

Community-Based Dual HIV/Syphilis POCT as a Solution for a Province-Wide Syphilis Outbreak in Alberta, Canada

Poct Dual Hiv/Sífilis Basado en la Comunidad Como Solución para un Brote de Sífilis en Toda la Provincia de Alberta, Canadá

Anna K. Füzéry, PhD, DABCC, FCACB, CPP

North Sector POCT Medical Lead, Alberta Precision Laboratories

Associate Clinical Professor, University of Alberta



Disclosures



- Employee, Alberta Precision Laboratories (APL)
- Member, College of Physicians and Surgeons of Alberta Laboratory Advisory Committee
- Member, CLSI POCT Expert Panel
- Honorarium from Nova Biomedical for a webinar on POCT in EMS (March 2023)



Acknowledgements

- SHACC Steering Committee (APL/AHS)
- APL Provincial Laboratory for Public Health
- AHS STI Centralized Services
- APL POCT
- AHS Information Technology

SHACC Steering Committee

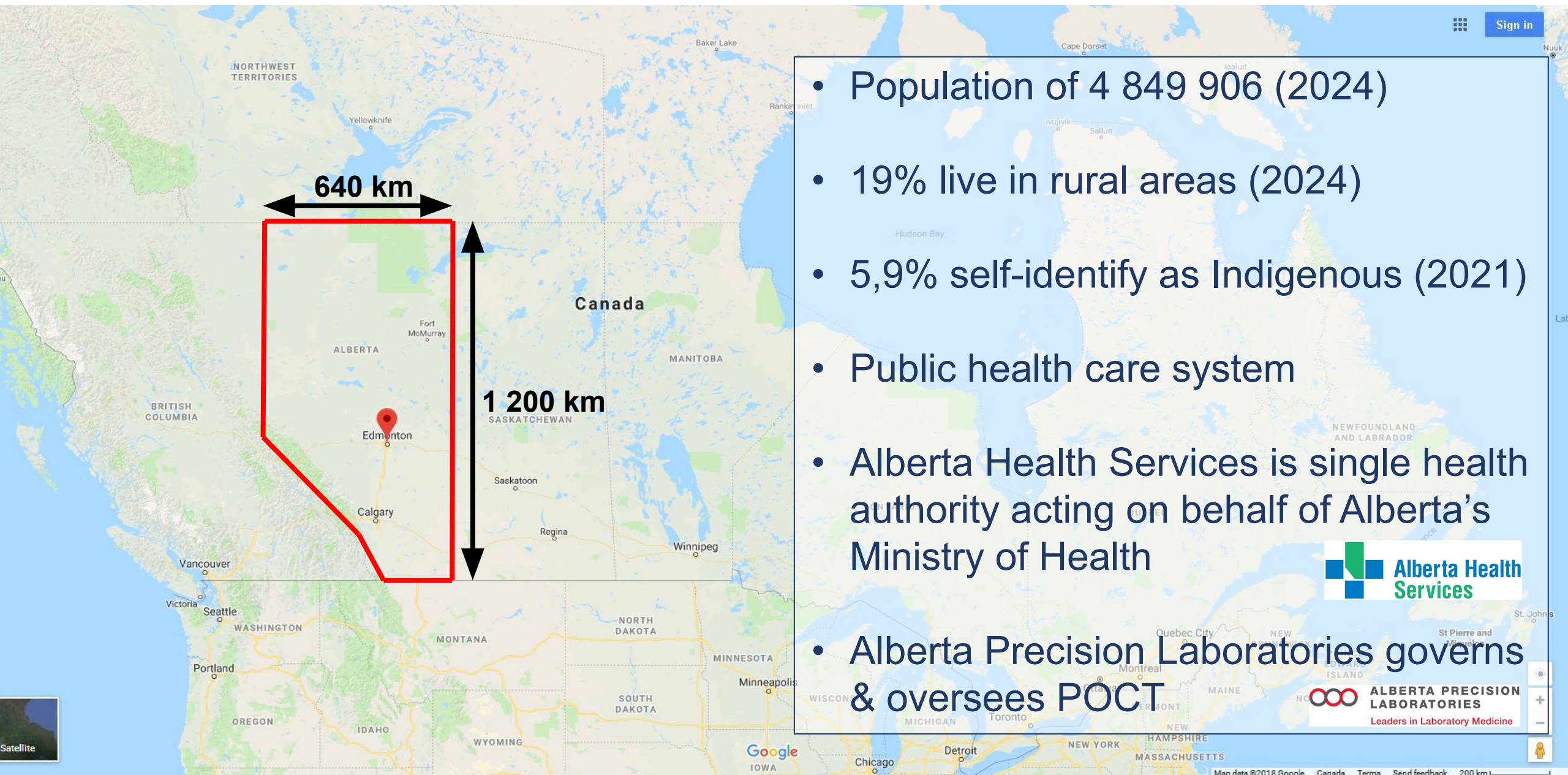
Alberta Precision Laboratories (APL):

Dr. Byron Berenger	Tracy Guttridge
Anastasia Eliopoulos	Dr. Will Stokes
Maria Falsetti	Dr. Graham Tipples
Dr. Kevin Fonseca	Dr. Allison Venner
Dr. Anna Fuezery	Dr. Hong Zhou

Alberta Health Services (AHS):

Dr. Cari Egan	Cristabel Sosa
Jennifer Gratrix	Dr. Petra Smyczek
Shenandoah Gallie	Stacy Valaire
Dr. Ameeta Singh	





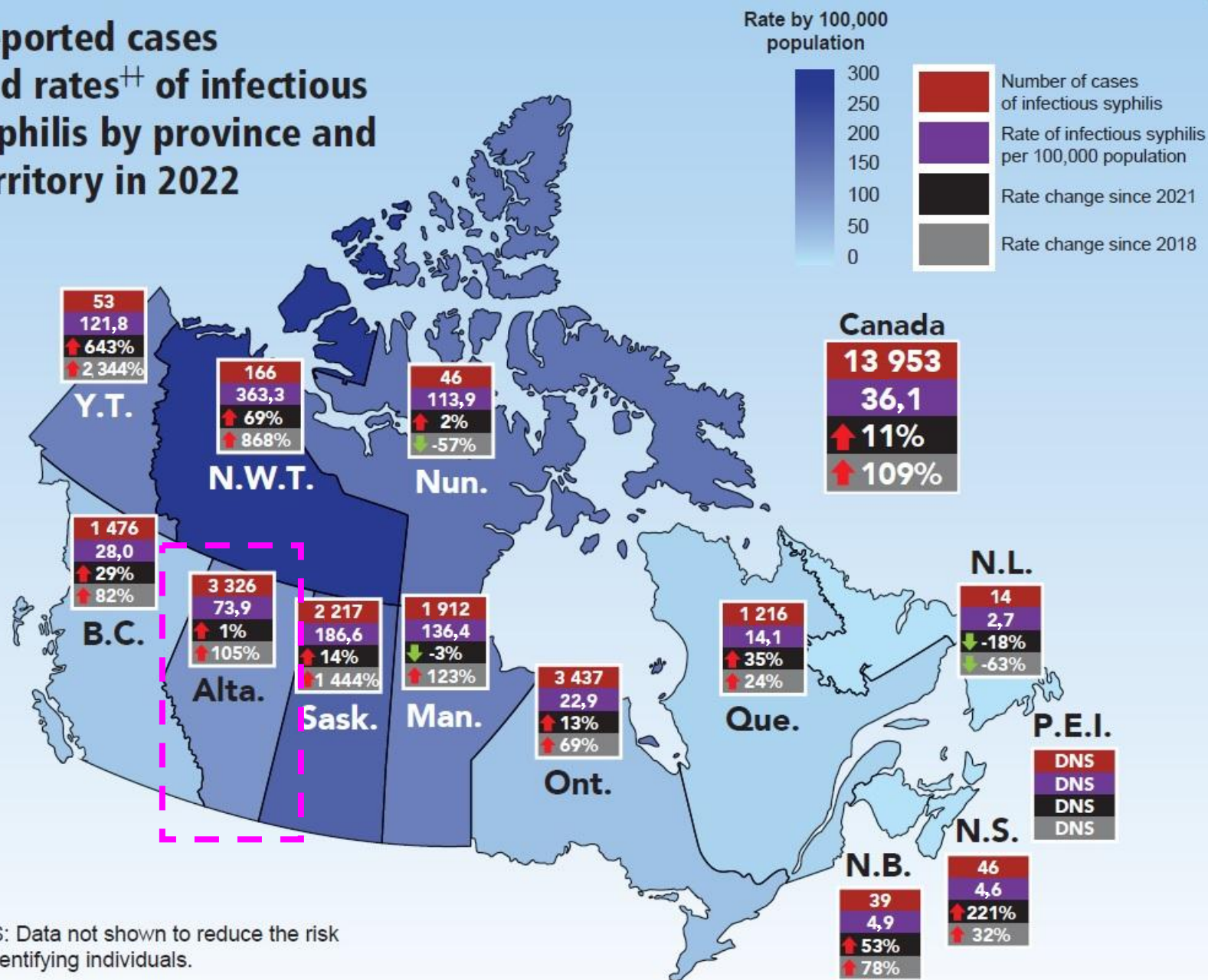
- Population of 4 849 906 (2024)
- 19% live in rural areas (2024)
- 5,9% self-identify as Indigenous (2021)
- Public health care system
- Alberta Health Services is single health authority acting on behalf of Alberta's Ministry of Health
- Alberta Precision Laboratories governs & oversees POCT



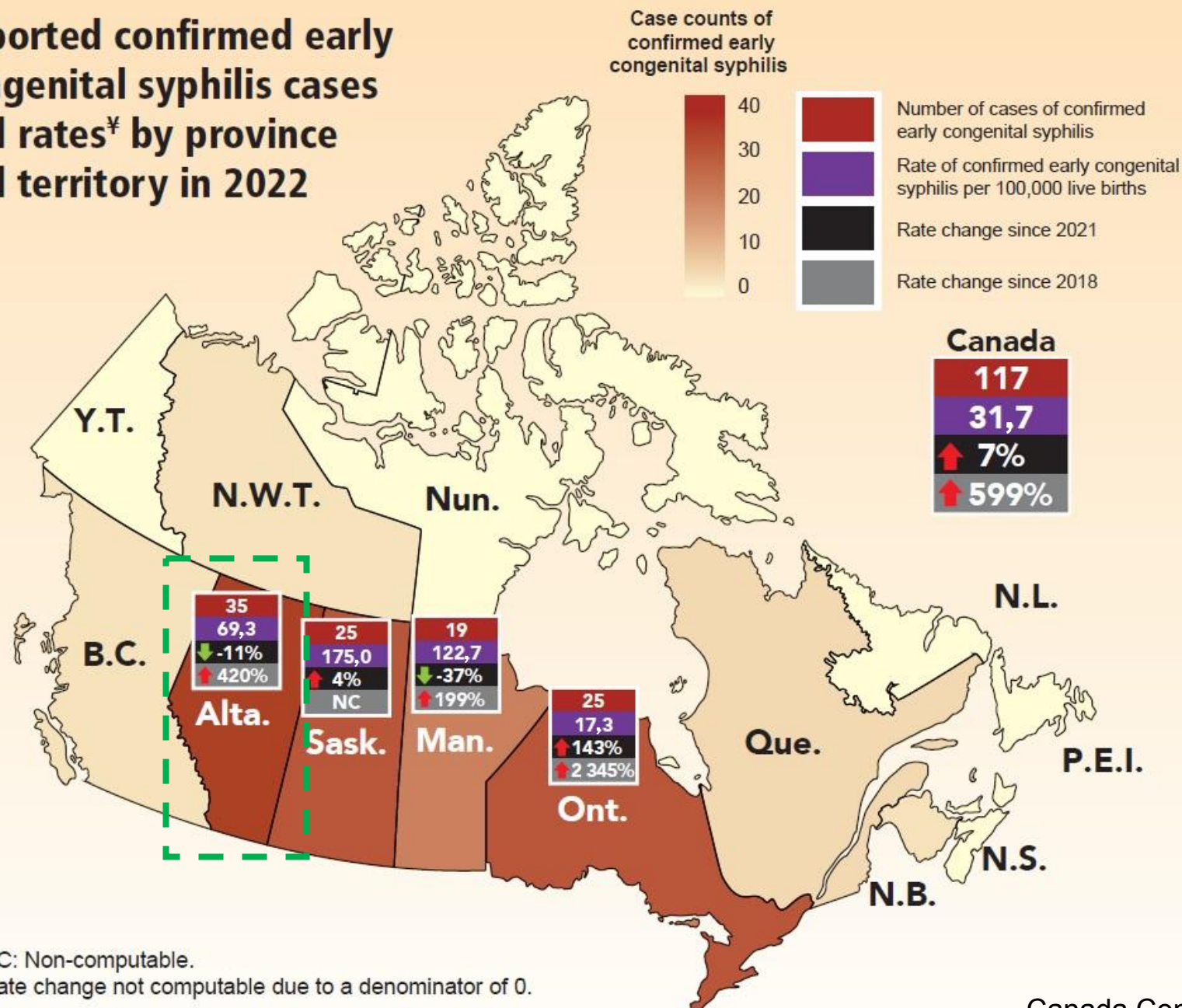




Reported cases and rates⁺⁺ of infectious syphilis by province and territory in 2022



Reported confirmed early congenital syphilis cases and rates[‡] by province and territory in 2022



NC: Non-computable.
Rate change not computable due to a denominator of 0.

Syphilis in Alberta

- Provincial syphilis outbreak in 2016 and 2019
- Significant proportion of diagnosed cases:
 - Heterosexual persons engaging in illicit drug use
 - Congenital syphilis: Indigenous women without prenatal care
- Recommendation for POCT & screening in non-traditional care settings for people at risk for being lost to follow-up



Singh et al. Off J Assoc Med Microbiol Infect Dis Canada (2019) 4.4., 215.
Gratrix et al. CCDR (2022) 48, 61.



AUDIENCE POLL

Do you oversee and/or support syphilis POCT?

- A. Yes
- B. No

What is your main barrier to introducing syphilis POCT?

- B. Syphilis is not a problem in my region
- C. \$\$\$\$\$
- D. Required expertise is unavailable
- E. Commercial test kit is unavailable
- F. Other



Ramon Casa (1900)

Alberta's Barrier

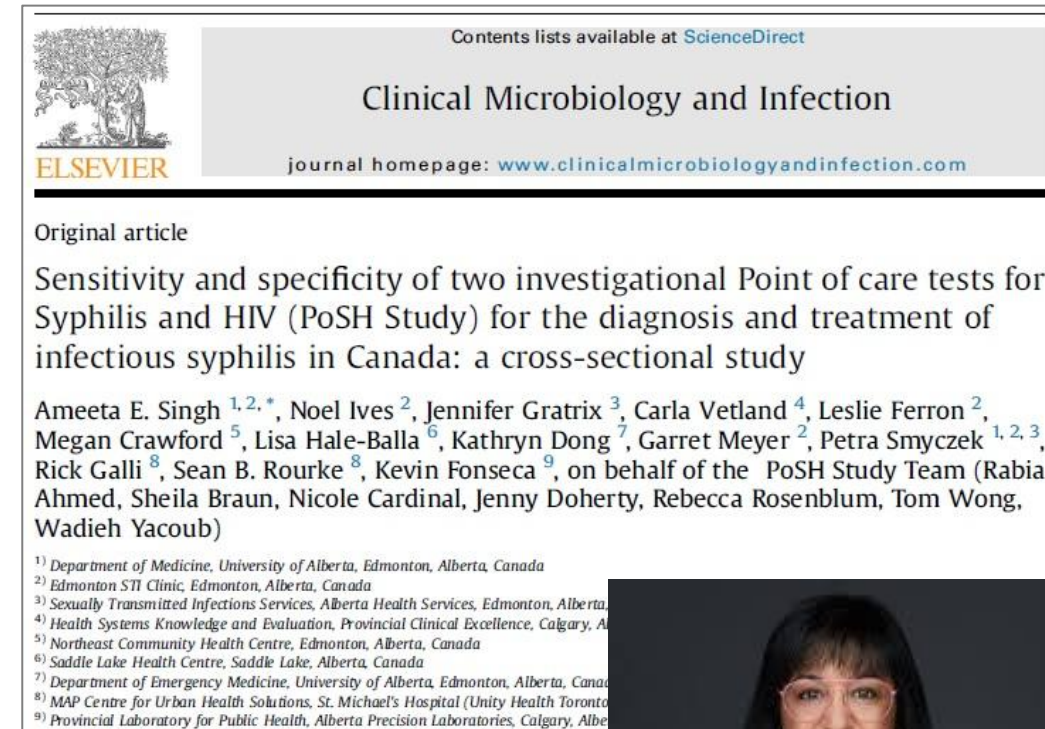


No Health Canada-approved POCT syphilis kits!!!!



PoSH Study

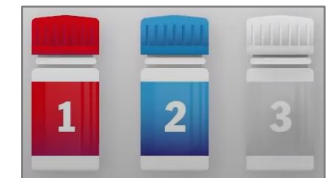
- Point of Care Tests for Syphilis and HIV
- August 2020 – February 2022
- 1 526 total visits
- 5 sites
- Patients ≥ 16 yrs receiving HIV and/or syphilis screening



Dr. Ameeta Singh

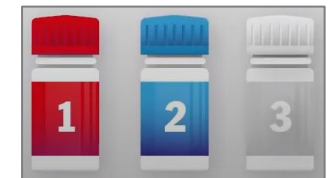
PoSH Study

- POCT during visit
 - 2 different kits
 - ≤5 mins testing time
 - Health Canada Investigational Testing Authorization approval
- Serology testing within 7 days of POCT



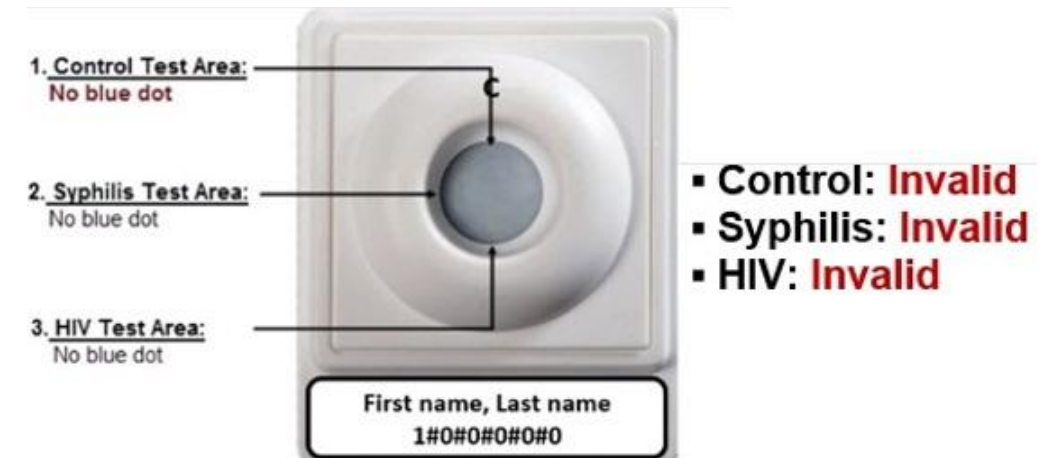
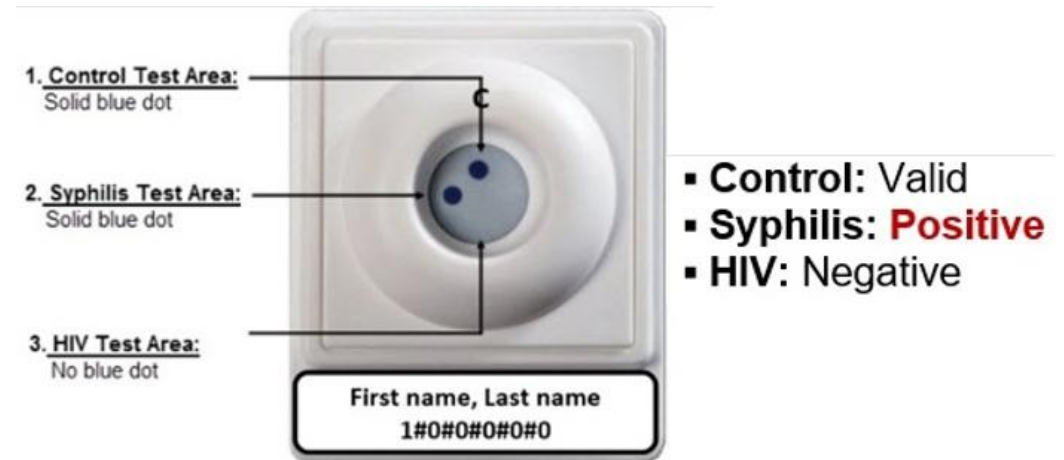
How Does It Work?

- Manual, visually read, flowthrough immuno-assay
- Detects anti-HIV-1/HIV-2 and anti-*T. pallidum* IgG and/or IgM antibodies
- Fingerstick capillary blood
- Addition of 3 different solutions to membrane kit



How Does It Work?

- Manual, visually read, flowthrough immuno-assay
- Detects anti-HIV-1/HIV-2 and anti-*T. pallidum* IgG and/or IgM antibodies
- Fingerstick capillary blood
- Addition of 3 different solutions to membrane kit
- Interpretation of 3 different dots (presence/absence)



PoSH Study

- Determined sensitivity, specificity, positive predictive value, and negative predictive value for HIV and syphilis for both POCT test kits
- Treated 85% (n=172) of participants with infectious syphilis on same day as positive POCT result
- Linked or relinked to care 100% (n=24) of participants with HIV

Singh et al. Clin Microbiol Infect (2023) 29, 940.e1.



Health Canada Approval

March 23, 2023



CLINICAL EVALUATION

Syphilis

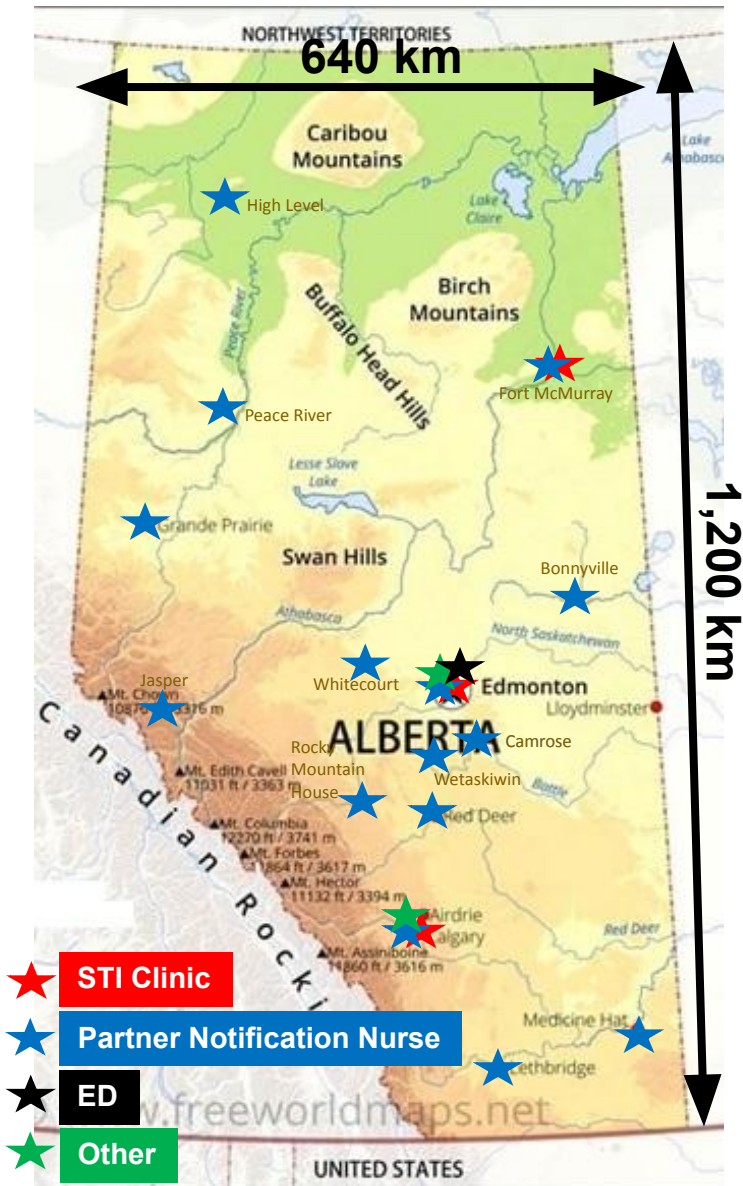
The clinical evaluation conducted in **Alberta** compared the performance of the test from fingerstick whole blood specimens with standard laboratory tests. Of the 1500 participants with eligible HIV POCT results, 55.9% were men with the majority (42.2%) between 26-35 years, 12 were pregnant and the majority (85.1%) of tests were conducted in a correctional facility. Of the 1508 participants with eligible syphilis POCT results, 55.9% were men with the majority (42.2%) between 26-35 years, 12 were pregnant and the majority (85.0%) were conducted in a correctional facility. In summary, the test performance on completed POCT reveals a PPA of 100.0%, and NPA of 99.7% for HIV (1498 completed POCT) and a PPA of 74.3% and NPA of 99.8% for syphilis (with any RPR value) when compared to serology (1494 completed POCT). The INSTI Multiplex has the greatest PPA to those who have RPR dilutions greater than or equal to 8 dilutions; a RPR titre of > 8 dilutions is generally considered to be a marker for an infectious case. The PPA, NPA, PPV, and NPV of the tests are summarized in below table 1 for primary analysis.

Table 1 Primary **Test Performance Calculations**

	PPA (%) (95% CI)	NPA (%) (95% CI)	PPV (%) (95% CI)	NPV (%) (95% CI)
PPA and NPA relative to the overall interpretation of the serology results:				
HIV	100.0% (85.1%-100.0%) N=22 22/(22+0)	99.7% (99.2%-99.9%) N=1476 1471/(1471+5)	81.5% (63.3%-91.8%) N=27 22/(22+5)	100.0% (99.7%-100.0%) N=1471 1471/(0+1471)
Syphilis	74.3% (70.4%-77.8%) N=529 393/(393+136)	99.8% (99.3%-99.9%) N=965 963/(963+2)	99.5% (98.2%-99.9%) N=395 393/(393+2)	87.6% (88.6%-89.4%) N=1099 963/(136+963)
Syphilis sub-analysis for different RPR dilution values:				



Full-Scale Implementation



- 18 community sites + 1 ED + 2 outreach groups
- Collaboration between:
 - APL POCT
 - APL Public Health Laboratory
 - AHS STI Centralized Services
 - AHS Information Technology
- Led by multidisciplinary steering committee (SHACC)
- 11 months of preparatory work
- Go-live starting December 2023

Testing Criteria

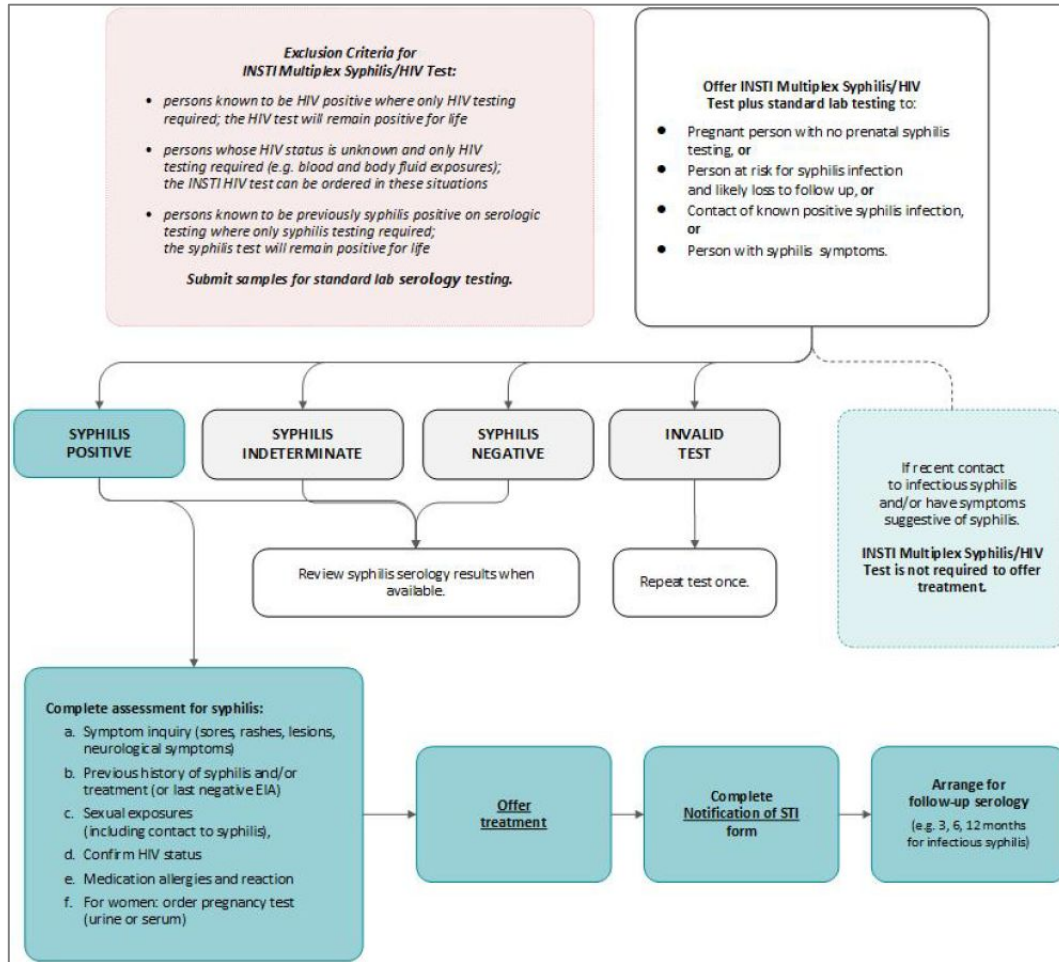
Recommended for persons ≥ 14 years with unknown syphilis status or who have previously tested negative and have 1 of following indications:

- Pregnant person with unknown syphilis status
- Pregnant with ongoing risk factors & negative syphilis test in current pregnancy
- Person at risk for syphilis and/or HIV infection and at risk of loss to follow-up
- Recent contact with a person with suspected syphilis and/or HIV infection
- Person with syphilis and/or HIV in the differential diagnosis

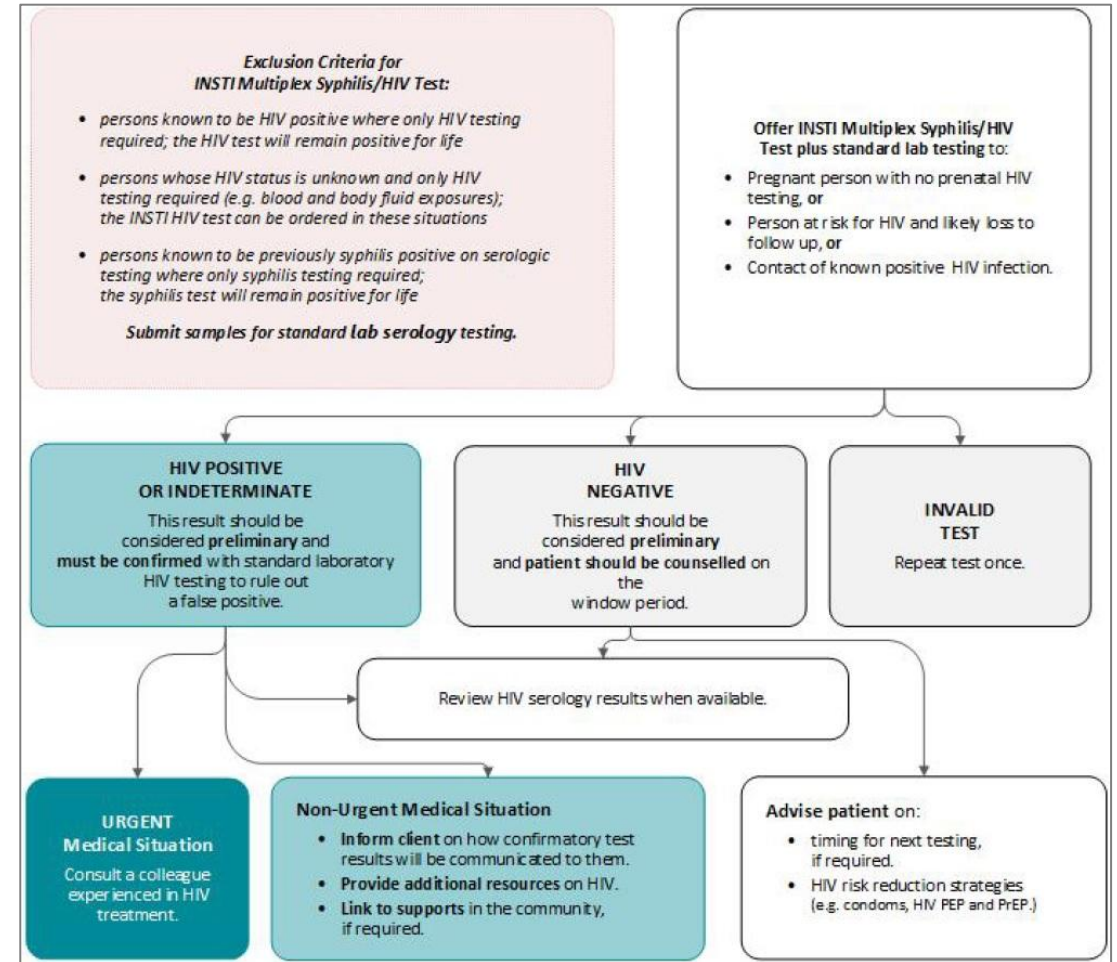


Clinical Care Pathways

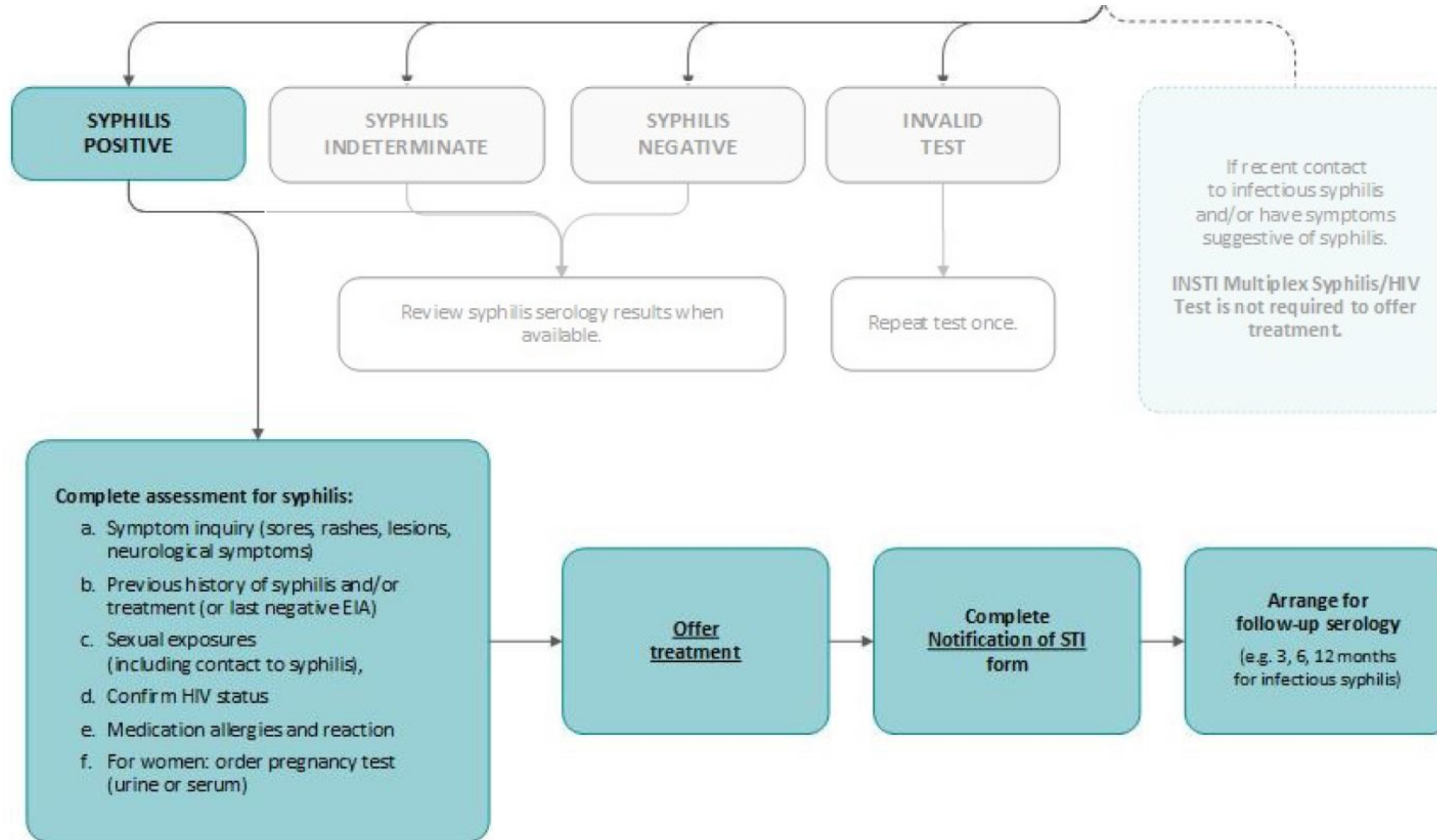
Syphilis



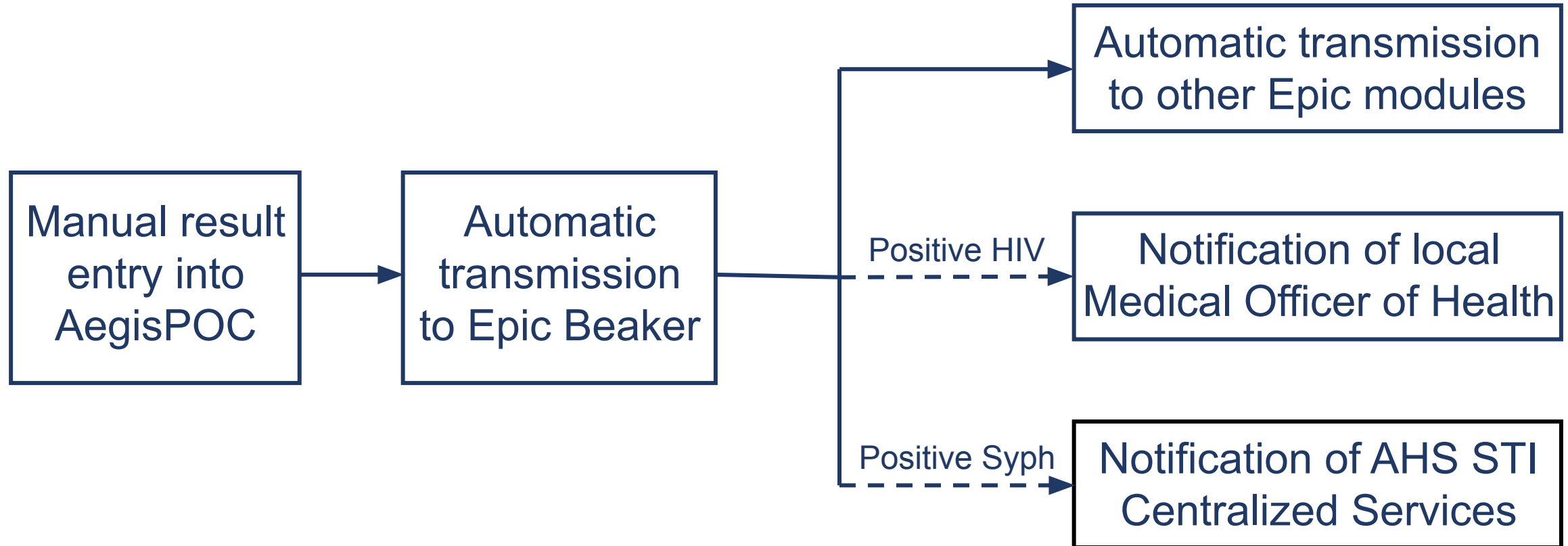
HIV



Clinical Care Pathways



Result Reporting



CSN: AC403323013554 pMRN: 3091667323
Last Name: TEST TEST CIND
DOB: 01/01/1997 Sex: Female
Physician: -Unknown-
Location: PATIENT SER

EDIT PATIENT

Facility: Manual Test
Station: MT Entry
Instrument: M-HIV Syphilis
Date/Time: 05/01/202 08:15:00
Lot: MT-HIV Syphilis LOT

Result Information

Analyzed by: JORDYNSTOLEE

Sample Type: Capillary

HIV (Antibodies): Positive

Syphilis: Positive

Indication for testing: Contact of known positive

FINISH

CANCEL

! Syphilis and HIV POCT

Order: 959229733

Status: Final result Visible to patient: No (not released)

0 Result Notes

! Newer results are available. Click to view them now.

Component

09:00

Ref Range & Units

HIV (Antibodies) POCT

Positive !

Indeterminate, Invalid, Negative

Comment: Refer to HIV 1 and 2 Serology report for the final HIV serology results.

Syphilis POCT

Positive !

Negative, Indeterminate, Invalid

Comment: A positive rapid Syphilis result in an untreated individual indicates treatment is required. Refer to the Suspected Syphilis order/smart set for guidance.

Resulting Agency

POCT LAB

Narrative

Performed by: POCT LAB

METHOD: Performed using the

Specimen Collected: 19/12/2023 09:00

Last Resulted: 19/12/2023 09:27

POCT QA Program



- **Initial training:** e-learning module + quiz + testing of 2 QC levels + training checklist
- **Annual competency:** 6 patient tests OR initial training written components
- **QC testing:** 3 QC levels monthly or with each new shipment
- **Proficiency testing:** not available
- **Patient comparisons:** no requirements yet
- **New lot validations:** performed by APL Public Health Laboratory
- **Documents:** developed and maintained by APL POCT
- **Other:** monthly QA reports, yearly audits

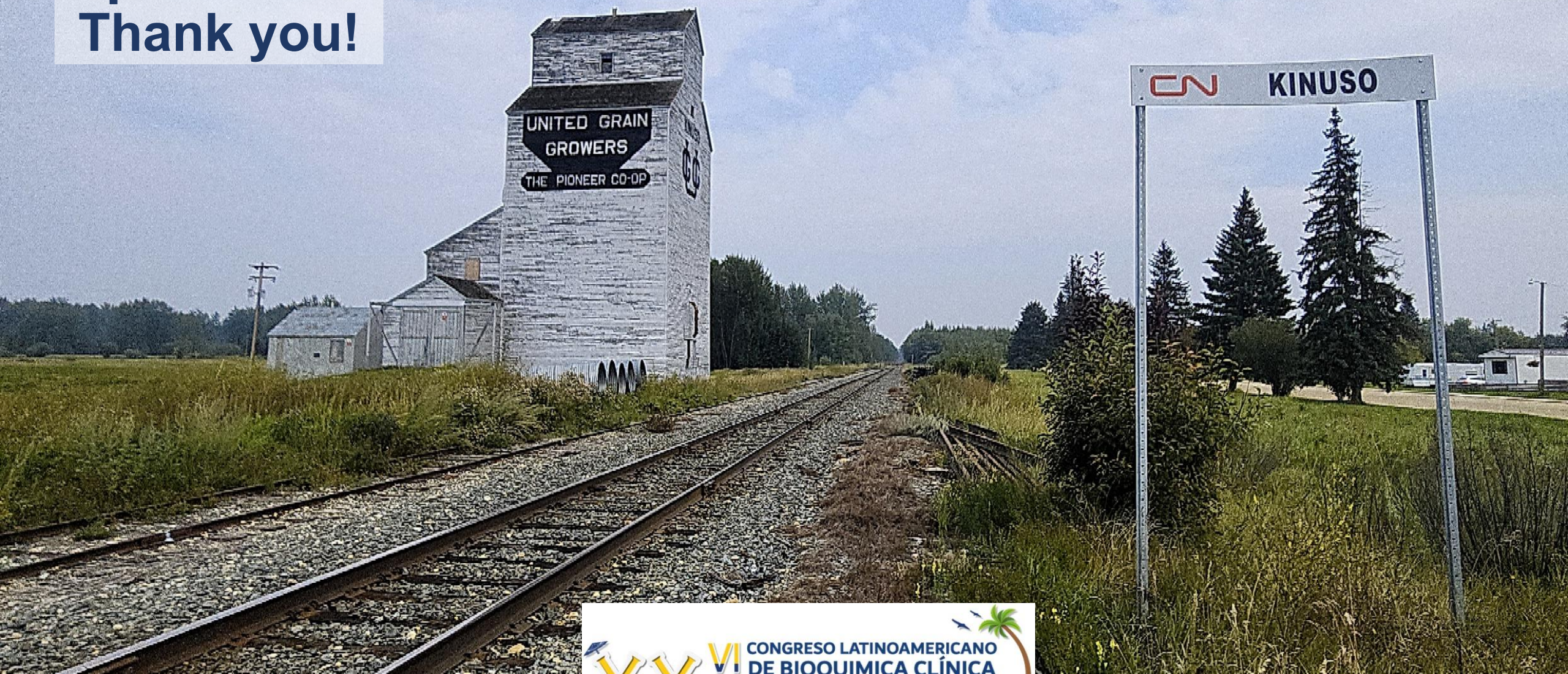


Where Are We Now?

- 433 tests performed since December 2023
- 45 positive syphilis tests (10% positivity rate)
 - 28 treated same day (62%)
- 4 positive HIV tests
- Good compliance with training and QC requirements
- Currently troubleshooting unusual test kit performance



¡Gracias!
Thank you!



COLABIOCLI
Confederación Latinoamericana
de Bioquímica Clínica



Colegio Nacional de Bacteriología



Cartagena, Colombia 3 al 6 OCTUBRE 2024

www.congresocolabiocli.com





Cartagena, Colombia 3 al 6 OCTUBRE 2024



COLABIOCLI
Confederación Latinoamericana
de Bioquímica Clínica



Colegio Nacional de Bacteriología

www.congresocolabiocli.com

