of these components of clinical governance apply to POCT (Pearson, 2006).

For each organisation, there should be a clearly defined governance body that regularly reviews all aspects of the organisation's POCT service. This will include the pathologist, POCT coordinator, clinical representation – including end-users from various craft specialties, and hospital and laboratory management.

POCT is conducted at a variety of sites: within hospitals (most clinical areas, particularly critical care, maternity, neonatal, surgical and outpatient areas), in the community (ambulances, community physician practices, clinics, pharmacies, other retail outlets, workplace screening) or in patients' own homes. The management of quality, risk, training and audit is therefore likely to be difficult, especially with the predicted growth of POCT and the increase in self-testing by patients.

Risk Management

POCT devices may be deceptively simple to use but the use of these devices is not without risk. The organisation needs to have an appropriate risk management strategy which identifies and manages risks and opportunities for improvement associated with the point of care test(s). This risk management strategy will also include a process to evaluate the effectiveness of any actions taken to address the risks and opportunities of improvement.

When considering risks related to POCT, the test results are available to clinicians much more quickly than conventional laboratory tests. However, this rapid result availability must be balanced by careful assessment of the test results and also the patient's clinical state because acting swiftly on basis of erroneous results can cause harm.

The major risks related to POCT include:

- Patient harm - clinically unreliable results, unnecessary tests causing wrong or delayed treatment. Erroneous and misleading results due to inadequate quality assurance and operator training, lack of supervision, poorly performing devices and uncertainty on how to act on results
- Risks to users – infectious disease transmission, excess workload and burnout, limited resource, stress, poor training, difficult technology
- Risks to equipment – damage to analysers due to incorrect operation, incorrect or unsuitable patient samples, wastage, poor QC
- Financial risks – inappropriate/misguided implementation, wastage of consumables, unnecessary or inappropriate testing, which may cause patient harm and increase patient morbidity, and costs of care
- Risks to the organisation – patient harm, patient or public loss of confidence, damage to reputation, litigation caused by POCT misadventure.
- Cultural risks: lack of consultation, planning, or respect for cultural norms

These risks can be effectively managed by good clinical governance, the implementation of robust quality management systems and accreditation. A thorough risk assessment of all POCT service activities should be undertaken and advice should be sought from an accredited laboratory.

Assessment of clinical need

In many cases improving the patient pathway and experience will be major considerations when introducing POCT. To be effective, POCT must be at least as clinically effective as the alternative and should be demonstrated to deliver significant improvement to patient outcomes and be applied within the correct setting. These questions will help in assessing the clinical need for POCT:

- Does the current method of providing the service adequately meet the clinical need, and if it does not, what is the problem, and can it be rectified?
- Is access to the laboratory a problem for patients, and can that be rectified?
- Which groups of patients need testing and what test(s) need to be performed?
- Will POCT enable more rapid or effective diagnosis, treatment or management?
- Will POCT provide a cost-effective alternative to laboratory testing?
- How would a POCT service compare to the current service in terms of quality?
- Would any change in quality be appropriate for best management of the patient?
- Can you provide evidence that POCT will provide a measurable clinical benefit?

Inclusion of laboratory input

An accredited laboratory should play a key role in the development and management of a POCT service. This is particularly true for secondary care and is recommended in the primary care setting. In the event of unavailability of laboratory support in the primary care setting, POCT should be performed under an adequate Quality Management System (QMS) that should include laboratory trained personnel.

Accredited laboratory staff can provide advice on a range of issues which include:

- Evaluation and purchase of suitable devices:
  Equipment selected should have an independent evaluation report available, preferably performed in New Zealand or Australia
- Verification of methodology and test performance:
  Tests performed should have a verification report available, preferably performed in an accredited laboratory in New Zealand
- Validation of methodology and test performance:
  Tests performed outside their intended scope should have a validation report available, preferably performed in an IANZ accredited laboratory in New Zealand.
- Evaluation in the clinical setting by the operators to assess suitability of the device by the end user.
- Training of users:
  All individuals who perform POCT must undergo appropriate training and be certified as competent

- Result interpretation:
  Medical alert/critical/panic values must be defined, and results in these ranges must be communicated immediately to the appropriate carer. For clinically discrepant results, samples should be retested in an accredited laboratory and the discrepancy investigated
- Quality control and quality assurance:
  There must be a process in place for routinely monitoring instrument performance.
- Documentation and records:
  Written policies must be in place for all aspects of POCT. This will include organisational structure, personnel considerations, method/instrument selection, testing procedures, safety/waste disposal, quality control, external quality assurance, maintenance, reporting of results and patient education
- Troubleshooting and problem solving
- Health and safety

There should be close liaison between users of POCT and an accredited medical laboratory on all issues relating to POCT. This liaison shall be formally defined by a service level agreement which specifies the range of products, services, operational details, the responsibilities of the accredited laboratory, the POCT facility and the user.

Cost Benefit Analysis

Notwithstanding the clinical benefits, POCT has fiscal implications. These costs may include:

- Capital costs:
  - initial purchase cost
  - accessories e.g., centrifuges and refrigerators
  - provision of a safe working environment
  - site alterations to accommodate POCT e.g. operator and storage space depreciation
  - computer interfacing with clinical information management systems
  - complete, accurate and timely records of patient results should be maintained and electronic transfer of POCT results should be implemented.

- Fixed costs:
  - routine and preventative maintenance
  - internal quality control material, external quality assessment scheme and regular sample comparison with an accredited medical laboratory.
  - accreditation compliance (if applicable)

- Variable costs:
  - consumables
  - record keeping e.g., data-handling system, licence costs
  - waste disposal
  - cleaning

- Professional costs:
  - indemnity insurance and legal liability (if applicable)
  - laboratory support
  - management of the POCT programme
  - appropriately qualified designated person acceptable to all stakeholders, responsible for ensuring that the appropriate standards of quality are maintained
  - operator time
  - staff training requirements

SELECTION AND VERIFICATION OF TECHNOLOGY

Once a clinical need has been established, the next step is to identify the most suitable test and device before purchase. Considerations in selecting suitable technology should include:

- Availability of an independent verification report preferably performed in New Zealand or Australia
- Expected workload/throughput
- Accuracy and precision of results
- Clinical parameters including sensitivity, specificity and predictive values of the test application
- The clinical environment in which the device will be used, e.g., hospital ward, operating theatre, intensive care unit or paediatric clinic
- Robustness of the device e.g., how tolerant is it to temperatures in the environment it will be used in; is the lid easily breakable?; is it sensitive to vibrations?
- Ease of use
- Results comparable or concordant with a local accredited medical laboratory, in terms of measurement units and expected ranges
- Performance verification against a recognised reference method
- Availability of acceptable quality control material
- Adequate space, and appropriate services e.g., power, water, IT requirements, refrigeration
- Limitations of testing e.g., measurement range of the device, interfering substances
- Connectivity for result recording
- Waste disposal requirements
- National supplier availability and support

It is important that the device is fit for purpose, and an accredited medical laboratory can help and advise in this process. Additional advice on selection procedures for POCT devices can be found in the CLSI document POCT-09A.

QUALITY MANAGEMENT SYSTEM (QMS)

A quality management system should be established for any POCT programme in order to ensure that the test results are clinically reliable and appropriate for patient care. The QMS is a key component of risk management and clinical safety and incorporates the following elements: staff training, competency and certification, quality control, documentation and

record keeping, defined roles and responsibilities, audit, adverse event reporting and accreditation.

Staff training, competency and certification

POCT must only be carried out by personnel who have undergone appropriate initial training and competency certification and who have their competency levels regularly assessed, in the interest of patient safety. Training should be overseen by a POCT coordinator who ideally should be a registered medical laboratory scientist. Training and competency assessment may be delivered by the POCT coordinator or their nominated representative who may be a registered medical laboratory practitioner, an experienced user of POCT, or the vendor of the device.

A POCT training programme should cover both theory and practice of POCT and include the following aspects as a minimum requirement:

- Setting the clinical scene (disease process and pathophysiology)
- Clinical utility and significance of the test
- Recommended frequency of performing the test
- Clinical decision limits or reference intervals
- Performance characteristics of the POCT instrument and its technical limitations
- Importance of correct patient identification
- Patient preparation and sample collection requirements (including correct preservative or anticoagulant)
- Reagent storage and preparation
- How to perform the test on the device (including quality control and calibration)
- Documentation and recording of test results
- Back up and/or confirmatory procedures for out of range or unexpected results
- The principles and practice of internal quality control (IQC) and external quality assurance (EQA)
- Maintenance and common troubleshooting
- Occupational health and safety issues including infection control practices, waste management
- Compliance with ISO15189

The practical side of training should include a complete demonstration by the primary trainer of how to use the device and perform a test, how to run QC and EQA samples and how to perform basic maintenance procedures, followed by a hands-on practical session for each person. The practical session should be conducted individually or in small groups, to ensure each trainee gains experience using the POCT technology in a practical 'hands-on' sense, and gains confidence prior to commencing patient testing. Train the trainer systems are often used in medium to large facilities to ensure ongoing certification and competency of new and existing staff.

When the formal training is complete, the competency of the trainee should be assessed both practically and theoretically to ensure a routine POCT test is conducted correctly, and

to ensure key theoretical concepts have been grasped. Competency must be formally and regularly reviewed e.g., annually to update annual practising certificates (APC). This review period would depend on device complexity, clinical risk, and number of test performed by individual operators per annum. Regular retraining and competency assessment must be regarded as a mandatory requirement of POCT performance. If a POCT operator fails a competency review then they must immediately cease testing and undergo formal retraining before being recertified.

A register of all persons receiving training and ongoing recertification must be kept and maintained. The maintenance of a competency register may be a requirement of accreditation or POCT testing contract.

Quality Control

An essential part of performing routine POCT is regular monitoring of the analytical performance of the device. This includes both internal quality control (IQC) and external quality assurance (EQA) testing. IQC and EQA samples are tested in the same manner as a patient sample, and the testing should be performed by POCT operators responsible for performing routine patient testing where practical.

Internal Quality Control (IQC)

Quality control material may be provided by the manufacturer of the device or obtained from another source. An accredited laboratory should be able to provide advice on suitable quality control materials, and a process to determine acceptable performance limits. Quality control results must be recorded along with the time and date of testing, operator name, and a comment on the acceptability or otherwise of the result. There must be a process in place to respond to IQC results which are outside the acceptable range.

As a minimum, and depending on the complexity of the testing, IQC testing must be performed prior to any patient testing:

- on each new shipment of reagents/cassettes/strips
- on each new lot number of reagents/cassettes/strips
- in the event of equipment problems or erroneous results

The frequency of further IQC monitoring is highly dependent on the importance of the analyte, the complexity of the analysis involved, the type of POCT device, stability of consumables and frequency of patient testing. This should be developed in consultation with an IANZ accredited medical laboratory and the manufacturer's guidelines and be fully documented. Also, clinical impact of test.

While the procedures outlined above are common to most POCT devices, there are other forms of quality control that can check selected parts of the POCT testing process. Electronic quality control assesses the electronic measurement circuitry of a POCT device. It uses a surrogate material (such as a reference cassette, coloured filter, coloured solution

or bar code) to generate an electric signal that would normally be produced by a sensor responding to an analyte in a patient sample. Thus, electronic quality control checks only test the 'reader' steps in the total testing process and should not be used as a substitute for conventional IQC material. It does not test the analytical process and does not ensure that the reagents/cassettes/strips are functioning correctly.

External Quality Control (EQA)

EQA testing is an essential part of the QMS. It is a system that assesses the quality of results by comparing analyser performance between different sites. All participating sites analyse an identical unknown specimen and compare results. EQA samples may be artificial samples provided by an external EQA provider, or it may be a patient sample exchanged between several sites including laboratories. There are a number of national and international EQA programmes available, and an accredited medical laboratory can provide advice on suitable programmes.

Where practical, periodic direct comparison tests using patient samples tested on both POCT devices and laboratory analysers should be undertaken to ensure ongoing reliability.

Review of all quality programmes should be undertaken at regular intervals depending on the frequency of testing. It is strongly recommended that this be in consultation with an accredited medical laboratory. If required, corrective action must be taken and documented.

Acceptance Testing of Reagents

A system shall be in place to ensure each new shipment and lot number of reagents are verified for performance before placing into use. This includes any consumable which can affect the reliability of the test such as test cartridges, test strips, cuvettes.

Acceptance testing may include IQC testing and patient comparisons against a previously validated lot number, with acceptable criteria defined, as evidence of acceptance.

Documentation and Record Keeping

There must be complete, accurate and timely documentation of all stages of POCT activity.

- Operator training and competency records:
  A register of all persons receiving training and ongoing recertification must be kept and maintained.

- POCT procedure/method manual:
  A documented process must be in place for all POCT performed and should include:

- organisational structure
- personnel considerations
- method/ instrument selection
- testing procedures - this may take the form of a laminated “Quick Guide”
- safety/waste disposal
- quality control and external quality assurance,
- maintenance
- reporting of results

- Reagent/Cassette/Test Strip management:
  There must be a system in place to record:
  - when reagents/cassettes/strips arrive
  - condition upon arrival
  - acceptance criteria are met
  - initials of receipting person
  - the batch/lot number
  - date opened
  - use by date
  - expiry date

- Patient results:
  It is imperative to keep accurate records of patient results from POCT devices. These records should include:
  - date and time of analysis
  - device type
  - batch/lot numbers
  - test result including unit of measure
  - operator identity
  - patient identity
  - documented policy around correction/amendment of results

- IQC/EQA results
  Most POCT devices will store quality control results in the device memory, but it is good practice, where connectivity is not possible or available, to also manually record the results on a work sheet which lists the assigned values and limits for each IQC level. The worksheet should provide space for the date of testing, operator identity and acceptance or not of the result.

- Device maintenance log
  A log should be kept for each POCT device of all problems and maintenance events.
  NOTE: Devices with electronic systems for recording lot numbers of reagents and QC materials, QC performance statistics and troubleshooting logs may simplify the documentation requirements.

- Risks and Opportunities for Improvement:

A record of all risks relating to the point of care test(s) should be kept which includes the degree of risk, actions taken to address the risk, evaluation of the actions taken for their effectiveness in mitigating the identified risk.

Definition of Roles and Responsibilities

Below are roles and responsibilities of professionals that oversee POCT, and members of a governance group, e.g., POCT Committee. There should be clearly defined lines of responsibility and accountability.

Pathologist

The pathologist will be a registered medical practitioner with vocational registration in Pathology and appropriately training in the discipline relevant to the test (e.g. Haematologist for D-Dimer). The pathologist is responsible for clinical oversight of POCT. The pathologist:

- Together with the governance group, oversee the clinical appropriateness of implementing new POCT tests/service
- Plans (with the Coordinator and stakeholders) and signs off verification of new POCT tests, as well as the appropriateness of the total testing process e.g., display of results and comments, if needed
- Liaises with the POCT Coordinator to provide clinical oversight of the POCT test
- review clinical significance of non-conforming work (e.g., IQC, EQA)
- Supports the investigation of clinical incidences and near misses
- Plans and supports ongoing quality improvement initiatives

POCT Coordinator

The POCT Coordinator will ideally be an experienced, registered Medical Laboratory Scientist who will:

- Be designated by the organisation's governance group to develop, document, implement and maintain the POCT Quality Management System
- Be responsible for ensuring that all POCT is performed to the same standard as would be expected from laboratory testing
- Maintain a record of all POCT equipment for which they have responsibility
- Be responsible for ensuring that all POCT users have current competency training and documentation
- Be responsible for ensuring regular quality assurance is maintained and quality control samples are analysed on POCT devices, with up-to-date documentation and history
- Maintain (monitor) service records for each device
- Be responsible for troubleshooting of POCT devices and oversee the maintenance of up-to-date documentation and history
- Communicate issues/concerns with the Site Manager, stakeholders and clinicians (including pathologists)

Site Manager

A Site Manager will ideally be a registered healthcare professional on the staff of the facility performing POCT and will:

- Be responsible for the day-to-day supervision or oversight of personnel performing POCT and reporting test results
- Be responsible for the day-to-day care of the system and control of environment contamination, and for the maintenance of stocks of consumables and reagents within their shelf life
- Ensure that all users of POCT devices are competent and authorised to use the devices
- Ensure their area complies with all POCT policy procedures
- Ensure that training records are kept for all users
- Ensure that quality control procedures are documented according to the relevant POCT policy
- Ensure that the relevant policies and procedures for the use of the device(s) in their area are in place and available to all users
- Follow SOP to communicate issues/concerns with the POCT Coordinator

POCT Trainer

The POCT trainer will be a suitably qualified healthcare professional, who may be the POCT Coordinator or will be designated by them as a trainer. They may be another registered laboratory practitioner, an experienced operator or a representative of the company supplying the device. They are responsible for:

- Ensuring that the operator has the knowledge and skills to accurately and reliably perform the task
- Assessing and documenting the competency of the operator
- Assessing and documenting that the operator has the required theoretical knowledge to perform the test and to recognize any errors or interferences in all stages of the testing process, pre-analytical, analytical or post-analytical
- Signing the completed competency and certification records for trainees

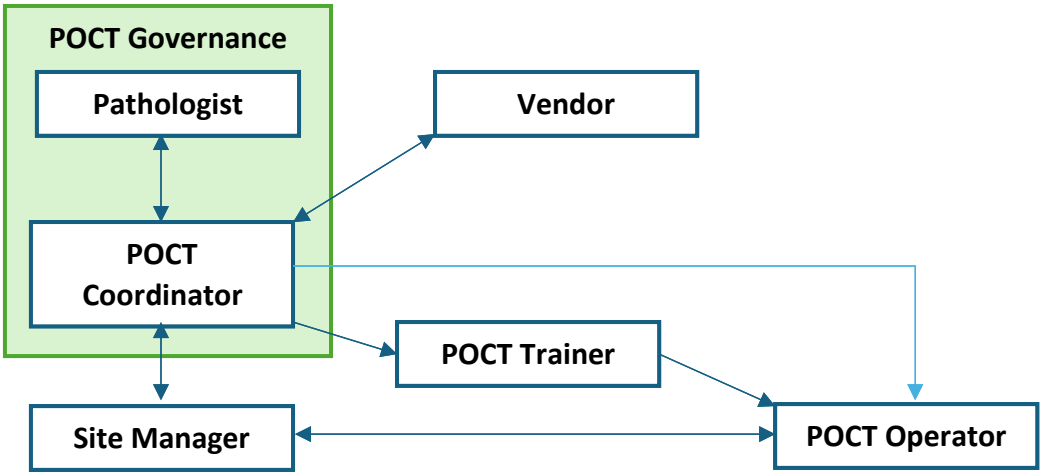
POCT Operator

The users of POCT devices will:

- Be trained and certified as competent to use the POCT device
- Be individually accountable for their practice and ensure that they acquire and maintain skills in the use of POCT devices. This will require the completion of documented competency processes as required, which will usually be on an annual basis
- Use the equipment in a safe and responsible manner
- Have a unique identifier (log-in or password) where applicable
- Not share their log-in or password with any other person – the individual is responsible for any test undertaken with their identification

- Remove the instrument from use if it becomes non-functional and inform the Site Manager and/or POCT Coordinator as soon as possible
- Complete the quality control requirements for the device as per protocol
- Document all patient and quality control results according to the protocol
- Ensure the device is left in a fit state for the next user
- Ensure all consumables are within expiry date and have been stored correctly as per manufacturer's recommendations
- Ensure that all used items, including but not exclusive to, reagents/cassettes/strips, lancets etc. are disposed of safely in accordance with the standard operating procedure

Relationship Diagram



Internal Auditing

There must be regular audits to ensure that the POCT device remains fit for purpose and compliant with these best practice guidelines. Advice on internal audit procedures can be obtained from the local accredited medical laboratory.

Adverse Event Reporting

An adverse event or near miss may cause, or may potentially cause, an unexpected or deleterious effect. In a POCT environment an adverse event may impact on the health and safety of patients, service providers or other persons. For example, an incorrect result may lead to a delay in treatment, inappropriate treatment, a life-threatening illness or injury, a serious deterioration in the state of health, or even death.

Any adverse event involving a POCT device or its reagents and consumables shall be investigated and reported via the organisational incident reporting system (if available) and to the supplier of the device. There is a documented process for reporting adverse events to Medsafe available on the Medsafe website.

A record of all incidents, near misses and actions taken must also be kept at the site/institution of POCT.

Accreditation

Accreditation by an external accreditation agency (such as IANZ) is an important element of risk management. Accreditation against the ISO 15189:2022 standard, while not mandatory in New Zealand, does provide objective endorsement of the organisation's overall quality management system for POCT and of competency to perform the testing and is recommended (where practical), for health providers who use POCT.

SOURCES OF ERROR

While POCT devices are generally straightforward and easy to use, there are a number of potential sources of error. Errors in POCT may occur in all stages of the testing process. These may be pre-analytical, analytical and post-analytical errors.

Pre-Analytical Errors

Errors which may occur **before** the analysis, this includes:

- Patient identification:
  It is essential to properly identify the patient to be tested
- Sample collection, timing and delay before testing:
  The quality of the sample can have a significant effect on POCT results, (see Appendix 1, Sample Collection Procedures, for information on sample collection)

Analytical Errors

Errors may occur **during** the testing process; this includes:

- Operator training and competency:
  All POCT operators must be trained and assessed as competent before commencing patient testing
- Out of date reagents/cassettes/strips:
  Document and monitor reagent expiry dates, including open vial/out of refrigeration expiry requirements
- Incorrect storage of equipment and disposables:
  Monitor and document temperatures of POCT areas and storage facilities to ensure they meet specifications
- Incorrect operation of the device:
  All POCT operators must follow the manufacturer's instructions/documented methodology for the correct operation of the device
- Failure of the device or consumables:
  Ensure that QC/EQA are performed regularly, results reviewed and responded to in a timely manner

- Device is not fit for purpose

Post-Analytical Errors

Errors which may occur **after** analysis, these include:

- Incorrect result documentation
- Incorrect result interpretation
- Use of incorrect reference ranges or incorrect units
- Failure to respond to out-of-range results
- Failure to adhere to safety requirements
- Failure to effectively incorporate POCT results into a clinical management pathway

Several POCT instruments are available which incorporate safeguards to minimise many of these potential sources of error, these may include password protection to exclude untrained operators, expired consumables lockout, QC lockout to ensure that QC is performed regularly and satisfactorily before testing can begin, and connectivity to ensure that results are transmitted directly to the patient record thus eliminating transcription errors. The advice of POCT Coordinators and pathologists should be sought regarding all sources of error.

REPORTING OF RESULTS

Ideally, results should be expressed in the same stated units of measurement as used by the local accredited medical laboratory. Reference intervals should be clearly defined, preferably in liaison with an accredited medical laboratory and/or with the relevant clinical pathways. Medical alert/critical/panic values must be defined and results in this range must be communicated to the appropriate carer immediately. All results should be returned to the requesting clinician responsible for the patient and placed in the patient's notes in a written format with appropriate reference intervals for the POCT device and recorded in the electronic patient record. It is strongly recommended that devices capable of electronic transfer of results should be used.

POCT generated results must be distinguished from laboratory results and the use of centralised data repositories will also help to ensure that test results are accessible to other providers.
NOTE: POCT generated results may be different from laboratory results and as such may have different reference intervals.

POCT INSTRUMENT/DEVICE CONNECTIVITY

All results obtained from POCT testing must be recorded and become part of the patient health record. It is strongly recommended that POCT devices that can be connected to the electronic patient record are used. Information technology (IT) capability can aid in minimising some of the potential sources of error in POCT testing and promote compliance

with operator and patient identification procedures, test procedures and quality control requirements.

IT capable devices should include software that:

- Requires operator identification
- Requires patient identification
- Requires reagent information
- Transfers results directly to the patient record

Other desirable features which should be considered include:

- Bidirectional data communication to allow patient data to be uploaded to the device, and results matched with patient information to be fed back to the information system
- Option for devices capable of being connected to any database/LIS/HIS system
- Access and data should be secure to ensure patient confidentiality
- Ability to scan barcodes to facilitate information entry, operator ID, patient ID and lot numbers for disposables
- Allow easy and regular monitoring of QC information to continually evaluate system performance
- Use common docks, ports and wiring for communication
- Wireless connectivity allows more flexibility with regard to location and use of devices and the data capture in different clinical settings

HEALTH AND SAFETY

The same standard of safety and waste disposal must be observed for the POCT location as for any other laboratory, hospital ward or healthcare facility. The procedures outlined below are for guidance and are not intended to replace the standards already in place that comply with accreditation that exists for the location where POCT is performed, where those standards exceed these recommendations.

Safety

All POCT procedures should be performed in such a manner that there is no compromise to the health and safety of the patient or POCT operator:

- The devices must be operated using the manufacturer's instructions
- Any electrical components must be checked for safety before the instrument is first used and electrical safety checks carried out as per the legal requirement for that instrument type
- The device should be cleaned and disinfected as per the manufacturers' instructions at the prescribed time intervals, or immediately after there has been any blood or body fluid contamination
- Devices with direct contact to multiple patients must be cleaned after every use

Infection Control

It is important to prevent the spread of possible infection at the POCT location and hand hygiene is one of the most important measures to achieve this. All operators must follow infection control precautions.

Decontamination

All devices used between individual patients (e.g. glucose meters) must be decontaminated/disinfected following the manufacturer's instructions, to prevent cross contamination and nosocomial infection.

The POCT work area should be cleaned and disinfected daily. Decontamination of the work area is necessary in the case of contamination from blood or body fluids.

Any blood and body fluid spills must be cleaned up immediately, following standard organisational protocols.

Waste Disposal

All biological waste must be considered hazardous and disposed of appropriately.

HELP AND SUPPORT

The quality of results generated by POCT is directly related to the ability to perform the test correctly in all stages of the process:

- Appropriately trained and competent staff
- The patient preparation and sample collection
- The quality and integrity of the consumables
- The performance of the test procedure
- The recognition of any anomaly
- The reporting and interpretation of the result

Many people consider POCT products to be very easy to use and therefore "foolproof", but there are currently no devices available which meet this goal. Managers of facilities where POCT services are provided must ensure that the help and support required for implementing and maintaining a quality service is provided to the operators. Because POCT operators are not laboratory based or trained, ongoing support is essential. The degree of help and support required will depend on the technology involved. The formation of a partnership between the POCT facility, an accredited medical laboratory and the POCT vendor is recommended.

A reputable POCT vendor (under the guidance of the POCT Coordinator) should be able to provide training for operators, simple to follow instructions for POCT use and other associated documents and advise on or provide suitable quality control materials for the specific device

or process. A number of vendors have call centres with knowledgeable staff that can provide answers to questions about their products raised by POCT facilities and users.

Some accredited medical laboratories now have dedicated POCT laboratory staff to deal with POCT requirements in the secondary care environment, and it is recommended that facilities in primary care pursue a partnership and good working relationship with an accredited medical laboratory for all areas of POCT support, but particularly for support with QC and quality assurance requirements.

Help and support may be required with:

- The routine operation of the POCT device
- Management of consumables and reagents
- Review of quality control and quality assurance results
- Basic troubleshooting as part of obtaining a reliable result
- Identification of pre, and post-analytical effects that may affect results
- Determining causes of failure of the device to meet specifications
- Resolving occasional but inevitable differences between POCT and laboratory results on the same patient.

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APPENDIX 1: Sample Collection Procedures

In POCT, the quality of the sample is known to have a significant effect on test results, and training in collection techniques such as fingerprick collection is essential. In accordance with other diagnostic testing, even though POCT is being performed near to the patient, there should be in place the same quality of patient identification, specimen collection and labelling as exists for laboratory testing. Providers are strongly recommended to consult their local accredited laboratory for detailed advice on sample collection procedures.

Collection of Capillary Samples

CLSI states that the skin puncture device should be a sterile, disposable, single-use device with a permanently retractable blade or needle to reduce the possibility of accidental needlestick injuries and reuse. For operator and patient safety do not use a manual lancet, blade or needle without the retractable feature.

Blood obtained via skin puncture is a mixture of blood from arterioles, venules, capillaries, plus interstitial and intracellular fluids.

Proper collection of capillary puncture samples is essential for accurate laboratory test results. Potential sources of errors in capillary sample collection include:

- Incorrect Site selection:
  Choosing the correct site prevents patient harm and ensures adequate sample volume and quality.
  - In Adults and children over one year, the fingertip of the middle and ring fingers on the non-dominant hand are preferred. The tip and sides of the finger are to be avoided as the tissue is half as thick as the central pad. Thumb and index fingers are more likely have calloused skin and in the fifth “pinky” finger the distance to the bone from the skin surface is less. The dominant hand will tend to have thicker skin.



  - Infants under one year, CSLI guidelines recommend a heelprick collection with a device penetrating no deeper than 2.00 mm. To avoid osteomyelitis of the heel bone and nerve damage, the posterior curve of the heel and central arch area must be avoided. The shaded areas on the diagram are the recommended sites for good safe heelprick collection.



- Use of wrong size or type of skin puncture device
  Choose a device designed to deliver the volume of blood required.
  Poor choices may result in slow or inadequate collection, excessive squeezing, poor specimen quality (haemolysis, clotting) and if high flow devices selected, prolonged bleeding post collection.

- Failure to pre warm the site
  Pre-warming the collection site will increase the blood flow up to seven times. A warm moist towel or warming device, no more than 42^{OC} applied for 3-5 minutes.
  Capillary blood gas or pH samples must be pre-warmed to arterialise the sample and adequately mixed to prevent clot formation.

- Failure to allow skin to dry after cleansing.
  Dry hands after washing and allow alcohol cleansed skin to air dry for effective disinfection.
  Residual water or alcohol on the skin may cause haemolysis of the blood sample. Puncturing the skin through alcohol causes discomfort to the patient.

- Failure to wipe away the appropriate drops of blood
  Note: Some procedures such as INR require the use of the first drop of blood. Follow manufacturer's instructions at all times.
  The skin puncture triggers the body's clotting response with the first platelets aggregating at the collection site. Wiping away this platelet plug prevents an early end to the collection.
  The first drop of blood is potentially contaminated with tissue fluid and skin cells which may cause erroneous results or haemolysis.

- Squeezing too hard, "milking" the heel or digit and scooping/scraping the blood from the skin surface
  Touch the end of the collection device to the drop of blood.
  Excess squeezing and milking of the surrounding tissues will cause contamination with tissue fluid and haemolysis.
  Scooping or scraping blood from the surface of the skin will haemolyse the blood and activate the platelets leading to platelet clumping and micro clots.

- Incorrect or inadequate anticoagulant
  Follow manufacturer's instructions as to choice of anticoagulant tube for tests required.
  Fill collection tubes to optimal level to prevent excess anticoagulant/blood ratio. Overfilled tubes will have insufficient anticoagulant to prevent clotted samples.

- Inadequate mixing
  Thorough mixing at time of collection will ensure anticoagulant is dissolved and dispersed throughout the sample, preventing clot formation. Placing a mixing wire into a capillary blood gas tube before collection will help.

Mixing of whole blood samples just prior to analysis delivers a homogenous sample for analysis

- Contamination
  Washing with warm water only is recommended because particular cleansers such as soaps and alcohol wipes are known to interfere with the analysis of certain analytes.
  An exception would be immune compromised patients.
  Uncleaned skin sites may be contaminated with environmental agents such as food that has been handled or creams/oils on baby heels.

- Presence of air bubbles in capillary blood gas samples
  Hold the heparinised capillary tube in a horizontal position. Touch the end of the tube to a well-formed drop of blood. Quickly filled capillary tubes from a free-flowing puncture site will minimise contact with air.
  Any air bubbles present should not be mixed into the blood sample. To do so will compromise the accuracy of the results.

Collection of Arterial Samples

The collection of arterial blood samples is technically difficult and is most sensitive to preanalytical errors. Training in arterial blood collection by appropriate personnel is essential. Improper collection or handling of arterial blood can lead to erroneous pH and blood gas results.
Potential sources of errors in arterial sample collection include:

- Failure to ascertain relevant patient temperature and ventilation status
  Blood gas results may be "corrected" to patient temperature by adjusting the analyser setting to the correct temperature of the patient.
  Patients who are breathing naturally should be comfortable and in a normal breathing pattern for 5 minutes before the collect. Anxiety, breath holding and crying will affect the results. Patients on supplementary oxygen should be on a stable amount of oxygen for 20 minutes before the collect.
  Take note of the ventilation status to allow calculation of all blood gas parameters.

- Inadequate sample volume
  Collect sufficient sample volume for the blood gas analyser in use. With 23 gauge or larger needles, the pressure in the artery will force blood into a well-lubricated syringe so that suction is not necessary. Excessive suction lowers the gas pressure of the sample and, therefore, the partial pressure of the individual gases.

- Presence of air bubbles in sample
  Any air in the sample will affect the results, especially pO_2. Expel any air bubbles from the syringe before mixing the sample. Gently tap the sides of the syringe to dislodge bubbles.

- Failure to mix sample after collection

To prevent clotting, the sample must be promptly and thoroughly mixed after collection. Roll the syringe horizontally between the palms and invert the syringe vertically.

- Clotted sample
  A clotted sample is not representative of the patient's blood gas status and should not be used. Introducing clots to the blood gas analyser will block the sample analysis of your collect and subsequent samples on the analyser.

- Failure to mix the blood before analysis
  Remix the sample immediately before analysis to introduce a homogenous sample. Whole blood will separate out on standing. Any sample showing visible separation of cells and plasma will need mixing for several minutes.

- Use of the wrong type or amount of anticoagulant
  The use of syringes specific to arterial blood gas collection is recommended. They are usually pre heparinised with dry electrolyte balanced heparin. Liquid heparin dilutes the blood giving erroneous results.

- Failure to remove first drops of blood before analysis
  Blood in the hub of the syringe is difficult to mix and prone to micro clots. Expel the first few drops onto gauze or tissue to prevent introducing clots to the analyser.

- Haemolysis
  Do not store samples directly on ice nor handle vigorously. Ruptured red blood cells will give false electrolyte and calcium results.

- Delay in analysis after collection
  Ideally analyse immediately after collection, delay no longer than 30 minutes. Cell metabolism continues after collection. Prolonged storage gives results that are not representative of the patient's status. Storage on ice does NOT delay deterioration.

Collection of Venous Samples

Improper collection of venous samples for POCT which use whole blood may cause problems which are not as easily detected in the POCT environment as in the laboratory environment where serum or plasma is used.
Potential sources of error include:

- Failure to adequately mix sample before analysis
  Remix immediately before analysis to present a homogenous sample for testing.

- Haemolysis due to poor collection technique
  Use of small bore needles and vigorous mixing can cause haemolysis which will not be visible in whole blood samples yet may alter results.

- Use of the incorrect or inadequate anticoagulant:
  Follow manufacturer's instructions as to choice of anticoagulant tube for tests required. Fill collection tubes to optimal level to prevent excess anticoagulant/blood ratio. Overfilled tubes will have insufficient anticoagulant to prevent clotted samples.

- Clotted sample:
  A clotted sample is not whole blood. Follow the manufacturer's instruction for inverting tubes after collection to anticoagulant the blood completely.

Collection of Urine Samples

- Freshly voided urine or bladder stab specimens may be used for POCT. Catheter and urine bag samples are not suitable.

- The urine must be collected in a clean dry container, labelled with patient's name, NHI number, date and time of collection, and initials of staff collecting sample.

- Samples should be tested as soon as possible after collection. If testing cannot be performed within one hour after collection, the specimen should be refrigerated at 2-8^{o} C immediately and returned to room temperature before testing.

Collection of Other Samples

The collection of other types of samples must be in accordance with manufacturer's instructions. These may include but are not restricted to:

- Urine samples for Drug Screening
- Faecal, eye or throat swabs
- Vaginal secretion swabs for prediction of pre-term delivery or pre-eclampsia

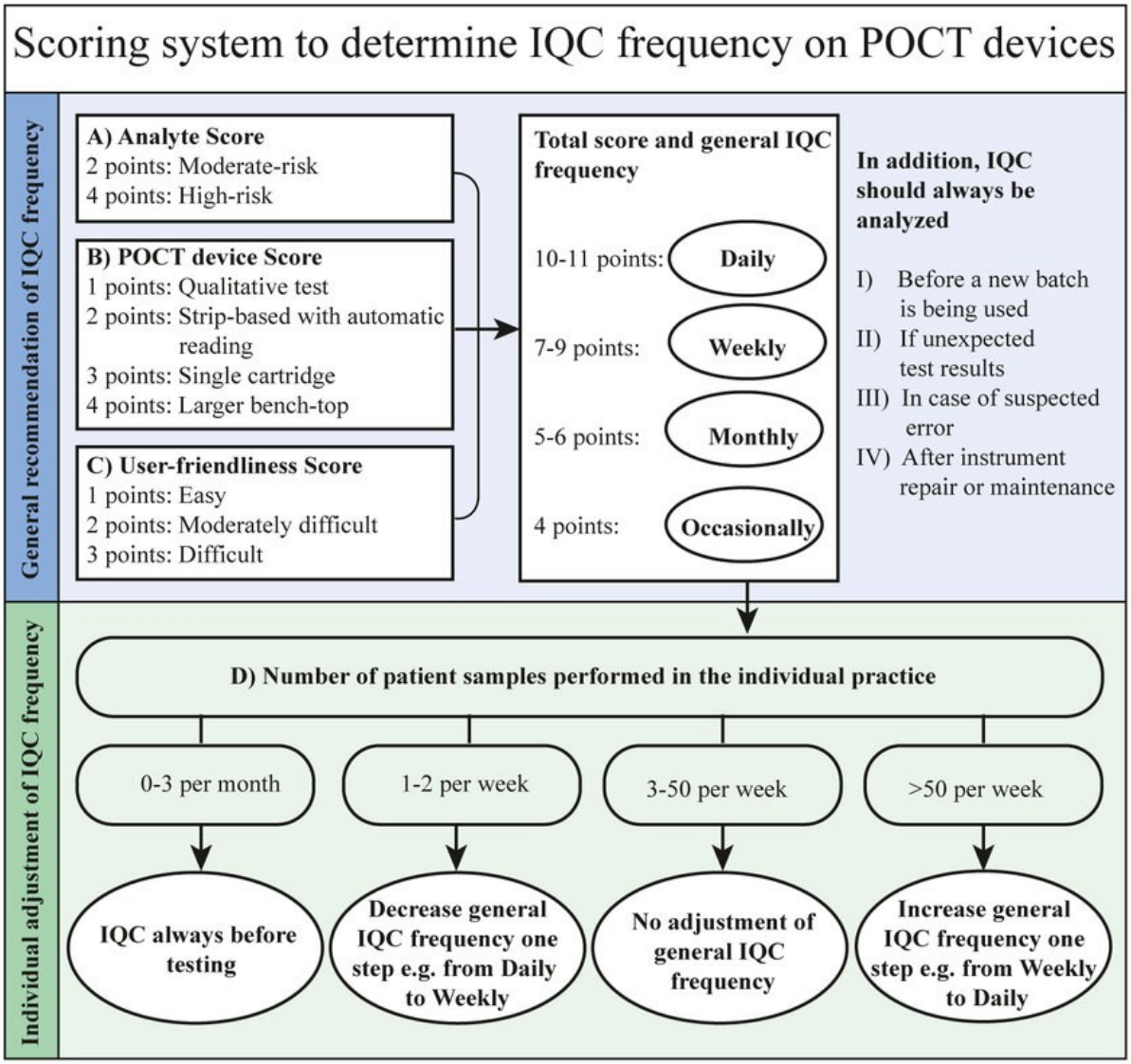
APPENDIX 2: Quality Control (QC) Intervals

Quality control intervals will vary with different POCT analysers.

Generally, if an analyser is used daily then daily QC should be performed, and if used weekly then weekly QC before any patient samples are completed. If an instrument is only used monthly, then QC should be performed monthly before any patient samples.

These QC requirements can be revised based on evidence of risk assessment, analyser reliability/performance, and test strip/cartridge stability.

Below is an example guide only, and you should seek appropriate advice from an accredited laboratory service before implementing QC procedures.



(Reference: Clinical Chemistry Lab Med (2022). Point-of-care testing in primary healthcare: a scoring system to determine the frequency of performing internal quality control)