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Review

Quality assurance practices for point of care testing programs: Recommendations by the Canadian society of clinical chemists point of care testing interest group

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ABSTRACT

Point of Care Testing (POCT) refers to clinical laboratory testing performed outside the central laboratory, nearer to the patient and sometimes at the patient bedside. The testing is usually performed by clinical staff, such as physicians or nurses, who are not laboratory trained. This document was developed by the POCT Interest group of the Canadian Society of Clinical Chemists (CSCC) as practical guidance for quality assurance practices related to POCT performed in hospital and outside hospital environments. The aspects of quality assurance addressed in this document include: (1) device selection, (2) initial device verification, (3) ongoing device verification, (4) ongoing quality assurance including reagent and quality control (QC) lot changes, and (5) quality management including operator and document management.

1. Introduction

Point of Care Testing (POCT) refers to clinical laboratory testing that is typically performed outside a clinical laboratory, nearer to the patient and sometimes at the patient bedside. This includes all testing performed by non-laboratory personnel, such as nurses, physicians and respiratory therapists, regardless of the location of examination. POCT is used widely in hospital settings, including in clinical scenarios where rapid turnaround time for results is necessary or where central laboratory testing is unavailable [1]. It may also be used in non-hospital settings, such as primary care physician offices [2], paramedic services [3], or pharmacy settings [4,5] and is poised to continue to evolve in its scope [6]. Devices that are used for patient self-testing, such as home glucose meters and home pregnancy tests, are not to be used for medical decision making by a qualified healthcare provider and, as such, are not included in the traditional definition of POCT in this document.

More recently, POCT has expanded beyond traditional hospital settings where laboratory professionals, such as clinical biochemists, are able to provide ongoing oversight and direction for POCT. This document was developed by the POCT Interest Group of the Canadian Society of Clinical Chemists (CSCC) to provide guidance to both hospital and non-hospital POCT users on the activities required to achieve high quality POCT results that are accurate, precise, and clinically valuable. This document aims to provide guidance and a framework for implementing and managing a robust, safe, high quality POCT program that keeps patient safety at its core. As a companion to our previously published CSCC position statement on POCT [7], the aspects of quality assurance addressed in this document include: (1) device selection, (2) initial device verification, (3) ongoing device verification, (4) ongoing quality assurance including reagent and quality control (QC) lot changes, and (5) quality management including operator and document management. Where applicable, recommendations have been categorized based on the complexity of the POCT as follows: low, moderate and high. Complexity has been previously defined by other international bodies, such as the Clinical Laboratory Improvement Amendments (CLIA) Act 1988 of United States of America [8] and the Therapeutics Goods Administration (TGA) from Australia [9]. While these definitions are in use for regulatory applications, this document focuses more on practical quality assurance in the clinical setting, and utilizes the following definitions:

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- **Low complexity** devices include testing that provides qualitative and semi-quantitative results from cassettes or single use strips or cards with a manual read of results (i.e. no automated device to read the results). Examples include manual urine human chorionic gonadotropin (hCG; pregnancy testing), fecal occult blood testing and urinalysis.
- **Moderate complexity** devices include testing that gives qualitative, semi-quantitative or quantitative results, and have simple to moderately complex instrumentation. Examples include automated urinalysis instruments, and devices measuring hemoglobin A1c (HbA1c) and glucose.
- **High complexity** devices have multifaceted internal parts and/or interface, and produce quantitative results. Examples include bench top blood gas analyzers and complete blood count (CBC) devices.

Complexity may be program specific and may depend on multiple factors, such as clinical use of results, number of analytes on a cartridge, number of cartridges within a program, the clinical setting(s) and number of devices and users in the program. Classification of complexity should be determined by a designated Laboratory Director, who could be a Clinical Laboratory Doctoral Scientist or Laboratory Physician with appropriate qualifications and expertise in POCT (subsequently referred as the POCT Director) with local, state/provincial, and national regulatory requirements taken into consideration. Ideally, a multidisciplinary committee with representation from POCT stakeholder groups within an organization, works with the POCT Director to oversee POCT programs.

Laboratory oversight in this document refers to the need for POCT programs to be overseen by a Laboratory Director and an accredited clinical laboratory to ensure all aspects of quality assurance are maintained and to mitigate common barriers to appropriate POCT adoption [10]. This oversight should ultimately be the responsibility of the POCT Director. The POCT Director will be able to refer to the recommendations in this document utilizing their training and clinical judgment and when necessary to modify verification criteria (e.g. required number of samples to verify per device). When POCT programs are in areas not directly associated with hospital laboratories, oversight from an accredited clinical laboratory should be sought. This can be a hospital or a community clinical laboratory.

Both minimal and optimal criteria have been provided for the described POCT quality assurance activities, where applicable. The acceptance criteria used to assess quality parameters are specific to the testing performed, therefore it is not appropriate nor feasible for this document to provide this detailed information. The use of minimal versus optimal criteria should be determined by the POCT Director, weighing known device quality, intended use, published information about the device/test, test methodology, patient safety, feasibility, human factors and all associated costs. For example, if a method has been comprehensively evaluated by an accredited laboratory with a similar patient population, in similar testing environments and for the same clinical use, minimal criteria may be considered appropriate. The specific recommendations included in this document regarding the number of samples to be analyzed were arrived at by consensus of all authors, and they are to be used as guidelines. Ultimate decisions about sample numbers required will depend on the type of device or assay, and should be made by the POCT Director. In addition, any concerns identified from analyses should prompt further discussion with the POCT Director, to determine next steps. This may include analysis of additional samples, follow-up with the vendor, and/or potential suspension of clinical testing.

2. Device selection (ideal device features)

Selecting a POCT device with clear clinical utility, optimally based on patient outcome evidence [11,12], will support strong POCT programs. The POCT Director together with a POCT multidisciplinary committee should provide input, and preferably decision, on device selection to ensure POCT device(s) selected are appropriate for the patient testing required [13], and that the device meets patient safety goals, organization policies and regulatory and/or accreditation requirements in their jurisdiction. Device features and considerations may include types of devices available (handheld versus bench top), acceptable specimen types, sample preparation requirements, test menu and performance, QC and management functions (e.g. QC and operator lockout), as well as software and connectivity capabilities. Clinical users should also be asked to provide human factors input, such as device size, display, ease of use, cleaning and maintenance requirements. QC and operator lockout functions and connectivity/data management systems are discussed in detail below.

2.1. Quality control (QC) and operator lockout

QC (internal, external and electronic as applicable) and operator lockout functions provide a reliable mechanism to encourage and maintain regulatory requirements for QC and operator management. QC testing is required prior to patient testing to ensure that POCT devices and reagents are functioning as expected. The simplicity of some POCT devices and the many competing priorities of healthcare professionals can tempt operators to take shortcuts around performing QC. When selecting a device, those with QC lockout function are desirable as this prevents an operator from using the POCT device if the QC frequency interval has been exceeded or a QC result is outside of acceptable limits. In addition, when combined with a data management system, QC results for each device and operator can be reviewed and evaluated for ongoing quality monitoring [14].

Devices with an operator lockout function will only permit valid users with up-to-date certification to operate the device. If an operator had initial training, but has an expired recertification, they will be locked out when they attempt to operate the POCT device and it will prevent them from performing patient testing. The user will not be able to use the device without completing competency requirements. By combining device operator lockout function with training management and data management systems, operator management can be automated to activate or inactivate operator status based on training and competency assessment status and frequency requirements. With appropriate software, automated user notification of approaching certification expiry is possible.

2.2. Connectivity and data management system

The integration of POCT results into the permanent patient health record supports a complete continuum healthcare model. As per the CSCC position statement on POCT, connectivity improves quality assurance compliance, enables timely access to stored results, supports test result interfacing with other health record applications used by healthcare professionals and/or patients, and reduces duplicate test ordering and testing [7,15]. Data management systems, or middleware, link the POCT device to the laboratory information system (LIS) and/or electronic patient medical record and permit management of POCT QC values, device operators, and patient results. Accordingly, the use of a connectivity/data management system, wherever possible, is recommended for all POCT programs. One important component is to ensure that POCT results are clearly distinguished from central laboratory results in the patient medical record.

Evaluation of new devices should include assessment and testing of the data management system and connectivity when these solutions are available. Key considerations include device and software ability to: 1) interface with available middleware and information systems, 2) perform positive patient identification with site/health system barcode scanning abilities, 3) connect to wired and wireless networks, and 4) comply with site/health system privacy and security policies. It is also important to consider the track record of the vendor in maintaining and

updating software versions, and the software compatibility with device and LIS operating system versions.

A data management system may also assist the POCT program in maintaining compliance with federal and provincial regulatory and accreditation requirements. Documentation of compliance is labour intensive and time consuming when done manually, especially for complex POCT programs that include a large number of operators, extensive POCT test menus, and the requirement of continuous quality improvement. Some ideal features of a data management system include device management, operator management, inventory management, competency assessment, QC review, data monitoring, and remote access. For instance, device management supports the ability for a POCT program to easily maintain a documented record of all POCT devices including instrument serial numbers, testing locations, purchase and retirement dates, instrument service dates and software versions. A data management system can provide an elegant solution to the challenges of managing regulatory and accreditation issues of POCT programs and departments of varying sizes.

3. Initial device verification

This section refers to the verification of a new POCT device/program. Regardless of the relative complexity, all POCT devices and tests are required to be verified for their analytical performance before use in clinical services to ensure the quality of results/device meet the intended clinical use. As a first step, the package inserts for potential devices and methods/test cartridges should be reviewed for the following information: intended use, methodology, traceability, sample types and volumes, analytical measuring range (AMR), interferences, limitations and manufacturer's quality claims. The investigator(s) should be familiar with the operation of the device prior to evaluation. The principles for evaluating POCT analytical performance should be the same as those for central clinical laboratory testing, and should be overseen by the POCT Director. Quality targets used as pre-defined acceptance criteria for verification studies are usually determined based on published analytical goals, regulatory requirements and/or performance stated in the manufacturer's package insert. Evaluation studies often include precision, linearity, accuracy, and method comparison across the AMR of the device or test. For POCT that provide qualitative or semi-quantitative results (e.g. urine hCG testing), the performance of clinical or analytical sensitivity, specificity, and negative and positive predictive values may need to be included.

The verification protocol should be determined based on intended use, methodology, reagent stability, sample availability and potential method limitations to ensure the evaluation is conducted with a focus on patient care, yet in a cost-efficient manner that meets the requirements of the POCT program. In some circumstances, the verification needs are complex and should be carried out in consultation with the POCT Director. For example, difficult-to-obtain specimens, such as scalp capillary blood or amniotic fluid, may require special consideration. In other situations, interference studies or additional evaluations are included to ensure appropriateness of the device to the patient needs and clinical setting. Specific interference assessment should be conducted based on patient population, intended use of POCT, methodology, literature review and manufacturer recommendations. There are published guidelines and protocols for device verification [16–20].

It should also be noted that testing not described by the manufacturer in their package insert(s) or manual(s), for example, an alternative specimen type, is considered "off-label" usage. This testing requires a more thorough analytical and clinical validation of the device, akin to a "laboratory developed test".

Multiple POCT devices, such as glucose meters, can use the same reagent lot of test strips or cards, but read and convert the signal to concentration of analyte individually within each device. These devices can be implemented into clinical service all at the same time. If this occurs, it is important to carefully consider the complexity of technology used in the device to determine the scope of verification studies required. It may be possible for the reagent strip or cartridge to be comprehensively verified by studies of linearity, accuracy, reportable range, precision, method comparison and interference on representative devices (for example 10% of total meters or determined by the POCT Director), however the signal reading can be verified on the rest of the devices by a simplified protocol (e.g. performing only linearity and accuracy studies). Such an approach may not be applicable to high complexity devices, such as blood gas instruments, and requires direction/decision by the POCT Director. See Table 1 below for specific initial verification recommendations.

Table 1
Guidance on initial device verification.

Device complexity	Criteria level	Precision	Comparison	Linearity
Low	Minimal	QC (negative and positive) once a day for 5 days.	5 abnormal and 5 normal patient specimens. Compare to central/ clinical lab method.	N/A
	Optimal	QC (negative and positive) in duplicate each day for 10 days.	10 positive and 10 negative patient specimens. Compare to central/ clinical lab method.	N/A
Moderate & High	Minimal	Within run (two levels of QC run a total of 5 times in one run)	20 patient specimens spanning the AMR. Compare to central/ clinical lab method.	Use vendor supplied linearity materials, if available, and measure all levels in duplicate. Otherwise use laboratory generated materials (e.g. a series of dilutions from a high patient specimen) and measure 3 levels in duplicate.
	Optimal	Within run (see above) and between run (two levels of QC run a total of 10 times, over minimum of 3 days)	40 patient specimens, spanning the AMR. Compare to central/ clinical lab method.	Use vendor supplied linearity materials, if available, and measure all levels in duplicate. Otherwise use laboratory generated materials (e.g. a series of dilutions from a high patient specimen) and measure 5 levels in triplicate.

N/A: Not applicable.

4. Ongoing device verification (for additional devices within an existing program)

Once a POCT program for a particular instrument has been established, it may be necessary to bring in additional instruments to support the growth of the POCT program, to replace non-functioning instruments, or to act as back-up instruments. In these situations, the scope of verification studies may not need to be as rigorous as it would for a new program. The type of ongoing verification to be done will vary depending on device type and complexity. All results from evaluation of a new instrument in an existing program should be compared to predefined limits or allowable error goals for acceptance, as defined in the original instrument evaluation. See Table 2 below for specific ongoing method verification recommendations.

5. Ongoing quality assurance

POCT programs require the establishment of ongoing quality assurance practices to ensure accurate instrument performance over time. New shipments and lots of reagent and QC material should be verified for precision and compared to central laboratory instruments (see [21] for an example of the importance of this quality practice). Once a new lot number of QC or reagent has been verified, QC testing should be performed at regular intervals, preferably daily (or at minimum when patient testing occurs), by the clinical personnel performing POCT. For cartridge-based devices such as a handheld or tabletop blood gas analyzer, it may be sufficient to analyze each level of QC once with each new reagent lot and shipment. Daily external QC may not be required with these devices. The majority of these devices have electronic QC that should be performed whenever patient testing is taking place, therefore daily performance may not be required.

Additionally, regular comparisons between POCT devices and central/clinical laboratory instruments are necessary to identify clinically meaningful differences and maintain comparability. External quality assessment (EQA) challenges, or proficiency testing (PT), should also be performed regularly to monitor operator compliance and ongoing instrument performance. Here, recommendations for ongoing quality assurance are provided, which include but are not limited to: reagent lot validation across the AMR, QC material validation, inter and intra-instrument comparisons and EQA. See Tables 3–5 below for specific recommendations. Please note that the guidance indicated in Tables 3a and b refer to evaluation of new lot numbers and/or new shipments of reagents and QC material, respectively. Evaluation studies should be performed whenever a new lot number or shipment of these materials is received. Evaluation of new shipments of reagent or QC material from previously validated lots may only require the minimal validation criteria after consultation with the POCT Director.

Table 2
Guidance on ongoing device verification.

Device complexity	Criteria level	Precision	Comparison	Linearity
Low	Minimal Optimal	These tests/devices do not require further evaluation once the initial full evaluation has been completed and accepted, **unless** there is a significant change to the manufacturing of the test cassettes, strips or cards. New shipments of reagent lots are to be assessed prior to routine clinical use, as outlined in the *Ongoing Quality Assurance* section.		
Moderate	Minimal	Within run (two levels of QC run a total of 5 times in one run)	5 to 10 patient comparison with central/clinical laboratory method. This could also be via measurement of EQA/PT specimens	Only required if linearity performance was marginal during initial verification
	Optimal	Within run (see above) and between run (two levels of QC run a total of 10 times, over minimum of 3 days)	10 to 20 patient comparisons that span the AMR	Use vendor supplied materials if available; all levels measured in duplicate
High	Minimal	Within run (two levels of QC run a total of 5 times in one run)	10 patient comparisons that span the AMR	Use vendor supplied materials if available; all levels measured in duplicate
	Optimal	Within run (see above) and between run (two levels of QC run a total of 10 times, over minimum of 3 days)	20 patient comparisons spanning the AMR. Consider including different sample types if applicable (e.g. arterial, venous).	Use vendor supplied materials, if available, and measure all levels in duplicate. Otherwise use laboratory generated materials (e.g. a series of dilution from a high patient specimen) and measure 5 levels in duplicate.

6. Additional quality management considerations

In addition to POCT device selection and verification, other quality activities should also be considered, including document control, training and recertification of users, audits and monitoring of quality indicators [22].

6.1. Document control

Policies and procedures are required for all POCT devices and processes. They require POCT Director approval and ongoing review at regular intervals as specified by policies of the local institution or local regulatory requirements. Local procedures, processes and record retention guidelines should be followed. Original results and evaluation approval should be kept at one location, and all locations using the device are to have a copy and/or access to the documentation for referencing at any time.

Table 3a
Guidance on new reagent lot evaluation.**

Device complexity	Criteria level	Precision	Comparison
Low	Minimal Optimal	Once with one QC Once with each of negative and positive QC	N/A
Moderate*	Minimal Optimal	Three times for each QC level	N/A 5 patients spanning the AMR
High*	Minimal Optimal	Three times for each QC level	N/A 5 patients spanning the AMR

N/A: Not applicable.
* Moderate and high complexity should include at least two QC levels.
** Evaluation studies should be performed for both new lot numbers and new shipments.

Table 3b
Guidance for new QC material lot evaluation.[**]

Device complexity	Criteria level	Precision	Comparison
Low	Minimal Optimal	Compare one measurement with previous QC material results to ensure concordance. Each QC level should be evaluated.	N/A
Moderate[*]	Minimal Optimal	Three times for each QC level.	Compare mean of values with mean of previous QC lot.
High[*]	Minimal Optimal	Three times for each QC level	Compare mean of values with mean of previous QC lot.

N/A: Not applicable.
[*] Moderate and high complexity should include at least two QC levels.
[**] Evaluation studies should be performed for both new lot numbers and new shipments.

Table 4
Guidance on intra- and inter-instrument comparisons.

Device complexity	Criteria level	Comparison
Low	Minimal	Intra-instrument comparison using PT or split-sample testing[*] once per year with a minimum of two specimens including normal and abnormal specimens.
	Optimal	Intra-instrument comparison using PT or split-sample testing[*] two to three times per year, with a minimum of two specimens (four specimens total per year). Samples should include normal and abnormal specimens.
Medium	Minimal	Intra-instrument comparison using PT or split-sample testing[*] once per year, with a minimum of two specimens including normal and abnormal.
	Optimal	Intra-instrument comparison using PT or split-sample testing[*] two to three times per year, with a minimum of three specimens (four specimens per year total). Samples should span the AMR of the test. Inter-instrument comparisons between POCT and the central/clinical laboratory should be performed twice per year[**] with a minimum of three specimens with low, medium and high concentration (six specimens total per year) on at least one instrument within a program.
High	Minimal	Intra-instrument comparison using PT or split-sample testing[*] once per year, with a minimum of two specimens including normal and abnormal.
	Optimal	Intra-instrument comparison using PT or split-sample testing[*] two to three times per year, with a minimum of three specimens (six specimens per year total). Samples should include normal and abnormal. Inter-instrument comparisons between POCT and the central/clinical laboratory should be performed at least twice per year[**] with a minimum of three specimens with low, medium and high concentration (six specimens per year total). This applies to all instruments in a given POCT program.

[*] Split sample testing should be with another accredited laboratory in a different institution.
[**] Could be at the time of reagent lot evaluation.

6.2. Training of users

All POCT users must receive training for the POCT device they will be using. Users must be deemed competent to perform the testing before being granted access. Training requirements should be developed in consultation with the POCT Director. Training can take various forms, including online or hands-on approaches. Minimally, users are required to complete an online training module and quiz to be certified to perform POCT on the specific device. Optimally, users are required to complete an online training module and quiz as well as participate in hands-on training provided by the manufacturer, laboratory and/or clinical super-users (clinical staff trained by the laboratory). Recertification may include a quiz, completion of a training checklist and/or hands-on testing, as indicated by the POCT Director. The process will also depend on the complexity of the test method/device.

Training should include, but not limited to:

- Reference to relevant accreditation standards for POCT
- Where to find POCT procedures
- Process for ordering and distribution of POCT reagents and supplies (QC, cuvettes etc.) and who is authorized to do so.
- Process for certification and recertification to perform testing.
- How reagents and QC material should be stored and expiry dates
- How to perform QC and at what frequency
- Explanation on the purpose of QC
- How to interpret QC results and troubleshooting, where applicable.
- Specimen labeling requirements
- Process and technique for specimen collection
- Any specimen labeling requirements
- Process and procedure to perform patient testing
- How to interpret patient results and guidance on any follow-up that may be required (e.g. critical results)
- Process for result documentation what must be included (if not recorded automatically in the EMR)
- Potential causes of inaccurate results and any limitations to the test device or method
- Device troubleshooting
- Process for alternative test method when results do not fit with the clinical presentation (e.g. send specimens to the central lab, if applicable)
- Safety considerations for specimen collection, performing testing and disposal of specimens and consumables
- Cleaning or maintenance requirements for the device
- Assessment of user competency to perform testing after completion of the training through a set of questions and/or by observation

Recent reports have demonstrated the vital role of operator training for quality POCT programs [14,23,24].

Table 5
Guidance on EQA/PT requirements.

Device complexity	Criteria level	Recommendation (per device)
All	Minimal	A minimum of two PT or split-samples[*] should be analyzed per year.
	Optimal	A minimum of four PT or split samples[*] should be analyzed per year and include both normal and abnormal samples.

[*] Split sample testing should be with another accredited laboratory in a different institution.

6.3. Recertification of users

POCT users need to be recertified at a defined frequency, as determined by the POCT Director based on local regulatory/accreditation requirements, to be able to continue to perform testing over time. There is no standard timeframe for recertification, but common practice is annual recertification. Recertification can be achieved through observation of acceptable testing or through an online module with test questions. When POCT instruments are connected to POCT middleware that also manages POCT users, criteria can be set up in the system to auto-certify users who perform regular QC and/or patient testing. The specific recertification criteria should be determined by the POCT

Director.

6.4. Audits

The most significant risk associated with POCT is the failure of clinical users to follow POCT policies and procedures. This can result in patient safety issues and jeopardize program compliance with accreditation standards. Regular audits are crucial to identify non-conformances. It is important that the POCT Director or a delegate follows-up with clinical areas on non-conformance to improve compliance and patient safety. At minimum, audits should be performed once a year per POCT program within an institution. Optimally, audits should be performed more often than annually per program and per institution, to facilitate regular audit and feedback to clinical users.

Audits should include, but are not limited to:

- Compliance with positive patient identification procedures
- Performance of QC at the frequency defined in the procedure
- Documentation of results, including all necessary components (e.g. reference intervals, units of measurement, date, time, traceable to individual performing test)
- Evidence of follow-up on results, as defined in the procedure
- Compliance with POCT ordering procedures and documentation
- Labeling and storage of reagents, as required and outlined in the procedure

6.5. Quality indicators

Regular monitoring of quality indicators measures the quality of the total POC testing process and is an important component of continuous quality improvement process. Quality indicators should facilitate identification of systemic issues related to quality so that root cause analysis can be initiated and strategies aimed at improving quality can be developed. Minimally, indicators should be monitored and reported annually. Optimally, indicators should be monitored and reported monthly.

The biggest risk to quality in POCT is related to clinical users not following policies and procedures. Quality indicators should be chosen to monitor this. Examples include, but are not limited to:

- Positive patient ID procedures, such as POCT results not associated with a valid patient medical record number
- Specimen and reagent labelling
- Performance of QC testing according to the procedure for the device
- EQA performance
- Compliance with policies related to follow-up on results, such as critical results, or results above or below the AMR of the POCT instrument

7. Summary

The POCT Interest Group of the CSCC has endeavoured to provide guidance on quality initiatives that are needed to ensure robust and high quality POCT programs in both hospital and non-hospital settings. The aspects of quality activities addressed in this document include: (1) device selection, (2) initial device verification, (3) ongoing device verification, (4) ongoing quality assurance such as reagent and QC lot changes, and (5) quality management such as operator and document management. Regardless of the setting in which POCT is performed, it is important to highlight that this testing is used for medical decision making. Accordingly, it requires oversight by an appropriate medical/scientific authority. Clinical biochemists, such as those making up the authors of this document, are specifically trained to act as this authority.

In many areas of the document, test comparisons to the central clinical laboratory or action by a laboratory POCT Director are referenced. We recognize that not all centres (e.g. some hospitals, private clinics, pharmacies) have immediate access to these resources. In these cases, it is advised to seek out consultation with a Clinical Laboratory Doctoral Scientist or Laboratory Physician with appropriate qualifications and expertise in POCT. Such relationships facilitate improvements in device selection, device verifications and ongoing device performance as well as provide a valuable resource for implementing POCT quality management systems [25].

8. Additional resources

In addition to CLSI documents, other practical summaries include the National Academy of Clinical Biochemistry's monograph (United States) [26], an AACC guidance document on POCT management [27], as well as the recent textbook by Dr. Mark Shephard (Australia) [28].

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