Non-Traditional STBBI Testing by Regional Public Health Teams

Final

Provincial Population & Public Health Guideline

Communicable Disease, Regional and Clinical Supports, Population and Public Health

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Contents

1. Abbreviations

Ab	Antibody
CPL	Cadham Provincial Laboratory
DBS	Dried blood spot
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
NML	National Microbiology Laboratory
POC	Point of care
RNA	Ribonucleic acid
STBBI	Sexually transmitted and blood-borne infections

2. Purpose

This document provides guidance and defines standards for the use of non-traditional sexually transmitted and blood-borne infections (STBBI) testing technologies by regional public health teams. Non-traditional STBBI testing in this document includes point of care (POC) tests and dried blood spot (DBS) collection.

Traditional serologic laboratory based STBBI testing is considered the gold standard; however, there are situations where alternative or non-traditional STBBI test modalities can offer unique benefits and enhance equity in access to initial STBBI screening, diagnosis, and expedited care. Laboratory-based testing is still required for confirmatory results and follow-up care, and in special populations (e.g., transplant, pediatric).

3. Scope

This document is intended to define and direct to standards that guide the use of non-traditional STBBI testing by regional public health teams. Only STBBI that can be detected through blood testing by current technologies are covered in this document (e.g., Human Immunodeficiency Virus [HIV], viral hepatitis, syphilis). This guidance applies whether public health is supporting a collaborative STBBI testing initiative, or operating a public health-led testing program.

POC is a form of testing in which the analysis is performed close or near to where healthcare is provided to the patient/client. Test devices or technologies that are not approved by Health Canada, or outside of Health Canada approved indications (e.g., devices used for or as part of research), are not covered in this guideline.

The information provided herein is not a substitute for training and competency assessments provided by laboratory specialists, nor is it intended to be used to start a non-traditional testing program/service without quality oversight.

Guidance on self-tests is not covered in this document. Self-test specimens are generally collected and the test performed by the client, rather than in a care encounter. Self-tests differ in that only inventory management/tracking, quality control, and client guidance is required by a distributing health care facility/organization, and a health care professional is not currently required for oversight of the program/site. Public health program guidance for distribution of HIV self-test kits is available at: https://www.gov.mb.ca/health/publichealth/staff-docs.html

4. Background

Reported rates of STBBI have been on the rise for the last decade in Canada, and a significant number of people remain undiagnosed[1]. Many populations impacted by STBBI experience barriers to testing due to stigma, structural disadvantage, and distrust with systems. STBBI prevention strategies can be significantly enhanced through the implementation of new and innovative STBBI testing modalities, as testing is often the gateway to the continuum of prevention, treatment, and care. Testing is critical to reduce the risk of long-term health effects for some STBBI and to prevent onward transmission. New technologies that simplify testing or diversify test settings can increase accessibility and are supported by the Government of Canada's Sexually Transmitted and Blood-Borne Infections (STBBI) Action Plan 2024-2030[2].

5. Public Health Recommendations: Use of Non-Traditional STBBI Tests

STBBI testing by public health is focused on efforts to support sexual health equity by increasing testing options for structurally disadvantaged and underserved populations at increased risk for STBBI or related harms, STBBI onward transmission, and others who may be epidemiologically linked to STBBI outbreaks.

STBBI testing programs are grounded in the principles of cultural safety, sex positivity, gender-based rights, trauma and violence informed care, harm reduction, and should serve to promote autonomy and build trust.

All STBBI testing initiatives using non-traditional testing technologies are informed by epidemiological information, community consultation, and best available evidence to ensure that technology suits the needs and priorities of the population served.

Dried Blood Spot Testing may be considered:

- Where phlebotomy or laboratory access is a significant challenge
- For clients with difficult venous access
- Where there may be delays in the transport of venous blood samples that compromise the sample integrity
- Where it may be beneficial to have the sample collected by a person who is not the testing practitioner (e.g., trained outreach providers who are connected to the community being served)
    - Note that the testing practitioner is responsible for receipt of and delivery of test results to the person tested AND
    - DBS lab testing services and support must be established and coordinated with the respective laboratory before sample collection can begin. DBS testing is not amenable to large scale laboratory support.

Point-of-Care STBBI Tests may be considered:

- Where rapid access to results may support needed immediate notification, expedited treatment, and linkage to care (e.g., during late pregnancy that has been lacking prenatal care, labour and delivery units, high risk emergency departments, correctional facilities)
- Where health care providers work with highest priority clients who have significant barriers to care or who are difficult to locate for follow-up care/treatment and provision of test results. The setting must be able to accommodate appropriate follow up (e.g., access to confirmatory testing and expedited treatment). Settings may include:
    - Outreach settings
    - Clients experiencing unstable housing or systemic distrust
    - Populations living rural or remote with lack of access to transportation or phone
    - In-reach to incarcerated people
- For assessment and care related to HIV post-exposure prophylaxis in the context of occupational or assault exposures (e.g., for rapid assessment of a source individual identified in an exposure). POCT does not replace conventional and legally appropriate testing in such circumstances. For more information see Post

Exposure Prophylaxis for HIV, HBV and HCV: Integrated Protocol for Managing Exposures to Blood and Body Fluids in Manitoba
https://www.gov.mb.ca/health/publichealth/cdc/protocol/pep.html

6. Test Ordering and Scope of Practice

Under the *Regulated Health Care Professions Act*[3]*, "*ordering or receiving reports of screening or diagnostic tests" is *Reserved Act #2*. The conditions under which regulated health care professionals may order screening and diagnostic tests are defined in the general regulations of the respective professional regulatory body. Professional regulatory bodies may also define the standards of care related to test ordering.

Tests ordered for processing at approved Manitoba laboratories (Shared Health Diagnostic Services laboratories or private laboratories) require a registered and authorized ordering practitioner (e.g., physician, nurse) on samples and requisitions received.

Dried blood spot (DBS) tests for STBBI are collected in the field but processed in a laboratory, and therefore require an authorized and registered testing practitioner on the requisition/sample. Collection of the DBS blood samples may be delegated to any appropriately trained individuals.

Point of care (POC) tests may be performed in various settings outside of a clinical laboratory, which provides an expanded scope of use. For physicians and regulated nurses, POC tests are in the scope of practice so long as employer (including facility or regional) policy supports the practice, and the individual practitioner is competent to perform, interpret, communicate the POC test result or diagnosis, and follow up appropriately. Employer policy may also have other conditions of quality programming that practitioners must be aware of.

Collection of the biological sample for POC testing needs to be consistent with employer policy and the practitioner's scope of practice. For example, a finger prick for blood collection is not a reserved act, and therefore can be performed by any appropriately trained individual.

Scope of practice does not necessarily imply that professional licensure, professional liability insurance or organizational accreditation structures and liability insurance fully support the activity. Practitioners and organizations must consider their due diligence before conducting non-traditional practices.

7. Laboratory-Based STBBI Tests

Conventional or traditional STBBI testing in Manitoba is conducted according to the Cadham Provincial Laboratory (CPL) Guide to Services[4] https://healthproviders.sharedhealthmb.ca/files/guide-to-services.pdf and are considered the gold standard for STBBI testing and diagnosis as the test methods provide the best available information to inform treatment and other care.

Laboratory-based tests for STBBI provide confirmatory results, and reporting of reactive or positive results to the Manitoba Health Surveillance Unit, as required under the *Reporting of Diseases and Conditions Regulation*[5], is routinized. Traditional laboratory STBBI testing and DBS testing are processed in a specialty laboratory. It can take up to one or two weeks to receive the confirmed results from laboratory-based testing on blood samples.

7.1 Dried Blood Spot (DBS) Testing

Dried blood spot (DBS) tests are performed on capillary blood samples obtained from a finger prick (in adolescents and adults), collected and applied to filter paper cards designed and verified explicitly for this purpose. The test cards are dried, labelled as required by the laboratory, packaged and shipped to CPL. For STBBI testing, CPL forwards the test cards to the National Microbiology Laboratory (NML). Samples are tested at the NML under an ISO 15189 accredited quality management system. Results are reported back to CPL within two weeks from the date of receipt.

7.1.1 Advantages and Limitations of DBS

DBS has several benefits over traditional STBBI testing modalities. Firstly, the sample does not require phlebotomy, and may be collected by a healthcare provider, paraprofessional / lay providers, peers, or collected by the client themselves. Even where phlebotomy is available, DBS may be useful for people with difficult venous access. Studies have demonstrated that the DBS samples collected by clients themselves are of the same quality as those collected by health care providers[7]. Studies where DBS has been implemented has demonstrated increased hepatitis C testing uptake and diagnosis[8]. Finally, the testing cards are relatively inexpensive and easy to ship and distribute. Once dried, and packaged, filter paper samples can be stored at room temperature in a Bitran bag with a humidity indicator card and desiccant to control humidity for up to 7 days from time of collection, thus they can be utilized in remote areas in which there may be delays in shipping completed cards to the laboratory.

Currently, DBS test cards can be used to test for HIV, hepatitis C, and syphilis. The DBS sample is submitted with a CPL requisition detailing which specific tests are requested

(see Appendix A for sample requisition). If enough sample is collected to perform RNA testing, results from HIV and hepatitis C DBS tests are considered confirmatory of infection. Manitoba is the first province to recognize DBS RNA results for HIV (as of February 2020), and hepatitis C (as of December 2022) as confirmatory, satisfying the Manitoba case definitions in the Manitoba Communicable Disease Protocols for HIV and hepatitis C. Accordingly, positive results for hepatitis C and HIV are reported through CPL to the Manitoba Health Surveillance Unit, and assigned to the appropriate regional public health unit.

There are also limitations to consider with DBS sample collection and testing programs. DBS provides screening results for syphilis only (Bio-Rad syphilis Total Ab) so further testing, client history, and exam are required for syphilis diagnosis and staging. DBS testing for syphilis cannot distinguish between a new or previous (already treated) syphilis infection. DBS also cannot distinguish between syphilis or non-venereal treponemal infections such as yaws, pinta, or bejel. Therefore, DBS has limited value for people who have already been exposed to syphilis or other treponemal infections, or with populations where treponemal infection rates are relatively high.

The ordering testing practitioner must deliver the test result, and if removed from sample collection, may involve communicating with an individual they have not developed a rapport or care relationship with yet. Verification of client information in outreach settings may be challenging, or not possible. If the person collecting the sample does not collect the accurate registered full name, date of birth, or other two unique identifiers of the person tested, the lab results will be assigned to a newly created “indeterminate client”, not flow to eChart, and may take additional efforts to correctly identify the individual. In these cases, sharing of results and appropriate follow up/linkage to care with the individual may not be possible, especially if accurate contact information (phone, address, mailbox) is not collected at the time of testing.

7.1.2 Considerations for Service Delivery

There are some important practical considerations in the implementation of DBS initiatives by regional public health teams. First, there may be limited opportunity to develop a care relationship between the person being tested and the practitioner ordering the test (on the sample/requisition) who is responsible for communicating the results and coordinating follow up. Further, the person distributing test materials or collecting the sample may not be a trustee of the test results or any other health information on the person being tested, especially if not a health professional or an established part of a health professional team.

Regional public health DBS testing programs must establish procedures for quality of care and quality assurance, and work collaboratively with the medical site lead (e.g.,

regional Medical Officer of Health) to determine how the testing program will operate and be overseen.

While there is overlap between the concepts of quality of care and quality assurance, quality of care encompasses service delivery activities that enhance health outcomes and comply with professional scope of practice and professional and organizational standards. Quality assurance includes a range of operational activities that enable DBS testing programs to achieve and maintain high levels of technical reliability, accuracy and proficiency in the test process. Quality assurance standards and criteria for testing sites may be determined by the supporting clinical laboratory, and can be anticipated to be designed to adhere to applicable accreditation requirements.

7.1.3 Quality of Care Standards for DBS

Quality of care refers to service delivery activities that enhance health outcomes and comply with professional scope of practice and professional and organizational standards. Regional public health teams who are operating STBBI DBS testing programs must, at a minimum:

- Adhere to their employer and profession's standards of practice and expectations.
- Follow accreditation standards for their organization
- Practice within their scope
- Follow their organizational policies and procedures such as (but not limited to):
    - infection prevention and control, personal protective equipment (PPE) donning and doffing, and routine practices such as hand hygiene
    - confirming client identity, documentation and maintenance of health records according to the *Personal Health Information Act*[9] (PHIA)
- Ensure all staff (including peers or volunteers involved in sample collection) are trained in quality assurance procedures for DBS testing
- Establish client eligibility criteria for DBS testing
- Ensure that staff have undergone hands on training for DBS sample collection, labelling, packaging, and transportation through the NML, and can provide a valid certificate (requires annual renewal)
- Ensure certified staff have access to NML's regularly updated manual and training video for reference
- Ensure staff have taken an online PHIA course and can provide a valid certificate
- Ensure staff have knowledge of STBBI, including but not limited to;
    - taking a focused sexual health, blood borne infection risk and relevant treatment history

  - providing information about the test, including standardized education if the person performing the test is not a health care professional, and how and when the individual can access their test results
  - obtaining and documenting informed or implied consent for the DBS test
  - knowledge about other concerns and services that a client may have and need
  - specimen labeling consistent with CPL requirements (two unique identifiers consistent with the person's health registration), and collection of locating information to ensure follow up and linkage to care is enabled.
- Ensure a plan for health care providers to communicate results and be prepared to support the needs of a client receiving a reactive result, including situational counselling.
- Ensure a clear pathway to connect service recipients with follow up or care appropriate to the STBBI test result (see Manitoba Communicable Disease Protocols for Hepatitis C, HIV, and Syphilis).
- Ensure a plan to submit client blood specimens to the referral lab for appropriate confirmatory testing if required (for syphilis results and indeterminate HIV or HCV results). Document in PHIMS, including treatment provided. If not able to document in PHIMS, complete Provider Report Form as appropriate https://www.gov.mb.ca/health/publichealth/surveillance/docs/mhsu_6781.pdf
- Document results and client visit as required, and/or ensure providers have instruction for appropriate documentation. Consider the development of a script and/or checklist if sample collection is performed by non-health care providers.

In developing a DBS testing program in partnership with community organizations, peers, or para-professionals, there are important considerations. Each public health team offering DBS testing requires a service delivery guideline that clearly describes:

- Who is going to collect the sample? NML provides DBS training/certification. If the individual is not a health care provider, confirmation that the individual has received DBS training/certification that is up to date (including ongoing re-certification). Collectors must also be trained in quality assurance procedures and management of personal health information and other requirements of PHIA.
  - If sample collection is performed by non-health care providers or peers, consider how the sample collector can access health care provider support if issues arise in the field.
- How the testing provider (ordering provider on the sample/requisition) will manage receipt of the results, and who will be communicating the results to the client. Pathways to further follow-up and care should be pre-established (e.g., primary care, referrals for HIV/HCV treatment).

- How informed or implied consent is obtained for DBS testing. Collectors must follow standardized processes to confirm client identity (e.g., two unique identifiers), and should be trained to follow standardized client education.
- How the individual's privacy is ensured before, during, and after specimen collection and testing
- What, if any, health history or information is collected from the person being tested, and where health records will be stored and transferred/communicated to the health care provider according to the *Personal Health Information Act.*
- For peer or outreach events - communication between the collection site/collectors on when the testing will occur, and a summary of the tests submitted after the event is completed. This will ensure the health care/test ordering provider is aware of and approves of the plan, volume of testing occurring, and confirms capacity and the plan to follow-up with results.
- How test results (both positive and negative) will be communicated to the person being tested, including providing a direct contact (e.g., phone number) for clients who are seeking test results
- How clients are informed that positive test results are automatically referred to public health

7.1.4 Quality Assurance for DBS

Quality assurance for DBS includes operational activities that enable DBS testing programs to achieve and maintain high levels of reliability, accuracy and proficiency in test processes that comply with laboratory and accreditation determined standards and criteria.

The supporting clinical laboratory (e.g., [NML]) will review all requests for DBS testing programs and events, and support required elements of a DBS testing program.

- The process to obtain testing materials from the laboratory should be established.
- A DBS testing program requires a clinical lead, generally a Medical Officer of Health for regional public health teams.
- The DBS testing site or program must ensure that the testing materials are kept under recommended conditions, including in outreach settings.
- An inventory management system must be in place to ensure stock is rotated and waste due to expiry of materials is minimized.
- Procedures and staff training for specimen collection, handling, packaging, and transportation of DBS samples to the lab must be established with a plan for maintaining competency. Generally, STBBI DBS samples are exempt from *Transportation of Dangerous Goods*[6] regulation requirements.

8. Non-Laboratory STBBI Testing

8.1 Point-of-Care STBBI Tests

There are Health Canada approved STBBI tests that can be processed outside of laboratory settings. Point-of-care (POC) testing is defined as a medical diagnostic or screening test performed outside of the clinical laboratory, in proximity to where the patient is receiving care. POC testing is performed by trained personnel who are non-laboratory staff, on simpler devices that are often hand-held or portable. While the test may be performed by any appropriately trained personnel, the results of STBBI POC must be delivered by a health care provider. All required pre and post-test counselling guidelines must be followed in each setting in which the tests are used. In this document, pre and post text counselling is articulated in terms of a focused client health history; informed consent including discussion of risks, benefits, and limitations of the test; communication of test results and implications; and connection to care appropriate to the STBBI POC test result(s).

Tests performed outside of the clinical laboratory require follow-up confirmatory testing performed in a laboratory. Syphilis POC testing has specific limitations as syphilis diagnoses and staging are informed by clinical and treatment history, physical assessment, and laboratory test results including semiquantitative results which are not provided by the currently available syphilis POC tests[10].

STBBI POC tests that are approved for use by health care professionals require clinical oversight or support for implementation in the field. The following general considerations for service delivery and quality assurance should be considered when implementing a POC STBBI testing program.

8.1.1 Considerations for Service Delivery

Regional public health teams or programs offering STBBI POC tests approved for use under clinical environments require appropriate clinical leadership. Clinical leadership is generally provided by a regional Medical Officer of Health, but alternatively the clinical lead could be any of the following:

- A licensed medical physician with diagnostic/laboratory experience and training
- A clinical scientist who holds a PhD in a biomedical field and has relevant clinical laboratory training (e.g., Clinical Biochemist, Clinical Microbiologist, Biochemical Geneticist, etc.)

- Another suitably-qualified healthcare professional with the appropriate professional, scientific and educational qualifications to verify and maintain day-to-day quality of POC testing, and communicate with other health providers or regulators on any or all related health issues

Health Canada approves companies to seel test devices for proven uses and ensures they are appropriate for the purpose and population served. Any use of POC tests outside of Health Canada approved use is generally not supported (by Health Canada, the manufacturer, or insurers) outside of well-contained pilot or research applications (with enhanced quality care and assurance procedures), and likely requires direction and approval by the clinical leadership.

Both quality of care *and* quality assurance considerations must be addressed in developing a POC testing program. A program or site-specific procedure for each is recommended.

8.1.2 Quality of Care Standards for POC

Quality of care broadly includes service delivery activities that enhance health outcomes and comply with professional scope of practice and professional and organizational standards.
Regional public health teams (HCPs) who are operating STBBI POC testing programs must:

- Adhere to their profession's standards of practice
- Practice within their scopes
- Follow their organizational policies and procedures such as, but not limited to:
    - infection prevention and control, personal protective (PPE) equipment donning and doffing, and routine practices such as hand hygiene
    - confirming client identity, documentation and maintenance of health records according to PHIA
- Ensure all staff are trained in quality assurance procedures for POC testing, including how to identify and address non-conformances
- Establish client eligibility criteria for POC testing
- Ensure all staff have been appropriately trained and deemed competent to perform POC testing
- Ensure staff have knowledge of sexually transmitted and bloodborne infections, including but not limited to;
    - taking a focused sexual health, blood borne infection risk, and relevant treatment history
    - providing information about the test, including standardized education if the person performing the test is not a health care professional
    - obtaining and documenting informed or implied consent for the POC test

- Ensure providers know how to interpret all possible POC test results according to manufacturer's instructions.
- Ensure there are health care providers available to communicate results, and staff are prepared to support the needs of a client receiving a reactive result including situational counselling. Post-test information should include recommendations for routine or follow testing, and STBBI prevention specific to the individual's STBBI risk (e.g., HIV PrEP)
- Ensure a clear pathway to connect service recipients with follow up or care appropriate to the STBBI test result (see Manitoba Communicable Disease Protocols for Hepatitis C, HIV, and Syphilis)
- For positive syphilis results, have appropriate treatments available on-site, or a process for providing treatment with minimal delay.
    - Ensure providers have access to PHIMS or eChart to provide information on previous syphilis test results and treatment records.
    - Ensure an anaphylactic kit and competent users available during medication administration
    - All publicly funded STI treatment administered at the point of care by public health providers should be entered directly into PHIMS (either in a disease investigation or a provider form investigation) OR reported to Manitoba Health Surveillance Unit using the **Provider Report Form of Sexually Transmitted and Blood-Borne Infections (STBBI) and STI Treatment** https://www.gov.mb.ca/health/publichealth/surveillance/docs/mhsu_6781.pdf
        - This reporting ensures the STI treatment information will flow to eChart.
- Ensure that POC testing is offered with concurrent ability to collect and submit the client's blood specimen for appropriate confirmatory testing. This may include either traditional STBBI testing with samples obtained from phlebotomy, or confirmatory testing with DBS samples (for HCV and HIV only) if phlebotomy is unavailable.
    - Each site must have a plan for reporting reactive STBBI test results when confirmatory/laboratory-based testing is not completed by the client. Use the **STBBI Case Report Form for Point of Care/Rapid Testing** https://www.gov.mb.ca/health/publichealth/surveillance/docs/mhsu_4487.pdf
- Document results and client visit as required, and/or ensure providers have instruction for appropriate documentation

8.1.3 Quality Assurance for POC Testing

Quality assurance in the context of POC tests encompasses operational activities that enable POC testing programs or sites to achieve and maintain high levels of reliability,

accuracy, and proficiency in test processes and comply with laboratory standards and criteria.

Each regional public health team offering non-laboratory testing requires procedures for quality assurance. This should include a consideration of the following:

- Clinical oversight and role definition of team members
- Inventory management and storage:
    - estimates to inform ordering volumes
    - tracking lot numbers/expiry and rotation of stock to avoid wastage
    - environmental control of test storage conditions, including when tests taken into the field
    - a plan for how to manage excursions to recommended environmental conditions
- Quality control test material storage (reference samples), handling and use if applicable. In some cases, centralized quality control testing of POC lots may be performed by CPL
- Staff training, ongoing competence and proficiency testing for sample collection, test performance, and test interpretation
- Maintenance of full process documentation is generally required, including
    - Maintenance of records for staff training and ongoing competency are required
    - Proficiency testing (the evaluation of practitioner performance against established criteria)

See Resources at https://healthproviders.sharedhealthmb.ca/forms/point-of-care-testing-training/#578-579-sops-and-forms and Shared Health Diagnostic Services, Point of Care Testing Policy (Document #100-140-06). *https://sharedhealthmb.ca/wpfd_file/point-of-care-testing-poct-policy/*

For additional considerations related to quality assurance and oversight and accreditation standards, see Appendix B.

9. Evaluation

Regional public health teams engaged in or overseeing a non-traditional STBBI testing service should establish the following elements of evaluation when launching or providing service:

- Inventory and program monitoring:
    - number of kits ordered, number used with clients, number wasted or expired, number used for quality assurance testing (if required)

    - number of reactive/positive and indeterminate tests, or percent positivity among population tested.
- Staff training and competency, completion of confirmatory testing
- Client experience or encounters
- Qualitative feedback from staff delivering the service

To structure an evaluation, regional public health teams may require the creation of additional tracking forms or procedures to be built into the service delivery guideline.

10. Procurement of Testing Kits and Materials

10.2 Dried Blood Spot Testing

All DBS initiatives are established in partnership with CPL and the National Microbiology Laboratory. Procurement of testing supplies, training, and coordination of sample submission must be arranged in consultation with these laboratories. Regional public health teams interested in pursuing DBS programs or events may contact: NML_DBS-LNM_GSS@phac-aspc.gc.ca to inquire.

10.3 Point of Care Testing

Shared Health Diagnostics and Cadham Provincial Laboratory supports the use of laboratory-validated POC kits approved for use in Manitoba, once program approval, training, and competencies are signed off. Programs and sites intending to provide POC STBBI testing are advised to perform a cost analysis of the proposed service, considering the funding required for kits, materials and consumable supplies. Testing supplies are most often purchased through RHA or Public Health budgets, depending on the type of program.

Information regarding ordering (e.g., vendor, validated lot numbers, and SAP numbers to order) will be provided to sites **after training is completed** and competencies are signed off.

Regional public health teams may be asked to partner with organizations who have procured POC tests through other means, however these would then fall outside of the quality frameworks already established and regions may be responsible for the fullness of the program conduct without Shared Health-CPL support. Regional public health teams should focus involvement on Health Canada approved POC devices supported by provincially-approved laboratory backed systems.

11. Resources

Title	Resource
Health Canada Medical Device Active License Listing	https://health-products.canada.ca/mdall-limh/?lang=eng
Accreditation Canada POCT QMentum Program	https://store.accreditation.ca/products/point-of-care-testing
Manitoba Quality Assurance Program (MANQAP)	https://www.cpsm.mb.ca/accredited-programs/the-manitoba-quality-assurance-program-manqap-1
Pan-Canadian STBBI Framework for Action (2018)	https://www.canada.ca/en/public-health/services/infectious-diseases/sexual-health-sexually-transmitted-infections/reports-publications/sexually-transmitted-blood-borne-infections-action-framework.html
Public Health Agency of Canada STBBI Prevention Guide: Screening and diagnostic testing	https://www.canada.ca/en/public-health/services/infectious-diseases/sexual-health-sexually-transmitted-infections/canadian-guidelines/stbbi-prevention-guide/screening-diagnostic-testing.html
Canadian Society of Clinical Chemists Position Statement on Point-of-Care testing	Clinical Biochemistry 53(2018): 156-159 https://pubmed.ncbi.nlm.nih.gov/29395090/
Quality Assurance Practices for Point-of-Care Testing Programs: Recommendations by the Canadian Society of Clinical Chemists	Clinical Biochemistry 88(2021): 11-17 https://pubmed.ncbi.nlm.nih.gov/33264650/
Shared Health Diagnostic Services, Point of Care (POC) Testing Policy (Document #100-140-06).	SH Health Providers Website https://sharedhealthmb.ca/wpfd_file/point-of-care-testing-poct-policy/
Cadham Provincial Laboratory Guide to Services	https://healthproviders.sharedhealthmb.ca/files/guide-to-services.pdf
Manitoba STBBI Case Report Form for Point of Care/Rapid Testing	https://www.gov.mb.ca/health/publichealth/surveillance/docs/mhsu_4487.pdf
Post Exposure Prophylaxis for HIV, HBV and HCV: Integrated Protocol for Managing Exposures to Blood and Body Fluids in Manitoba	https://www.gov.mb.ca/health/publichealth/cdc/protocol/pep.html

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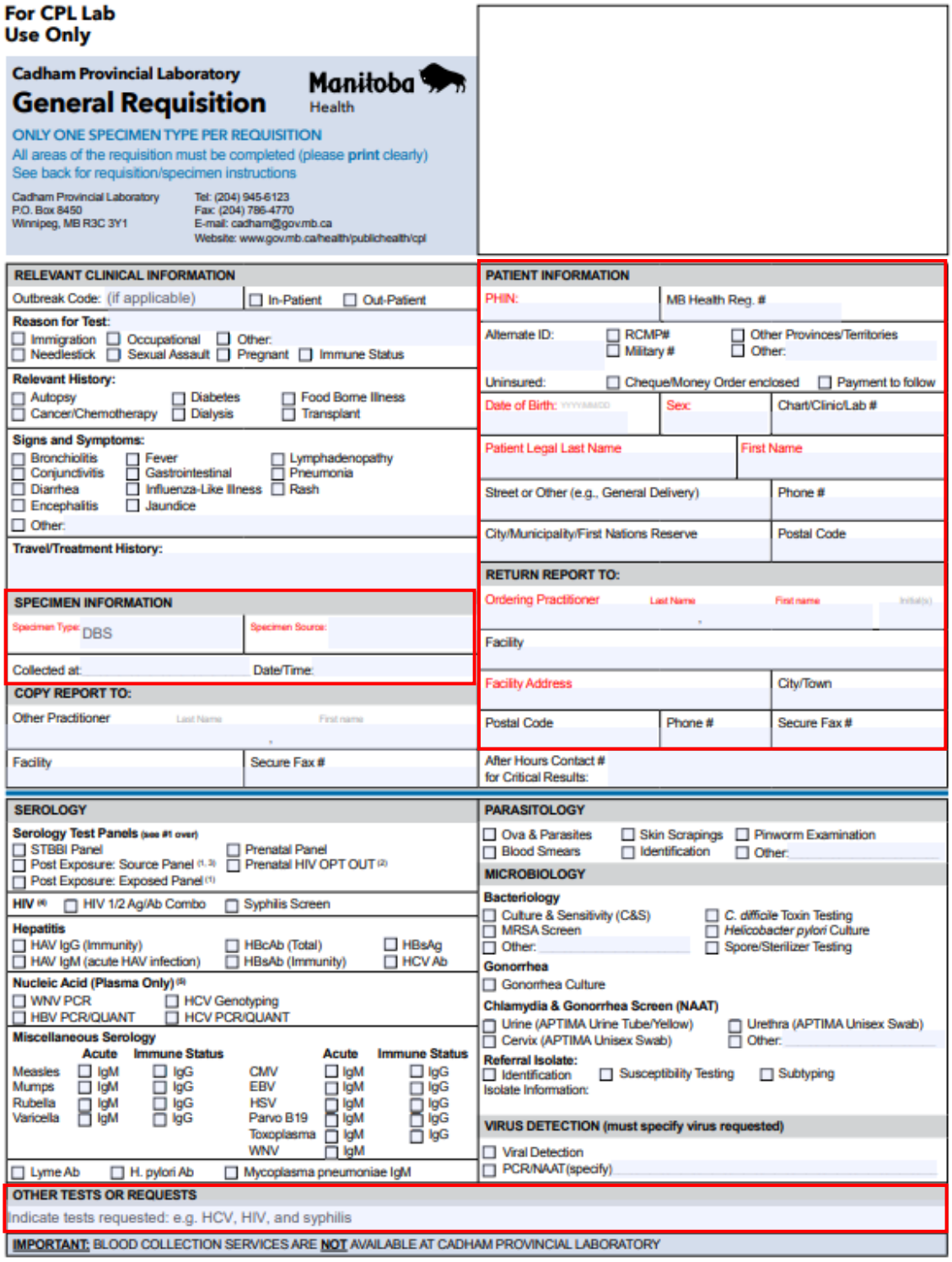
Appendix A - Sample CPL Requisition for DBS Testing

Required fields are boxed in red



For CPL Lab Use Only

Cadham Provincial Laboratory

General Requisition

Manitoba Health

ONLY ONE SPECIMEN TYPE PER REQUISITION
All areas of the requisition must be completed (please **print** clearly)
See back for requisition/specimen instructions

Cadham Provincial Laboratory
P.O. Box 8450
Winnipeg, MB R3C 3Y1

Tel: (204) 945-6123
Fax: (204) 786-4770
E-mail: cadham@gov.mb.ca
Website: www.gov.mb.ca/health/publichealth/cpl

RELEVANT CLINICAL INFORMATION

Outbreak Code: (if applicable) ☐ In-Patient ☐ Out-Patient

Reason for Test:
☐ Immigration ☐ Occupational ☐ Other:
☐ Needlestick ☐ Sexual Assault ☐ Pregnant ☐ Immune Status

Relevant History:
☐ Autopsy ☐ Diabetes ☐ Food Borne Illness
☐ Cancer/Chemotherapy ☐ Dialysis ☐ Transplant

Signs and Symptoms:
☐ Bronchiolitis ☐ Fever ☐ Lymphadenopathy
☐ Conjunctivitis ☐ Gastrointestinal ☐ Pneumonia
☐ Diarrhea ☐ Influenza-Like Illness ☐ Rash
☐ Encephalitis ☐ Jaundice
☐ Other:

Travel/Treatment History:

SPECIMEN INFORMATION

Specimen Type: DBS | Specimen Source:

Collected at: | Date/Time:

COPY REPORT TO:

Other Practitioner | Last Name | First name

Facility | Secure Fax #

PATIENT INFORMATION

PHIN: | MB Health Reg. #

Alternate ID: ☐ RCMP# ☐ Other Provinces/Territories ☐ Military # ☐ Other:

Uninsured: ☐ Cheque/Money Order enclosed ☐ Payment to follow

Date of Birth: YYYY/MM/DD | Sex: | Chart/Clinic/Lab #

Patient Legal Last Name | First Name

Street or Other (e.g., General Delivery) | Phone #

City/Municipality/First Nations Reserve | Postal Code

RETURN REPORT TO:

Ordering Practitioner | Last Name | First name | Initial(s)

Facility

Facility Address | City/Town

Postal Code | Phone # | Secure Fax #

After Hours Contact # for Critical Results:

SEROLOGY

Serology Test Panels (see #1 over)
☐ STBBI Panel ☐ Prenatal Panel
☐ Post Exposure: Source Panel (1, 3) ☐ Prenatal HIV OPT OUT (2)
☐ Post Exposure: Exposed Panel (1)

HIV (4) ☐ HIV 1/2 Ag/Ab Combo ☐ Syphilis Screen

Hepatitis
☐ HAV IgG (Immunity) ☐ HBcAb (Total) ☐ HBsAg
☐ HAV IgM (acute HAV infection) ☐ HBsAb (Immunity) ☐ HCV Ab

Nucleic Acid (Plasma Only) (5)
☐ WNV PCR ☐ HCV Genotyping
☐ HBV PCR/QUANT ☐ HCV PCR/QUANT

Miscellaneous Serology

	Acute	Immune Status		Acute	Immune Status
Measles	☐ IgM	☐ IgG	CMV	☐ IgM	☐ IgG
Mumps	☐ IgM	☐ IgG	EBV	☐ IgM	☐ IgG
Rubella	☐ IgM	☐ IgG	HSV	☐ IgM	☐ IgG
Varicella	☐ IgM	☐ IgG	Parvo B19	☐ IgM	☐ IgG
			Toxoplasma	☐ IgM	☐ IgG
			WNV	☐ IgM	

☐ Lyme Ab ☐ H. pylori Ab ☐ Mycoplasma pneumoniae IgM

PARASITOLOGY
☐ Ova & Parasites ☐ Skin Scrapings ☐ Pinworm Examination
☐ Blood Smears ☐ Identification ☐ Other:

MICROBIOLOGY

Bacteriology
☐ Culture & Sensitivity (C&S) ☐ *C. difficile* Toxin Testing
☐ MRSA Screen ☐ *Helicobacter pylori* Culture
☐ Other: ☐ Spore/Sterilizer Testing

Gonorrhea
☐ Gonorrhea Culture

Chlamydia & Gonorrhea Screen (NAAT)
☐ Urine (APTIMA Urine Tube/Yellow) ☐ Urethra (APTIMA Unisex Swab)
☐ Cervix (APTIMA Unisex Swab) ☐ Other:

Referral Isolate:
☐ Identification ☐ Susceptibility Testing ☐ Subtyping
Isolate Information:

VIRUS DETECTION (must specify virus requested)
☐ Viral Detection
☐ PCR/NAAT (specify)

OTHER TESTS OR REQUESTS
Indicate tests requested: e.g. HCV, HIV, and syphilis

IMPORTANT: BLOOD COLLECTION SERVICES ARE **NOT** AVAILABLE AT CADHAM PROVINCIAL LABORATORY

MG-696 (02/20)

Appendix B - Additional Considerations for Point of Care

Quality oversight by POC testing laboratory specialists is strongly encouraged. Sites will be expected to operate within the quality requirements of the Manitoba Quality Assurance Program (MANQAP), adjudicated by the College of Physicians and Surgeons of Manitoba (CPSM). This ensures consistency among various testing sites, and improves the quality of testing, and ultimately the quality of care for the client.

CPL supported sites must first be evaluated for their suitability for POC testing; after which they will be provided with training, protocols, and other resources to ensure the quality of testing.

Some essentials for the delivery of quality POC testing include:

- **Organization and Leadership**
  - Have the appropriate clinical leaders been identified to direct the POC program?
  - Is there a formal quality management team or selected individuals responsible to maintain the quality of the POC testing program?
  - Does the site have access to a POC resource person for technical and operational advice?

- **Personnel**
  - Are there adequate personnel to collect the sample, perform and interpret the results of POC testing?
  - What are the plans to ensure the personnel maintain their competency to perform POC testing?

- **Documentation**
  - Are there clear policies regarding information management, including the storage and reporting of patient results?
  - Can important documents be made available at the point of work?
  - Can sensitive documents be stored in a secure manner?

- **Facilities**
  - Are the candidate facilities appropriate for POC testing?
  - Is adequate storage present at the POC testing site?
  - Can devices, reagents, and consumables be stored and monitored in an accurate and reliable way?
  - Is the site set up to communicate results and perform further testing/treatment, ensuring privacy and safety?

- **Inventory**

  - Are one or more individuals at the candidate POC testing site able to maintain the required inventory? This includes monitoring reagent and quality control material storage conditions, test kit expiry dates, and overall utilization/test volume.

- **Quality Control Testing**
  - How is internal quality control testing of test kits accomplished: centrally by the supporting laboratory for each lot number or by each site/program on receipt of a new lot?
  - POC kits must be checked regularly to ensure that they are performing properly. If quality control testing is performed by each program/site, the program/site must determine:
    - Procurement and storage of quality control test materials
    - Indications, frequency, oversight, and record keeping for quality control testing, including the procedure for management of unacceptable quality control test results
  - All available staff involved in POC testing should be encouraged to participate in internal quality control testing as an opportunity for maintaining competence at test interpretation

- **Safety of Personnel Performing POCT and Individuals Being Tested**
  - Are samples being collected in a secure and safe manner?
  - Are all specimens, testing devices, and other consumables able to be discarded in a safe manner?
  - Can the privacy of clients be ensured during all stages of testing and follow-up?
  - Are there processes in place to identify and correct process non-conformances?

- **Test or Device Selection**
  - Is the selected test suitable for the POC testing program (e.g., screening, diagnostic, monitoring)?
  - Is the test's analytical performance fit-for-purpose?
  - Are there clear selection criteria for performing POC testing for an individual?
  - Are there known limitations to the test? Interferences that may affect test results?

- **Proficiency Testing**
  - Are there any third-party external proficiency testing (EPT) programs available to assess the quality of the POC testing program?

- Some examples of EPT Providers include:
  - The Institute for Quality Management in Healthcare (IQMH) https://iqmh.org/Proficiency-Testing/Catalogue#ptcatalogue
  - The College of American Pathologists (CAP) https://www.cap.org/laboratory-improvement/catalogs-ordering-and-shipping

Further information regarding quality standards for POC testing can be found through accreditation organizations:

Accreditation Canada POCT QMentum Program
https://store.accreditation.ca/products/point-of-care-testing

Manitoba Quality Assurance Program (MANQAP)
https://www.cpsm.mb.ca/accredited-programs/the-manitoba-quality-assurance-program-manqap-1