Review Article

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Planning education for best practices in point-of-care testing

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Abstract: The increasing availability and use of POCT are influenced by many factors, including the industry trend toward patient-centered care and decentralization of health care; the increasing prevalence of infectious diseases, which includes the current use of rapid SARS-CoV-2 testing; the increasing incidence of lifestyle diseases such as diabetes, heart disease, and hypertension; and advances in *in-vitro* medical diagnostics. The use of POCT can increase the efficiency of services and improve patient outcomes. However, the variability of the testing environment and conditions, as well as the competency of the staff performing the tests, can have a significant impact on the quality and accuracy of POCT results. Most personnel performing POCT are not trained laboratory staff and may not be as familiar with the processes associated with testing, such as patient preparation, specimen collection, management of equipment and supplies, calibration and maintenance of equipment, the performance of the test, quality control, interpretation of results, and reporting/documentation of results related to the particular patient. Therefore, personnel performing POCT must have the appropriate training and experience to ensure that test results are accurate and reliable. This review outlines the specific personnel training requirements based on international standards that must be considered to ensure the quality of test results and describe the competency criteria required for POCT compliance.

Keywords: competency assessment; education; laboratory management; point-of-care testing (POCT); staff training.

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Introduction

Point-of-care testing (POCT) is a fairly broad term that encompasses all diagnostic tests performed near or at the site of the patient where a specimen is collected, outside of the traditional clinical laboratory, whether in a physician's office, emergency department, intensive care unit, operating room, or outpatient clinic. These tests are waived under the Clinical Laboratory Improvement Amendments (CLIA) of 1988 in the United States and can be molecular, antigen, or antibody tests [1]. POCT includes three levels of complexity, from simple procedures such as blood glucose testing to procedures of moderate complexity (including microscopy procedures performed by the provider) to highly complex procedures such as influenza testing. Health care professionals performing POCT typically use test kits that contain portable equipment or are otherwise transported close to the patient for immediate testing (e.g., capillary blood glucose) or analyzers that are temporarily brought to a patient care location in a hospital to measure the analytes in blood, saliva, or urine samples [2–4]. The main advantage of POCT is the faster turn-around time for results. They provide results within minutes (depending on the test) rather than hours, leading to a potential change in patient care in various settings such as physician offices, emergency rooms, pharmacies, school clinics, long-term care facilities, and nursing homes, as well as at transient sites such as drive-through locations managed by local organizations [5]. Another advantage is that these tests often require less sample volume than tests performed in the laboratory.

Recent and ongoing changes in clinical laboratory technology have had a significant impact on the need for laboratory personnel. POCT is typically performed by individuals who are not trained in the laboratory, such as nurses, nursing assistants, physicians, residents, students, technical assistants, respiratory therapists, emergency technicians, pharmacists, and others. There are many "official" and expert-based standards and guidelines that define how POCT should be performed and managed, and how the quality of performance should be reviewed

and maintained. Most professionally based guidelines follow a similar template and contain similar information, including specific references to staff training and competency assessment [6–10].

Organizations that have a central biomedical laboratory should use these standards in POCT–specific requirements for quality and competence based on ISO 22870:2016. This standard is to be used in conjunction with ISO 15189:2012 and applies when POCT is performed in a hospital, clinic, or healthcare facility that provides ambulatory care. Patient self-testing in the home or community setting is excluded, but elements of this document can be applied. Table 1 provides a list of selected International Organization for Standardization (ISO) standards to consider in the context of POCT training and competency assessment requirements [11–18].

A well-organized POC program requires careful planning and continuous monitoring and supervision [19, 20]. In this regard, the AACC has released a new guide, developed by experts in the association's academy, describing best practices that hospitals and other health care facilities should follow when implementing a point-of-

Table 1: International standards define or are associated with medical laboratory and POCT competency and training.

Standard	Definition	Scope of the document
ISO 17593:2007	Clinical laboratory testing and *in vitro* medical devices – requirements for *in vitro* monitoring systems for self-testing of oral anticoagulant therapy.	– Specifies requirements for *in vitro* measuring systems for self-monitoring of vitamin-K antagonist therapy, including performance, quality assurance, and user training and procedures for the verification and validation of performance by the intended users under actual and simulated conditions of use. – Pertains solely to PT measuring systems used by individuals for monitoring their vitamin-K antagonist therapy, and which report results as international normalized ratios (INR).
ISO 15189:2012	Medical laboratories – particular requirements for quality and competence.	– Specifies requirements for quality and competence in medical laboratories. – can be used by medical laboratories in developing their quality management systems and assessing their competence. It can also be used for confirming or recognizing the competence of medical laboratories by laboratory customers, regulating authorities, and accreditation bodies.
ISO 15197:2013	*In vitro* diagnostic test systems — requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.	– Specifies requirements for *in vitro* glucose monitoring systems that measure glucose concentrations in capillary blood samples, for specific design verification procedures, and the validation of performance by the intended users. These systems are intended for self-measurement by laypersons for the management of diabetes mellitus. – Applies to manufacturers of such systems and those other organizations (e.g., regulatory authorities and conformity assessment bodies) having the responsibility for assessing the performance of these systems.
ISO 22870:2016	Point-of-care testing – requirements for quality and competence.	– Gives specific requirements applicable to point-of-care testing and is intended to be used in conjunction with ISO 15189. The requirements of this document apply when POCT is carried out in a hospital, clinic, and by a healthcare organization providing ambulatory care. This document can be applied to transcutaneous measurements, the analysis of expired air, and *in vivo* monitoring of physiological parameters. – Patient self-testing in a home or community setting is excluded, but elements of this document can be applied.
ISO/TS 22583:2019	Guidance for supervisors and operators of point-of-care testing (POCT) devices	– Gives guidance for supervisors and operators of POCT services where POCT is performed without medical laboratory training, supervision, or support. It includes the key components that should be considered to provide safe and reliable POCT results.
ISO/TS 20914:2019	Medical laboratories — practical guidance for the estimation of measurement uncertainty	– Provides practical guidance for the estimation and expression of the MU of quantitative measure and values produced by medical laboratories. Quantitative measure and values produced near the medical decision threshold by POCT systems are also included in this scope. This document also applies to the estimation of MU for results produced by qualitative (nominal) methods which include a measurement step. It is not recommended that estimates of MU be routinely reported with patient test results but should be available on request.
ISO 15190:2020	Medical laboratories — requirements for safety	– Specifies requirements to establish and maintain a safe working environment in a medical laboratory. As with all such safety guidelines, requirements are set forth to specify the role and responsibilities of the laboratory safety officer in ensuring that all employees take personal responsibility for their safety at work, and the safety of others who can be affected by it.

ISO, the international organization for standardization; PT, prothrombin time; POCT, point-of-care testing; MU, measurement uncertainty.

care testing program [21]. The guidance document discusses that point-of-care testing programs should be managed by interdisciplinary committees that include all relevant stakeholders, from laboratory experts to clinicians. This is particularly important because, unlike standard laboratory testing, many of the users who perform point-of-care testing are healthcare providers who do not have clinical laboratory training. Close collaboration between laboratory experts and healthcare providers is therefore critical to the success of point-of-care testing programs. Laboratory experts bring invaluable expertise on the benefits and limitations of the tests themselves, while clinicians can provide important insights into the testing needs of an institution's patient population. In conjunction with creating a long-term public health model of rapid diagnosis at the point of need, a recent paper identifies the necessary competencies for POCT for new curricula in colleges, schools, and public health programs so that faculty can train students and public health professionals in POC strategies for highly contagious diseases, emergency management, and crisis preparedness [22].

The Joint Commission International (JCI) requires that a qualified individual be responsible for oversight and monitoring of the point-of-care testing program (Standard AOP.5.1.1) [23]. Senior leadership can be involved in the planning process by determining and approving the resources allocated to the POCT program and the policies and procedures for managing and monitoring the program [24, 25]. When considering tasks performed by individuals who do not have technical skills and training, it should be noted that many countries have licensing laws that preclude the performance of certain testing procedures by non-technical personnel [26, 27]. CLIA requirements in the United States, which pertain to tests of moderate and high-complexity tests, prohibit the use of non-technical personnel for certain testing procedures [28]. The College of Physicians and Surgeons of Alberta provides detailed recommendations for the use of POCT outside of an accredited laboratory, including documentation, training of non-technical personnel, quality control, etc. In this context, the Alberta College of Pharmacy Council has approved amendments to the college's Standards for laboratory and point-of-care testing after receiving input from officials at Alberta Health [29].

Training requirements for point-of-care testing

A majority of the staff who perform POCT are not trained laboratory staff members and may not be as knowledgeable about the processes involved in testing, such as patient preparation, sample collection, instrument calibration, instrument maintenance, and quality control. Therefore, staff performing POCT must have the proper training and competency assessment to ensure test results are accurate and reliable [30, 31]. A recent article published in this journal provides common guidance for training and competency in POCT [32].

Alternatively, laboratory staff may take responsibility, if preferred, for some of the POCT activities, such as managing instrument maintenance and acting on instrument failures. Before training for POCT, each staff member must have qualifications verified with state or national authority requirements and accreditation agencies, if appropriate. For institutions performing POCT utilizing waived or non-waived testing, CLIA regulations require a high school diploma or equivalency in the US [33]. Some state regulating agencies require a license and/or a specific level of professional qualifications for persons performing laboratory testing in any setting, including point-of-care. Each qualified POCT user must complete initial training and orientation on each test method before initiation of testing and following any changes or update in instrumentation, kits, or test methods. Initial training must be completed before the user performs any patient testing and competence must be documented. This initial training must include direct observation, be documented, and the documentation retained in the individual's training record.

Following any changes or updates in methodology, training of personnel in the new methodology must occur and be documented before performing patient testing. All training must be performed by a qualified individual such as a certified laboratory technical staff or the manufacturer/company representative and the competency of the tester verified before performing patient testing. A qualified trainer must have been trained and demonstrated competency for all methods for which training is being conducted [34].

Competency assessment requirements for point-of-care testing

Competence confirms the effectiveness of training. The assessment of competency is an evaluation of the training and verification that the training is applied to the test performance. After initial training and proficiency, the standards require that personnel performing POCT be reassessed for competency at regular intervals to ensure

accuracy and reliability of results and quality and safety of patient care. Re-training and reassessment of competency should occur when deviations or adverse events related to patient testing occur. Competency assessment should include policies and procedures that outline the process for assessing competency. As with all policies and procedures, the laboratory director must approve the procedure at the outset and after any major revision. All reviews and approvals are documented with signatures and dates. All policies and procedures must be reviewed periodically, annually, or biennially (every two years), depending on regulatory and accreditation requirements, by the laboratory director or designee, and this review is documented with the date of the review.

As with initial training, the competency of each employee performing POCT must be evaluated and

Table 2: A training and education program for staff shall include the following learning on assessment procedures and tools, as appropriate. All POCT operators must complete a comprehensive training program that includes an understanding of the purpose and limitations of the test and an awareness of procedures and processes related to all aspects of instrument operation.

Procedure	Potential tools for assessment
Pre-analytic phase	
– General background information	
The context and clinical utility of POCT and the theoretical aspects of the measuring system	Review of the manufacturer's guides, standard operating procedure documents referring to the international and national quality standards, and training resources
– Instrument and equipment	
Direct observations of the use of POCT instruments and devices for ensuring readiness	Review of equipment/kit validation/verification to ensure they are performing as intended, inspection and validation of incoming materials and new lot numbers, verification of reference range for the population being tested (e.g., pediatric vs. adult)
Direct observations of the performance of instrument maintenance, calibration of equipment (instrument/reagent system) if required by the manufacturer, and function checks	Checklist and preventive maintenance records
Review of troubleshooting when an instrument fails	Checklist
Direct observations of reagent storage	Review of worksheets, inventory logs, expiration dates
– Patient safety	
Direct observations in the specimen collection and preparation	Checklist for patient identification, patient preparation (e.g., fasting, lack of interfering drugs), proper specimen collection at the appropriate time (e.g., toxicology or therapeutic drug monitoring (TDM) tests), volume, handling, and processing by the manufacturer's instructions
Analytic phase	
– Evaluation of the analytical performance	
Assessment of test performance and limitations of the measuring systems	Checklist for unknown and previously analyzed specimens, internal blind testing samples, internal quality control, or external proficiency testing samples
Direct observations of routine patient test performance	Checklist
Post-analytic phase	
Monitoring the record-keeping and reporting of test results	Review of worksheets, permanent records (which may be the patient's chart or directly into an electronic medical record, if applicable) Logs for the length of time that records are retained (must comply with established best practice guidelines)
Direct observations of documentation and reporting requirements of test results	Review of arrangements/processes in place to respond to and act upon any critical POCT laboratory results. Checklist and review of worksheets
Review of response to results outside predefined limits	Checklist
Assessment of quality control program	Review of quality control records, proficiency testing or EQA sample results, split samples
Assessment of problem-solving skills	Case studies, quizzes, tests
Health and biosafety	
Direct observations of infection control	Review of implementation of a safety training program for employees who routinely work with blood or other infectious materials Review of worksheets related to the management of biological/medical waste disposal, logs for handwash practice, cleaning and disinfecting requirements for contaminated surfaces, supplies, and equipment Review of personal protective equipment when dealing with patients and testing of samples(e.g., gloves, gowns/coats) and evaluation and follow-up of workers after accidental exposure to blood and body fluids Review of the protocol for the management of patient adverse events/reactions (e.g., fainting)

Table 2: (continued)

Procedure	Potential tools for assessment
Direct observations of risk assessment	Review worksheets for performing a risk assessment to identify what could go wrong, such as breathing in infectious material or touching contaminated objects and surfaces. Checklist for implementing appropriate control measures to prevent these potentially negative outcomes from happening Review of hazard assessment for the identification and mitigation of possible hazards that could be encountered when using the POCT device

EQA, external quality assessment.

documented after training and before patient testing is performed. Documentation must be maintained for each procedure the employee performs. If the test method is changed or a new test is added, the initial training and competency evaluation must be completed and documented. For each employee performing POCT, an ongoing competency evaluation must be completed at specified intervals for each test method the employee performs. To comply with C LIA regulations, competency must be assessed for each POCT that is not waived at six months and 12 months after initial training and annually thereafter. The assessment of competency should include the preanalytical, analytical, and post-analytical phases of testing. At a minimum, to comply with POCT regulations, all personnel performing POCT tests must complete six procedures to assess their competency. Table 2 provides a summary of the assessment procedures for POCT, including requirements for operator training, demonstration of competence, quality control, and external quality assessment. Most agencies issue statements on POCT that include mandatory quality procedures as defined by regulations or specific guidance.

Each of the required procedures will not be appropriate for every activity in a comprehensive competency assessment program. Procedures will be used as needed, assessed with an appropriate assessment instrument, results evaluated, discussed with the employee, and documented. Tools used for competency assessment include checklists (for direct observation), case studies (problem-solving), quizzes (problem-solving), unknown sample testing (test performance), review of retained records, proficiency testing results, and other appropriate mechanisms for assessing competency.

Like other processes in a laboratory, errors can happen at any phase of POCT. A study by Cantero, et al. looked at the error rates during all phases of testing in the central laboratory and the performance of POCT. A higher rate of pre-analytical errors was found to be associated with POCT compared to central laboratory testing [35]. In this context, the organization needs to identify the risk points in the process where errors in POCT may occur and take action to mitigate those risks. Monitoring and evaluation of the risks in performing POCT are essential and must be included in the training program.

One of the major challenges in POCT is keeping track of training and competency assessments for a large number of users at different sites, many of whom are not laboratory technicians [36]. These challenges are primarily related to new instrument evaluation, user compliance, testing environments, data management, handling QC errors, correlations to the core laboratory, management of competency assessments, and inspections.

Every operator is required to have documented training on each device before reporting outpatient results. Ongoing assessments are performed at the first six months, and then annually thereafter. In a large healthcare organization, this can include several device types and thousands of operators. Facilities that need to track a large number of POCT operators may decide to use an online training tool such as a learning management system (LMS). POCT management software can automate reminders to users who are due for their competency assessment. When devices are capable, the POCT management software can block users from using a device until their certification is valid [37].

Personnel qualified to perform competency assessment

Specifically, ISO 22870:2016 recommends that organizations establish a multidisciplinary POCT committee to oversee the PoCT service. The POCT management committee is responsible for designating personnel to perform POCT and establishing a program to train POCT operators and assess their competencies. Assessing the competencies of personnel performing moderately complex tests (which accounts for the majority of non-waived POCT) is the responsibility of the technical consultant. This is a requirement for compliance with CLIA. The laboratory

Table 3: Summary of key responsibilities of a laboratory director and testing personnel.

Laboratory Director	–	Selection of a test methodology appropriate for clinical use of the test results
	–	Review of testing procedures performed and determination of laboratory test performance characteristics, including precision and accuracy of individual tests and test systems
	–	Enrollment and participation in an external quality assessment program appropriate to the services provided
	–	Establishing a quality control program appropriate for the testing performed and setting the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the sample, through sample analysis and reporting of test results
	–	Resolving technical issues and ensuring that corrective actions are taken when test systems deviate from the laboratory's established performance specifications;
	–	Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly;
	–	Identifying training needs and ensuring that everyone who performs tests receives regular in-service and continuing education appropriate to the type and complexity of the laboratory service performed
	–	Evaluating the competency of all testing personnel and ensuring that personnel remain capable of performing testing procedures and reporting test results promptly, accurately, and proficiently.
	–	Evaluating and documenting the performance of individuals responsible for POCT at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, before reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.
Testing personnel	–	Specimen collection, labeling, preparation, etc.
	–	Implementing laboratory procedures
	–	Performing assigned tests
	–	Conducting preventive maintenance, troubleshooting, and calibration
	–	Knowledge of reagent stability and storage
	–	Performing quality control (QC) procedures
	–	Knowledge of factors affecting test results
	–	Validation of patient test results with QC before reporting

director may serve as the technical consultant and perform the competency assessment if he or she also meets the personnel qualification requirements in terms of education, experience, and training for the position to perform the duties. The qualifications for a technical consultant or POCT are defined in 42 CFR §493.1411 [38]. The qualified laboratory director will conduct a competency evaluation. Technical consultants are the only staff required to submit NOT to an annual competency evaluation. The laboratory director is responsible for ensuring that all competency evaluations are performed and that testing personnel are competent and consistently report accurate test results. The competency evaluation may also be performed by any person who would be qualified as a technical consultant but is not serving in that capacity. If the qualifications of a technical consultant are met, testing personnel acting as a peer may perform the competency assessment.

The laboratory director as a technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant need not always be on-site when tests are performed; however, he or she must be available to the laboratory to provide on-site, telephone, or electronic consultation. The responsibilities of the laboratory director [39] and the capabilities of the testing staff [40] are listed in Table 3.

Summary

The increase in point-of-care testing that does not need to be performed by laboratory technicians may mean that more medical support staff will be needed in hospitals, physician offices, and organizations that do not have a central biomedical laboratory (e.g., long-term care, home care, or community pharmacies) but may have an agreement with and work with a central biomedical laboratory off-site. To ensure that POCTs are performed safely and correctly, a clearly defined and well-structured approach to POCT management is required. In addition, a robust training strategy for personnel performing POCT must be in place to ensure POCT compliance, including specific requirements for POCT policies and procedures based on ISO 22870, personnel training, and continuing education. Finally, a POCT program for training and competency assessment

must be implemented, and POCT operators must be evaluated periodically to ensure that the program is meeting the training needs of personnel performing POCT.

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