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STANDARDS

Point-of-Care Testing

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POINT-OF-CARE TESTING

The Point-of-Care Testing Standards apply to organizations that provide point-of-care testing as defined below. Organizations that have a central biomedical lab are to use these standards in conjunction with Accreditation Canada's Biomedical Lab Services Standards and the Transfusion Services Standards.

The Point-of-Care Testing Standards reference the Canadian Standards Association (CSA) Standards Z22870-07, *Point-of-care testing - requirements for quality and competence* (based on ISO standard Z22870: 2006) published by the CSA in November 2007. Organizations are to use the Point-of-Care Testing Standards in conjunction with *Plus 15189: The ISO 15189:2003 Essentials* published by the CSA in 2007.

Point-of-care testing (POCT) refers to any testing conducted outside a lab, in a hospital, in a clinic or by a health care organization providing ambulatory care. Point-of-Care Testing should be prescribed and all results should be entered into the client record. This includes testing performed at sites outside the traditional lab dedicated to medical biology, near where care is delivered to the client.(1) Point-of-care test results may lead to a change in the care of the client.(2) POCT ranges between three levels of complexity, from simple procedures such as glucose testing, moderate-complexity procedures (including provider performed microscopy procedures), or high-complexity procedures such as influenza testing. Health care professionals delivering POCT usually use test kits, which may include hand-held devices to read blood, saliva, or urine samples.

In the POCT Standards, the term "organization" is used in place of the term "lab" since POCT may be carried out in organizations that do not have a central biomedical lab (e.g. long term care, home care, or a community pharmacy), but have an agreement and work with a central biomedical lab that is offsite. Further, POCT may be carried out in both public and private organizations. The roles and responsibilities of a lab director are also adaptable to health care settings without a lab with the addition of the qualifier "or suitably qualified health care professional."

This standard section covers the following subsections:

- **Having the Right Supports in Place for POCT**
- **Making Sure People are Competent**
- **Complying with Good Lab Practice**
- **Delivering Safe and Effective POCT**
- **Monitoring Quality and Achieving Positive Outcomes**

1) Joint Commission (2005-2006). *Comprehensive Accreditation Manual for Lab and Point-of-Care Testing.*
2) Canadian Standards Association/ ISO (2007). Point-of-care testing- requirements for quality and competence.

Client
A person from whom a point-of-care test sample is obtained for the purposes of POCT and analysis. The term client has been chosen instead of patient or user.

Clinician
A physician who requests a point-of-care test by a medical prescription, as well as any health care professional capable of initiating a request for POCT in compliance with their professional association and the legislation in force.
Non-physician professionals may be nurses, pharmacists, midwives or emergency medical technicians practising within their qualifications. When this non-physician professional does not perform the actual POCT, they must submit a signed request in compliance with the requirements of the organization.

Clinical Sample
A clinical sample is a biological substance of human origin collected from the client for the purpose of conducting the required Standard Operating Procedures (SOPs) and determining a POCT result.

Central Biomedical Lab
A privately or publicly registered biomedical lab. A central biomedical lab operates independently under subcontract when it enters into a contract with an organization.

Critical Value
A result that will cause the patient to suffer a life-threatening event if not communicated and treated immediately. These results show marked deviation from reference ranges suggesting that, if unexpected, a patient's life is in danger and prompt medical action may be required.

Interdisciplinary Professional Committee (Medical Advisory Committee or Professional Qualifications

Committee)
An interdisciplinary professional committee consisting of interdisciplinary members from the lab, administration, and clinical (such as nursing) departments. The committee is established to define the scope of POCT service delivery, advise on selection criteria for instruments and reagents used in POCT, and assess quality management outcomes.

Lab Director or Suitably Qualified Health Care Professional
The lab director is responsible for the oversight of the quality of POCT and is either a physician with lab-specific experience and training or holds a PhD in a biomedical field such as, but not limited to, biochemistry, chemistry, biology, microbiology, molecular biology, hematology or pathology. For the day-to-day management and supervision of POCT, the lab director may assign responsibility to a designate. This designate is a suitably qualified health care professional with the appropriate professional, scientific, and educational qualifications to verify and maintain the day-to-day quality of POCT.

Organization
An organization is an entity that carries out the services related to POCT, such as responding to test requests, performing POCT, collecting samples, and managing the POCT results for a client and a clinician.

POCT Equipment and Instrument
Equipment, devices or instruments required to perform a point-of-care test. This includes disposable or non-disposable materials.

POCT Reagent
One or more chemical or physical products necessary for the reactions required to obtain a POCT result. It includes enzymes, antibodies, primers, dyes, and culture media. It excludes POCT instruments.

POCT Result
A POCT result is a written, recorded document that includes the results of the POCT analysis. Test results that fall within reference ranges are normal test results.

POCT Self-testing
POCT self-administration by a client.

Health Care Professional Delivering POCT
A professional recognized as qualified by the appropriate professional association and pursuant to the professional legislation in force, following appropriate training, to perform the duties of collecting clinical samples and determining the result of POCT as well as counselling the client if necessary. This health care professional may be, a physician, medical technologist, nurse, licenced practical nurse, pharmacist, or

pharmacist technician provided that they are members of their medical associations and have received appropriate training.

Reference Range
Specific to the point-of-care test and are the values that 95% of the population fall into. These may also be called reference values or intervals.

Standard Operating Procedure (SOP)
A Standard Operating Procedure encompasses all the processes or techniques required to conduct the POCT.

Legend

Dimensions

Population Focus: Work with my community to anticipate and meet our needs

Accessibility: Give me timely and equitable services

Safety: Keep me safe

Worklife: Take care of those who take care of me

Client-centred Services: Partner with me and my family in our care

Continuity: Coordinate my care across the continuum

Appropriateness: Do the right thing to achieve the best results

Efficiency: Make the best use of resources

Criterion Types

High Priority High priority criteria are criteria related to safety, ethics, risk management, and quality improvement. They are identified in the standards.

Required Organizational Practices Required Organizational Practices (ROPs) are essential practices that an organization must have in place to enhance client safety and minimize risk.

Tests for Compliance

Minor Minor tests for compliance support safety culture and quality improvement, yet require more time to be implemented.

Major Major tests for compliance have an immediate impact on safety.

Performance Measures Performance measures are evidence-based instruments and indicators that are used to measure and evaluate the degree to which an organization has achieved its goals, objectives, and program activities.

HAVING THE RIGHT SUPPORTS IN PLACE FOR POCT

1.0 The organization defines who is responsible for POCT.

Appropriateness

1.1 The organization has a policy that clearly defines reporting and contractual relationships and roles and responsibilities for POCT.

Guidelines

The policy must include who is responsible for overseeing POCT and maintaining quality.

Appropriateness

1.2 A lab director or suitably qualified health care professional oversees, manages and supervises POCT.
CSA Reference: Z22870:07, 5.1.2.

Guidelines

The lab director is either a physician with lab-specific experience and training or holds a PhD in a biomedical field such as, but not limited to, biochemistry, chemistry, biology, microbiology, molecular biology, hematology or pathology.
In some provinces, the lab director or suitably qualified health care professional must be appointed in accordance with the professional laws in the province. For example, in Quebec, the Professional Chemists Act specifies that to practice chemistry, a person must be a member of the Ordre des chemists du Quebec, unless they are covered under the Medical Act, the Engineers Act or the Pharmacy Act.

If the organization does not have a lab director, it must consult an external lab director with the appropriate qualifications to make statistical and clinical decisions about POCT. These decisions include the developing POCT procedures and reagent lot validation protocols; establishing criteria for selecting and evaluating equipment, reagents and media; verification and validation protocols; setting quality control and calibration expectations; establishing a documented policy on quality and performance for all POCT; establishing a training program and setting competency assessment expectations; and designating the day to day operations to a POCT manager, coordinator, or person responsible for POCT.

The lab director is available to discuss issues with the day-to-day operations manager, coordinator, or person responsible for POCT when necessary.

The day-to-day supervision of POCT may be assumed by a suitably qualified health professional with the appropriate professional, scientific, and educational qualifications to verify and maintain the day-to-day quality of POCT. This suitably qualified health care professional may be a physician, medical technologist, registered nurse, licensed practical nurse, clinical biochemist, pharmacist, provided they are licensed members in good standing with their professional college and have received appropriate training.

The individual that manages the day-to-day operations of POCT is responsible for implementing the protocols and policies developed by the lab director; managing health professionals delivering POCT; managing quality control; managing lots of reagents; and discussing issues with the lab director as required.

Appropriateness

1.3 The lab director or suitably qualified health care professional works with an interdisciplinary professional committee to define the scope of services and oversee the delivery of POCT.
CSA Reference: Z22870:07, 4.1.2.

Guidelines

The interdisciplinary professional committee is made up of individuals from the central lab, POCT services, and clinical (such as nursing) departments. Where the organization has a formal contract with an offsite lab, representatives from that organization must also be part of the interdisciplinary professional committee. The interdisciplinary professional committee may be a sub-committee of the Medical Advisory Committee (MAC).

In defining the scope of POCT, the interdisciplinary professional committee considers what services are needed and what resources are required to meet those needs, e.g. deciding what procedures to offer or withdraw (withdrawal may happen due to noncompliance or underutilization of services). The interdisciplinary professional committee also provides advice on the selection of equipment and reagents and performance criteria, e.g. precision, detection limits; monitors conflict of interest; and the use of best practices and evidence that inform the content of the standard operating procedures (SOPs).

Appropriateness

1.4 The interdisciplinary committee review POCT quality control data on an annual basis and make improvements as needed.
CSA Reference: Z22870:07, 5.6.6.

Guidelines

The organization must adjust POCT policies, processes, and procedures based on the quality control results.

Appropriateness

1.5 When an organization does not have its own central biomedical lab, it establishes a formal contract with an offsite accredited biomedical lab to define the scope of the POCT and assure quality.


Appropriateness

1.6 The organization reviews the contract with the offsite central biomedical lab annually, or according to the term of the contract.


Appropriateness

1.7 The organization has a standard operating procedure (SOP) that clearly defines the roles and responsibilities of all health care professionals delivering POCT.
CSA Reference: Z22870:07, 5.1.4.

Guidelines

The SOP clearly outlines the health professionals' roles and responsibilities in maintaining equipment and assuring overall quality.

2.0 The organization has the necessary resources to deliver high-quality POCT.


Appropriateness

2.1 The organization has the appropriate mix and number of staff to carry out POCT.
CSA Reference: Z22870:07, 5.1.1.

Guidelines

This includes having the appropriate number of staff to maintain quality and train health care professionals delivering POCT.


Appropriateness

2.2 Health care professionals delivering POCT have access to a resource person.
CSA Reference: Z22870:07, 5.1.5.

Guidelines

The resource person is identified and known to all staff involved in delivering POCT and is the person to whom POCT equipment and procedure problems or questions can be directed.

Appropriateness

2.3 The organization's workspace complies with manufacturers' recommendations when using POCT reagents and media.

Guidelines

Manufacturers' recommendations may include temperature and humidity controls.

Appropriateness

2.4 The organization has a policy in place to prevent a conflict of interest between providers of POCT equipment and supplies, clients, and clinicians.

MAKING SURE PEOPLE ARE COMPETENT

3.0 **Health care professionals delivering POCT are trained and competent.**

Appropriateness

3.1 The organization orients and trains all health care professionals delivering POCT on the standard operating procedures (SOPs) for POCT.

Appropriateness

3.2 Health care professionals delivering POCT receive ongoing training and development.
CSA Reference: Z22870:07, 5.15.

Guidelines

The organization considers the needs of the health care professionals delivering POCT and the organization when designing and delivering its education and training. Qualified health professionals may include physicians, pharmacists, registered nurses, licensed practical nurses, medical technologists, midwives, emergency medical technicians, biological chemists, or inhalation therapist.

Appropriateness

3.3 The organization evaluates the performance of health care professionals delivering POCT annually.
CSA Reference: Z22870:07, 5.1.5.

Appropriateness

3.4 As part of their performance evaluation, health care professionals delivering POCT must routinely demonstrate their competence.
CSA Reference: Z22870:07, 5.1.5.

Guidelines

Competence includes both knowledge and skills. Knowledge and skills may include the ability to demonstrate an understanding of the appropriate use of equipment and reagents, including quality controls; as well as knowledge of the pre and post analytical aspects of POCT such as positive client identification, sample collection, clinical utility and limitations; and reporting results to the client.

Appropriateness

3.5 The organization documents performance evaluation results in the personnel files of health care professionals delivering POCT.

COMPLYING WITH GOOD LAB PRACTICE

4.0 Health care professionals consistently follow the POCT standard operating procedures (SOPs).

Appropriateness

4.1 The organization has SOPs for each point-of-care test it performs.

Appropriateness

4.2 Each SOP contains the title and purpose of the SOP, number of pages, unique identification number, date it was implemented or revised, signature of the authorizing person(s) and date of authorization, steps to be followed in the procedure, and the individual responsible for checking, reviewing, and approving the SOP.

Appropriateness

4.3 Each SOP contains the purpose and limitations of the test; step-by-step instructions on how to properly complete the test and use the corresponding instruments; reference ranges for the results, including critical values; criteria for accepting and rejecting samples; quality control procedures; and literature references.

Guidelines

Step-by-step instructions include information on how to maintain sample integrity, prepare reagents, and calibrate equipment. Instructions on how to use the corresponding equipment include procedures for operating and maintaining the equipment and actions to be taken if equipment is inoperable, e.g. the resource person. These should be consistent with the manufacturers' instructions. Quality control procedures include testing and taking corrective action. Information in the SOP about reference ranges must also include procedures to follow when results do not fall within these ranges.

Appropriateness

4.4 The organization places the SOPs in areas where health care professionals delivering POCT can easily access them.

Appropriateness

4.5 The lab director or suitably qualified health care professional verifies that health care professionals performing POCT are trained prior to implementing a new or revised SOP.

Appropriateness

4.6 The lab director or suitably qualified health care professional annually reviews and evaluates the effectiveness of the SOPs and adjusts the SOPs, training activities, or monitoring processes as necessary.

Guidelines

The review process includes tracking changes and version numbers, and identifying the team members responsible for carrying out the review and making changes. The review and approval of revisions are documented and all previous SOP versions in circulation must be replaced.

Appropriateness

4.7 The lab director or suitably qualified health care professional reviews the SOPs following a patient safety incident, changes in regulatory or legal requirements, internal or external audits, and other situations as defined in the organization's policies.

Appropriateness

4.8 The organization has a policy on POCT client self-testing.

Guidelines

Policies on POCT client self-testing apply to self-testing conducted in the organization. Health care professionals delivering POCT are not responsible for knowing how to use a client's POCT instrument.

5.0 The organization safely uses POCT equipment.

Safety

5.1 The organization maintains an accurate and up to date inventory of all POCT equipment.

Guidelines

The inventory must include the lot or serial number; manufacturer or supplier; the date purchased; a complete service or maintenance history; the expiry or out-of-service dates; and a technical performance log demonstrating the equipment's accuracy and reliability.
The service or maintenance history must include the date, time of the repair, and name of the person who completed the repairs.

Appropriateness

5.2 The organization has an individual who is responsible for inventory control of POCT equipment.

Guidelines

The lab director or suitably qualified health care professional determines who is responsible for managing the POCT inventory and equipment.

Safety

5.3 The organization follows a documented process for setting-up, validating, and calibrating all new POCT equipment.


Safety

5.4 The organization follows written procedures to store, handle, clean, and disinfect POCT equipment.


Safety

5.5 The organization periodically verifies that the POCT equipment currently being used is working properly.
CSA Reference: 22870:07, 5.3.2.

Guidelines

According to the organization's SOP, health professionals delivering POCT validate manufacturers' equipment claims.


Safety

5.6 The organization removes all POCT equipment that are inappropriate, non compliant, deteriorated, and substandard.


Safety

5.7 The organization controls the use of POCT equipment by assigning each health care professional delivering POCT unique identification numbers.

Guidelines

Only trained and certified health care professionals delivering POCT are authorized to use POCT equipment.

Appropriateness

5.8 The organization monitors and verifies that health care professionals delivering POCT use only the unique identification numbers assigned to them.

Guidelines

Monitoring the use of identification numbers should prevent health care professionals delivering POCT from using numbers assigned to other people.

Safety

5.9 When the organization uses different types of POCT equipment for the same procedure, the lab director or suitably qualified health care professional works with a central biomedical lab to verify that each type of equipment gives the same result in all cases.

Safety

5.10 The organization prevents the reuse of POCT single-use devices (SUD).

Safety

5.11 The organization has formal written agreements in place with point-of-care equipment manufacturers and suppliers that require them to promptly report patient safety incidents and recalls.

6.0 The organization safely uses POCT supplies, reagents, and media.

Appropriateness

6.1 The organization maintains an accurate and up-to-date inventory for all POCT supplies, reagents, and media.

Guidelines

The inventory must include the lot or serial number; manufacturer or supplier; the date purchased; and the dates when the supplies, reagents, or media expire.


Appropriateness

6.2 The organization has a person who is responsible for inventory control of POCT supplies, reagents and media.

Guidelines

The lab director or suitably qualified health care professional determines who is responsible for managing the POCT inventory, supplies, reagents and media.


Safety

! 6.3 The organization follows a documented process for testing all new POCT supplies, reagents and media.


Safety

! 6.4 The organization periodically verifies that POCT reagents currently being used are working properly, not expired or deteriorated and appropriate for use. CSA Reference: 22870:07, 5.3.2.

Guidelines

According to the SOP, health professional delivering POCT must have in their possession the quality control checks carried out by the manufacturer and must validate the quality of the reagents prior to their use.


Safety

! 6.5 The organization promptly removes from storage inappropriate, expired, deteriorated and substandard POCT supplies, reagents, and media and discards them.


Safety

6.6 The organization uses a standardized and consistent format to label POCT supplies, reagents, and media.

Guidelines

Labels include the product name, the concentration, conditions for storage, expiry date, date opened, and special precautions as applicable.


Safety

6.7 The organization stores its POCT supplies, reagents, and media under proper environmental conditions.

Guidelines

Proper environmental conditions include temperature, humidity, and pH.


Safety

6.8 The organization has formal written agreements in place with POCT media and reagent suppliers requiring them to promptly report patient safety incidents and recalls.

DELIVERING SAFE AND EFFECTIVE POCT

7.0 **Health care professionals delivering POCT properly prepare for the point-of-care test.**


Safety

7.1 For each point-of-care test, the health care professional delivering POCT must receive a written or electronic request from a clinician.


Safety

7.2 Before performing the test, the health care professional delivering POCT verifies that the clinician has complied with the procedure for requesting a point-of-care test.


Safety

7.3 In cases where the organization receives a verbal request for POCT, there is a written procedure for responding to the clinician and requesting a written or electronic request.

Guidelines

A verbal request is not sufficient to carry out POCT. Requests must be written or electronically transmitted.


Safety

7.4 The organization uses a standard POCT request form for gathering all necessary information about the client, samples, and tests requested.

Appropriateness

7.5 Immediately prior to performing the point-of-care test, the health care professional verifies that the POCT equipment is in proper working order by means of a quality control check.

Guidelines

The guidelines for completing the quality control check must be outlined in the organization's SOP.

Client-centred Services

7.6 Before performing the test, the health care professional delivering POCT provides the client with complete and accurate information about the test.

Guidelines

Information about the test is contained in the SOP. This must include details on how and when test will be provided, the limitations and possible outcomes of the test, possible side effects and risks, and how to prepare for the test.

8.0 Health care professionals delivering POCT safely and effectively carry out the tests.

Client-centred Services

8.1 Before performing the test, the health professional delivering POCT obtains informed consent.

Guidelines

In most cases, consent is implied when the client voluntarily arrives to have the test. In emergencies, consent is also implied, provided the procedures are in the client's best interest.

Safety

8.2 REQUIRED ORGANIZATIONAL PRACTICE: Working in partnership with clients and families, at least two person-specific identifiers are used to confirm that clients receive the service or procedure intended for them.

Guidelines

Using person-specific identifiers to confirm that clients receive the service or procedure intended for them can avoid harmful incidents such as privacy breaches, allergic reactions, discharge of clients to the wrong families, medication errors, and wrong-person procedures.

The person-specific identifiers used depends on the population served and client preferences. Examples of person-specific identifiers include the client's full name, home address (when confirmed by the client or family), date of birth, personal identification number, or an accurate photograph. In settings where there is long-term or continuing care and the team member is familiar with the client, one person-specific identifier can be facial recognition. The client's room or bed number, or using a home address without confirming it with the client or family, is not person-specific and should not be used as an identifier.

Client identification is done in partnership with clients and families by explaining the reason for this important safety practice and asking them for the identifiers (e.g., “What is your name?”). When clients and families are not able to provide this information, other sources of identifiers can include wristbands, health records, or government-issued identification. Two identifiers may be taken from the same source.

Test(s) for Compliance

Major	8.2.1	At least two person-specific identifiers are used to confirm that clients receive the service or procedure intended for them, in partnership with clients and families.

Safety

8.3 Before performing the point-of-care test, health care professionals properly label the request form and the samples in front of the client, with the same information (family name, given name, record number and Medicare number) so that they can maintain traceability between the client and the sample.

Guidelines

In some circumstances, it may be impossible to identify some samples, e.g. a blood droplet placed directly on an instrument.

Safety

8.4 Health care professionals delivering POCT follow the SOP when collecting samples to maintain sample integrity and client safety.

Client-centred Services

8.5 During the test, health care professionals delivering POCT protect the client's privacy and confidentiality.

Guidelines

Health care professionals delivering POCT maintain clients' privacy by performing tests and disposing of waste in physical areas separate from the waiting and admitting or reception areas.

When performing POCT, health care professionals do not verbally communicate client information in an open area. Health care professionals delivering POCT securely store client information in paper or electronic form.

Appropriateness

8.6 When conducting POCT, health care professionals adhere to instrument-specific quality controls.
CSA Reference: Z22870:07, 5.5.3, 5.5.4.

Guidelines

Quality controls are based on the SOPs, manufacturer's recommendations or instrument-generated quality controls.

Safety

8.7 When conducting POCT, health care professionals wear personal protective equipment (PPE) consistent with the manufacturer's instructions or the organization's SOPs.

Guidelines

PPE may include gloves, gowns, face or eye protection.


Safety

8.8 Health care professionals delivering POCT remove PPE before leaving the testing area.


Safety

8.9 When not in use, health care professionals delivering POCT store clean PPE appropriately, away from working areas.


Safety

8.10 The health care professional delivering POCT documents the date and time of the test, the individual carrying out the test and the results of the test on the result form.


Safety

8.11 The organization safeguards samples against loss, damage or contamination.

Guidelines

The organization only needs to retain samples from medium to high complexity procedures. For example, glucose testing samples would not be saved.


Safety

8.12 In the event that samples are lost or damaged, the organization reports the incident to the appropriate person or people as specified in the SOP.


Safety

8.13 The organization follows written criteria for accepting or rejecting POCT samples.

Guidelines

Criteria for accepting and rejecting samples are outlined in the organization's SOP.


Safety

8.14 The organization safely disposes of POCT samples consistent with biomedical waste management requirements and regulations.

Guidelines

When samples no longer have to be kept for testing or the results have been validated, the organization may dispose of them.

9.0 The organization accurately and securely reports POCT results.


Client-centred Services

9.1 The organization has a standardized written or electronic policy or procedure on how to report and disclose all POCT results.
CSA Reference: Z22870:07, 5.8.2.

Guidelines

The policy must include the individuals authorized to report results to clients and clinicians as well as the procedure to follow in cases of positive infectious disease results.


Appropriateness

9.2 Before releasing any test results, health care professionals delivering POCT verify that the results comply with set acceptability criteria.

Client-centred Services

9.3 Health care professionals reporting POCT results carefully explain the results to clients.

Safety

9.4 Health care professionals reporting POCT results follow a documented procedure for communicating and sharing results when they are outside of reference ranges for normal values.

Safety

9.5 When the health care professional verbally reports POCT results to clinicians, the results and methods used to obtain those results must later be documented in a written format and identified as POCT results.

Appropriateness

9.6 The health care professional delivering POCT completes a comprehensive and accurate report for every point-of-care test carried out that is distinct from clinician notes in the record.

Guidelines

The report includes the date and time of the test, the health care professional that carried out the test, the test-specific reference ranges, and the condition of the samples gathered.


Appropriateness

9.7 The health care professional delivering POCT legibly writes the report using language and vocabulary that complies with recommendations from international, national, or regional professional organizations.


Appropriateness

9.8 When completing the POCT report and filing it in the client record, the health care professional delivering POCT clearly labels the results as “POCT”.

Guidelines

The organization clearly distinguishes the POCT results from clinician's notes or results from other sources or labs.


Appropriateness

9.9 The health care professional delivering POCT files the POCT report in the client record.


Safety

9.10 The organization informs clinicians in writing of point-of-care tests that were not completed due to inappropriate samples or technical difficulties.


Safety

9.11 The organization securely retains records of all POCT request forms and their corresponding results for the period consistent with provincial regulations or guidelines.

MONITORING QUALITY AND ACHIEVING POSITIVE OUTCOMES

10.0 The organization regularly monitors and improves the quality of POCT.

Appropriateness

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10.1 The organization has a POCT quality improvement process.
CSA Reference: Z22870:07, 4.2.2, 4.2.4.

Guidelines

The quality improvement process is continually reviewed for its effectiveness and improved accordingly. The lab director or suitably qualified health care professional, along with the interdisciplinary committee, establish measurable annual objectives for the POCT quality improvement process. They identify the criteria to monitor, measure and analyze these processes. The lab director or suitably qualified health care professional may delegate certain functions of the quality improvement process.

Appropriateness

10.2 The lab director or suitably qualified health care professional develops and maintains a POCT quality improvement manual.

Guidelines

The manual includes objectives, policies and procedures; documented standards; and other documents required by the organization to plan, operate, and control processes.

Appropriateness

10.3 The lab director or suitably qualified health care professional communicates the quality improvement policies to health care professionals delivering POCT and verifies that they follow them.

Appropriateness

10.4 The organization regularly monitors a set of POCT quality indicators.

Guidelines

The quality indicators may include both process and outcome measures. The indicators may be used to evaluate the client experience, cost-effectiveness, or the performance or impact of certain tests.

Appropriateness

10.5 The lab director or suitably qualified health care professional uses the indicator information to guide decision making and make timely improvements to POCT.

Guidelines

Working with the interdisciplinary committee, the lab director or suitably qualified health care professional uses the results of all reviews and corrective action carried out to evaluate effectiveness, identify opportunities for improvement, and make planning decisions about POCT activities and services. Improvements are made within a reasonable time frame.

Appropriateness

10.6 Health professionals delivering POCT gather and record quality control data for each point-of-care test.

Guidelines

Performance sample testing is conducted in the same manner as client sample testing. The frequency of performance testing is specified for each point-of-care test and is determined by the lab director or suitably qualified health care professional according to manufacturer's recommendations.

Appropriateness

10.7 Health professionals delivering POCT record quality control data in a daily a log.

Guidelines

The individual performing the point-of-care test signs and dates the quality control log or worksheet.

Appropriateness

10.8 Health professionals delivering POCT regularly compare and correlate their quality control results with a central lab.

Appropriateness

10.9 The organization participates in an external POCT quality control program.
CSA Reference: Z22870:07, 5.6.

Appropriateness

10.10 The lab director or suitably qualified health care professional reviews the quality control data on a monthly basis and make improvements as needed.

Appropriateness

10.11 When the lab director or suitably qualified health care professional identifies potential sources of nonconformities and their root causes, they implement and monitor action plans to prevent the nonconformities from recurring.
CSA Reference: Z22870:07, 4.9.2, 4.10.3, 4.11.2, 4.11.3.

Guidelines

The protocols for preventing and addressing nonconformities are outlined in the SOPs. These policies include requirements for reviewing nonconformities (responding to complaints), determining the cause, evaluating the need for corrective action to prevent recurrence, recording the results of the corrective action, and reviewing the corrective action taken.

Appropriateness

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10.12 The organization has a protocol for addressing POCT patient safety incidents and recalls of POCT equipment, supplies, reagents and media.

Guidelines

Patient safety incidents and recalls that occur in relation to equipment, supplies, reagents and media used in the lab are communicated to clients.

Appropriateness

10.13 The organization retains records of quality control results and nonconformities for POCT for at least two years.

Accreditation Canada would appreciate your feedback on these standards

Your Name: _____

Organization Name: _____

Email address or telephone number: _____

(A Product Development Specialist may contact you about your feedback.)

Feedback: Please indicate the name of the standard, as well as the criterion number in your comments. Please be as specific as possible in your comments.

For example: I would like to provide comments on the Long-Term Care Services standards, criterion 3.12. Clients should be included in this process. I suggest you change the wording to "The team engages staff, service providers, and clients in the process to plan services."

You may also submit your feedback online HERE

[YOUR COMMENTS HERE]

Thank you for your input! Please send this page to:
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