

Indigenous Services Canada

Crown-Indigenous Relations  
and Northern Affairs Canada

# INSTI Multiplex Point-of-Care Test for Syphilis and HIV Type 1/Type 2

Sexually Transmitted and Blood Borne Infections (STBBI)  
Prevention Program

First Nations and Inuit Health Branch Alberta Region  
Indigenous Services Canada  
Government of Canada



Government  
of Canada

Gouvernement  
du Canada

Canada

# Meet the Speakers



**Primrose Sotocinal**



**Nicole Allam**



**Lidia Arapis**



# Agenda

- Introduction
- Requirements for Use
- Benefits and Limitations
- Eligibility for POCT
- Priority testing groups
- Storage and Handling
- Steps for using INSTI Multiplex POCT
- Interpreting and Reporting Results
- Providing Treatment
- Questions/Comments



# Introduction

- Syphilis rates continue to rise across Alberta, and First Nations individuals are overrepresented in the numbers. Increasing access to testing and limiting the time between test results and treatment may help reduce transmission and improve patient care.
- The INSTI Multiplex POCT is an antibody test that screens for HIV type 1/type 2 and *Treponema pallidum* (syphilis) by using whole blood from a finger prick.
- FNIHB MOH, Dr. Sarin has been granted permission to procure tests under the special access program.
- The test can provide preliminary results in as little as one minute, identifying individuals who need syphilis and/or HIV treatment.



# Introduction

- The manufacturer for the *INSTI Multiplex HIV-1 / HIV-2 / Syphilis Antibody Tests* (INSTI Multiplex POCT) has obtained approval from Health Canada, these tests have recently been studied for use in Alberta.
- The FNIHB Sexually Transmitted and Blood Borne Infection (STBBI) Team has developed a protocol for health centers that would like to use the INSTI Multiplex POCT under Dr. Chris Sarin's authority.
- Healthcare professionals using the INSTI Multiplex POCT will follow the protocol and identified reporting requirements. The INSTI Multiplex POCT can be added to the testing processes in already established clinics, during wellness events, or during routine clinic visits.



# Resources on OneHealth

- *Protocol for Use of a Biolytical INSTI Multiplex POCT*
- *INSTI Multiplex POCT Lab Reporting Form*
- *Syphilis Treatment Protocol for use with INSTI Multiplex POCT*
- *INSTI Multiplex POCT Instructions for Use Package insert*
- *INSTI Multiplex POCT YouTube video transcript*
- *Syphilis HIV POCT Pathway*

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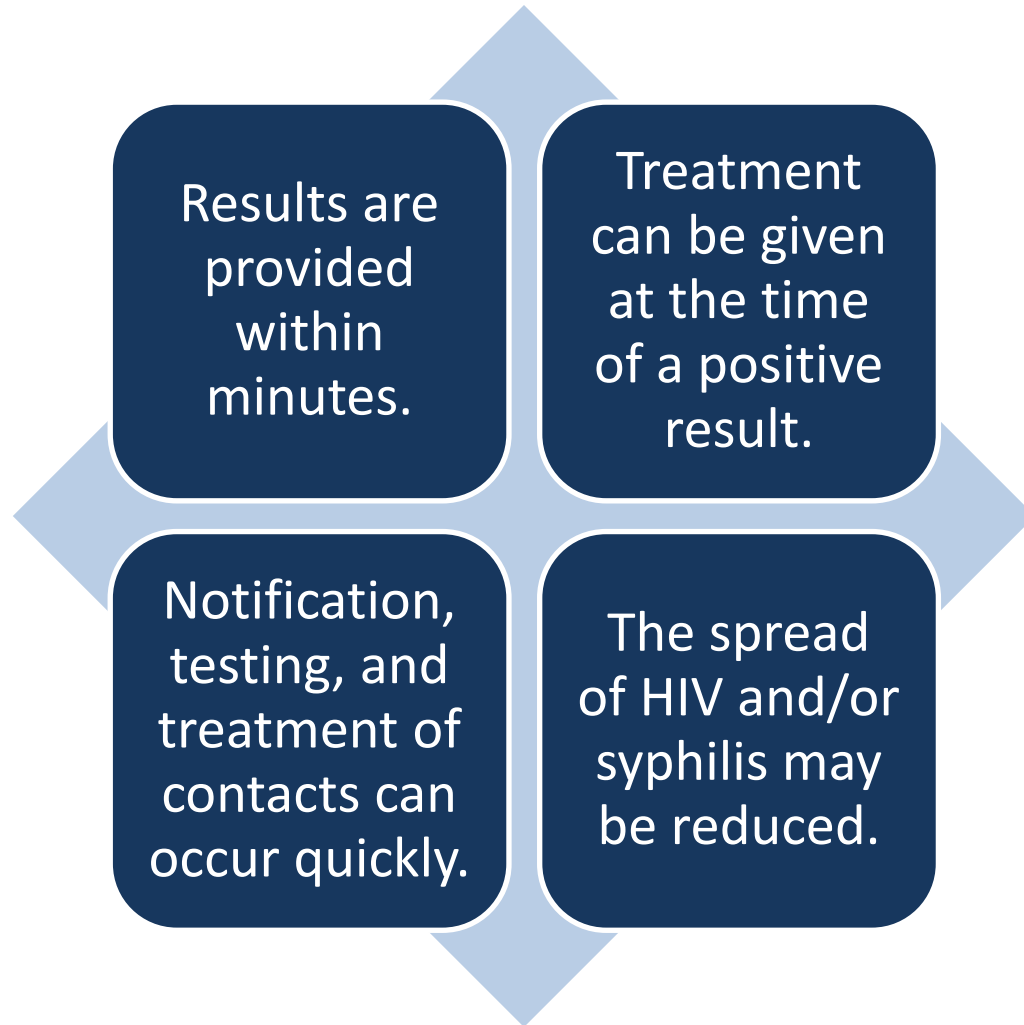


# Requirements for Use

- Hold a current *FNIHB Alberta Region Test and Treat Provider Certificate*
- Have Long Acting Benzathine Penicillin G 2.4 million units (Bicillin L-A) IM and Doxycycline 100 mg PO available
- Review the anaphylactic policy on OneHealth and have a kit available during medication administration
- Perform, or organize, serology testing prior to using the POCT
  - Serology can be ordered under the regular community process
  - Dr. Sarin does not need to be copied on results
- Have read the entire *Instructions for Use* package insert
- Know how to interpret the POCT results according to manufacturers instructions
- Have knowledge of STBBIs, taking a thorough sexual health and treatment history, providing pre- and post-test counseling, medication administration
- Complete and submit required documentation to appropriate recipients



# Benefits of the INSTI Multiplex POCT



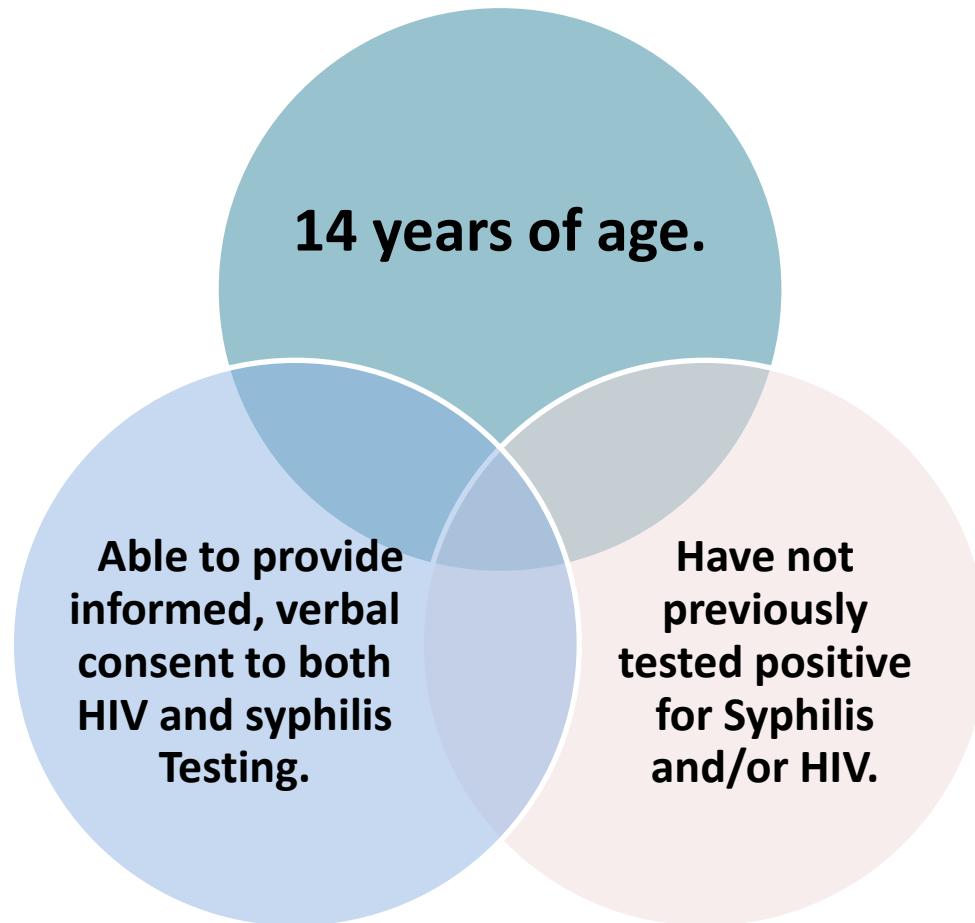


# Limitations of the INSTI Multiplex POCT

- If an individual previously tested positive for syphilis, the POCT cannot be used to test for syphilis. It cannot determine if the positive result is from a previous infection or a current infection.
- POCT results are preliminary. Phlebotomy must be performed prior to the POCT to confirm the results and provide staging.
- If syphilis dilutions are less than 8, the POCT may not pick up on the infection.

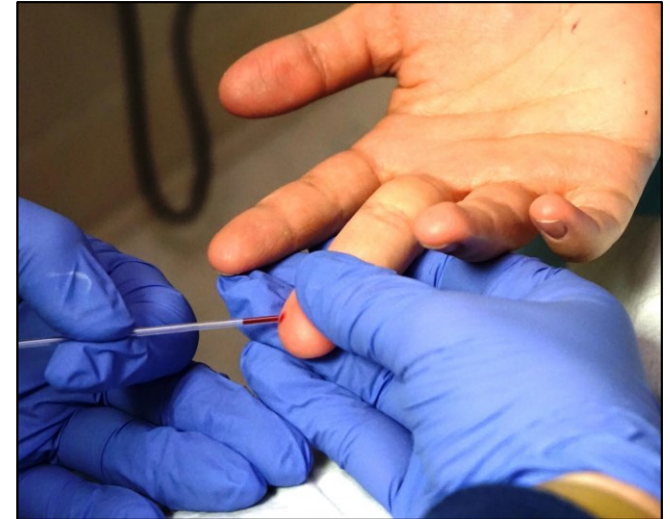


# Test Eligibility Criteria



# Priority Testing Groups

- Clients who are difficult to locate
- Clients who may be lost to follow-up after testing
- Clients that have difficulty accessing care
- Clients who present with symptoms of syphilis (i.e., chancre and/or syphilitic rash) or another sexually transmitted infection
- Clients with social and behavioral risk factors for a STI (substance use disorder, sex workers, etc.)
- Pregnant clients, as earlier treatment may result in improved fetal, maternal and neonatal outcomes.
- Clients who are contacts to a confirmed case.



# Storage and Handling

- **Kits should be stored at 15-30°C.**
  - If the test kit is exposed to temperatures outside of 15°– 30°C, ensure it is brought to this temperature range before performing testing.
  - If unsure of kit validity, contact the FNIHB STBBI team.
- All kit components are individually packaged.
- All kits are for single use only.
- All INSTI components must be used immediately once opened.
- Do not use a kit that is damaged or previously opened.
- Do not use reagents or kits beyond the stated expiration date.
- Do not mix reagents from different lots.
- Do not smoke, eat, or drink in areas where specimens or kit reagents are being handled.



# How to Use INSTI Multiplex POCT

1. Obtain client's sexual and treatment history by filling out the *Notification of STI Form* (to remain with clients chart as documentation)
2. Check Netcare for a previous positive result (Syphilis and/or HIV)
3. Ensure that client meets criteria to receive a POCT
4. Obtain informed, verbal consent by using this standard POCT script:

"The <bioLytical Multiplex > rapid testing is designed to tell you if you have detectable antibodies to syphilis and HIV infection. This point of care test is awaiting Health Canada approval and is used to provide a preliminary result to determine if you have either a current infection, or detectable antibodies to past infection such as treated syphilis. A negative result on rapid testing does not always mean that syphilis or HIV infection is absent (false negative), and likewise, a positive result with rapid testing does not always mean that syphilis or HIV infection is present (false positive). You may be offered treatment on the basis of a positive rapid test. Serology and laboratory testing from your blood sample is needed to determine your true HIV and syphilis status. Do you consent to proceeding with rapid point of care testing?"
5. Document informed verbal consent was received



# How to Use INSTI Multiplex POCT

6. Provide any applicable teaching (i.e. need for confirmatory serology, safer sex practices, risk of false positives, window period):
  - a. [Syphilis resource](#)
  - b. [HIV resource](#)
  - c. Window period: the period of time between exposure to HIV and/or syphilis to when the *INSTI Multiplex POCT* can detect antibodies
    - i. HIV: 3 to 12 weeks. An individual may test positive in as little as 21-22 days after infection, however it can take as long as 3 months to produce a positive result.
    - ii. Syphilis: 6 to 7 weeks.
  - d. Outline health center process of relaying negative serology results (i.e. notification for only positive results, client to call health center, all results relayed, etc.)
7. Don PPE and prepare your phlebotomy supplies
8. Collect blood specimen using phlebotomy – must be done prior to POCT
  - a. Note: Serology may be collected under the community MRP following the communities organizational process, or under the FNIHB MOH.
9. Prepare blood specimen and lab requisition for submission to lab
10. Perform POCT test according to the following manufacturer instruction sections:



# INSTI Multiplex POCT YouTube Video

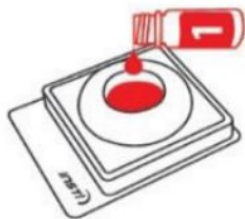
## [INSTI Multiplex POCT Video](#)

**Note:** Transcript for this video is also available on OneHealth.



# Steps for adding a sample to the membrane unit

1. Open **Bottle 1** and pour the entire contents into the center of the sample membrane unit well, the liquid should absorb quickly. Ensure **Bottle 1** is fully absorbed.
2. Re-suspend the color developer (**Bottle 2**) by inverting gently and slowly until the reagent is evenly suspended.
3. Open **Bottle 2** and pour the entire contents into the center of the membrane unit well. The solution should absorb quickly. Ensure **Bottle 2** is fully absorbed.
4. Open **Bottle 3** and pour the entire contents into the center of the membrane unit well, the solution will absorb quickly.
  - a. The clarifying solution in Bottle 3 will reduce background to provide more contrast to the spots and facilitate reading.
5. Immediately read the result while the membrane is still wet.
  - a. **Do not** read the results if more than 5 minutes have elapsed following the addition of the clarifying solution (Bottle 3).
6. When reading the results make sure the tab of the membrane unit is facing the provider.





# Tips for using the INSTI Multiplex POCT

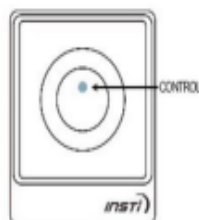
- Position the membrane unit with the tab facing you
  - Can also label the tab with patient identifiers if running multiple tests
- Warm hand prior to testing
- Do not need to wipe away first drop of blood
- Ensure the blood bead is large enough before pipetting
- **Pour slowly** – or the liquid may spill



# Interpreting INSTI Multiplex POCT Results

**Non-reactive results:** 1 distinctive blue control dot appears

- The control dot ensures that the test has been performed correctly and a human specimen has been used.



**Reactive results:** 2 or 3 distinctive blue dots appear.

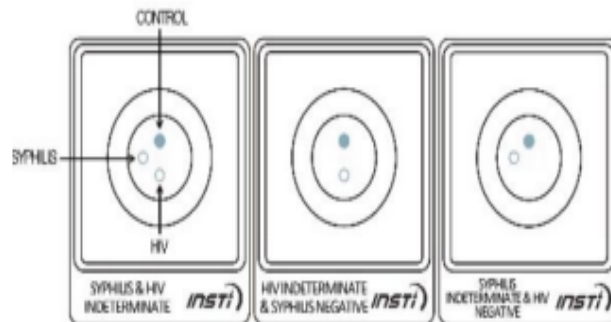
- These dots indicate that the specimen contains HIV 1 and/or HIV 2 and/or syphilis antibodies. Depending on the position of the dots.
- Following the reactive test result HIV and/or syphilis confirmatory serology should be conducted.



# Interpreting INSTI Multiplex POCT Results

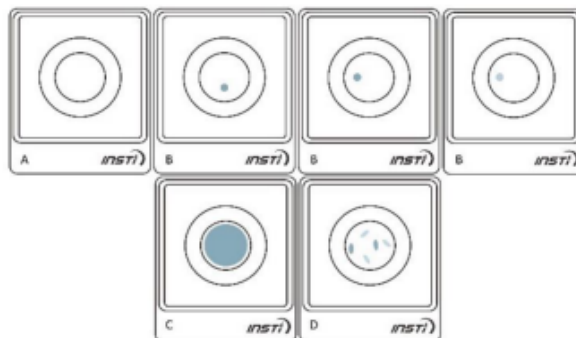
**Indeterminate results:** One control dot and a faint background ring will appear.

- Following an indeterminate test result confirmatory serology testing should be completed.

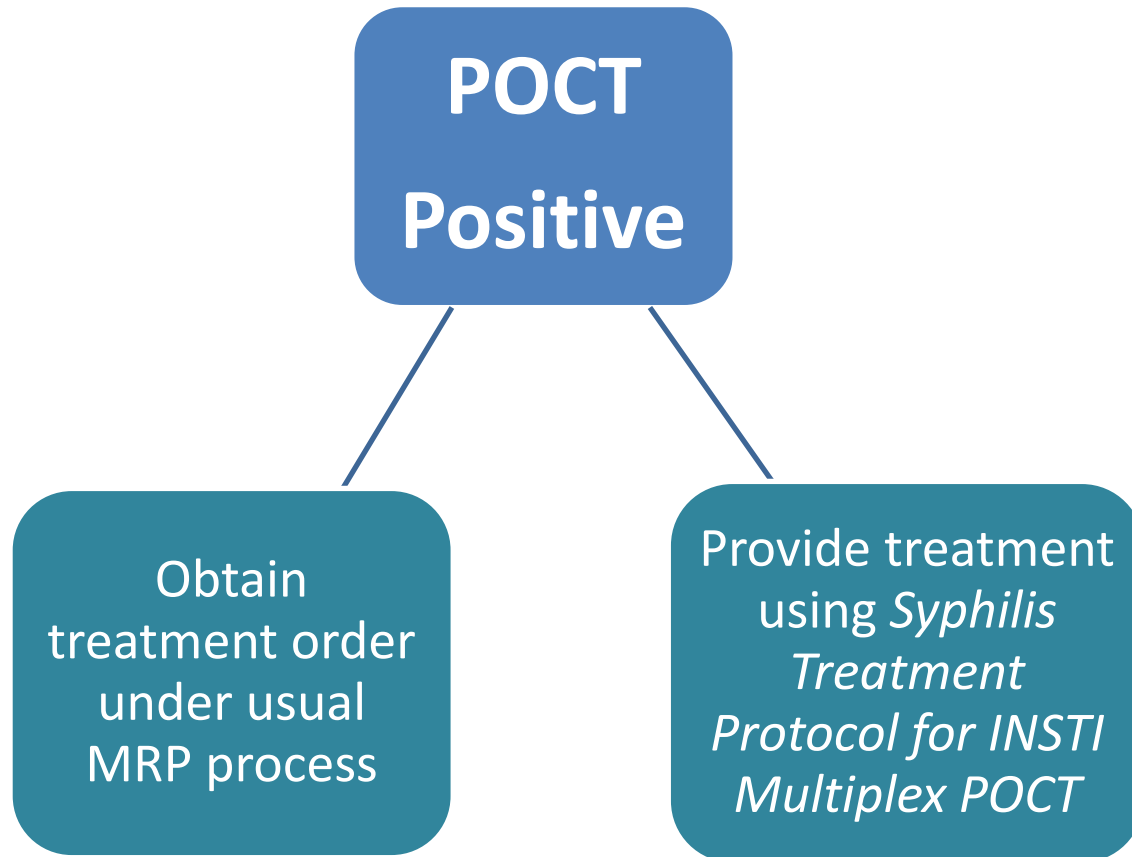


**Invalid test:** No control dot appears.

- This may indicate the test was run incorrectly or insufficient specimen was added.
- Any invalid test results cannot be interpreted and a new fresh specimen should be used to repeat testing.



# Providing Syphilis Treatment



# Providing Syphilis Treatment

**Syphilis Treatment Protocol for use with INSTI Multiplex POCT**  
 Submit this form to the FNHB CDC Team: [equipcomtab-abcdteam@aac-iac.gc.ca](mailto:equipcomtab-abcdteam@aac-iac.gc.ca) or fax 780-495-8070

Community: \_\_\_\_\_ Date: \_\_\_\_\_

**Client Information**  
 First Name: \_\_\_\_\_ Last Name: \_\_\_\_\_ DOB: \_\_\_\_\_ PHN: \_\_\_\_\_

Documented previous positive:  Yes  No Informed consent received:  Yes  No

Pregnant:  Yes, date of Last Normal Menstrual Period (LNMP): \_\_\_\_\_  No  Unknown

**\*notes:**  
 • If client is pregnant or potentially pregnant, Doxycycline treatment should not be administered. Pregnancy status needs to be confirmed.  
 • If a pregnant client is over 20 weeks gestation or unsure of their gestational age, client should not be administered Bicillin L-A treatment. Further assessment is required (discussion with MRP to determine need for ultrasound and fetal heart monitoring, prior to treatment.)

History of penicillin allergy:  Yes\*  No If yes, name of drug: \_\_\_\_\_ Reaction: \_\_\_\_\_

**\*notes:**  
 • If client has a documented history of penicillin anaphylaxis, penicillin should not be administered and STICS should be consulted for further direction and an alternative of treatment of Doxycycline may be considered for non-pregnant clients.  
 • If client has a documented history of penicillin allergies (rash, hives, etc.) STICS should be consulted, and an alternative of treatment of Doxycycline may be considered for non-pregnant clients.

**Authorized syphilis treatment**

Following a positive syphilis result on the INSTI Multiplex POCT for Syphilis and HIV 1/2, the Senior FNHB Medical Officer of Health of Alberta, Dr. Christopher Sarin, authorizes:

- Long Acting Benzathine Penicillin G 2.4 million units (Bicillin L-A) IM, as a single dose
- or
- For penicillin allergic patients, Doxycycline 100 mg PO BID for 14 days


Dr. Christopher Sarin: CS Date: March 8, 2023  
 This Syphilis treatment Protocol for use with INST Multiplex POCT is valid until: August 30<sup>th</sup>, 2023

**Treatment Information**  
 Name of treatment provider: \_\_\_\_\_ Designation: \_\_\_\_\_  
 Date of treatment: \_\_\_\_\_ Time of treatment: \_\_\_\_\_

Long Acting Benzathine Penicillin G 2.4 million units (Bicillin L-A) IM as a single dose  
 For penicillin allergic patients\*: Doxycycline 100 mg PO BID for 14 days  
**\*note:** Doxycycline is contraindicated during pregnancy.

**Resources and Teaching:**

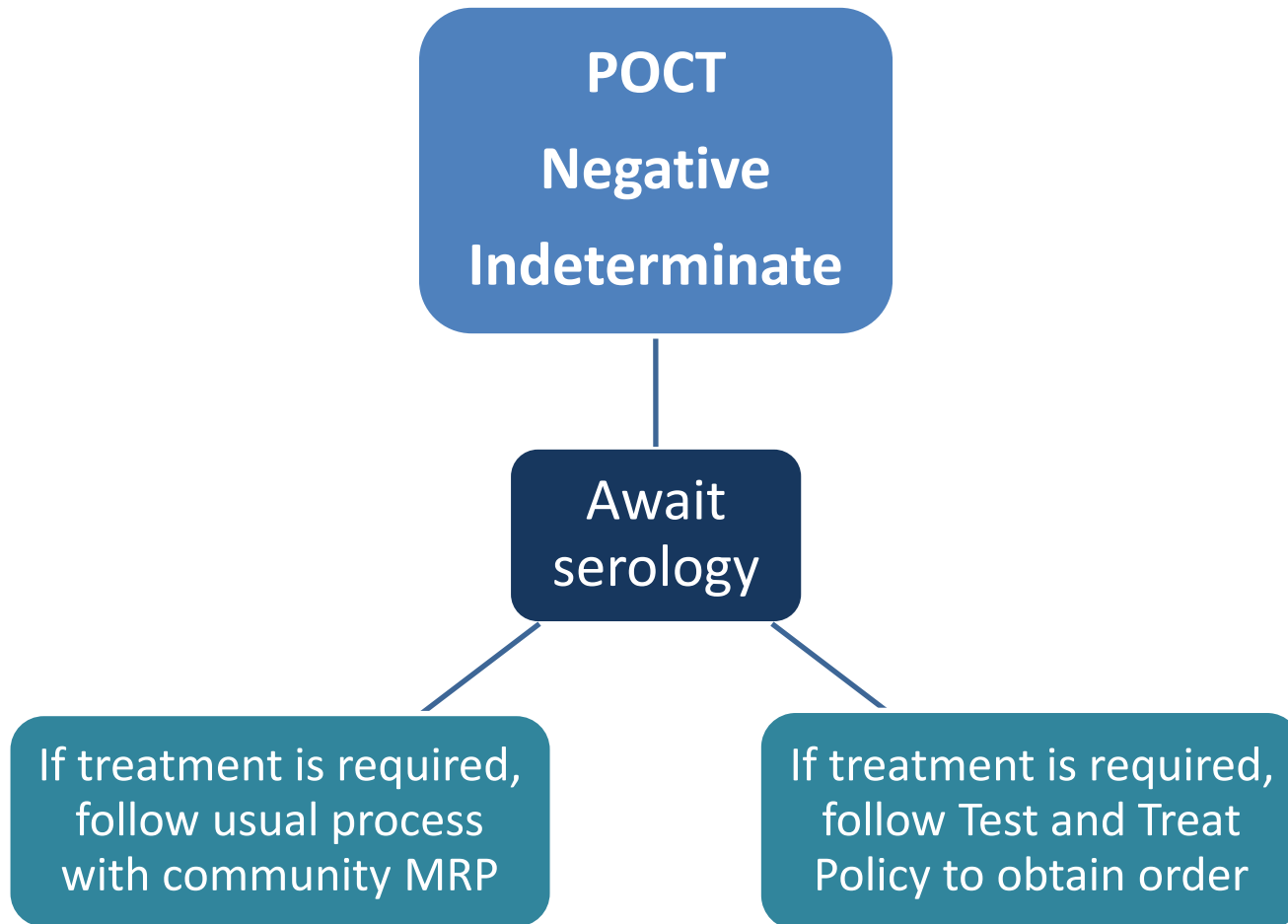
- Treating with Bicillin L-A: Being treated with Bicillin L-A for syphilis: Care instructions (alberta.ca)
- Client should wait at health center for 15 minutes after medication administration
- Client should abstain from any sexual activity for 7 days post treatment
- Bicillin L-A may cause: mild diarrhea, stomach upset, nausea, vomiting, irritation at the injection sites
- Doxycycline may cause: stomach upset, diarrhea, nausea, or vomiting
- If symptoms persist or worsen, instruct client to call their healthcare provider

 Indigenous Services Canada Services aux Autochtones Canada Date: March 2023

- If providing treatment under Dr. Sarin, complete the *Syphilis Treatment Protocol for Use with the INSTI Multiplex POCT*, available on the OneHealth website.
- This form authorizes one dose of treatment.
- Test providers can also order treatment under their regular process with the community MRP.
  - Dr. Sarin does not need to be copied on these results.



# Providing Syphilis Treatment



# Treatment Considerations

- Caution should be taken prior to administering treatment to clients who are unsure of their gestational age, and/or pregnancy status. These clients may require further assessment (i.e., ultrasound, pregnancy test, fetal heart monitoring).
  - Pregnant clients greater than 20 weeks gestation should undergo fetal monitoring for 24 hours after administration of Bicillin L-A. Ideally, this is done in a hospital setting. Contact STICS for direction.
  - Pregnancy tests should be offered to clients as indicated.
- **Penicillin Allergies**
  - Bicillin L-A IM allergic clients must have a pregnancy test prior to considering treatment with doxycycline.
  - Doxycycline is contraindicated during pregnancy. Contact STICS for direction with Bicillin L-A allergic pregnant clients.



# Reporting INSTI Multiplex POCT Results

- All results (positive, negative, invalid and indeterminate) must be reported to the FNIHB CDC team using the *INSTI Multiplex POCT Lab Reporting Form*.
- This form is available on the OneHealth Website.
- For positive results, a *Notification of STI Form* must also be completed and sent to STICS and the FNIHB CDC Team.

Indigenous Services Canada | Services aux Autochtones Canada | Disclaimer: This form must be completed using PDF software

### INSTI Multiplex POCT Lab Reporting Form

**Client Demographics:**

AB Health Number :	Date of Birth:
Last name:	First name:
Alias or Alternative Names:	
Does the client live on-reserve? <input type="checkbox"/> Yes, indicate reserve: <input type="checkbox"/> No	
Sex assigned at birth: <input type="checkbox"/> Female <input type="checkbox"/> Male	Client Phone Number:
Pregnant: <input type="checkbox"/> Yes, date of last normal menstrual period*: <input type="checkbox"/> No <input type="checkbox"/> Unknown	

*\*note: Doxycycline is contraindicated during pregnancy*

**Authorizing Provider Information: Dr. Sarin, Christopher**

Location of Physician: Canada Place 730 – 9700 Jasper Ave NW Edmonton AB T5J 4C3	Healthcare Provider ID: 63486 001974M	Phone: 403-613-4169
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**Consent:**

Client consent obtained and documented for POCT\*?  Yes  
*\*note: consent must be obtained. Clients should be advised they may also receive a phone call from STICS and/or their test provider.*

Does client consent to serology\*?  Yes  
*\*note: client is not eligible for POCT if serology is not completed.*

**Test Information:**

**Serology must be collected prior to performing a POCT**

Date of test: \_\_\_\_\_ Time of test: \_\_\_\_\_  
*\*note: all results are to be reported within 24 hours to the appropriate recipients*

Kit Lot number: \_\_\_\_\_ Kit Expiration Date: \_\_\_\_\_

Syphilis:  Reactive  Non-reactive  Invalid  Indeterminate  
 HIV 1/2:  Reactive  Non-reactive  Invalid  Indeterminate

Has client been informed of their results\*?  Yes  No, indicate reason: \_\_\_\_\_  
*\*note: clients should be advised that POCT results are preliminary, serology results provide final syphilis and HIV status.*

**Healthcare Provider and Health Centre Information:**

Health Centre Name:	
Health Centre Phone Number:	
Phlebotomy performed by:	Contact Number:
POCT performed by:	Contact Number:

**Additional Comments:**

Date: March 2023

Email this form to the FNIHB CDC Team:  
[equipecmtab-abcdcteam@sac-isc.gc.ca](mailto:equipecmtab-abcdcteam@sac-isc.gc.ca)





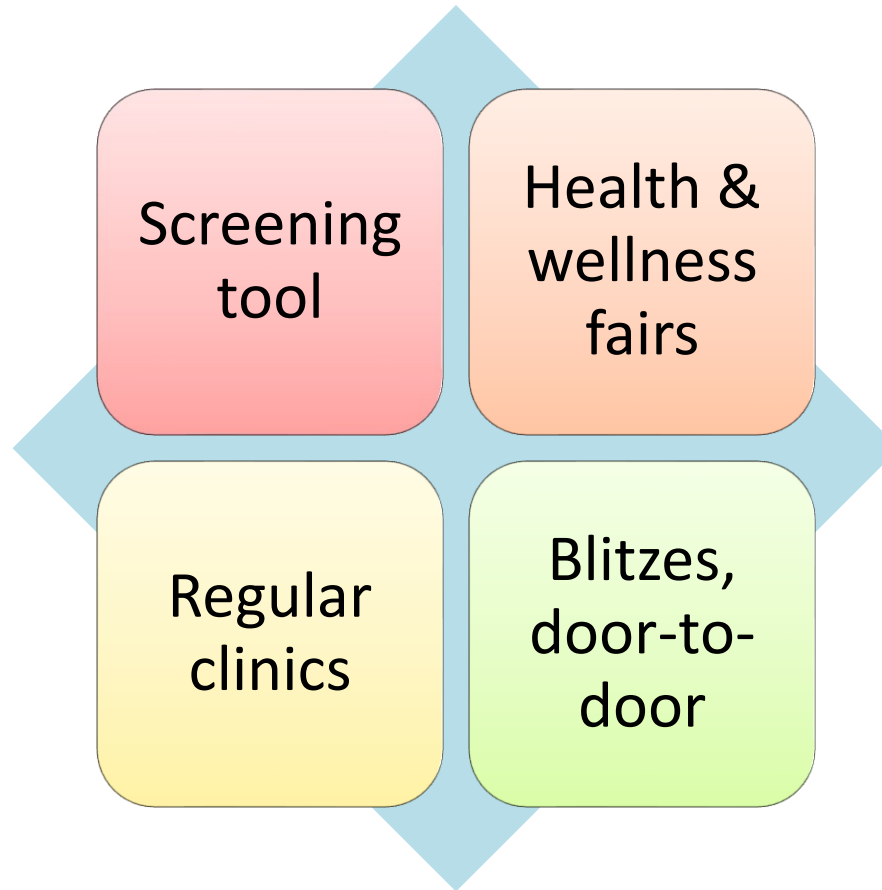
# Reporting INSTI Multiplex POCT Results

Following a **positive** POCT result, the following forms need to be submitted:

Required forms	STI Centralized Services (STICS) Email to Fax: <a href="mailto:1-780-659-3347@fax.hc-sc.gc.ca">1-780-659-3347@fax.hc-sc.gc.ca</a> Fax: 1-780-659-3347	FNIHB CDC team Email: <a href="mailto:equipecmtab-abcdcteam@sac-isc.gc.ca">equipecmtab-abcdcteam@sac-isc.gc.ca</a> Fax: 780-495-8070
<i>Notification of STI Form</i>	x	x
<i>Syphilis Treatment Protocol for use with INSTI Multiplex POCT</i>		x
<i>INSTI Multiplex POCT Lab Reporting Form</i>		x



# Implementing POCT



# How to order INSTI Multiplex POCT kits

If you'd like to order INSTI Multiplex POCT kits for your community, please send an email to the CDC Inbox:

[equipecmtab-abcdcteam@sac-isc.gc.ca](mailto:equipecmtab-abcdcteam@sac-isc.gc.ca)



# Questions? Comments?



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