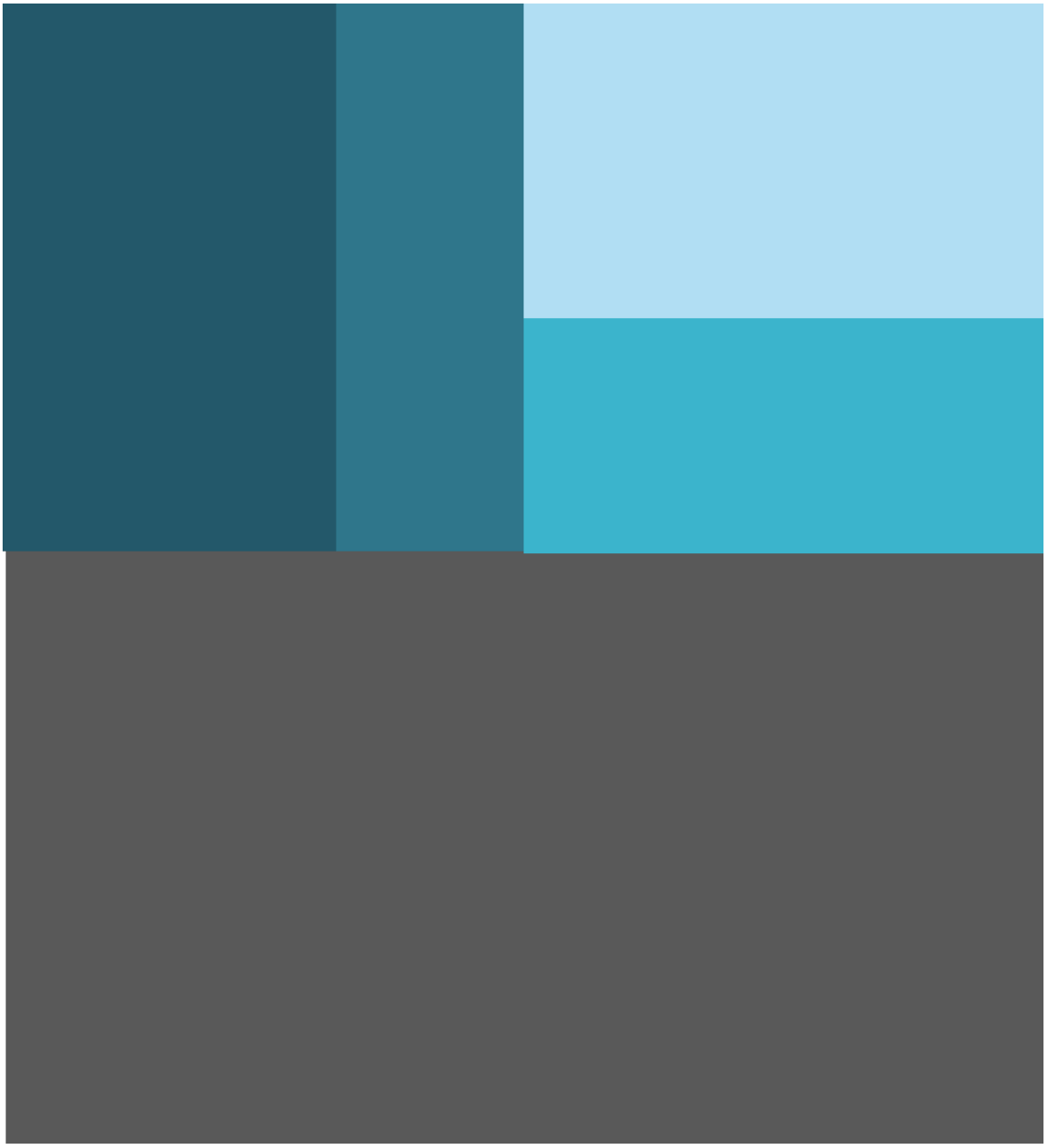

This document offers recommendations and direction concerning the management and application of community-based Point-of-Care Testing (POCT)

COMMUNITY BASED POINT-OF-CARE-TESTING (POCT) FRAMEWORK

Public Health Agency of Canada

Agence de la santé publique du Canada

Canada

POINT OF CARE TESTING (POCT) POLICY AND GUIDELINE

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Share Your Thoughts
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Email CPHLN-RLSPC@phac-aspc.gc.ca

Table of Contents

ABBREVIATIONS

ABBREVIATION	DESCRIPTION
AACB	Australasian Association of Clinical Biochemists
CAP	College of American Pathologists
CLIA	Clinical Laboratory Improvement Amendments
CPHLN	Canadian Public Health Laboratory Network
DMS	Data Management Systems
EMR	Electronic Medical Record
EQA	External Quality Assurance
FDA	Food and Drug Administration
HER	Electronic Health Record
HIMS	Hospital Information Management System
ID NOW	A specific diagnostic device used for point-of-care testing
IHR	International Health Regulations
IQC	Internal Quality Control
ISO	International Organization for Standardization
LIMS/LIS	Laboratory Information Management System/Laboratory Information System
LOD	Limit of Detection
LOQ	Limit of Quantification
MORE	Mobile Orders and Results Entry (platform)
NMLB	National Microbiology Laboratory Branch
NPAAC	National Pathology Accreditation Advisory Council
NPV	Negative Predictive Value
NT	Northern Territory
P/T	Provincial and Territorial
PHAC	Public Health Agency of Canada
POCT	Point of Care Testing
PPV	Positive Predictive Value
RDT	Rapid Diagnostic Test
SAP	Special Access Program
SOP	Standard Operating Procedure

Canadian Public Health Laboratory Network POCT Working Group

In response to the demonstrated utility of Point-of-Care Testing (POCT) during the COVID-19 pandemic, the Canadian Public Health Laboratory Network (CPHLN) POCT Working Group was formed in May 2023 with the goal to enhance the quality, scalability, and integration of POCT in Canada. By drawing on the experiences and lessons of the pandemic, the group is committed to addressing existing challenges while embedding POCT as a strategic testing tool within broader public health infrastructure.

Since its inception, the Working Group has come together to identify key challenges and is actively working to address them. It recognizes the critical importance of decentralized testing frameworks and views community-based testing as essential to both emergency response and ongoing patient care. With the rapidly changing landscape of technology, the POCT Working Group has prioritized making quality assured POCT accessible, sustainable, and standardized in Canada. To achieve this, the group brings together members from all jurisdictions to collaborate and find practical solutions to current challenges. This group is constantly evolving, striving for inclusivity by expanding its membership to include diverse stakeholders. This expansion ensures the group's solutions and recommendations address the needs of all communities, keeping the approach adaptable and responsive to Canada's complex and dynamic healthcare landscape.

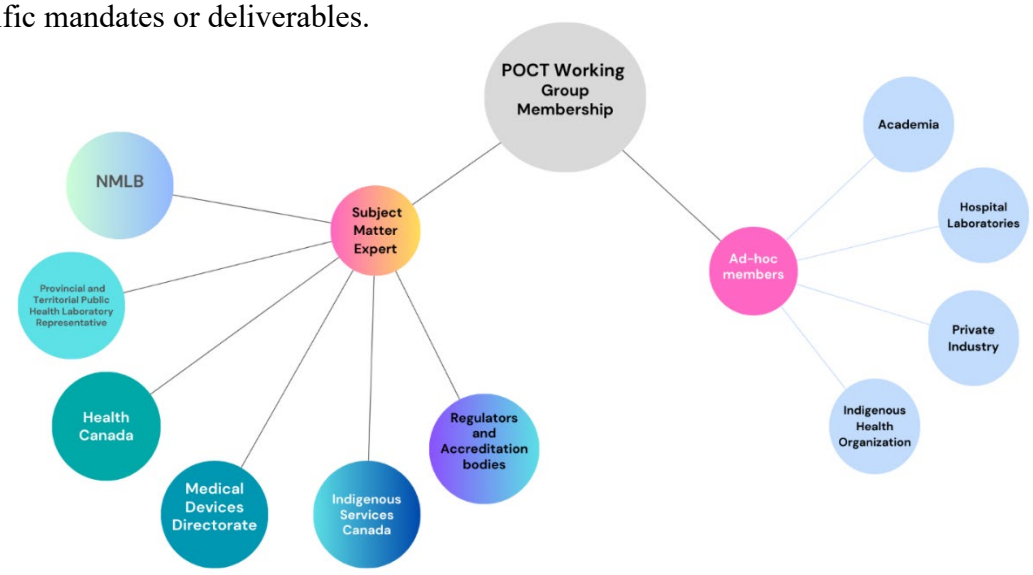
By building on these foundational principles, the POCT Working Group aims to position community-based POCT as an additional diagnostic tool to improve reach and access to appropriate diagnostic testing in remote, rural, Indigenous, as well as urban settings with vulnerable populations in Canada.

Membership

The CPHLN POCT WG is composed of:

- One expert from the National Microbiology Laboratory Branch (NMLB)
- One subject matter expert from each provincial public health laboratory and territorial equivalent.
- Representatives from the Health Canada Medical Devices Directorate, Indigenous Services Canada, and relevant regulatory and accreditation bodies.

Additional Expertise: Specialists from academia, hospital laboratories, private industry, and Indigenous health organizations with relevant expertise may also be invited to participate as ad-hoc, non-voting members. These participants are approved by the working group co-chairs and to contribute to specific mandates or deliverables.



EXECUTIVE SUMMARY

Continued Commitment to Advance Healthcare Excellence

The COVID-19 pandemic demonstrated the transformative potential of Point-of-Care Testing (POCT) to expand diagnostic services beyond traditional laboratory settings. POCT improves access to timely diagnosis and care, particularly in community-based environments. However, effective implementation requires a comprehensive framework that integrates testing into broader care pathways and aligns with existing or enhanced health services.

This document outlines the essential quality principles and requirements for successful POCT implementation in the Canadian context. A multidisciplinary approach is necessary to improving operational efficiency, optimizing clinical outcomes, and aligning with community-identified, as well as overall health priorities. Lessons from the COVID-19 response underscore how POCT can reduce health disparities by improving service reach, strengthening Canada's capacity to respond to current and future public health needs and potential threats.

The framework emphasizes critical components such as training and competency standards, quality assurance, regulatory compliance, and professional oversight. It also highlights the need for culturally safe practices that build trust within communities and across the health system.

Additionally, the framework addresses the legal and regulatory landscape for POCT in Canada, underscoring the importance of adhering to national and provincial/territorial requirements. As Canada advances its use of POCT, this document aims to support community health providers and system planners in developing effective care pathways and safeguarding public health nationwide.

A critical element is for decision makers to understand that for community-based POCT tradeoffs need to be made. Proposed quality assurance measures need to reflect the realities of the communities and populations that need to be reached and engaged into care. Excessive procedures may improve testing quality, but the price could be a barrier to POCT adoption. A test that is performed but is less than perfect, is still better than having a person denied the opportunity for diagnostic testing and the potential for their engagement into care. A key element is to develop close collaboration and communications between affected communities and health professionals to ensure that decisions are focused on how best to address individual, and population needs so that POCT and its oversight is planned in the context of appropriate engagement into care.

OBJECTIVES OF THE POCT GUIDELINE

The objective of this POCT guideline is to provide a comprehensive framework to establish standardized procedures and protocols for implementation of Point-of-Care Testing in community settings. It aims to ensure culturally safe practices, enhance client safety, and improve health outcomes by supporting communities to take an active role in their own healthcare.

The framework outlines key considerations for decision-makers across the planning, implementation, and evaluation phases of POCT programs. It emphasizes the need for appropriate training and education tailored to the type of POCT being used, along with clear protocols for documentation, result reporting, and equipment selection and maintenance.

Additionally, the guideline promotes client-centered care by integrating POCT within broader care pathways. It highlights the importance of culturally sensitive, community-led training initiatives informed by the experience of local organizations involved in POCT delivery.

1. INTRODUCTION

1.1 Understanding POCT

Point-of-Care Testing (POCT) refers to diagnostic testing conducted near the patient, at the bedside, in primary care, or in community settings, rather than in a centralized laboratory. As of November 26, 2024, per the Medical Devices Regulations (SOR/98-282), point-of-care devices are designated for use by healthcare professionals without formal laboratory training. For example, a near-patient in vitro diagnostic device (near-patient IVDD) is defined as one intended for use outside a lab environment, such as at home, in pharmacies, clinics, or at the bedside.

POCT is typically performed by trained non-laboratory personnel, including nurses, EMTs, dentists, physicians, pharmacists, and non-regulated staff or peers. The COVID-19 pandemic and rapid technological progress have highlighted the value of offering diagnostic services in non-traditional settings, including remote and underserved communities.

A key benefit of POCT is its ability to accelerate diagnosis and treatment, enabling healthcare providers to take immediate action—adjusting care plans, offering reassurance, and delivering results during the same patient encounter. This immediacy improves health outcomes, enhances patient satisfaction, and reduces barriers to care, supporting greater health equity. In addition, timely diagnoses can promote responsible behavior changes that help protect public health, such as, implementing treatment after a syphilis diagnosis or isolation following a positive COVID-19 test.

Despite these advantages, immediate results can also present challenges, especially in small or close-knit communities. Concerns about confidentiality, stigma, and discrimination require thoughtful handling and appropriate training to ensure patient privacy, dignity, and emotional support are upheld. Beyond diagnostics, POCT enables a more holistic model of care, incorporating counselling, education, and personalized health management.
Various Health Canada-approved POCT methods are available, offering results in minutes to an hour. These include:

- **Antigen detection** (e.g., SARS-CoV-2 rapid antigen tests)
- **Antibody detection** (e.g., HIV, syphilis, and HCV rapid tests)
- **Toxin detection** (e.g., *Clostridioides difficile*)
- **RNA detection** via molecular platforms (e.g., GeneXpert by Cepheid, Abbott ID NOW)

1.2 Purpose of POCT

POCT plays a critical role in promoting equitable access to diagnostic and treatment services, particularly where access to traditional labs is limited. By delivering testing at the point of care, POCT reduces delays, supports timely decision-making, and improves patient outcomes, especially in remote, underserved, or emergency settings.

It is a powerful tool for enhancing healthcare delivery and rebuilding trust in communities historically marginalized or underserved by the healthcare system, such as First Nations. By providing immediate, accessible, and personalized testing, POCT not only addresses urgent medical needs but also fosters empowerment, trust, and engagement in care, laying the foundation for more inclusive, responsive, and equitable health services.

2. IMPORTANCE OF POCT IN HEALTH CARE

Point-of-Care Testing (POCT) provides healthcare practitioners with rapid access to high-quality diagnostic results, enabling timely, well-informed treatment decisions. This leads to improved patient care, more efficient service delivery, and better health outcomes.

Key benefits of POCT in healthcare include:

- **Faster Diagnostic Turnaround:** POCT significantly reduces the time required to obtain test results, improving patient management and potentially saving lives during emergencies and outbreaks.
- **Improved Accessibility:** POCT is vital for individuals who face barriers to traditional testing, such as long travel distances, lack of transportation, or fear of stigma and discrimination. By offering local, discreet, and timely testing, POCT increases access and builds trust within underserved communities. However, in smaller settings, the immediacy of results may raise concerns about confidentiality and unintended disclosure.
- **Support in Remote and Resource-Limited Settings:** POCT is especially valuable in areas with limited access to centralized laboratories, ensuring that essential diagnostic services remain available regardless of location.
- **Real-Time Monitoring:** POCT enables real-time monitoring of patient health, allowing for immediate adjustments in treatment. For example, continuous glucose monitoring supports better diabetes management.
- **Enhanced Patient Engagement:** The convenience of on-the-spot testing empowers patients to take a more active role in their healthcare, leading to improved adherence and outcomes.
- **Rapid Linkage to Care:** POCT facilitates immediate diagnosis and swift connection to appropriate care pathways, helping to reduce delays in treatment initiation.

3. ADVANTAGES AND POTENTIAL CHALLENGES OF POC TESTING

While centralized laboratory testing remains essential for comprehensive and confirmatory diagnostics, Point-of-Care Testing (POCT) plays a critical role in accelerating diagnosis, especially in urgent or hard-to-reach situations. When used together, both methods offer a well-rounded diagnostic approach that supports diverse clinical and community needs. POCT not only enhances timely access to care but also helps reduce gaps in service delivery, particularly for populations at risk of being lost to follow-up.

3.1 Advantages of POCT

- ***Rapid Test Results:*** POCT enables quicker diagnosis and treatment decisions, improving outcomes and reducing delays.

- ***Improved Access in Remote or Underserved Areas*****:** POCT provides essential diagnostic services closer to patients, minimizing travel burdens and enhancing healthcare equity in resource-limited regions.

- ***Improved Surveillance of Long-term Health Conditions:*** Frequent, convenient testing supports real-time monitoring and timely adjustments in treatment, especially for conditions like diabetes or hypertension.

- ***Enhanced Patient Engagement:*** Timely access to testing encourages patient involvement and shared decision-making, fostering a greater sense of ownership over one's health.

- ***Improved Treatment Adherence:*** Immediate results support faster linkage to care, particularly for patients at risk of disengagement. Understanding test outcomes can motivate patients to follow through with care plans.

- ***Community Empowerment:*** Fully integrating POCT into communities allows individuals to make informed decisions about their health, promoting autonomy and self adherence.

3.2 Potential Challenges of POCT

- ***Accuracy:*** Some POCTS may have lower sensitivity or specificity compared to centralized laboratory tests, increasing the risk of misdiagnosis. Confirmatory testing may still be necessary.

- ***Sample Collection Issues:*** Collecting adequate samples—especially for antibody testing—can be difficult in certain populations, such as older adults or individuals with substance use disorders.

- ***Quality Control Measures:*** Inconsistent adherence to quality assurance measures may impact reliability. Enrolling in External Quality Assurance (EQA) and proficiency testing programs helps mitigate this.

- ***Lack of Professional Partnership:*** Without direct clinical partnerships, there is a higher risk of incorrect test selection or result misinterpretation. Strong partnerships and adequate training are essential.

- ***Poor Documentation and Integration*****:** Limited access to record-keeping systems can hinder continuity of care and make it difficult to track patient history.

- ***Insufficient Training:*** Personnel without adequate training may struggle with proper test execution and result interpretation, reducing diagnostic accuracy.

- ***Misinterpretation of Results:*** Non-laboratory personnel may not fully understand limitations such as false positives/negatives, potentially leading to inappropriate care decisions.

- ***Overuse of Testing*****:** Easy access to POCT may result in unnecessary testing, contributing to increased costs and inefficient resource use.

- ***Consent and Communications Issues:*** Failing to properly inform patients about test limitations or obtain informed consent can result in negative experiences or misuse of results.

- ***Confidentiality Concerns:*** Especially in small communities, privacy must be carefully managed to prevent unintended disclosure.

- ***Higher Per-Test Costs:*** POCT May be more expensive on a per-test basis due to test kit pricing and increased staff time.

Despite its limitations, POCT has evolved significantly, especially during the COVID-19 pandemic, with improved public trust and broader application. Historically hindered by governance gaps, POCT now benefits from structured frameworks that support consistent and safe use.

This guideline offers provinces and territories a standardized yet adaptable approach to address regional needs. While the upfront costs of implementation can be high, POCT reduces repeat healthcare visits, eases system burden, optimizes resource use, and facilitates timely diagnoses—making it a valuable and cost-effective tool in modern healthcare delivery.

4. FRAMEWORK FOR POINT OF CARE TESTING

4.1 Settings of POCT

Community setting:

- Family Physicians' clinic
- Walk-in clinics
- Community-based health centers, event gathers and programs
- Pharmacies
- Long term care facilities
- Nursing home
- Dental office
- Mobile health clinics
- Sporting events, marathons, concerts
- Field hospital: Medical tents.

Inside hospital:

- Emergency Department
- Triage
- Outpatient
- In-patient wards
- Nursing stations
- EMT
- Operating theater

***Self-testing*:** although self-testing falls outside the formal scope of Point-of-Care Testing (POCT), it operates in a similar manner by providing rapid, reliable results directly to users without the need for a clinical laboratory. Common examples include pregnancy tests, COVID-19 tests, blood glucose monitors, and self-administered HIV tests. This area of testing is expected to continue expanding as new technologies become available.

4.2 Categorization

In accordance with Medical Device Regulations (MDR), medical devices in Canada are classified into four categories based on the level of risk they pose to users and patients. This risk-based classification considers factors such as invasiveness, duration of contact, the body system affected, and whether the effects are local or systemic(2).

Overview of Devices Classes:

- ***Class I***: Minimal risk.
  Example: *Urine dipsticks* used for routine urinalysis to detect substances like glucose or protein.
- ***Class II***: Moderate risk.
  Example: Rapid influenza tests that provide quick results but require user interpretation.
- ***Class III***: Higher risk requiring more regulatory oversight.
  Example: PCR kits for tuberculosis detection, using molecular techniques to identify TB DNA.
- ***Class IV***: Highest risk, requiring the most stringent regulation.
  Example: High-sensitivity troponin tests for diagnosing acute myocardial infarction, where accuracy is critical.

In Canada, all near-patient In Vitro Diagnostic Devices (IVDDs), including most POCT devices, are classified as Class III and must undergo pre-market evaluation by Health Canada to obtain a Medical Device License. Some devices may fall under Class IV, depending on their risk profile.

POCT devices can also be categorized based on functionality and usage (4,5):

- ***Qualitative POC Testing****:* Detects the presence or absence of a substance or pathogen.
- ***Single-use POCT kits****:* Individually packaged, no instrumentation required and disposed of after one use. *Example: COVID-19 antigen test kits.*
- ***Portable analyzers***: Handheld devices capable of multi-analyte testing using different cartridges. *Example: i-STAT system.*
- ***Benchtop analyzers:*** Larger devices installed at a specific site for more complex or multi-analyte testing.
- ***Continuous POCT systems****:* Provide ongoing measurements, such as for blood glucose.

Many POCTs fall into more than once category, and their features may overlap.
POCT Certification:

Although most POCTs are simple to use, POCT certification ensures both personnel and facilities are competent in test administration. This is especially important in community programs, remote or resource-limited settings, and small healthcare facilities.

Certification supports:

- Establishing structured training programs
- Ensuring compliance with testing standards
- Maintaining quality and consistency across diverse care settings

4.3 Target audience of POCT

POCT delivers significant benefits to a diverse range of stakeholders:

***Patients**:* Receive faster diagnostic results, leading to quicker treatment decisions, improved health outcomes, and increased engagement in their own care.

Healthcare providers: Including physicians, nurses, pharmacists, and primary care teams, benefit from real-time data that supports timely, informed clinical decisions.

Emergency medical teams: Use POCT for rapid assessments in urgent situations, enabling prompt interventions, reducing unnecessary tests or hospital admissions, and improving patient flow.

***Non-regulated professionals and Peers*:** With proper training, can effectively administer and interpret tests. This not only improves access to care but also allows regulated healthcare professions to focus on tasks within their scope of practice—an important strategy for addressing workforce shortages.

Healthcare facilities: Such as hospitals and clinics, see improved efficiency, reduced delays, and enhanced quality of care.

***Remote and underserved areas*:** Gain critical access to diagnostic services that may otherwise be unavailable due to geographic or resource limitations.

***Public health authorities*:** Utilize POCT for surveillance, early detection, and disease prevention, supporting timely public health interventions.

POCT has wide-range applications that strengthen healthcare systems, improve access and equity, and support better patient outcomes across diverse environments.

Group A Streptococcal (GAS) Screening in Community-Based Settings - Québec

Overview
Group A streptococcal (GAS) infections are a leading cause of pediatric emergency room visits in Quebec. To address this, Points de service locaux (PSLs)—community health centers set up during the COVID-19 pandemic—were repurposed to provide accessible GAS screening. Staffed primarily by retired nurses, these centers offer POCT in non-traditional settings, such as shopping malls and other community locations, bringing healthcare closer to the public.

Implementation

- Patients can book appointments online via the **Clic Santé** platform and visit a PSL of their choice.
- Nurses conduct a physical assessment and perform on-site GAS screening using rapid tests or NAAT devices.
- Results are available within minutes, and patients receive a prescription for treatment during the same visit.

Outcomes

- **Improved Access**: Free GAS screening services are now more accessible to the population, reducing the need for emergency room visits.
- **Faster Treatment**: Immediate test results enable quicker initiation of treatment, reducing the risk of complications and secondary infections.
- **Patient-Centered Care**: The streamlined process enhances the patient experience by providing screening, results, and treatment in a single appointment.
- **Reduced ER Visits:** The initiative helps divert patients from emergency rooms, improving healthcare efficiency.

Challenges

- **Staffing:** Most PSL staff are retired nurses with restricted licenses, limiting their ability to fully perform screening tasks.
- **Service Variability:** Different testing methods and collective prescriptions create inconsistencies across PSL locations.
- **Communication Gaps:** Ensuring proper referral mechanisms to PSLs proved challenging.

Solutions

- **Quality Assurance:** A national protocol for GAS screening is being developed to standardize practices.
- **Staffing Adjustments:** Workflow modifications ensure adequate staffing with licensed nurses.

Improved Communication: Regional efforts are focused on improving service awareness

Lessons Learned

- The importance of standardized protocols and quality assurance in POCT implementation.
- The need for effective communication strategies to promote new POCT services and ensure uptake.
- The value of community-based POCT in improving healthcare access and reducing system strain.

5. CLINICAL GOVERNANCE

Establishing a dedicated Point-of-Care Testing (POCT) committee at the Provincial/Territorial (p/T) level is essential to support strong clinical governance and ensure high-quality, reliability, and timely testing services. The committee will be responsible for overseeing all aspects of POCT within its jurisdiction, including tests performed near or at the patient's bedside. Its work will focus on enhancing patient safety, improving healthcare quality, and ensuring consistent and accurate results.

Core Responsibilities of the POCT Committee:

- ***Quality Assurance:*** Developing and implement protocols to ensure accuracy and reliability of POCT.
- ***Regulatory Compliance:*** Monitoring adherence to local, national, and international standards.
- ***Education and Training:*** Provide healthcare providers with the necessary knowledge and skills for effective POCT use.
- ***Documentation****:* Maintain detailed records of all POCT activities for accountability and continuous review.
- ***Risk Management:*** Identify and mitigate potential risks associated with POCT**.**
- ***Interdisciplinary Collaboration*****:** Foster teamwork among healthcare professionals to optimize patient care.
- ***Data Management and Privacy*****:** Protect patient information and ensure compliance with privacy regulations.
- ***Continuous Improvement:*** Promote innovation and integrate best practices into POCT operations.

Community involvement is key. POCT efforts must align with local needs, and community representatives should be included to ensure responsiveness and cultural appropriateness.

POCT Committees and Regulatory Frameworks Across Countries

In the UK, POCT committees are typically formed within National Health Service (NHS) Trusts to oversee the management and quality of POCT services. These committees, led by a senior clinician authorized by the Medical Director, are responsible for ensuring that POCT devices comply with the standards established by the Medicines and Healthcare Products Regulatory Agency (MHRA)(23,24). In the United States, the POCT committee within the College of American Pathologists (CAP) is dedicated to enhancing the quality of patient care and safety in physician office laboratories (POLs), small hospital laboratories, and POCT facilities (18).

Similarly, in Australia, the Therapeutic Goods Administration (TGA) has established the Point-of-Care Manufacturing of Medical Devices Steering Committee to oversee the regulation and quality assurance of POCT devices(25). Furthermore, the Australasian Association of Clinical Biochemists (AACB) supports the implementation of best practices in POCT, emphasizing training, quality assurance, and clinical governance(20).

A comparable committee could be established in Canada with the responsibility for clinical governance.

Committee Composition at the P/T Level:

The POCT committee should be multidisciplinary, including key stakeholders who either perform POCT or use its results for clinical decisions. Members may include:

- ***Medical Director:*** Provides leadership and ensures the committee achieves its objectives.
- ***Indigenous Representatives:*** Ensure the unique healthcare needs and cultural priorities of Indigenous communities are integrated into POCT programs.
- ***POCT Coordinator:*** Manages daily operations, ensures compliance, and supports safe and effective testing across all settings, including underserved communities.
- ***Clinical Laboratory Representative:*** Aligns POCT with broader laboratory services and practices.
- ***Clinical Specialists:*** Offer expertise in specific fields (e.g., cardiology, infectious diseases) to guide relevant POCT applications.
- ***Nursing Representatives:*** Help integrate POCT into patient care workflows based on frontline experience.
- ***Quality Assurance Representative:*** Oversees adherence to quality and regulatory standards.
- ***Community Representative****:* Provides input on local health needs to ensure the program reflects community values and priorities.

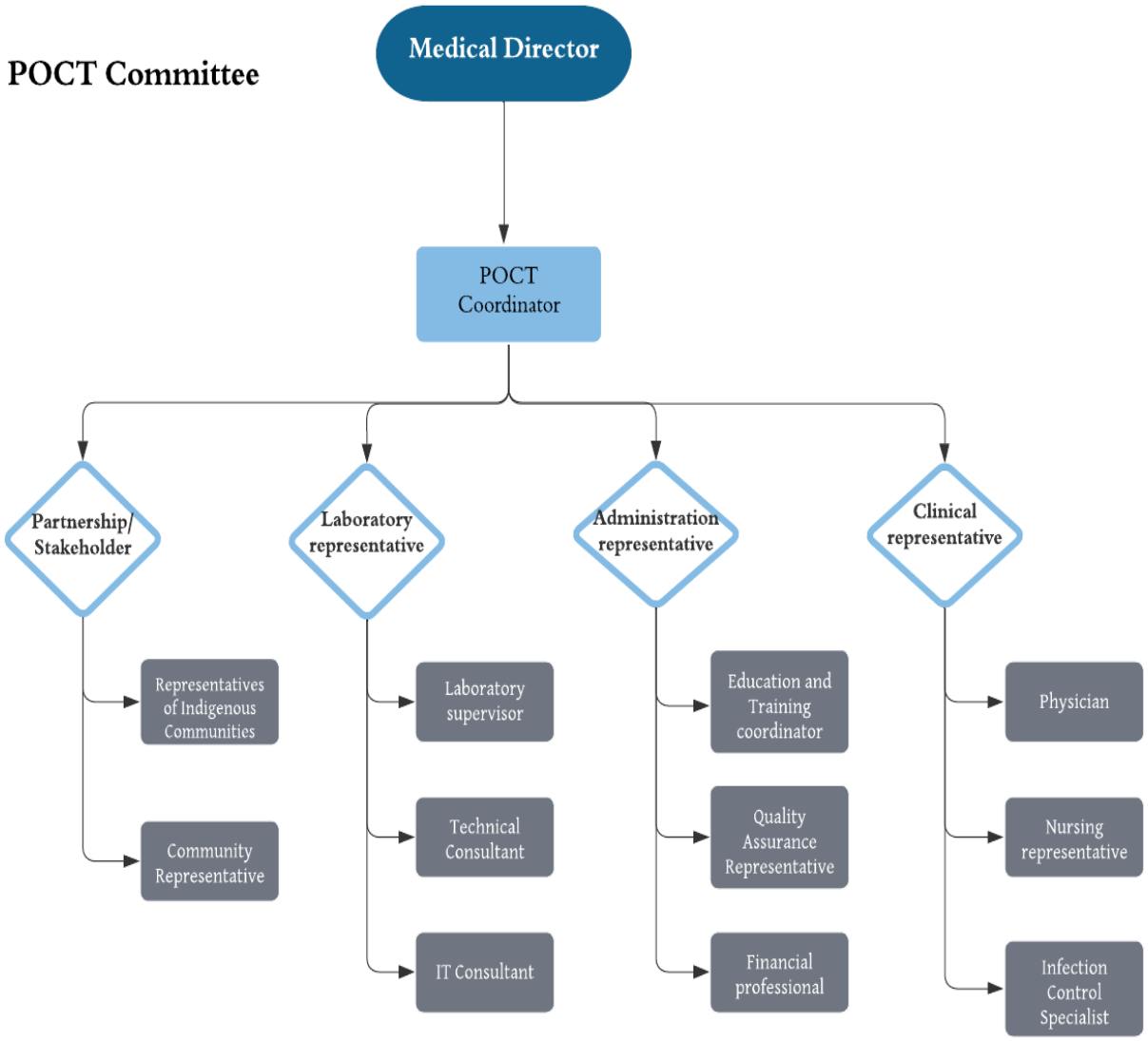


***Figure 1**: Framework for a Proposed POCT Governance Committee*

National POCT coordination:

To support consistent and effective POCT implementation across Canada, a national POCT committee is recommended. This body should include P/T representatives, Indigenous representatives (selected through Indigenous governance structures), and experts in POCT.

The national committee would:

- Act as liaison between regional and national efforts.
- Promote culturally sensitive and regionally tailored POCT strategies.
- Provide consultive support to local and regional committees, including guidance on:

- Program development and expansion
- Regulatory compliance
- Quality assurance
- Workflow optimization
- Technology integration

Such a committee would serve as a vital resource for ensuring best practices, standardization, and high-quality POCT services across the country.

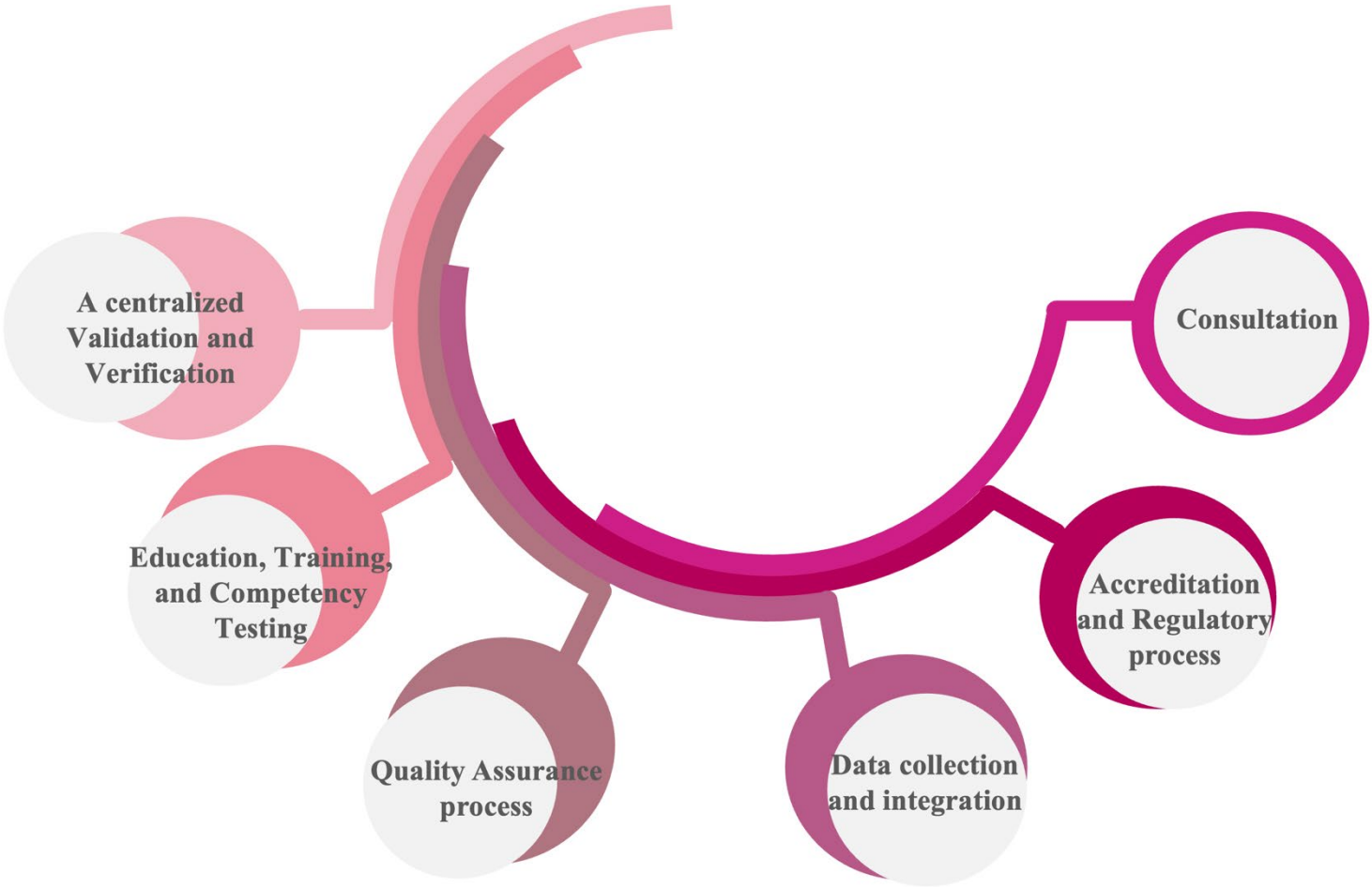


***Figure 2**: Model for National POCT Oversight Committee*

6. INITIAL STEPS BEFORE INTRODUCING POCT

6.1 Appropriate use of POCT

Effective integration of POCT into healthcare systems requires its appropriate use. Not all clinical situations are suited for POCT, so careful test selection is essential. This decision should

be based on the clinical context, patient needs, and healthcare setting. When properly implemented, POCT can reduce healthcare barriers and improve access to timely diagnostic services, especially in underserved areas.

6.2 Identifying the Need for POCT

Before implementing assess the necessity of POCT by considering the following:

- ***Clinical Necessity:*** Baes decisions on local clinical and community health priorities. POCT is particularly useful when rapid results can directly improve patient outcomes, such as in emergency care or where traditional lab access is limited.
- ***Patient Benefits:*** POCT can enhance the patient experience by reducing delays and improving health outcomes. This is especially valuable in remote or underserved areas.

Community input through regional POCT committees can help identify needs and benefits specific to their populations.

6.3 Establishing Standardized Processes

As POCT demand grows, standardized procedures are essential to ensure accuracy, reliability, and integration into care workflows. Especially where POCT serves as a primary diagnostic too, ensure the following:

- Accuracy and precision of test results
- Device durability and reliability
- Proper documentation and linkage to follow-up care

Standardization minimizes errors, reduces repeat testing, and improves care efficiency.

6.4 Provincial/Territorial Steps for Considerations

Effective POCT implementation at the Provincial/Territorial (P/T) level involves a structured evaluation process. The following table outlines key steps:

Table: 1. Steps to Consider for Implementing POCT at Provincial and Territorial Levels.

STEPS	STRATEGY	METHOD/EVALUATION
Determine Need	Assess regional health needs and service gaps	Evaluate clinical and operational requirements for the proposed POCT
Select Appropriate POCT	Review available devices and technologies	Choose devices based on accuracy, reliability, and usability
Identify Effective Settings	Determine where POCT will have the greatest impact (e.g., ER, clinics, remote areas)	Evaluate benefits such as reduced wait times and improved care
Assess Impact on Current Practices	Identify how POCT improves efficiency and outcomes	Measure improvements in care delivery and resource use
Secure Funding	Explore financial support options	Seek government programs, grants, and partnerships
Staffing	Identify who will perform POCT (e.g., regulated/unregulated providers, peers)	Ensure staff availability and capability
Support Infrastructure	Assess site readiness (e.g., lab support, quality measures)	Participate in quality programs (EQA, PT) and implement QC
Regulatory Requirements	Identifying who will oversee and handle the regulatory requirements for implementing POCT.	Identify the responsible parties for overseeing and managing regulatory aspects of POCT implementation.
IT Needs	Assessing the IT needs for POCT, which includes integrating test results with current systems and addressing data management requirements	Develop systems for integrating POCT results with Laboratory Information Systems (LIS) and/or electronic health records (EHR).
Coordination	Collaborate with site/unit managers and POCT committee	Align with clinical and operational goals
Training	Provide staff training and certification	Implement initial and ongoing competency assessments
Result Reporting	Establish reporting protocols	Integrate results into LIS/HER systems
Quality Assurance	Maintain ongoing QA activities	Monitor performance through EQA, PT, and QC

Introducing POCT in community settings requires thoughtful planning to ensure accessibility, quality, and proper integration. Core considerations include regulatory requirements, staff training, quality assurance, and data reporting. A detailed checklist is provided in Appendix C.

7. REGULATORY LANDSCAPES FOR POCT AND ACCREDITATION:

7.1 In Vitro Diagnostic Regulation in Canada

In Canada, in vitro diagnostic devices (IVDDs) are regulated by Health Canada under the *Medical Devices Regulations* (SOR/98-282), pursuant to the *Food and Drugs Act.* POCT devices typically fall under **Class III**, with exceptions:

- **Class IV devices:** Near patient IVDDs for transmissible agents (e.g., HIV, hepatitis).
- **Class II devices:** Devices used for pregnancy detection, fertility, or menopause testing under rule 6 IVDD (6,7)

These regulations ensure the safety, efficacy, and proper use of medical devices.

Key Regulatory Aspects:

1. Device Licensing and Sale:
- Devices must be licensed by Health Canada before sale.
- Manufacturers must provide detailed documentation on intended use, design, and safety.
- Establishment licenses are required for manufacturers, importers, and distributors to ensure compliance with quality systems.

2. Implementation and Monitoring:
- Licensed devices are subject to ongoing compliance, including labeling, distribution records, and incident reporting.
- Healthcare providers must follow Health Canada standards to maintain device safety and effectiveness.
- Post-market surveillance allows Health Canada to act on safety concerns.

3. Approval of Intended Use (8,9) **:**
- Manufacturers must clearly define a device's intended use and provide clinical evidence of its safety and performance.
- Health Canada evaluates applications based on the device's benefits and risks

4. Amendments and Special Access:
- Changes to a device's intended use require amendment applications.
- Custom or special-access devices (e.g., for public health emergencies) must follow alternate regulatory pathways.

Special Access Program (15,16)

The **Special Access Program (SAP)** enables healthcare professionals to access medical devices that are not yet authorized for sale in Canada. This includes custom-made devices and those required for special access due to urgent public health needs. This program is designed to address situations where conventional therapies have failed, are unavailable, or are unsuitable for treating a patient.

Special access authorization is mandatory for all unlicensed medical devices and certain custom-made devises before they can be use in Canada.

Under Part 2 (Special Access Provisions) of the *Medical Devices Regulations*, established under the *Food and Drugs Act,* healthcare professionals are permitted to obtain custom-made and unlicensed medical devices to address these exceptional circumstances.

7.2 Accreditation and Certification

7.2.1 Current Status

Accreditation ensures POCT delivers accurate and reliable diagnostic services outside traditional laboratories, supporting timely clinical decisions and patient confidence. However, there is no national mandatory accreditation for laboratories or POCT in Canada. Accreditation and regulation fall under Provincial/Territorial (P/T) authority, leading to variable standards across regions.

Provincial regulatory oversight is often handled by:

- Provincial Colleges of Physicians and Surgeons
- Colleges of Medical Laboratory Technologists
- Accreditation organizations such as:
    - Accreditation Canada
    - Standards Council of Canada

7.2.2. Future direction

While P/T oversight plays a vital role, developing a national guideline aligned with international standards and specifications, such as *ISO TS 22583*, would help establish consistent, high-quality POCT services across Canada. Suh a framework would support:

- Standardized quality assurance and accreditation
- Consistent training and proficiency testing
- Better regulatory compliance in all settings

A simplified, localized onboarding process is critical, especially for rural remote sites facing resource constraints. The '*POCT Site Recognition Form/POCT Site Application Form'* (Appendix A), offers a streamlined method for bringing new POCT sites into compliance while reducing administrative burden

COVID-19 as a Case Study

During the pandemic, regulatory flexibility enabled faster deployment of POCT (e.g., ID NOW devices). Regulatory bodies adapted frameworks, such as amendments to *Ontario's Laboratory and Specimen Collection Centre Licensing Act (LSCCLA)*, to allow trained non-laboratory staff to conduct testing.

This led to:

- Rapid implementation in underserved areas
- Reduced testing bottlenecks
- Use of real-time reporting tools (e.g., MORE system)
- Continued quality assurance through device validation and reporting protocols

The following example shows that streamlined regulation paired with strong QA measures can expand POCT capacity while maintaining standards.

Transforming Testing: Overcoming Barriers with ID NOW

Overview
The ID NOW test is a molecular testing tool used to detect COVID-19 genetic material, offering results in just 15 minutes. The initiative aimed to provide equitable access to COVID-19 testing in rural, remote, and Indigenous communities, where traditional laboratory-based PCR testing may not be readily available. This program helped improve testing turnaround times (TAT), early outbreak detection, and the timely distribution of therapeutics.

Implementation

- **Partnerships**: Collaboration with PHAC and Ontario Health ensured alignment and resource sharing.
- **Training and Support**: Comprehensive training materials and verification panels were provided.
- **Regulatory Changes**: Amendments to the LSCCLA allowed non-laboratory personnel to perform ID NOW testing.
- **Reporting Infrastructure**: The MORE platform enabled electronic reporting of results.

Strengths

- **Rapid Results:** ID NOW delivers results within 15 minutes, greatly reducing waiting times compared to traditional PCR testing.
- **Equitable Access:** The initiative ensured COVID-19 testing availability in underserved areas, including Indigenous and rural communities.
- **Strong Partnerships:** The program benefited from collaborations with organizations like the Public Health Agency of Canada (PHAC) and Ontario Health, leading to effective implementation, including tailored support for Indigenous communities.
- **Quality Assurance:** Validation of ID NOW devices through partnerships with Mount Sinai Hospital ensured accurate results.

Challenges

- **Resource-Intensive Onboarding:** Onboarding new testing sites required significant time and resources, especially in remote areas.
- **Compliance and Reporting Issues:** Challenges included low compliance with test result reporting in Indigenous communities and delays in integrating the Mobile Orders and Results Entry (MORE) platform.
- **Staff Turnover:** High turnover of trained staff in remote and Indigenous sites led to additional training requirements.

Solutions

- **Regulatory Adjustments:** Amendments to Ontario's Laboratory and Specimen Collection Centre Licensing Act (LSCCLA) enabled non-laboratory staff to conduct COVID-19 testing with ID NOW, streamlining implementation.
- **Reporting Infrastructure:** The MORE platform was developed to simplify the reporting of test results into the Ontario Laboratory Information System (OLIS), improving efficiency.
- **Tailored Support for Indigenous Communities:** Efforts were made to ensure that supplies and training reached remote Indigenous communities through a dedicated logistics program and referrals.

Impact

- **Widespread Implementation:** 165 sites were operational with ID NOW, improving testing accessibility and turnaround times across Ontario, especially in at-risk communities.
- **Reduced TAT:** Rapid testing reduced delays in patient treatment, addressing mental health and outbreak control issues caused by long isolation periods in long-term care (LTC) facilities.
- **Support for At-Risk Populations:** ID NOW facilitated testing in high-risk communities, helping to combat socio-economic and healthcare disparities.

Standardization, community engagement, and flexibility are critical to successful POCT implementation.

7.3 Accreditation Support and Oversight

Sites may apply for accreditation prior to implementing POCT. Regional POCT committees will:

- Provide guidance and assist with applications
- Ensure compliance with relevant regulations
- Liaise with regulatory bodies to stay current with best practices

To support implementation, committees will also:

- Coordinate with manufacturers for timely supply of POCT kits and equipment
- Facilitate training, documentation, and proficiency testing
- Support equitable distribution and operations in remote and underserved areas

By enabling centralized reporting and ensuring consistent compliance, these committees help promote health equity and effective use of POCT across all healthcare settings.

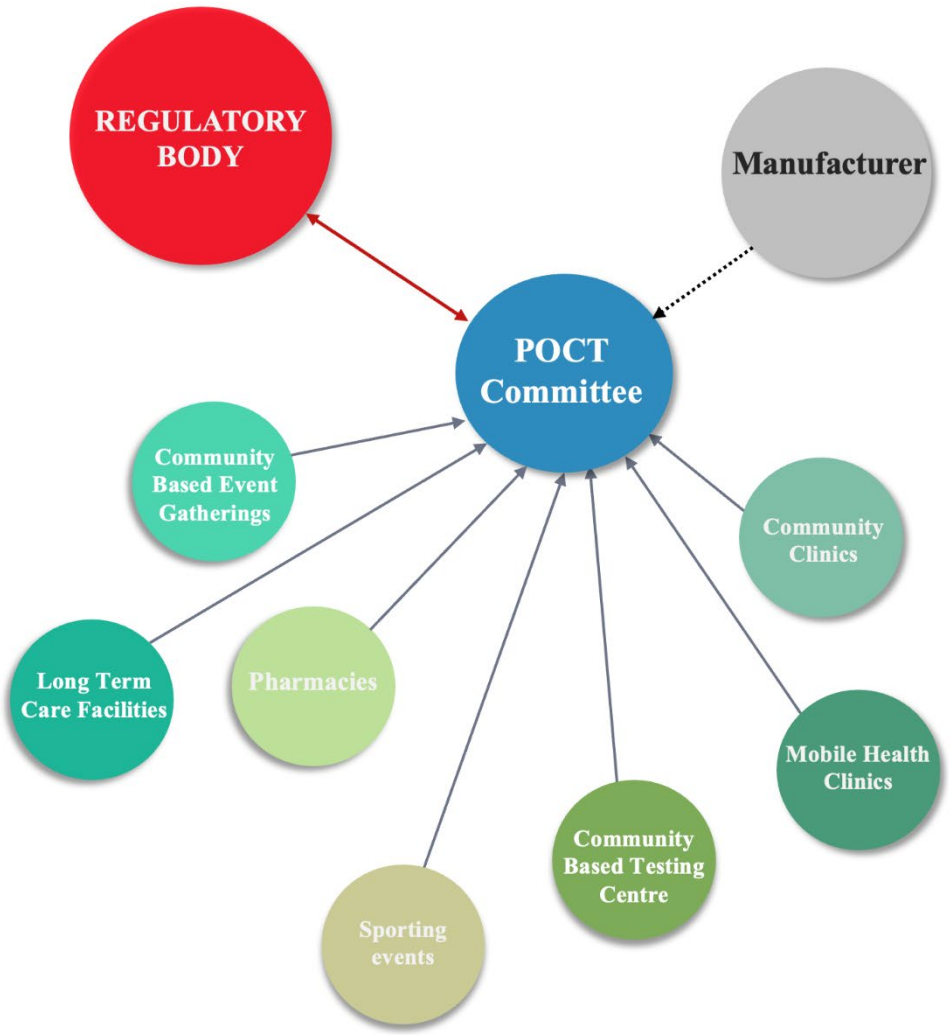


Figure 3: Community – Integrated Point-of-Care Testing Network (CIPOCTN)

Key Stages for Successful POCT Site Onboarding	
Stage	**Description**
1. Application Submission	Site completes and submits the *POCT Site Recognition Form* to the POCT committee.
2. Evaluation and Needs Assessment	The committee reviews site readiness, including infrastructure, staffing, and available resources. Early identification of potential challenges is addressed.
3. Tailored Support Plan	A customized plan is developed, detailing required resources, training, and infrastructure support. Remote guidance is offered for rural and remote locations.
4. Implementation Steps	POCT is rolled out in phases, with full collaboration and documentation. Each phase is adapted to the site's specific context and regional requirements.
5. Accreditation Enrollment	The committee assists the site in registering with the appropriate regional accreditation body, simplifying compliance with regulatory standards.
6. Quality Assurance and Proficiency Testing	The site begins participation in PT and QA programs to ensure reliable testing and adherence to quality standards.
7. Ongoing Support & Monitoring	Continuous support is provided through check-ins, training refreshers, and troubleshooting to maintain service quality and compliance.
8. Feedback & Continuous Improvement	Regular feedback is gathered from sites to refine the onboarding process and improve efficiency, effectiveness, and sustainability

8. COMPONENTS OF POCT

Validation and verification are essential steps to ensure Point-of-Care Testing (POCT) devices are accurate, reliable, and suitable for their intended use. These processes must be completed before implementation, in collaboration with local laboratories, as required by regional accreditation standards.

Validation is the process of confirming that a test, method, or device performs as intended and meets the manufacturer's specifications for its intended use.

Verification ensures that the validated test, method, or device continues to perform as expected in the specific environment where it is being used.

8.1 Validation

Validation confirms that a POCT device consistently performs according to manufacturer specifications under expected conditions. It ensures the device is fit for purpose and suitable for real-world use.

Manufacturer Validation: Manufacturers usually conduct validation in controlled laboratory settings. These results can typically be accepted by end users unless the device is used off-label or modified.

Local Validation: When off-label use is intended or validation is incomplete, sites should work with accredited local or regional laboratories. Regional POCT committees can help facilitate these partnerships.

Scope of Validation: Manufacturer validation practices vary. Some reflect real-world conditions, while others do not. It is critical for POCT supervisors and regional committees to understand the scope and limitations of these validations, especially when deploying devices in diverse settings (10) (e.g., rural areas, varying climates).

When Should Sites Perform the POCT Validation Process?

- **Modification of Equipment or Test:** When the POCT device or test has been altered from its original configuration, such as changes to testing protocols.
- **In-House Development**: When a test or equipment is developed internally by a site and lacks manufacturer validation, requiring full validation to ensure it meets performance standards.
- **Off-Label Use**: When a test or equipment is used for purposes or in clinical settings not validated by the manufacturer, such as diagnosing conditions or populations outside the intended use.
- **New Clinical Setting**: When the device is introduced to a different clinical environment or patient population that was not included in the manufacturer's original validation studies.
- **Regulatory or Compliance Requirements**: When local regulations or accreditation standards mandate site-level validation for specific tests or equipment to meet compliance criteria.

8.2 Analytical Performance

The first step in validation is to assess the analytical performance of the device. This is typically carried out by trained laboratory staff.

Key performance characteristics include:

1. Accuracy
2. Precision
3. Linearity
4. Comparative testing with other devices
5. Reportable range
6. Reference interval relevant to the target population

Per ISO 22583, validation must include, at a minimum, evaluations of *accuracy, precision, linearity*, and *comparisons with other devices* (10).

Steps in Validation

1. **Method Selection**: Identify appropriate reference methods to evaluate the POCT device's performance. These reference methods should be reliable, well-documented, and aligned with industry standards to ensure valid comparisons.
2. **Comparison to Reference Methods**: Compare the results from the POCT device with those obtained from laboratory-based tests or established reference methods. This step helps assess the accuracy and consistency of the POCT device under test conditions.
3. **Pilot Testing**: Conduct pilot tests under real-world conditions to evaluate the reliability, reproducibility, and practicality of the POCT device in its intended operational environment.

Sample Selection for Validation

The selection of appropriate samples is critical for the success of POCT., Validation parameters can vary depending on the matrix used. To ensure the accuracy and relevance of results:

- Use the same matrix for validation that will be used during the actual POCT measurements (e.g., whole blood, serum, urine).
- If using the intended matrix is not feasible, consider utilizing manufacturer-provided control materials or certified reference materials as substitutes.

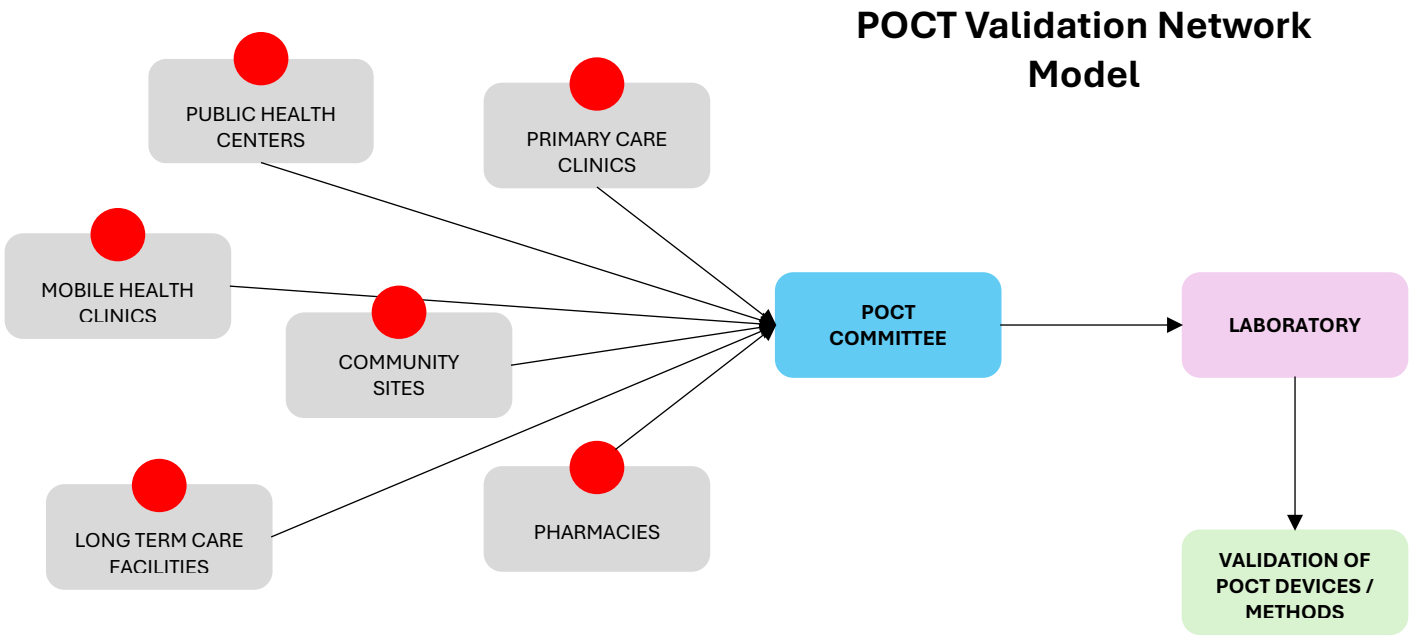


***Figure 4**: Model for validating Point-of-Care Testing (POCT) systems*

8.3 Verification

Verification confirms that a validated device continues to perform as expected in its specific operational environment. It demonstrates that the POCT device meets performance claims under real-world conditions.

Verification Process:

1. Collect two patient sample simultaneously.
2. Test one using the POCT device.
3. Send the second to a central of clinical laboratory.
4. Compare results to evaluate accuracy, precision, sensitivity, and specificity.

According to ISO 22583, at least 20 samples are recommended for verification studies to ensure statistical significance (10).

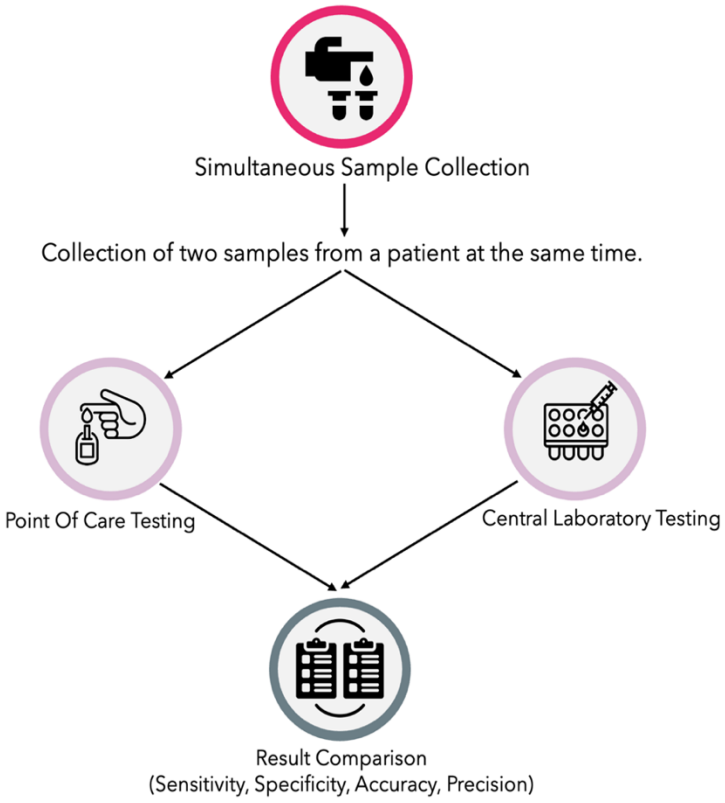


Fig 5: Verification Process

8.4 Validation and Verification Strategies

Due to the simpler design of many POCT devices, Provinces and Territories (P/Ts) can adopt the following streamlined validation and verification approaches:

Scenario 1: Unified Acceptance Model
Devices validated by an accredited lab in Canada should be recognized nationally. Only regional-specific verification would be required, based on the device's complexity and intended use.

Scenario 2 Standardized Validation Approach
Devices approved by Health Canada should be accepted across all regions. Additional regional verification may be conducted as needed, depending on the device's risk level and application.

Scenario 3: Flexible Accreditation Framework
A scalable quality assurance model should be adopted to reflect real-world variability in:

- **Testing environments** (e.g., low- vs. high-volume sites)
- **Device risk** levels, applying:
  - Comprehensive validation for high-risk devices
  - Basic verification for low-risk or routine devices

Best Practices: BC's Approach to HIV Testing

In British Columbia (BC), HIV testing using POCT devices is exempt from formal accreditation requirements to facilitate broader accessibility in community settings. To maintain high-quality standards, the province has implemented a **practical quality assurance program.** Key components of this program include:

- **Proficiency Testing Program**: Scheduled twice a year, this program evaluates the accuracy and reliability of the HIV testing devices, ensuring they meet established performance standards.
- **Support and Training:** Comprehensive training and ongoing support are provided to personnel performing HIV POCT. This ensures they have the knowledge and resources to uphold testing standards and address any operational issues effectively.

By adopting this approach, BC successfully balances the flexibility needed for widespread community-based HIV POCT use with the critical need for rigorous quality assurance.

9. QUALITY ASSURANCE AND CONTROL:

Point-of-care testing (POCT) requires both Internal Quality Control (IQC) and External Quality Assurance (EQA), except for some continuous monitoring devices where such testing is not feasible.

9.1 Internal Quality Control (IQC)

IQC ensures the accuracy and reliability of POCT devices and results through routine checks using control materials with known values, typically provided by the manufacturer. These controls are tested before patient specimens to confirm proper device function.

Each POCT method must have a defined IQC protocol based on risk management principles and manufacturers guidelines. Factors to consider include text complexity, built-in system checks, patient safety risk, and usage frequency (11,12). For example, simple visual lateral flow assays rely heavily on the operator's interpretation. These tests often include built-in control lines, emphasizing the need for proper training and adherence to standard operating procedures (SOPs).

IQC protocols should be designed with consideration for local resources, especially in community and remote settings. This includes evaluating available infrastructure, equipment, and staffing to ensure the protocol is practical and effective in various environments.

The IQC program must:

- Include acceptance criteria for test results, clearly documented and accessible to operators.
- Define procedures for investigating results outside acceptable limits, supported by the manufacturer or on-site resources.
- Outline acceptance testing for both single-use devices and instruments.
- Provide clear steps for handling out-of-range QC results.

Regular calibration and maintenance of POCT equipment should be scheduled to sustain accuracy. All IQC activities, including test results, calibrations, and maintenance, must be documented for ongoing performance monitoring.

Strategic Points for Performing Internal Quality Control (IQC) in POCT / Key Moments for Conducting Internal Quality Control in POCT

In addition to routine quality assurance protocols, IQC is essential at key moments to ensure accuracy and reliability:

- Upon receipt of new batches or deliveries of supplies.
- Following maintenance procedures.
- If there is suspicion of physical damage, such as exposure to extreme temperatures or accidental impact.
- When applicable, after software updates

The recommended frequency for conducting IQC is typically outlined in the device manual or should be in accordance with the regional POCT committee guidelines.

9.2 External Quality Assurance (EQA):

EQA involves testing unknown samples provided by an external source to assess the accuracy and reliability of POCT results. These programs may be offered by device manufacturers or specialized EQA providers.

EQA evaluates both the operator proficiency and system performance under simulated patient testing conditions. Participation helps identify strengths and areas needing improvement.

Key Steps in EQA Participation:

1. **Enrollment** – Choose a program aligned with the types of POCT performed.
2. **Testing and Reporting** – Periodically test supplied samples and submit results for analysis.
3. **Follow-up** – Receive reports with benchmarks and feedback; address any performance issues.

Sites should establish clear procedures for timely results submission and documentation. In case of poor performance, support from the manufacturer of the regional POCT committee should be available to guide corrective actions.

Participation in EQA is strongly recommended whenever possible. However, for remote or resource-limited sites, logistical challenges may arise. In such cases, regional POCT committees can support quality efforts by:

- Coordinating resource sharing among nearby sites.
- Facilitating sample exchanges between facilities using similar methods.
- Promoting shared learning and access to QA programs.

These collaborative strategies can help maintain consistent quality across all settings.

IQC	EQA
Control Material Selection: Selecting control samples with known values that reflect the expected range of test results for the specific device and testing scenario. **Integrating Control Samples:** Incorporating IQC samples with patient samples at defined intervals to evaluate the accuracy and precision of test results effectively. **Evaluating Test Outcomes:** • **Quantitative Tests**: Compare IQC results to defined statistical limits to ensure consistency and accuracy. • **Qualitative Tests:** Verify IQC results against expected outcomes to identify any discrepancies or trends that may indicate variations in test performance. **Addressing Deviations:** • Investigate the root cause of any identified deviations promptly. • Implement corrective actions mitigate issues and maintain testing accuracy and reliability.	**Engaging in Proficiency Programs:** Participate in EQA programs specific to the types of tests performed in the community-based POCT settings to ensure adherence to quality standards. **Assessing Blind Samples:** Analyzing EQA samples with unknown values, comparing results to the expected outcomes provided by the EQA program. This practice helps ensure consistent performance across different test sites. **Reviewing Performance Feedback:** • Examine detailed performance reports from the EQA program • Identify any discrepancies or trends by comparing local testing results with those from peer community-based POCT sites, ensuring alignment with broader quality standards. **Implementing Corrective Measures:** Addressing any issues identified from EQA feedback by implementing targeted corrective actions to enhance overall testing quality

Both IQC and EQA require oversight by a laboratory professional to ensure the accuracy and reliability of POCT results. This oversight should be carried out by either the local pathology service, the regional laboratory supervisor serving on the POCT committee, or a comparable healthcare entity tasked with upholding diagnostic testing quality and standards.

10. TRAINING:

10.1 Framework of education and training:

POCT is often performed by non-laboratory personnel, such as nurses, physicians, and other healthcare providers, including non-regulated professionals. This highlights the critical need for comprehensive training to ensure accurate test performance and result interpretation, which directly impacts patient care.

10.1.1 Training Modules:

Training must be provided for each POCT method used and should build on the manufacturer's Instructions for Use (MIFU). Key topics include:

- Test procedures and result interpretation
- Quality control and clinical protocols
- Test limitations and troubleshooting
- Biosafety measures
- Patient confidentiality and data privacy

Training delivery options may include:

- **In-person sessions:** Theoretical and hands-on instruction
- **Online training:** Live or pre-recorded modules
- **Hybrid formats:** Combining online and in-person learning
- **Self-paced videos:** For remote or flexible access

Personnel must demonstrate competency through formal education, practical instruction, and hands-on experience. Training methods, materials, and standards should be guided by regional POCT committees or regulatory bodies. These groups should also determine the need for training after operational pauses and set the frequency of refresher training.

POCT Training Process and Key Steps

When designing the training curriculum, the following aspects must be considered: The curriculum should balance theoretical knowledge with hands-on experience, whenever possible, to maximize learning outcomes. Below are the key areas to include:

1. Theoretical Understanding

Clinical Indication of the POCT

- **Clinical Background**: Understanding the disease process and pathophysiology.
- **Clinical Utility**: How the test aids in diagnosing, monitoring, and treatment decisions.
- **Reference Intervals**: Familiarize with test-specific reference ranges and units.

Performance Characteristics

- **Device Limitations**: Sensitivity, specificity, accuracy, and range of the device.
- **Sample Collection**: Patient preparation, correct sample collection methods, and preservatives.
- **Reagents**: Proper preparation, storage, and handling.

Test Procedure

- **Performing the Test**: How to use the device, including calibration.
- **Result Interpretation**: Understanding results, including abnormal readings, and reporting protocols.
- **Handling Errors**: Troubleshooting common test errors and device malfunctions.

Quality Control and Accreditation

- **QC & EQA**: Understanding internal and external quality assurance practices.
- **Compliance**: Adherence to accreditation standards and regulatory requirements.

2. Practical Application

Device Demonstration

- **POCT Lead Demonstration**: Full demonstration of using the device, running tests, and performing basic maintenance.
- **QC/EQA Samples**: How to run quality control and proficiency samples.

Hands-On Practice

- **Practical Session**: Trainees perform tests on the device, including calibration, running QC samples, and troubleshooting.
- **Maintenance**: Basic maintenance procedures for the POCT device.
- **Infection Control and Waste Management**
- **PPE**: Correct usage of personal protective equipment.
- **Waste Disposal**: Safe handling and disposal of biohazardous waste.

3. Final Evaluation and Certification

- **Knowledge Check**: A brief assessment of theoretical knowledge.
- **Practical Evaluation**: Hands-on testing, running QC samples, and using the device correctly.
- **Certification**: Awarded based on successful assessments.

10.2 Competency Assessment and Certification:

Certification is required to confirm that individuals performing POCT are competent. This is achieved through completion of training and successful competency assessment, which may include written exams, practical evaluations, or proficiency testing.

In remote or resource-limited settings, flexible certification pathways are essential. Online and remote options should be available to improve accessibility and ensure personnel can meet competency standards, even without direct access to central labs.

All POCT personnel must be familiar with the manufacturer's instructions for each device. Competency assessments must confirm their ability to apply this knowledge in practice.

Proficiency testing

Proficiency testing is an essential component of training for POCT operators, ensuring personnel are capable of performing tests accurately and reliably in real-world conditions. As part of their training, operators should participate in proficiency testing programs designed to assess their ability to achieve the correct results on unknown samples. These programs provide valuable feedback to operators and training providers, highlighting areas for improvement and helping operators maintain high levels of competency.

Regional regulatory bodies or POCT committees should establish protocols for integrating proficiency testing into the training curriculum. These protocols should include setting intervals for testing, evaluating performance, and determining the appropriate corrective actions for any deficiencies identified.

10.3 Continuing Education and Skill Development:

Regular refresher training is necessary to keep knowledge and skills current, particularly when new devices are introduced or procedures change. Recertification may be required to reflect updates in technology, protocols, or best practices.

The frequency of refresher training and recertification should be determined by local regulatory authorities in coordination with Provincial and Territorial (P/T) POCT committees.

10.4 Standard Operating Procedure (SOPs)

SOPs are essential for consistent and reliable POCT. These should be readily available to users and aligned with manufacturer instructions and safety alerts.

SOPs should:

- Provide clear result interpretation guidance
- Outline steps for equipment malfunction or failure
- Be reviewed and updated regularly to reflect current best practices

Regional POCT committees may adapt SOPs to suit local needs, while centralized SOP development can help maintain consistency and ensure compliance with national standards.

11. DOCUMENTATION AND DATA INTEGRATION

Establishing a strong data documentation and integration framework is essential for ensuring accuracy, continuity of care, and system-wide data accessibility. Wherever possible, POCT devices should be integrated into Laboratory Information Systems (LIS/LIMS) and Hospital Information Systems (HIS).

11.1 Record keeping guidelines and Data recording

Standardized documentation procedures are critical for consistent and accurate recording of POCT results. *Appendix B* provides a sample Testing Result Reporting Form as a reference template.

Each test record should include at minimum:

- Date and time of test
- Test type and result (with units)
- Device and operator identification
- Patient identifiers

Clear protocols should define how and where data is entered into central systems when applicable.

11.2 Central reporting

Robust IT infrastructure is needed to support the electronic transmission of POCT results into Electronic Health Records (EHRs) and for reporting communicable disease results.

All POCT providers, including third-party vendors, primary care offices, and frontline healthcare settings, should include the following in their reports:

- Provider and site identification
- Specimen type and collection date
- Test performed and result codes
- Date of test performance

11.3 Electronic Health Record (HER) integration

Given the clinical importance of POCT results, comprehensive documentation is required. This includes:

- Test name, results, and reference intervals
- Units of measure
- Date/time of testing
- Device serial number and operator ID

POCT results must be clearly distinguished form central lab results to avoid confusion and ensure proper interpretation.

Integration Methods:

- **Manual Entry:** Suitable where digital infrastructure is limited; involves recording results directly onto paper of digital forms.
- **POCT Connectivity/Data Management Systems (DMS):** Enable automatic, bidirectional integration from various POCT devices into central systems (e.g., EMR, LIS, HIS). This streamlines data flow and supports traceability.

A combination of these methods may be used, depending on site capabilities and available resources.

Enhancing POCT Reporting: The Role of Infrastructure and Real-Time Data Integration

During the initial deployment of ID NOW in Ontario, there was a lack of infrastructure for directly reporting test results into the Ontario Laboratory Information System (OLIS). As a result, test results could only be reported if a partner lab agreed to submit them on behalf of the testing sites. To resolve this issue, Ontario Health's Digital Excellence in Health team developed the **Mobile Orders and Results Entry (MORE)** platform. This intuitive tool enables electronic reporting of ID NOW results into OLIS, streamlining the process and improving accessibility.

However, the initial focus on setting up testing capabilities, rather than robust reporting mechanisms, led to a significant gap in test result reporting—especially for sites that were onboarded before the MORE platform was introduced. This created challenges, particularly in Indigenous communities, where reporting remained low. To address this, sites that are now onboarding to ID NOW are integrated with the MORE system from the start, ensuring test results are recorded in real-time and minimizing delays in reporting.

Ontario's approach highlights the critical need to link POCT results to patient files and the importance of developing systems like MORE to facilitate seamless, real-time reporting. This model can be scaled to other jurisdictions, not only supporting clinical decision-making but also enhancing public health surveillance by ensuring that testing data is integrated into broader health information systems for improved health outcomes.

11.4 Adaptability and Oversight

Not all integration methods are suitable for every setting. Provincial and Territorial (P/T) POCT committees must evaluate site-specific needs, resources, and infrastructure to determine the most appropriate and effective documentation systems. Customization may be required to ensure efficiency and usability.

Regardless of method, all POCT results should be integrated into the patient's electronic medical record to support timely and informed clinical decision-making.

P/T health systems play a vital role in enabling this integration by:

- Ensuring system interoperability
- Aligning POCT data pathways with existing digital health infrastructure
- Removing barriers that may impede data access, care coordination, or patient safety

A standardized and well-supported documentation approach improves test reliability, reduces redundant testing, strengthens continuity of care, and contributes to population health monitoring.

12. EVALUATION

Evaluating a point-of-care testing (POCT) program is essential to ensure the quality, accuracy, and effectiveness of testing services. Regular evaluation helps identify gaps in performance, training, or workflow, allowing for timely improvements. It also ensures that patients are accurately diagnosed, appropriately linked to care, and that resources are being used efficiently. Ultimately, evaluation supports accountability, continuous quality improvement, and better health outcomes.

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Appendix A

POCT SITE APPLICATION FORM

GENERAL INFORMATION

ORGANIZATION NAME/ TESTING SITE

SITE IDENTIFICATION NUMBER
(If applying for the first time, a number will be assigned)

EMAIL

CONTACT PERSON/ SITE LEAD

NAME

POSITION

EMAIL

PHONE

ORGANIZATION ADDRESS

MAILING ADDRESS

CITY

CITY

PROVINCE

POSTAL CODE

PROVINCE

POSTAL CODE

TELEPHONE NUMBER

FAX NUMBER

TELEPHONE NUMBER

FAX NUMBER

FOR OFFICE USE ONLY

DATE RECEIVED:

IDENTFICATION NUMBER:

TYPE OF (HEALTHCARE) ORGANIZATION

- ☐ 01 Assisted Living Facility
- ☐ 02 Community Nursing Station
- ☐ 03 Community Health Center
- ☐ 04 Community-based event gathers
- ☐ 05 Dental Office
- ☐ 06 Family Physician office
- ☐ 07 Specialist office
- ☐ 08 Field hospital
- ☐ 09 Hospice
- ☐ 10 Mobile Health Clinic
- ☐ 11 Nursing Home
- ☐ 12 Pharmacy
- ☐ 13 Student Health Center
- ☐ 14 Sporting events
- ☐ 15 Other (Specify) _____

MULTI-SITE APPLICATIONS:

If you are applying for a single site certification to cover multiple testing location; details must be provided below:

SITE NO	TYPE OF FACILITY	POCT PERFORMED AT THIS SITE	CONTACT DETAILS

POC TESTING DETAILS

POC TESTING START DATE

EXPECTED QUANTITY OF POCT/ MONTH

NUMBER OF POC TESTING SERVICE PROVIDER

HAVE POCT PROVIDERS RECEIVED TRAINING/ ARE POCT PROVIDERS CERTIFIED

DOES THE SITE HAVE QUALITY CONTROL MEASURES IN PLACE?

☐ YES ☐ NO

HAS THE SITE ENROLLED IN PROFICIENCY TESTING (PT)

☐ YES ☐ NO

SCOPE OF POINT OF CARE TESTING:

SL No	SPECIALITY	AUTHORIZED SPECIMENS	TESTING EQUIPMENT
1	Respiratory	Throat swap	

LINKAGE TO CARE ☐ **YES** ☐ **NO**

If yes, please provide the name of the care facilities:

DECLARATION:

- I declare that I am authorised, on behalf of the organisation, to submit this application, and that the information contained herein is both correct and accurate to the best of my knowledge and belief.

PRINT NAME

SIGNATURE

POSITION

DATE

Appendix B

Point of Care Test Result Reporting Form

Facility Name	
Facility Adress	
Site Identification Number	
Phone Number	
Email Address	

PATIENT INFORMATION:

Family Name		**Given Name**	
Date of Birth (DD-MM-YYYY)			

Gender : □ Male □ Female □ Non-Binary □ Prefer not to say

TEST RESULT DETAILS:

Specimen Type: _____ Specimen Collection Date: _____

Date of Result: _____

NAME OF TEST	RESULT	REFERENCE VALUE	NAME OF PERSON PERFORMING TEST	DATE (DD-MM-YYYY)

COMMENTS/NOTES:

PRINT NAME

DATE

Appendix C

Comprehensive Checklist for Community-Based POCT Implementation	Yes	No	If no,
1. Assess Community Needs and Context			
• Has a community health needs assessment been conducted to identify prevalent health conditions (e.g., chronic diseases, infectious diseases, maternal and child health)?	☐	☐	If no, conduct a thorough assessment to determine local health priorities.
• Have available resources, including infrastructure, personnel, and technology, been evaluated to determine feasible POCT devices and services?	☐	☐	If no, assess local capacity and address gaps before implementation
• Have local stakeholders, such as elder, local health workers and community leaders, been engaged to align POCT with community health goals?	☐	☐	If no, establish partnerships and engage key stakeholders in planning discussions.
2. Select Appropriate POCT Devices and Tests			
• Have POCT devices been selected based on accessibility, affordability, and ease of use?	☐	☐	If no, evaluate available POCT devices and choose those suitable for the community.
• Have tests been prioritized based on the most prevalent health conditions in the community?	☐	☐	If no, reassess disease burden and select relevant POCT tests accordingly.
3. Ensure Staff Training and Competency			
• Are community POCT providers enrolled in training programs on device usage and sample handling?	☐	☐	If no, ensure staff are enrolled in a training program.
• Are ongoing competency assessments and refresher courses in place to maintain staff skills, especially for new devices?	☐	☐	If no, implement a competency assessment schedule
• Have local champions been identified and trained to mentor others and ensure adherence to POCT protocols?	☐	☐	If no, identify key individuals and provide them with additional support
4. Establish Appropriate Quality Assurance (QA) System			
• Are Internal Quality Control (IQC) measures, such as daily device calibration and routine accuracy checks, in place?	☐	☐	If no, establish and document IQC procedures.

• Does the program participate in External Quality Assessment (EQA) programs, or has an inter-site sample exchange been set up?	☐	☐	If no, explore feasible EQA options
• Is there a peer review system for community health workers to compare results and enhance learning?	☐	☐	If no, implement a peer review mechanism.
5. Integrate POCT into the Community Healthcare Workflow			
• Have standard operating procedures (SOPs) been developed for sample collection and handling?	☐	☐	If no, develop and distribute SOPs to all relevant staff
• Are there clear reporting mechanisms for ensuring timely communication of results and integration into health records or referral systems?	☐	☐	If no, establish an efficient reporting system
• Is there a process in place to involve patients in their care, including initiating treatment or referring them for further diagnosis and management?	☐	☐	If no, implement a structured approach for patient follow-up and care.
• Is there a follow-up system for patients with abnormal test results?	☐	☐	If no, establish and track follow-up procedures.
6. Ensure Infection Prevention and Control (IPC) in Community Settings			
• Is tailored personal protective equipment (PPE) available for health workers and patients based on local infection risks?	☐	☐	If no, ensure adequate PPE supply and distribution.
• Are hand hygiene stations with alcohol-based sanitizers and soap/water available for proper handwashing?	☐	☐	If no, set up hygiene stations in testing areas.
• Is there a safe disposal system for medical waste, including sharps and used test materials?	☐	☐	If no, establish proper waste management protocols.
• Are routine environmental cleaning procedures in place, and is staff trained in proper sanitation practices?	☐	☐	If no, implement cleaning protocols and provide training.
7. Implement Patient Protection and Safety Protocols			
• Are sterile, single-use supplies available, and is safe disposal ensured after use?	☐	☐	If no, ensure procurement and training on safe disposal.
• Are patients educated on the POCT process and related safety protocols?	☐	☐	If no, implement patient education sessions

• Are special precautions in place for vulnerable populations, such as immunocompromised individuals, pregnant women, and children?	☐	☐	If no, develop targeted protection measures.
8. Monitor POCT Performance and Take Corrective Actions			
• Is data collected on POCT usage, challenges, and overall program performance?	☐	☐	If no, establish a data collection and reporting framework.
• Is there a process for addressing issues such as failed tests or equipment malfunctions?	☐	☐	If no, create and implement a corrective action plan.
9. Ensure Sustainability and Long-Term Impact			
• Are there plans in place to sustain POCT services, including training local health workers and securing long-term resources?	☐	☐	If no, develop a sustainability strategy.
• Are regular evaluations conducted to assess the effectiveness of the POCT program and inform improvements?	☐	☐	If no, schedule and perform regular evaluations.
• Is there community ownership and involvement to integrate POCT into the healthcare system and align with long-term health goals?	☐	☐	If no, engage the community through education and participation programs.
10. Secure Adequate Funding and Financial Resources			
• Has funding been secured to support POCT implementation and sustainability?	☐	☐	If no, identify potential funding sources, including government programs, grants, and partnerships.
• Are financial resources allocated efficiently to cover equipment, training, and operational costs?	☐	☐	If no, create a budget plan to ensure sustainable financial support for POCT services.
• Have stakeholders and funding agencies been engaged to ensure continued financial support?	☐	☐	If no, establish partnerships and advocacy efforts to secure long-term funding.