Stopping Syphilis:
The HHS Summer Seminar Series

Office of Infectious Disease and HIV/AIDS Policy

Office of the Assistant Secretary for Health

July 31, 2024

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U.S. Department of Health and Human Services

Enhancing the health and well-being of all Americans

Statement from Assistant Secretary for Health Levine on Point of Care Testing for Syphilis

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Webinar Agenda

Topic
Welcome and Opening Remarks
Considerations for Syphilis Rapid Point of Care (POC) Testing
Implementation of Syphilis POC Testing
Overview of Best Practices for 2.4MU IM Bicillin L-A® Injections
Q&A Session
Close

Webinar Objectives

- Summarize current syphilis diagnostic methods and best practices.
- Evaluate the benefits and limitations of POC syphilis tests.
- Identify specific settings where POC syphilis tests would be most beneficial.
- Highlight key considerations for effectively implementing POC syphilis tests.
- Highlight best practices for 2.4MU IM Bicillin L-A® Injections.

Considerations for Syphilis Rapid Point of Care (POC) Testing

Phoebe Thorpe, MD, MPH

Prevent, Screen, and Diagnose Subcommittee Co-Chair

National Syphilis and Congenital Syphilis Syndemic Federal Task Force

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High-level Overview of Diagnosing Syphilis: Recognizing Symptoms, Testing, Knowing Prior Medical and Sexual History Are Key Components

If syphilis signs/symptoms present, then test and treat same day

- Ask about symptoms, sexual history and exposures
- Conduct physical exam
- Order tests (2 types)
  - ✓ Treponemal tests (qualitive TPPA, EIA)
  - ✓ Nontreponemal tests (quantitative RPR, VDRL)
    - Nontreponemal support diagnosis and patient follow-up/management
- Provide treatment
- Counsel on disease, prevention, including partner treatment

Briefly, diagnosing and treating syphilis is a combination of recognizing symptoms, looking at test results, knowing prior medical and sexual history and potential exposures. If signs or symptoms are present, it can be pretty straightforward, you order the tests for further mgmt. and offer treatment the same day.

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High-level Overview of Diagnosing Syphilis: Recognizing Symptoms, Testing, Knowing Prior Medical and Sexual History Are Key Components

If no signs/symptoms, diagnosis is less straight forward

- Ask about symptoms, sexual history and exposures
- Order treponemal and nontreponemal lab-based blood tests to detect asymptomatic infection

Results not available same day, often patient leaves without treatment

If results reactive or positive…

- Review syphilis lab and treatment history to determine new or previously treated
- Schedule patient to return for treatment

However if there are no symptoms, the diagnosis is less straightforward. IN addition to asking about their sexual history and possible exposures, clinician has to order lab-based treponemal and non treponemal titer tests, which will return in a few days to weeks, after patient has left. If positive, the provider needs to review previous history and labs to determine if this is a **new or previously treated syphilis** infection. If new, ask the person to return for treatment.

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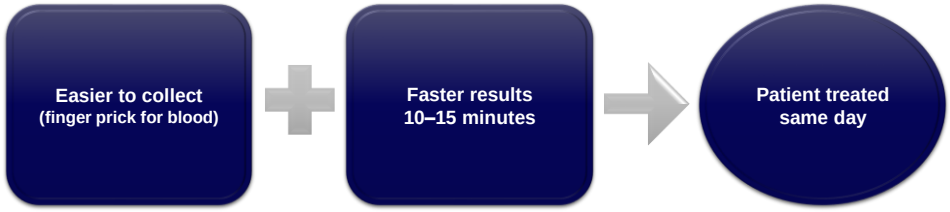
Two point-of-care (POC) tests available in the U.S.

Advantages of Syphilis Health Check™ and Chembio DPP® HIV-Syphilis include:



POCT: Point-of-care testing refers to a rapid test that can be performed close enough to patient care that results can be acted on during the same visit

What if test results were available the same day? There are two point of care tests for syphilis available for use in the US, the Syphilis Health Check™ and the Chembio DPP® HIV/Syphilis dual test. Advantages of these tests include: specimen is a finger prick which is much easier to collect than venous blood, and the results take 10 to 15 minutes allowing patients to be treated at the same visit.

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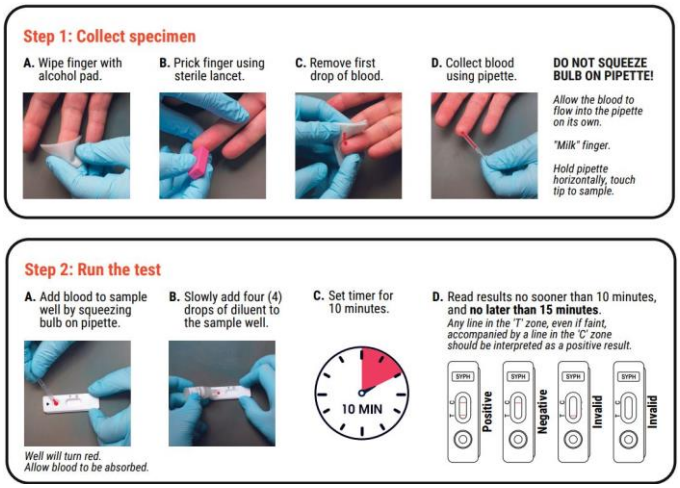
Syphilis Health Check™ (SHC)



Source: SHC Package insert

This shows how it is performed, You prick the finger, use the pipette to collect the blood, drop it onto the test well and then add the dil-u-ent, wait 10 minutes, and you have the results.

Source: SHC Package insert: download at https://www.diagnosticsdirect2u.com/downloadmanager/download.aspx?id=1.aspx (diagnosticsdirect2u.com)

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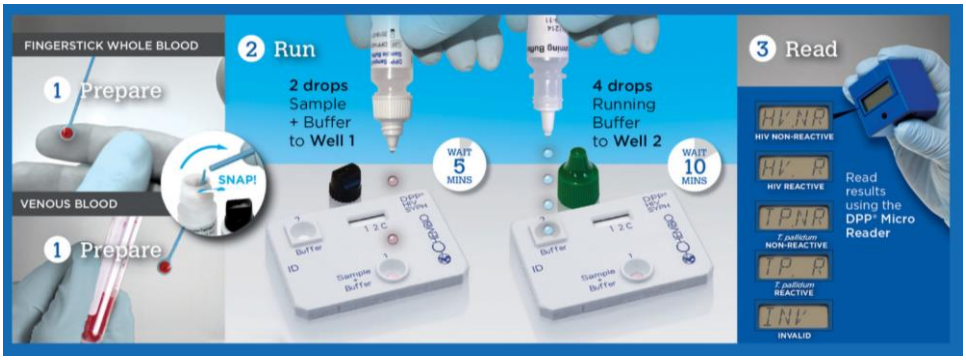
Test for HIV & Syphilis in 3 Easy Steps with Chembio DPP® HIV-Syphilis



https://chembio.com/products/dpp-hiv-syphilis-usa/

This illustrates how the Chembio test works. Similar finger prick, add drops in 2 steps, wait 15 minutes. On the right in step 3, one difference is that Chembio developed a reader that interprets the results.

These tests are fast. However there are some limitations.

Source: DPP® HIV Syphilis USA – Chembio Diagnostics, Inc.
https://chembio.com/products/dpp-hiv-syphilis-usa/

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Some reasons POC tests are NOT used all the time

1. Current POC tests provide only Treponemal results
   - When positive, results indicate syphilitic infection at some point, which may or may not indicate new infection
2. Need nontreponemal (titers) for patient management
   - Nontreponemal tests distinguish new vs. prior infection
   - Are needed for patient follow-up
   - Not currently available as rapid test
3. Persons previously treated for syphilis should not be screened using current POC tests
   - Treponemal results typically stay positive, even after treatment

CDC Laboratory Recommendations for Syphilis Testing, United States, 2024 | MMWR
https://www.cdc.gov/mmwr/volumes/73/rr/rr7301a1.htm

Some drawbacks are that the current POCT only include treponemal results, which indicates an infection at some point, but does not distinguish a new infection or need for treatment. Non treponemal titers are used in disease management, to determine whether this is new or previously treated infection, but they are not available as POCT. This means if the POCT is positive, in addition to an assessing the person, nontrep titers should be ordered.

What this ALSO means is that POCT cannot be used to screen those previously treated for syphilis. The point of care will be positive, but does not necessarily indicate a new infection.

Reference:

"Antibodies detected in treponemal tests typically persist for life despite treatment unless treatment occurs early in the course of infection; approximately 15%–25% of patients treated for primary syphilis can revert to a nonreactive treponemal test (FTA-ABS and MHA-TP) result within 2–3 years after treatment (61,62). In these two studies, no patients treated for secondary syphilis or stages of longer duration of infection seroreverted the reactive treponemal test. Seroreversion of treponemal tests can also occur in patients with advanced HIV disease and AIDS (72,73)."

CDC Laboratory Recommendations for Syphilis Testing, United States, 2024 | MMWR

Reference for 'typically stay positive':

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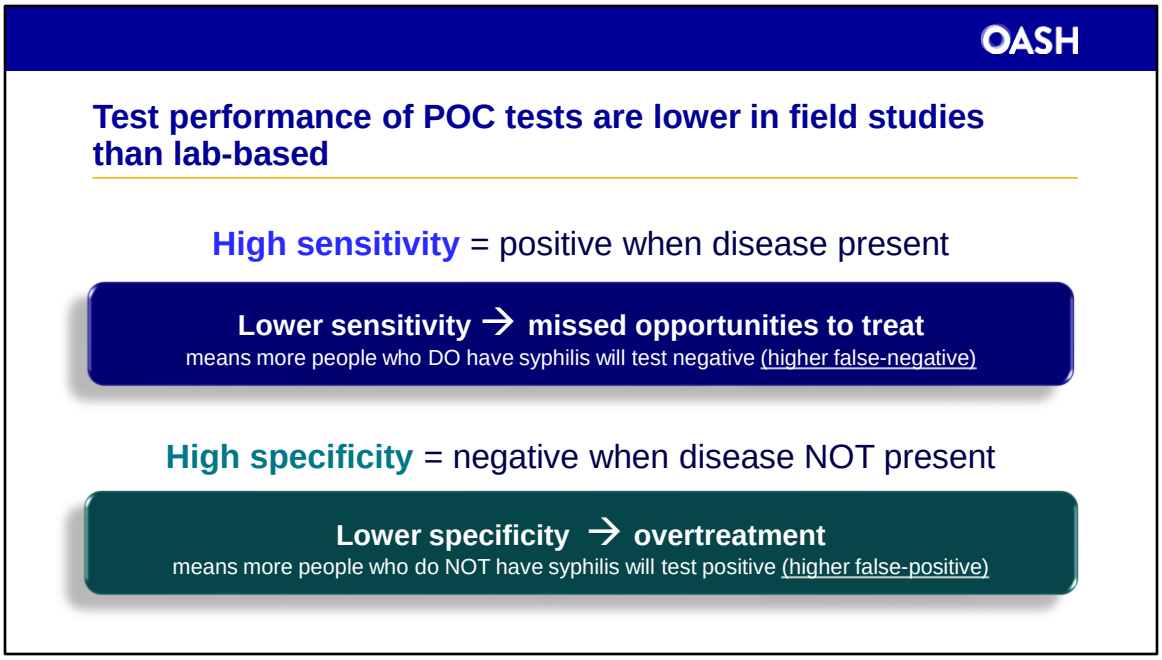

Another reason is the test performance, that is the sensitivity and specificity of point of care tests are lower when they're used in the field than when they are used in labs and compared to lab-based tests.

Briefly as reminder, lower sensitivity means that those who have syphilis will test negative and we'll miss opportunities to treat them. Lower specificity means that those who do not have syphilis will test positive, which can lead to overtreatment. Let's take a look at actual numbers on the next slide.

Syphilis Testing Sensitivity and Specificity

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Test Name and Type	Testing Site	Sensitivity %	Specificity %	Time to Results and Specimen
Chembio DPP® HIV-Syphilis HIV, Syphilis Treponemal	In field	**About 90%* (range: 85-100)**	**96%***	Rapid (15-minute fingerstick or venous whole blood)
Syphilis Health Check™ Syphilis Treponemal	In field	**96% (range: 77-100)**	**97%**	Rapid (10-minute fingerstick whole blood)
TPPA, EIA Treponemal Tests	Lab	**99%****	**99%**	Several days
RPR, VDRL Nontreponemal Tests	Lab	**About 94%^**	**99%**	Several days

Performance estimates and ranges based on unpublished CDC metanalysis from limited published data. See references in slide notes.
*Insufficient data for true point estimate for sensitivity, range is included. Specificity point estimate from 1 study
**For syphilis primary stage, sensitivity ranges between 90%-95%; for secondary and latent stages, 100% sensitivity
^For primary stage, sensitivity ranges between 75%-85%; for secondary and latent stages, sensitivity ranges 95%-100%

This chart shows sensitivity and specificity of POCT in the field and routine laboratory based testing. On the top line is Chembio. On the second line, the syphilis health check, rows below that show the lab-based testing.

For reference:
SHC: Performance of the Syphilis Health Check in Clinic and Laboratory-Based Settings - PubMed (nih.gov)
Laboratory Evaluation of a Commercially Available Rapid Syphilis Test - PubMed (nih.gov)

References:
1. Obafemi OA, Wendel KA, Anderson TS, Scott TE, Rowan SE, Travanty EA, Rietmeijer CA. Rapid Syphilis Testing for Men Who Have Sex With Men in Outreach Settings: Evaluation of Test Performance and Impact on Time to Treatment. Sex Transm Dis. 2019 Mar;46(3):191-195. doi: 10.1097/OLQ.0000000000000932. PMID: 30363029.
2. Fakile, Y. F., Markowitz, N., Zhu, W., Mumby, K., Dankerlui, D., McCormick, J. K., Ham, D. C., Hopkins, A., Manteuffel, J., Sun, Y., Huang, Y. A., Peters, P. J., & Hoover, K. W. (2019). Evaluation of a Rapid Syphilis Test in an Emergency Department Setting in Detroit, Michigan. *Sexually transmitted diseases*, *46*(7), 429–433. https://doi.org/10.1097/OLQ.0000000000000993
3. Fakile, Y. F., Brinson, M., Mobley, V., Park, I. U., & Gaynor, A. M. (2019). Performance of the Syphilis Health Check in Clinic and Laboratory-Based Settings. *Sexually transmitted diseases*, *46*(4), 250–253. https://doi.org/10.1097/OLQ.0000000000000974
4.US Food and Drug Administration. 501(k) Premarket Notification Decision Summary: Syphilis Health Check. 510(k) number: K102400, 2011. Available at: K102400. Accessed 6 July 2019.
5. Matthias J, Dwiggins P, Totten Y, Blackmore C, Wilson C, Peterman TA. Notes from the Field. Evaluation of the Sensitivity and Specificity of a Commercially Available Rapid Syphilis Test — Escambia County, Florida, 2016. MMWR Morb Mortal Wkly Rep 2016;65:1174–1175. DOI: http://dx.doi.org/10.15585/mmwr.mm6542a5
6. Kasaro, M. P., Bosomprah, S., Taylor, M. M., Sindano, N., Phiri, C., Tambatamba, B., Malumo, S., Freeman, B., Chibwe, B., Laverty, M., Owiredu, M. N., Newman, L., & Sikazwe, I. (2019). Field performance evaluation of dual rapid HIV and syphilis tests in three antenatal care clinics in Zambia. *International journal of STD & AIDS*, *30*(4), 323–328. https://doi.org/10.1177/0956462418800872
7. Bowen, V.B. (2016). A Bundle of Health: Syphilis Test Performance in the Field Evaluation of a Novel Dual HIV/Syphilis Rapid Test—Malawi, 2014-2015.
8. FDA insert: https://www.fda.gov/media/142615/download

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An analysis of the few studies available on POCT have shown that field use results in lower sensitivity and lower specificity compared to lab-based testing as you can see in the now blue and turquoise columns. I would like to point out that lab-based testing is designed to use treponemal and non treponemal tests together, and serially, so when their results are taken in their entirety, lab-based tests' accuracy of diagnosis is quite high.

Environmental conditions in the field are not the same as inside a lab. Some difference could arise from this. We've heard anecdotally that the PCO tests results can be more difficult to read. This maybe why the Chembio test comes with a reader. Programs that have implemented POCT mentioned on-going trainings to ensure results are read accurately. We recommend quality assurance reviews to track and increase the performance of the POCT.

Another important step to remember in establishing POCT program is that the tests are CLIA waived. Organizations need to establish a relationship with a CLIA approved laboratory and then apply for a CLIA waiver through that laboratory.

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References:
1. Obafemi OA, Wendel KA, Anderson TS, Scott TE, Rowan SE, Travanty EA, Rietmeijer CA. Rapid Syphilis Testing for Men Who Have Sex With Men in Outreach Settings: Evaluation of Test Performance and Impact on Time to Treatment. Sex Transm Dis. 2019 Mar;46(3):191-195. doi: 10.1097/OLQ.0000000000000932. PMID: 30363029.
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RECAP: Benefits and Challenges of POC Tests

Advantages

1. Quick results
2. Easier test
3. Could treat same day
4. Reduce loss to follow-up

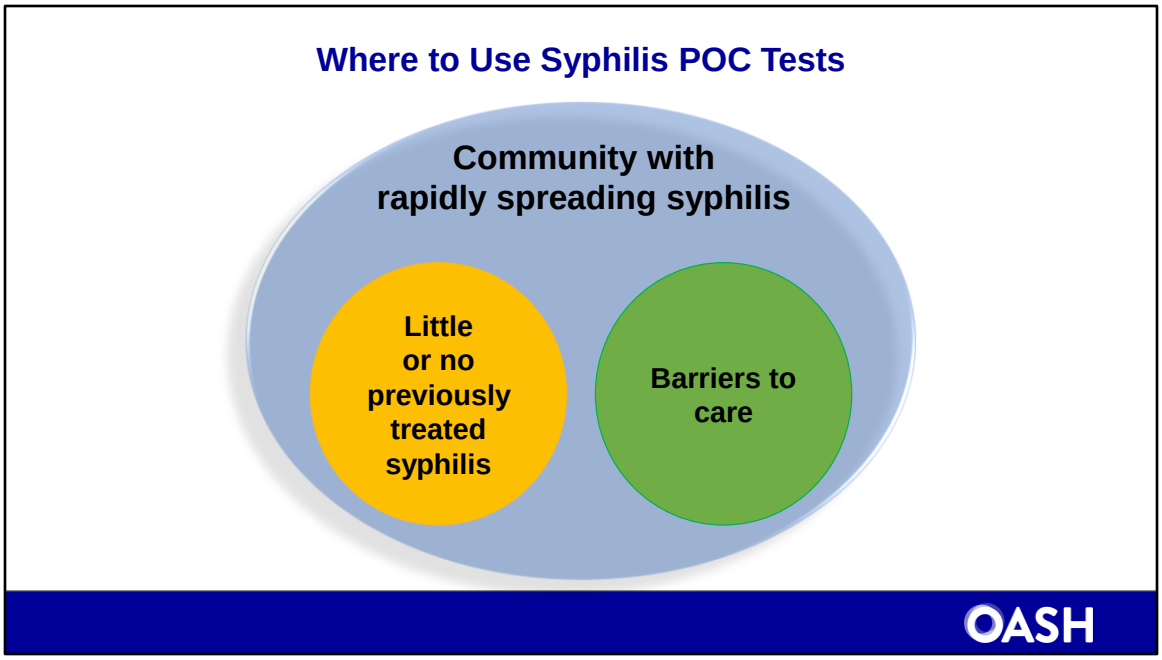
Challenges

1. Could lead to missed diagnosis or overtreatment
2. Only treponemal tests
3. Cannot be used in those with previously history of syphilis

As a quick recap, the advantages of point of care tests are quick results, easier to test and person could be treated on the same day which reduces lost to follow-up. Challenges include potential misdiagnosis or overtreatment; only offers treponemal tests and cannot be used in those the previous history of syphilis.

But with syphilis rates skyrocketing over the past decade, it's important to look for innovations and tools that could be used to detect syphilis.

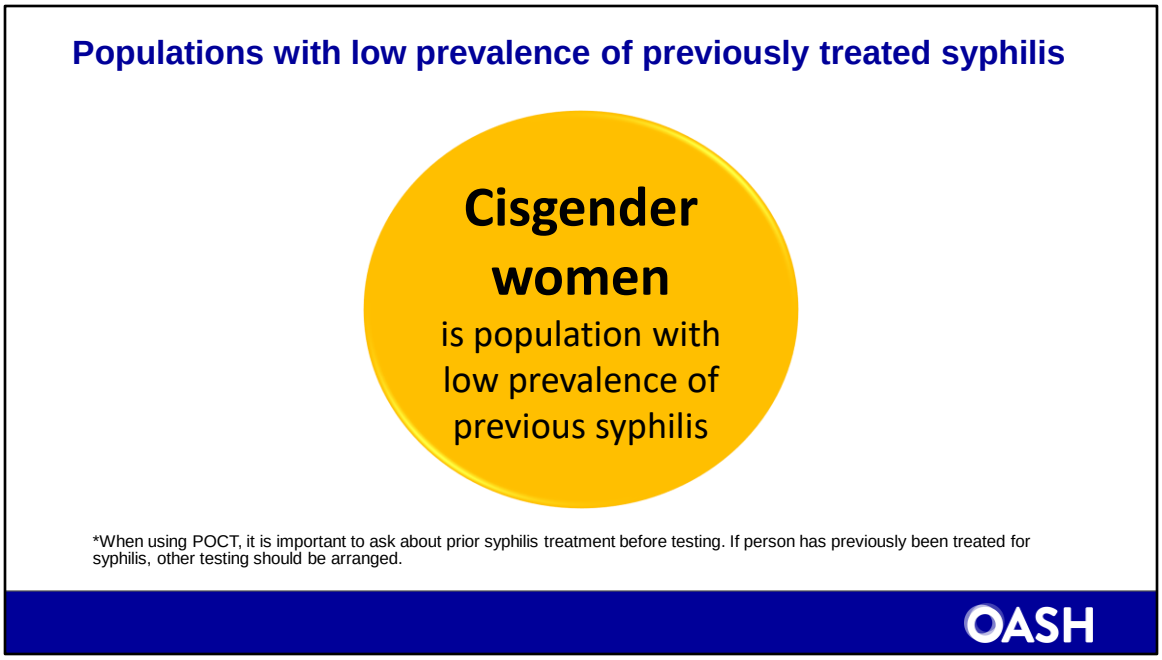
So how do we maximize the benefits and minimize the risks?



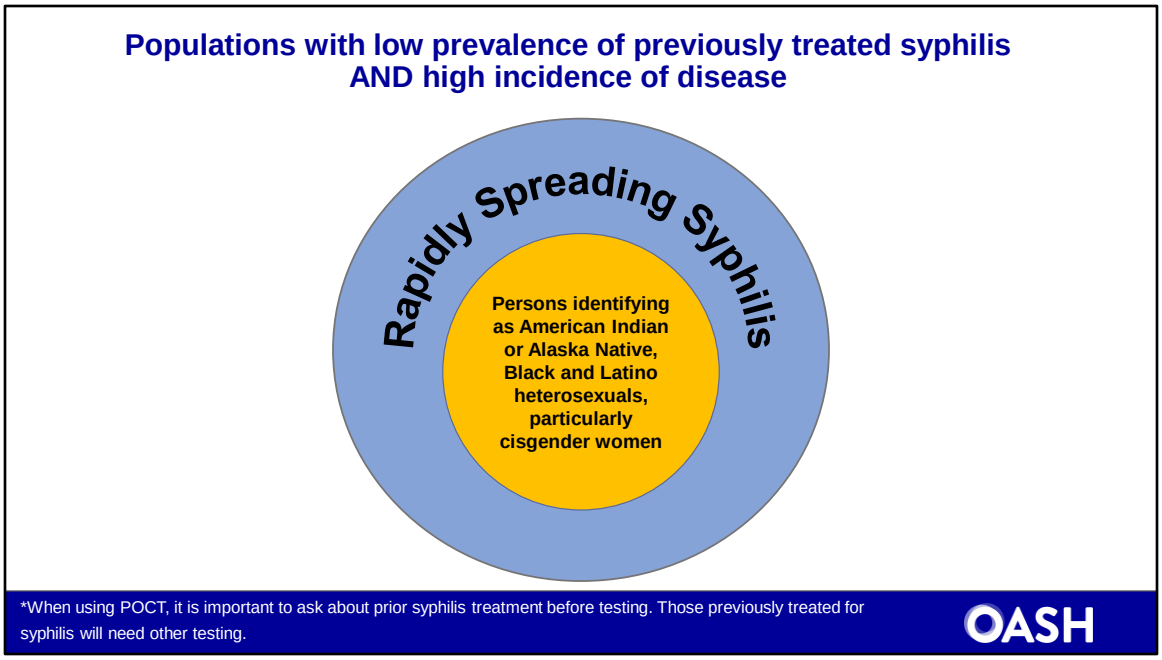
Here is diagram to illustrate where **syphilis** POCT could be implemented and take advantage of the opportunities it offers. Let's start with the large blue circle, which represents areas where syphilis is spreading rapidly, Focusing our efforts in areas of high incidence of disease makes sense intuitively. In these areas, there are populations such as those less likely to have previously treated syphilis (yellow circle), and those facing barriers to care (represented here as the green areas) where offering POCT also makes sense.

This may sound like niche marketing and it kinda is. It reflects different populations that are at increasing risk of syphilis and need to be reached. POCT creates this opportunity to test and treat on the same day.

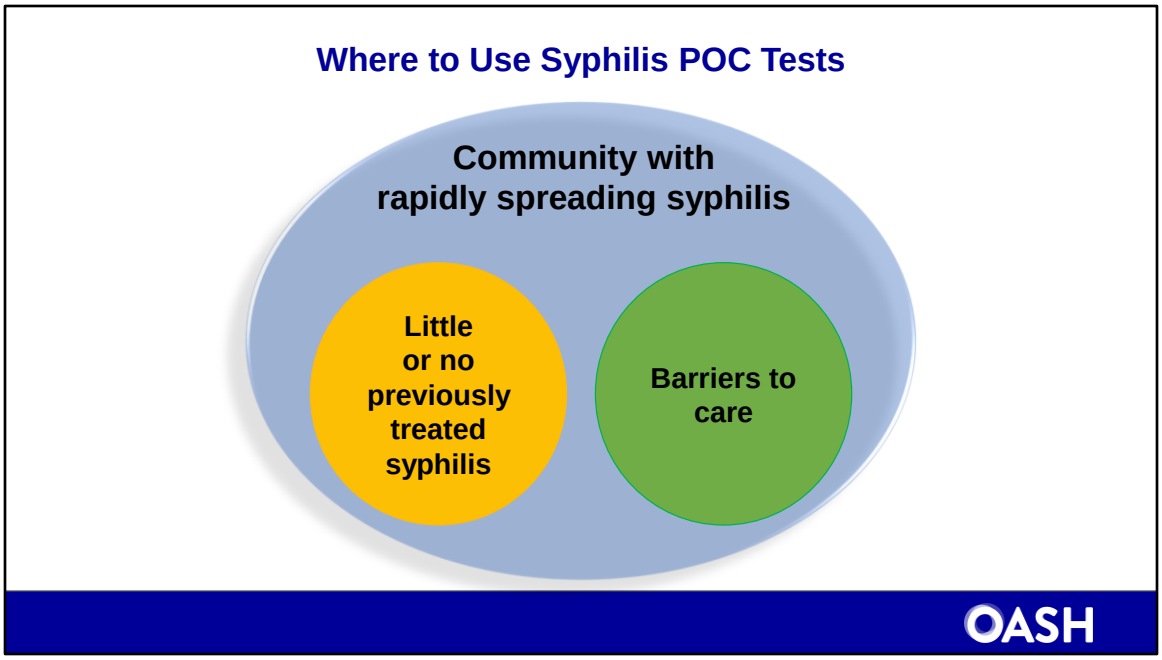
Let's look more closely at the yellow and then green areas.



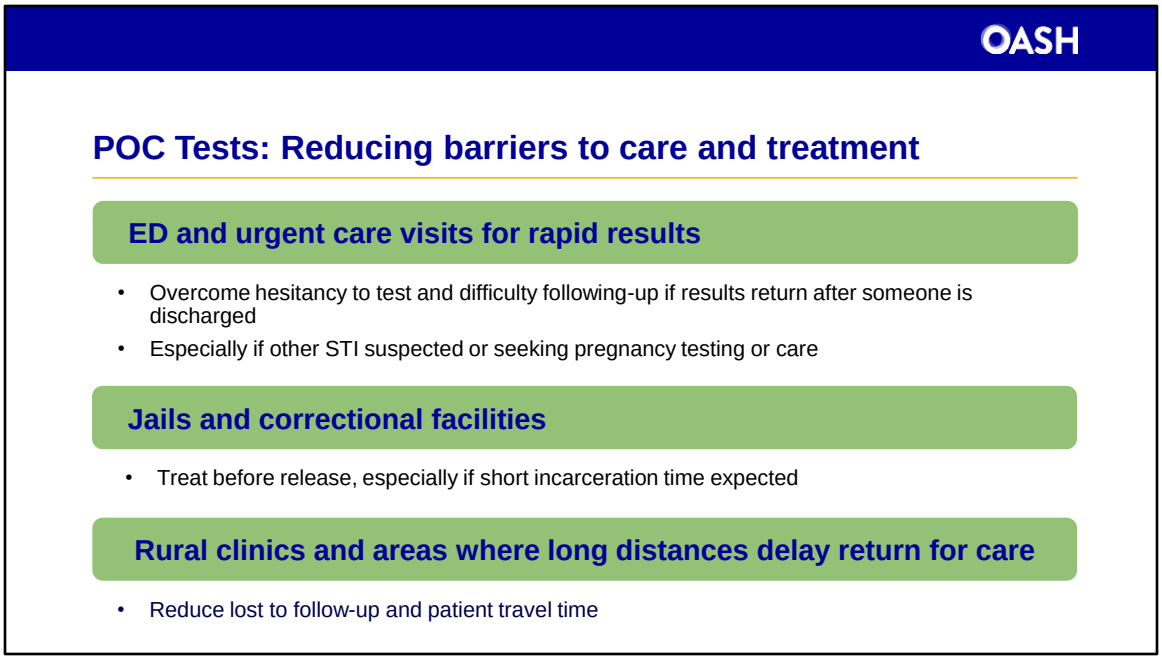
Where is there low prevalence of previously treated syphilis? As a population, cisgender women, are less likely to have recurrent infections with syphilis, thus they have low prevalence of previously treated syphilis.



Some populations with CURRENTLY high incidence of syphilis and low prevalence of prior syphilis include persons identifying as American Indian or Alaska Native, particularly women and Black and Latino heterosexuals, particularly women.



Returning to our diagram, the green circle represents those with barriers to care, of which there are many. POCT provides results at the same visit allowing treatment at the same visit. The person doesn't have to overcome the same barrier TWICE to get needed care.



For sites that already have the capacity to provide treatment, POCT provides the rapid results to act on. For example, use in emergency departments and urgent care sites would allow clinicians to provide treatment while the person is still at the facility. This would be especially important if another STI is suspected, or the person is seeking pregnancy testing or seeking care while pregnant.

Jails would be another place that point of care testing could be used to ensure test results and treatment are available in a timely fashion.

For rural areas and clinics, long travel time is a barrier to care. Use of POCT would allow same day treatment and reduce lost to follow-up.

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Where else would POC tests be useful to overcome barriers to care?

Substance use care and harm reduction sites

- Many are tested for HIV, can syphilis POCT be added?

Shelters and other short-term service facilities

- High turn-over and often vulnerable population

There are other sites where care is provided, and rapid results could be implemented to detect a syphilis infection. Many who seek care at substance use and harm reduction sites are tested for HIV, POCT for syphilis for could be added.
Many shelters serve vulnerable populations and have a high turn over.

Clinical Considerations of Positive POC Tests

1. **Ask about symptoms and sexual history**
   (Determines syphilis stage, length of infection and treatment course)

2. **Physical exam for signs,** if possible
3. **Screen** for neuro-, oto-, and ocular syphilis

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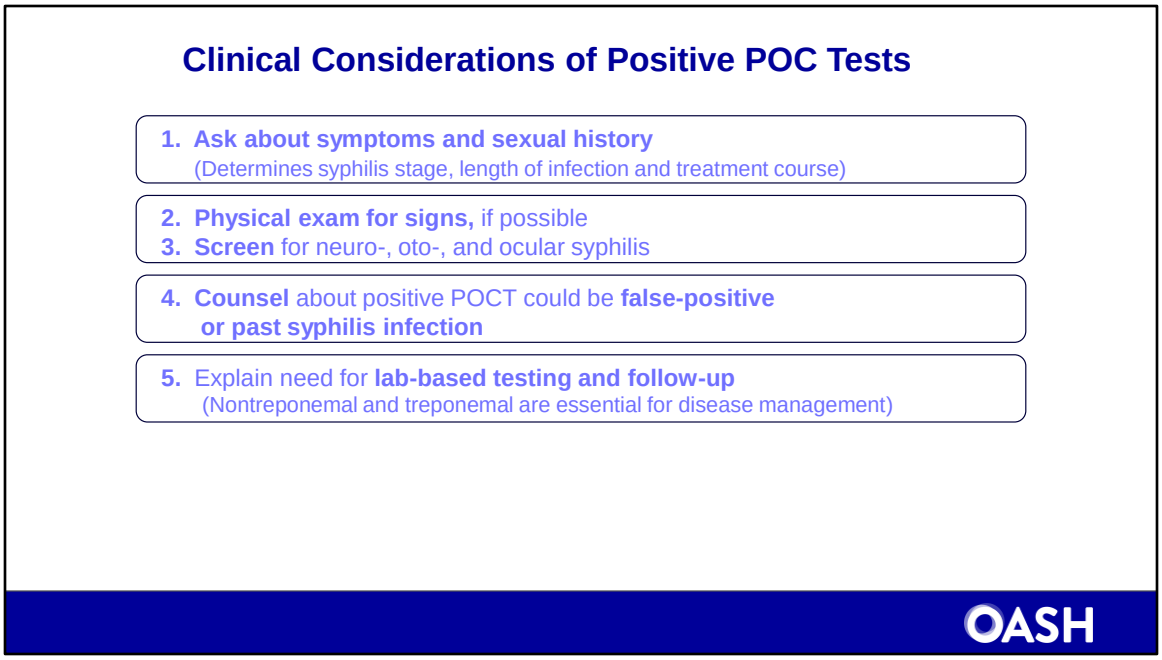
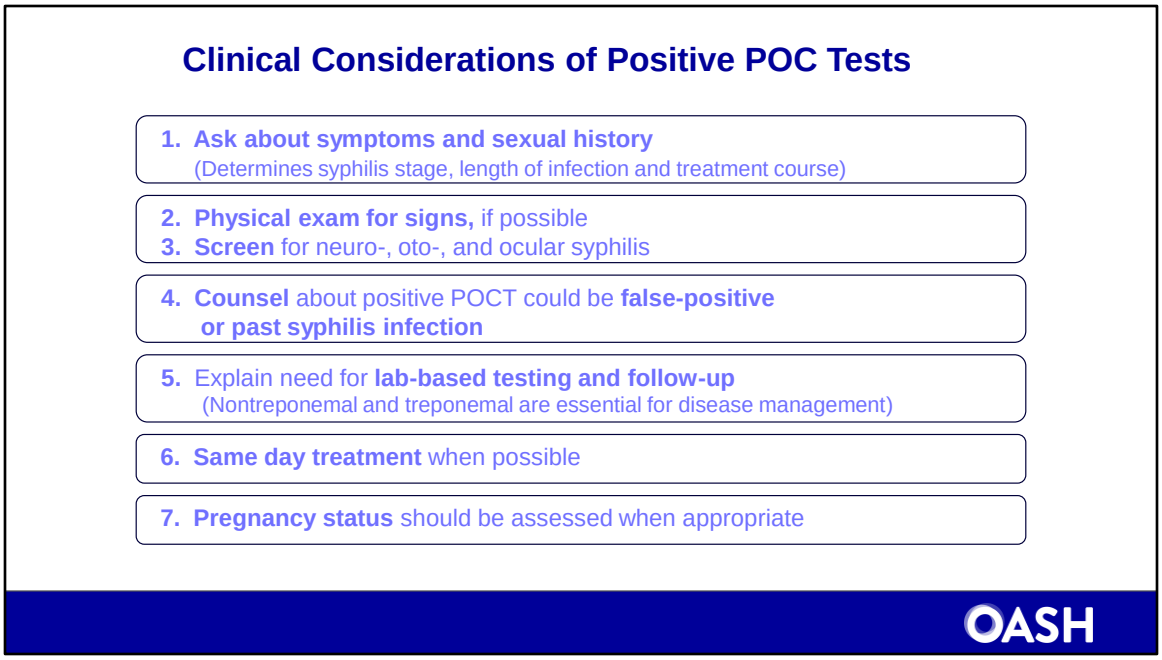
I would like pivot and to cover some clinical considerations that are included in the document when the point of care test is positive. Asking about symptoms and sexual history can help determine stage of syphilis and The length of infection, which determines the treatment course.
If possible, a physical exam for signs/symptoms and an assessment for neuro, otic, and ocular syphilis should be done.



People with positive results should be counseled that the POCT results could be a false positive or reflect a past syphilis infection and they need confirmatory lab-based testing and follow up.



When possible, same day treatment should be given based on the length of an infection.

Anyone with reproductive capacity should be offered a pregnancy test.

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What else would support implementation …

- Overcome barriers to providing immediate treatment, especially if testing done in the field
- Hotline or warm line to review syphilis history and determine if treatment needed
- Increase HCP comfort with presumptive treatment
- Training and education (laboratorians, physicians, partners, public health staff, community)

What else would support or make point of care testing more effective? Looking for ways to overcome barriers to provide **immediate** treatment, including bicillin and especially if the testing is done in the field. The treatment should be provided in the field too.

While not absolutely necessary to make a decision to treat the person in front of you, a hotline or a warm line with syphilis lab and treatment history could be available to coach and help determine if treatment is needed. If we want others to engage in this work, we need to support their efforts to enter it. We need training and education of everybody involved, laboratorians, physicians, partners, public health staff and the community.

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Caveats to POC Tests…

- POC tests can complement lab-based testing
  - ✓ Will require confirmatory lab-based testing
- Coupling immediate treatment with test will be important
- CLIA waiver can delay implementation
- Needs a quality assurance plan to maximize test performance
- Collaboration with health department and other partners to implement

In summary, POCTs have some limitations but can be used to augment and compliment lab-based testing. Figuring out how to get immediate treatment when testing positive is important.

They need a CLIA waiver, so start this step early in process.
POCT should be implemented with a quality assurance plan for results and in collaboration with health department and other partners.

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POC Tests can…

- Expand access to care and meet people where they are
- Detect asymptomatic infections rapidly
- Create opportunity to immediately treat
- Be a tool to eliminate syphilis

POCT can meet people where they are and provide the care they need.

Be used to rapidly detect infections and create the opportunity to immediately treat.

It's tool we can use to reduce syphilis

Implementation of Syphilis Point of Care Testing

Stephanie N. Taylor, MD
Med. Director, LA Office of Public Health STI/HIV/Hepatitis Program
Professor of Medicine – Infectious Diseases
LSU School of Medicine – New Orleans, LA

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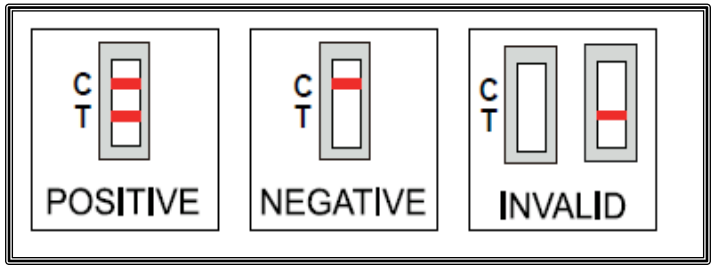
Rapid Syphilis Testing

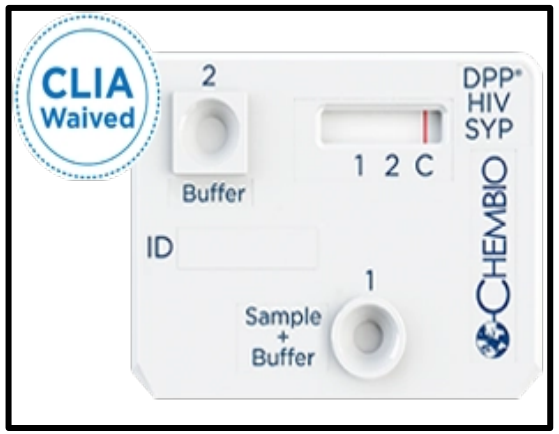
- Trinity Biotech - Rapid Syphilis Health Check

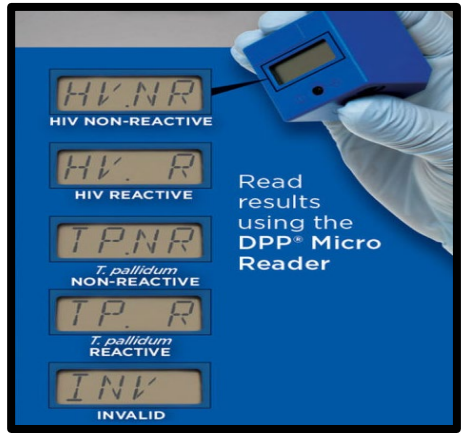
- First FDA-approved and CLIA-waived rapid syphilis test in U.S.
- Uganda and Zambia
  - **< 10% of infected women treated prior to SHC**
  - **Same day testing and treatment – 90% of Infected women were treated (J Acquir Immune Defic Syndr.2012;61:e40-46)**
- Serum, plasma, finger stick and whole blood



Dual Rapid Syphilis and HIV Tests

- **ChemBio DPP® HIV-Syphilis**
- Fingerstick whole blood, venous whole blood, or plasma specimens
- First & only FDA-approved and CLIA-waived HIV-Syphilis Rapid Test





Settings for Syphilis POCT

- **Personal Experience**
  - LSU-CrescentCare Sexual Health Center and New Orleans Delgado STD Clinic – 3,000 – 3,500 tests/month for 10 years (400,000 – 500,000 tests)
  - LA Office of Public Health Clinics, Pre-natal Unit, Community Health Fairs

- **Other settings to consider:**
  - After delivery and before discharge:
    - In women with no pre-natal care and/or no syphilis serology during pregnancy and results of syphilis serology drawn at delivery will not be available prior to discharge.
    - Example – Friday/weekend discharge or weekday when lab unable to perform test prior to discharge
  - Correction facilities
  - Emergency Departments
  - Substance Use Treatment Programs, and Harm Reduction Program
  - Outreach Events and Community-based care
  - Rural communities and Shelters

Populations for Syphilis POCT

- **Personal Experience**
  - Clinics and other settings where there may only be a single or limited interaction with healthcare – STI Clinics and transient populations
  - Challenge locating individual to bring back after traditional lab results available
  - Decreased phlebotomy. Only needed for patients with previous history.

- **Other Populations:**
  - At delivery if no prenatal care or syphilis serology
  - Persons using substances and not engaged in health care
  - Populations with limited access to healthcare
  - Geographic areas where syphilis is spreading rapidly

Positive Experiences Syphilis POCT

- **Patient and client satisfaction**
  - No phlebotomy **
  - Same day results and treatment
- **Clinic Staff and DIS (partner services) satisfaction**
  - Clinic flow and same day results/treatment
  - Ease of performance and increased number of patients screened
  - Decreased need for phlebotomy (Decreases time in lab, especially if difficult blood draw)
  - Decreased refusals due to need for phlebotomy
  - Addresses difficulty in locating patients after traditional results are available
  - Assist with supply chain issues with tubes, needles, etc.

Setting up Syphilis POCT and Challenges

- **Clinic or healthcare setting**
  - Clinic flow, EHR orders and billing
  - Collaboration – DIS, Lab with CLIA license for CLIA-waived test
  - Training – Staff confidence, decrease false positive results, controls, etc.

- **Community Screening**
  - Planning and outreach prior to the event (with DIS for some events)
  - Selective locations and events
  - Training - Staff confidence, decreased false positive results, controls, etc.
  - Collaboration – Lab with CLIA license, health dept., referrals, DIS
  - Phlebotomy onsite or referral for phlebotomy and treatment
  - Health fairs – Screening then phlebotomy in the van

Community Syphilis Rapid Test Screening

COVID-Associated Supply Chain Difficulties Pre- and Post Implementation of Syphilis POCT

December 2021-March 2022

- POCT - New positive pregnancy tests in clinic
- POCT - LA Office of Public Health provided tests to Community-based organizations
- 9,582 patients had STI panel
- 6,246 patients - phlebotomy and lab testing
- **65% screened**
- Expansion roll out April 2022

May 2022-August 2022

- Expanded to all Public Health Clinics
- 9,462 patients had STI panel after expansion of POCT
- 8,355 patients - Rapid syphilis POCT (Those with previous history had phlebotomy and lab testing
- **88% screened**
- Rapid Syphilis POCT continued

Rapid Syphilis POCT Experience - Summary

- Excellent experience and satisfaction with syphilis POCT – even considering challenges
- Increased screening within clinic
- Same day testing and treatment if needed
- Opportunity for engagement and collaboration with Health Department and community – Combine with other services, flu/COVID vaccine, etc.
- Expansion of testing beyond the clinic to other settings and community
- Ability to combine with HIV testing is exciting

Overview of Best Practices for 2.4MU IM Bicillin L-A® Injections

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Office of Infectious Disease and HIV/AIDS Policy

OASH | Office of the Assistant Secretary for Health

Best Practices for 2.4MU IM Bicillin L-A® Injections

Acknowledge patient anxiety and fear and reassure them. Employ relaxation technique like deep breathing.

Warm dose prior to injection and shake the contents between hands 3-4 minutes.

Divide dose into 2 and give smaller bilateral injections; inject the medicine over 15-20 seconds.

Give the dose while patient is lying prone on the exam table; advise that they walk around after injection.

Thank You and Contact Information

For more information, or if you have any questions or feedback, contact the HHS Sexually Transmitted Infections Inbox at STI@hhs.gov

Notify CDC's DSTDP (stdshortages@cdc.gov) of any shortage or low inventories of STI treatments in your jurisdiction so CDC can continue monitoring treatment availability.

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