



Public Health  
Agency of Canada

Agence de la santé  
publique du Canada

Canada

# Supporting Decentralized STBBI Diagnostics

*Lowering barriers without compromising quality*

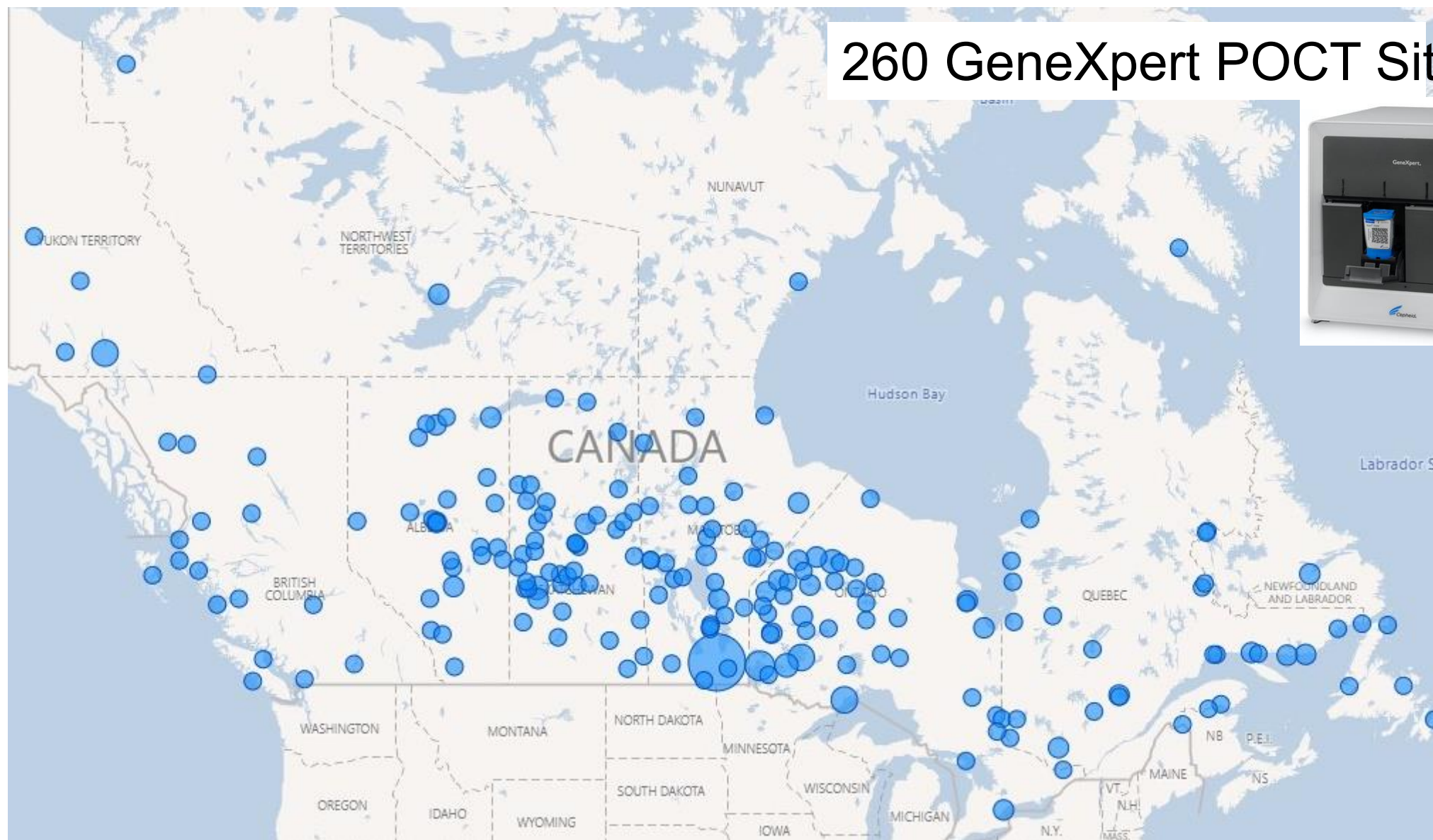
The National Microbiology Laboratory

PROTECTING AND EMPOWERING CANADIANS  
TO IMPROVE THEIR HEALTH



# GeneXpert POCT Capacity

260 GeneXpert POCT Sites





# Community Leadership/Staying in Our Lane

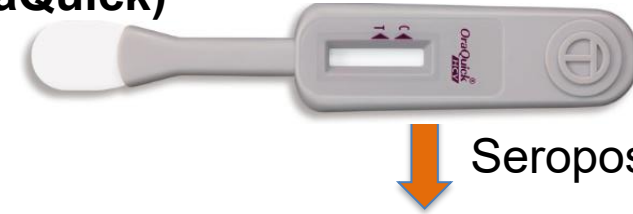


# Present, Future

## Development of Community-Based Testing for HCV

### 1. Screen: Health Canada approved rapid antibody test (OraQuick)

- Negative HCV antibody testing (1-20 minutes)
- Positive HCV antibody testing (1-5 minutes)



Seropositive

### 2. Molecular test: Xpert HCV VL Fingerstick Assay

#### Quantitative Assay

- Intended Use: Aid in Diagnostics and Management of patients undergoing antiviral therapy
- Supports Adherence Counselling
- Results in 60 minutes
- Enables diagnosis and treatment in a single visit
- Increases testing acceptability
- Decreases loss to follow-up
- Good technical accuracy (100% sensitivity/specificity)
- LOQ 100 IU/mL



# QASI® External Quality Assessment Program for NRI sites

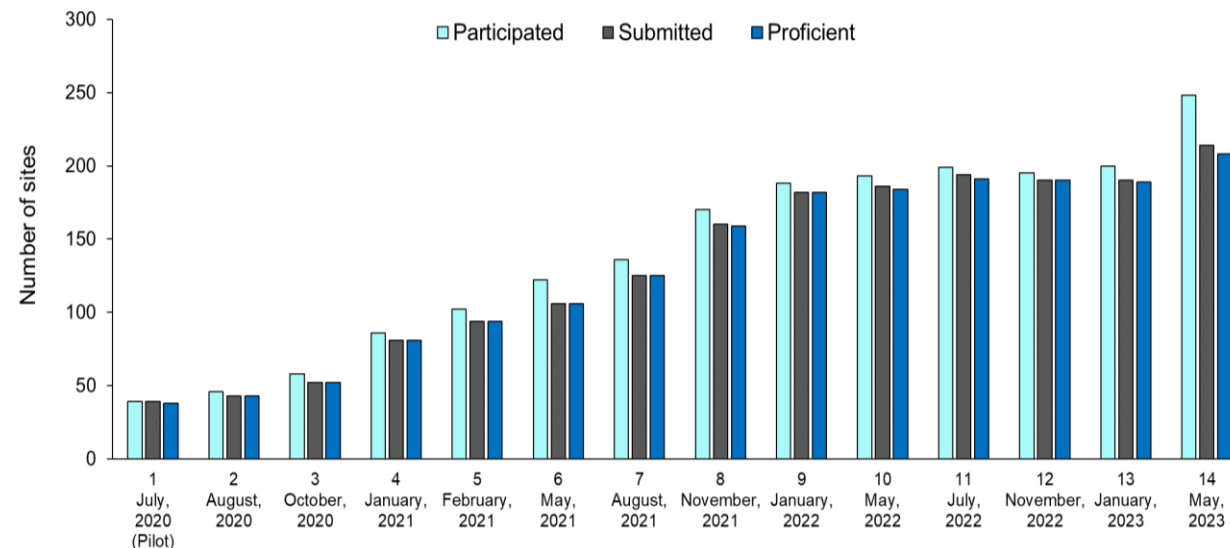
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## ➤ QASI® External Quality Assessment Program for NRI sites

- Based on international QASI® EQA programming in operation for >20 years
- >250 unique NRI sites enrolled across both programs

- *Sessions used to inform Health Canada (post-market surveillance and lot monitoring)*
- *Regular sessions provide confidence in equipment, test operators and results*
- *Keeps testing operational for future emergency responses*

## Community Testing Capacity via enrollment in GeneXpert QASI® EQA Programs



**Demonstrates the potential to massively decentralize infectious disease diagnostics without compromising quality**



## Dried Blood Spots



clinical chemistry

tb

HbA<sub>1c</sub>

## Dried Urine Strips



syphilis

CoV-2

HSV-1/2

HIV

Hep C

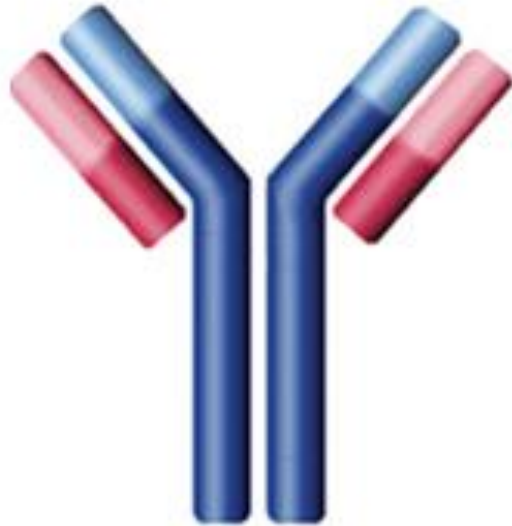
Hep B

HTLV

CT/NG / DUS

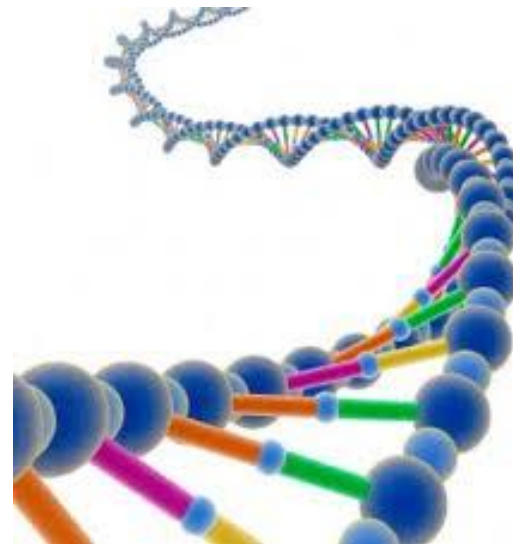
# Screening for HCV (HIV)

Serological (Antibody)



**SCREEN**

Molecular (DNA/RNA)

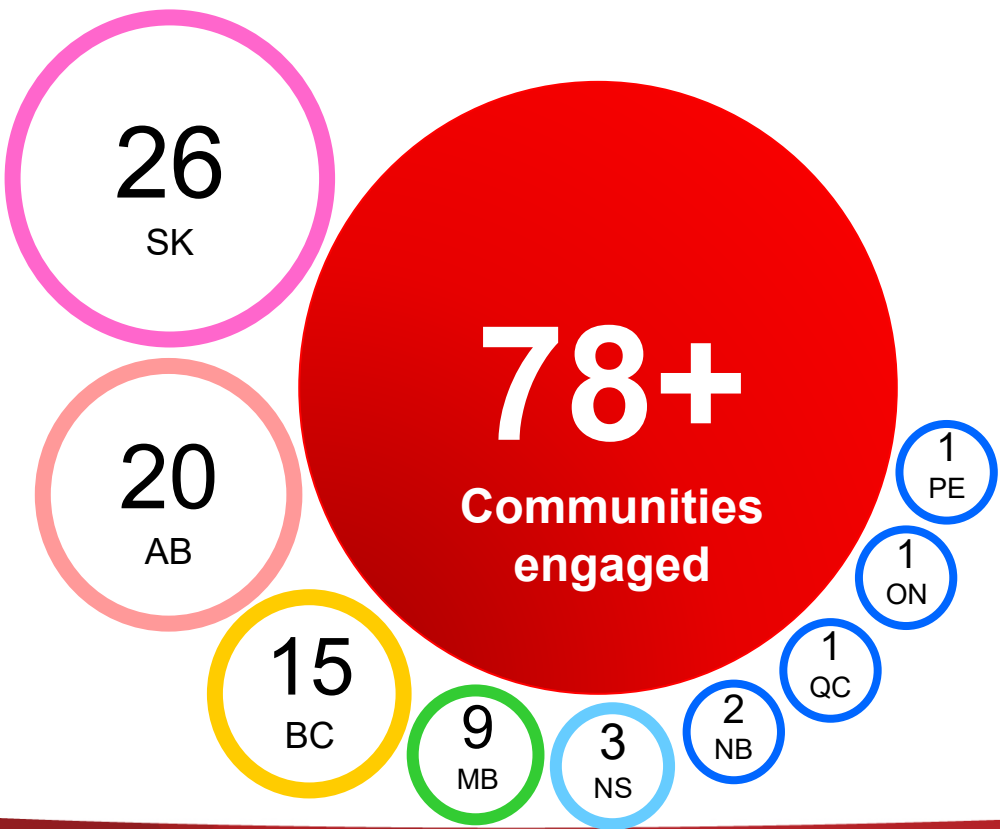
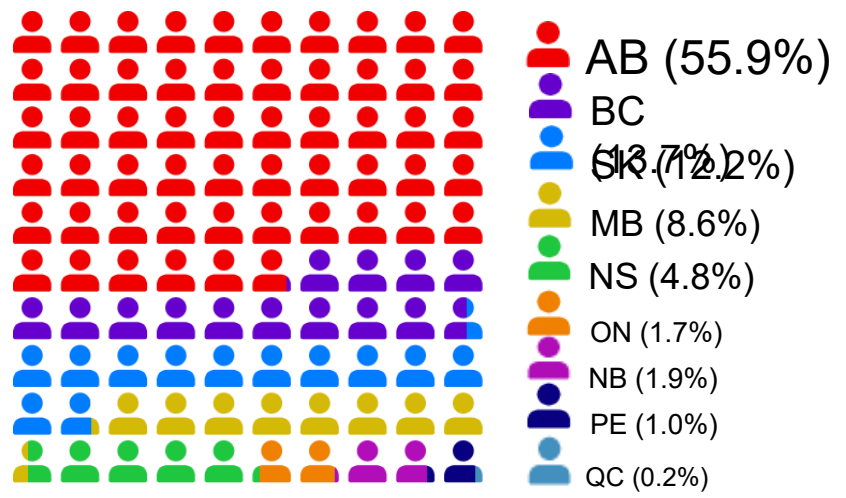


**CONFIRM**

# Impact of DBS – Relationship building

524

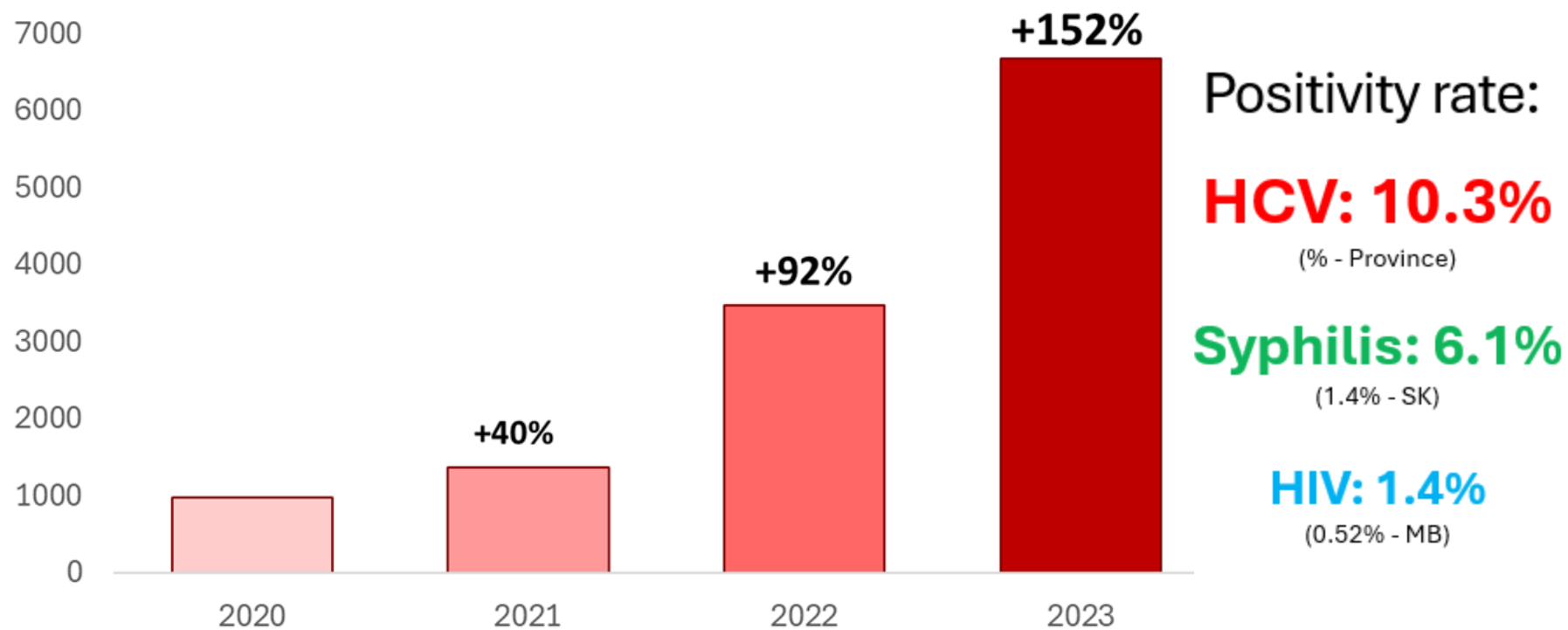
Individuals trained



78+  
Communities engaged



## Year-Over-Year DBS Testing (HIV, HCV, Syphilis, HBsAg)



# Structural level implementation - DBS

## British Columbia

**Dried Blood Spot (DBS) Sampling in British Columbia: Evaluating Implementation**

Submitted by:  
Janice Duddy, Kate Twohig, and Jennifer Kopetzky

NORTHERN HEALTH

Dried Blood Spot Testing (DBST): HIV, HCV, & Syphilis

REGIONAL CHRONIC DISEASES PROGRAM

## Saskatchewan

**Saskatchewan Health Authority**

**Clinical Procedure**

**Dried Blood Spot Testing**  
Collection of Specimens and Interpretation of Results for Syphilis, Human Immunodeficiency Virus, Hepatitis B and C

Document Number: CS-CP-XXXX  
Effective Date: Click or tap to enter a date.  
Next Review Date: Click or tap to enter a date.

**POLICY #:** PHU 001-2019

**TITLE:** Procedure for Collection and Shipment of Blood by Dried Blood Spot Testing  
**UNIT:** Public Health Unit  
**SOURCE:** Communicable Disease Control  
**APPROVED BY:** Medical Health Officer  
**EFFECTIVE DATE:** May 6, 2019  
**APPROVAL DATE:** May 6, 2019  
**LAST REVIEWED:** October 30, 2019

**Purpose**  
Ensure proper collection and shipment of blood specimens tested by the Dried Blood Spot (DBS) method for HIV, hepatitis B and hepatitis C and syphilis. The specimen will be collected in accordance with the current procedures recommended by the National Microbiology Laboratory (NML) which is also known as JC Wilt Infectious Disease Research Centre in Winnipeg, MB, and the Roy Romanow Provincial Laboratory (RRPL) in Regina, SK.

## Manitoba

**Manitoba**  
Health, Seniors and Long-Term Care

**Non-Traditional STBBI Testing by Regional Public Health Teams**

**Provincial Population & Public Health Guideline**  
Communicable Disease Control Clinical, Population and Public Health

Date approved: Click or tap to enter a date.  
Deadline for next review: Click or tap to enter a date.

Communicable Disease Management Protocol—Hepatitis C  
December 2023

Communicable Disease Management Protocol—HIV  
January 2024

## Alberta

**Alberta Health**

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PO Box 1380, Stn. Main  
Edmonton, Alberta T5J 2N3  
Canada  
[www.health.alberta.ca](http://www.health.alberta.ca)

March 8, 2023

To: All Alberta Medical Officers of Health

Dear Colleagues:

**Re: Dried Blood Spot (DBS) Testing for HIV/HBV/HCV and reporting requirements**

Dried Blood Spot (DBS) testing is being used in some parts of Alberta and can be a valuable tool to assist in diagnosing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV) and Hepatitis C Virus (HCV), especially in remote communities and in hard to reach populations. DBS testing performed at an accredited laboratory is considered an appropriate clinical specimen for the confirmation of HIV/HBV/HCV infection. The following DBS test results meet the confirmed case definition and reporting requirements as outlined in the [Alberta Health Public Health Disease Management Guidelines](#):

**Confirmed cases**

- HCV antibody positive & HCV RNA positive
- HIV antibody positive & HIV RNA positive
- tHBsAg positive & HBV DNA positive

## Ontario

**Public Health Ontario | Santé publique Ontario**

**LABSTRACT – Released July 2017, updated April 2020**

**Hepatitis C Virus (HCV) RNA detection using Dried Blood Spots (DBS) – Update**

**Audience**  
Clinicians assessing patients for the presence of current/active HCV infection and need for treatment

**Overview**  
The submission of DBS samples must meet the criteria described below. Any request that does not meet these criteria requires approval from a Public Health Ontario (PHO) Laboratory microbiologist prior to collection and submission. PHO Laboratory will accept appropriately collected DBS samples for the detection and quantification of HCV RNA in the following circumstances:

- ✓ Case definition
- ✓ Proficiency testing

## Irene Martin

In Canada, the Gonococcal Antimicrobial Surveillance Program (GASP-Canada) is a culture based surveillance system that tracks AMR *Neisseria gonorrhoeae* in order to monitor trends, support outbreak and treatment failure investigations and the development of treatment guidelines. <https://healthinfobase.canada.ca/gasp/>

For regions in the country that cannot culture *Neisseria gonorrhoeae* (and therefore have had no AMR gonorrhea surveillance data), the NML has developed assays that can predict AMR directly from clinical specimens. <https://cnphi.canada.ca/gts/reference-diagnostic-test/15061?alphaReturn=pathogenByLetter&alphaChar=N>

## Kathleen Whyte / Meika Richmond / Ramond Tsang

The Laboratory for Syphilis Diagnostics has undertaken three investigational testing studies to evaluate rapid point-of-care tests to aid syphilis diagnosis. Use of these tests can lead to earlier treatment, thereby limiting spread of infection, as well as facilitating antimicrobial stewardship. (Tests: MedMira Inc. Reveal TP (Syphilis) Antibody Test; MedMira Inc. Multiplo Complete Syphilis (TP/nTP) Antibody Test; Chembio Diagnostics Systems, Inc. DPP Syphilis Screen & Confirm)