#### PrEP Learning Collaborative: Rapid Syphilis Testing in Practice Moderated by: Wyatt Hanft, MD MPH

#### **Guest Speakers**

- Stephanie Taylor, MD; Louisiana State University
- Jamie Morris, BSN, RN; El Paso County Public Health (CO)
- Alyson Decker, AGNP-BC, MPH; San Francisco DPH (CA)



December 5th, 2024 · Virtual · 12:00-1:30PM (PT)

## Agenda

- 12:00 12:10pm PT: Welcome & Introductions
- 12:10 12:25pm PT: Overview of Syphilis Diagnostics and Point-of-Care Syphilis Tests (Wyatt Hanft, MD)
- 12:25 12:40pm PT: Stephanie Taylor, MD
- 12:40 12:55pm PT: Jamie Morris, RN
- 12:55 1:10pm PT: Alyson Decker, AGNP-BC, MPH
- 1:10 1:30pm PT: Q&A and Discussion



#### Stephanie Taylor, MD



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 Stephanie N. Taylor, MD is a Professor of Medicine in the Section of Infectious Diseases at Louisiana State University (LSU) Health Sciences Center in New Orleans. She is board certified in both Internal Medicine and Infectious Diseases and her clinical practice and research focus on sexually transmitted infections, STIrelated diagnostic trials and STI clinical drug trials. Dr. Taylor is the medical director of the LSU Infectious Diseases STD laboratory and the Louisiana Office of Public Health STD/HIV Program and she was previously medical director of the LSU STI Research Program and LSU-CrescentCare Sexual Health Center.

#### Jamie Morris, RN BSN



• Jamie Morris, BSN, RN, is the Reproductive Health Clinic Manager at El Paso County Public Health in Colorado. Prior to her current role, Jamie was the Public Health Nurse who developed the congenital syphilis prevention program within the Criminal Justice Center (CJC). In that role, Jamie built and successfully launched this program in collaboration with CJC, El Paso County Sheriff's Office and the contracted medical groups at CJC. Prior to her work in El Paso County Public Health, Jamie was a labor and delivery triage and nursery nurse for 8 years. She has a passion for meeting patients where they are at, and providing care for the most vulnerable populations in her community, which has carried over into her work in public health.



### Alyson Decker, NP, MPH



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 Alyson Decker leads the HIV/STI training and technical assistance program with Disease Prevention & Control at the San Francisco Department of Public Health. In this role, she provides training and capacity building assistance to healthcare providers and frontline staff around improving sexual healthcare and HIV and STI prevention and treatment. She manages a rapid syphilis testing program with people experiencing homelessness and is leading city-wide efforts to address rising rates of congenital syphilis. Alyson is also a nurse practitioner at SF City Clinic, San Francisco's only municipal sexual health clinic.

### Learning objectives

- List the three available point-of-care (rapid) syphilis tests and differentiate them based on at least two key features
- Describe how rapid syphilis testing is being used in at least two different healthcare settings
- Identify at least two benefits and two challenges associated with point-ofcare syphilis testing
- Recognize at least two populations for whom rapid syphilis testing would be most appropriate



# Syphilis diagnostics & point-of-care (rapid) tests



## Syphilis serologies

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Non-Treponemal Tests	Treponemal Tests
Examples: RPR and VDRL	Examples: TPPA, FTA-ABS, EIA, point-of-care (rapid) tests
Measures anti-lipoidal antibodies which are non- specific and may be positive in other conditions	Detects antibodies specific to T. pallidum, the causative organism of syphilis
Result is quantitative (e.g., non-reactive, 1:1, 1:2, 1:4, 1:8, 1:16, etc.)	Result is qualitative (e.g., reactive or non-reactive)
Value increases with re-infection and decreases after treatment or over time (even without treatment)	Antibodies usually stay positive for life after initial infection (even with treatment)
Used to assess disease burden, treatment adequacy, and re-infection	Used to identify a history of syphilis infection (treated or untreated)

- A past or current syphilis infection can be diagnosed with one of the following:
  - Reactive non-treponemal + reactive treponemal test (e.g., reactive RPR + reactive TPPA), <u>OR</u>
  - Two reactive **treponemal** tests (e.g., reactive **EIA** + reactive **TPPA**)

### Syphilis serology timeline

- Treponemal tests

   usually stay positive
   forever after infection
   (regardless of treatment)
- Performing a treponemal test in someone with a known history of syphilis will not tell you if they have been reinfected

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Attribution: Papp et al 2024.

## Point-of-care syphilis testing

#### • All rapid tests are **treponemal** tests

- Should not be used for people with a known history of syphilis
- Rapid syphilis tests are **not** diagnostic
- Used as:

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- Initial screening test, or
- In conjunction with nontreponemal lab-based test and clinical findings for diagnosis

	Syphilis Health Check	DPP HIV-Syphilis System	First to Know Syphilis Test
Used to detect:	Syphilis	Syphilis and HIV	Syphilis
Who can perform:	CLIA-waived – performed under CLIA waiver by healthcare provider; DIS & HIV counselors under certain circumstances*		Over-the- counter – performed by patient

\*DIS may perform CLIA-waived tests under the supervision of local public health laboratory director – see <u>link</u> for additional details. HIV counselors may perform CLIA-waived tests if trained by CDPH Office of AIDS – see <u>link</u> for additional detail.

### Advantages and disadvantages

#### Advantages:

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- Quicker results: 15 minutes versus hours-days
- Easier to collect: fingerstick versus venipuncture
- Easier to perform: non-clinical staff versus phlebotomist/lab technician
- Can facilitate same day treatment for people who may have difficulty following up or who are at high risk for morbidity (e.g., pregnant people or people experiencing homelessness)

#### • Disadvantages:

- Not diagnostic alone: require labbased tests to confirm
- Less accurate: lower sensitivity and specificity than lab-based tests in combination (e.g., RPR + TPPA)
- Should not be used for people with a known history of syphilis

## When may POC syphilis testing be helpful?

#### • Settings:

- Correction facilities
- Emergency departments
- Substance use treatment programs
- Syringe services and other harm reduction programs
- Outreach programs
- Rural communities
- Shelters



#### Populations:

- Pregnant people not engaged in prenatal care
- Persons using substances and not engaged in healthcare
- Populations with limited access to healthcare
- Geographic areas where syphilis is spreading rapidly







## Syphilis Health Check (Diagnostics Direct, LLC)

- Detects *T. pallidum* antibodies with enzyme immunoassay using 20uL fingerstick whole blood and buffer solution
- Ages ≥ 13

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- Results in 10 minutes
- Accuracy compared to a combination of FDA-cleared serologic tests:
  - Positive percent agreement: ~96%
  - Negative percent agreement: ~97%





Attribution: ZSFG Laboratory Procedure Manual; Syphilis Health Check

#### DPP<sup>®</sup> HIV-Syphilis System (Chembio Diagnostics, Inc)

- Detects HIV-1&2 and T. pallidum antibodies with multiplex immunoassay using 10uL fingerstick whole blood and buffer solution
- Cannot be visually read requires DPP Micro Reader (purchased separately)
- Results in **15 minutes**
- Ages ≥ 13

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- Accuracy compared to a combination of FDA-cleared serologic tests:
  - Positive percent agreement: ~90%
  - Negative percent agreement: ~96%



**DPP**<sup>®</sup>

**Micro** 

Reader

Test device







## DPP® HIV-Syphilis System (Chembio Diagnostics, Inc)





**HIV Non-Reactive** 



**HIV Reactive** 



Treponemal Reactive



Reactive

INV

**Invalid Result** 

• Each DPP<sup>®</sup> Micro Reader can be used 3000 times



### Who can perform CLIA-waived tests?

- Three pathways in California for becoming eligible to perform CLIAwaived rapid syphilis tests:
  - Any health care provider able to perform CLIA-waived tests within their scope of practice under <u>Business and Professions Code</u> (<u>BPC</u>) 1206.5 (e.g., physicians, APCs, pharmacists, RNs, etc.)
  - 2. <u>Disease investigation specialists (DIS)</u> or other non-licensed health department staff under local public health laboratory supervision
  - 3. <u>HIV test counselors</u> (pending) who have either been trained by, or completed training approved by, CDPH Office of AIDS

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## CLIA-waived syphilis test resources

 California Prevention Training Center: CLIA-Waived Syphilis Point-of-Care Testing Options for Providers (available soon)

 National Syphilis and Congenital Syphilis Syndemic Federal Task Force: <u>Considerations</u> <u>for the Implementation of POCTs for Syphilis</u>



	SYPHILIS HEALTH CHECK	HIV SYPHILIS SYSTEM		
Manufacturer	Diagnostics Direct, LLC	Chembio Diagnostic Systems, Inc.		
What it tests for	Syphilis	Syphilis and HIV <sup>1</sup>		
Age parameters	Persons aged 13 or older	Persons aged 13 or older		
Who can	These are CLIA-waived tests and can on	ly be performed by healthcare providers as		
perform these tests	defined in <u>Business and Professions Code 1206.5</u> , as well as Disease Intervention Specialists and HIV Test Counselors under specific circumstances (see pg. 3).			
Who should be	Both tests may be used for:			
screened with	<ul> <li>initial syphilis screening of asympt</li> </ul>	tomatic patients without a known history of		
these tests	syphilis, or	• • •		
	<ul> <li>diagnosis of syphilis in symptomatic patients in conjunction with a non-treponemal test (e.g., rapid plasma reagin (PPP)) and clinical findings</li> </ul>			
	Both tests may be used in groups that meet synhilis screening and expanded screening			
	criteria. They may be particularly useful for populations with increased syphilis			
	<ul> <li>men who have sex with men</li> </ul>	onowing up for treatment, including.		
	<ul> <li>commercial sex workers and their c</li> </ul>	lients		
	<ul> <li>people who are incarcerated</li> </ul>	incritis		
	<ul> <li>people who are incarcerated</li> <li>people who use substances, especially methamphatamine</li> </ul>			
	people who use substances, especially methamphetamine     people experiencing homelessness			
	people experiencing nomelessness     people visiting emergency denartments or			
	<ul> <li>pregnant patients with limited or no prenatal care</li> </ul>			
Window period	Syphilis detection: 10-90 days after	Syphilis detection: 10-90 days after		
	exposure	exposure		
		HIV detection: 23-90 days after exposure		
Who should	People with a known history of syphilis	People with a known history of syphilis or HIV		
NOT be	People with a history of syphilis	<ul> <li>People with a history of syphilis should</li> </ul>		
screened with	should see a provider for lab-based	see a provider for lab-based testing		
these tests	testing including a non-	including a non-treponemal test (e.g.,		
	treponemal test (e.g., RPR or	RPR/VDRL)		
	laboratory (VORI)	<ul> <li>People with a history of HIV should be linked to one to one of the history of HIV should be</li> </ul>		
		treatment and resources		
Method of	A qualitative enzyme immunoassay	A qualitative, multiplex, immunoassay for		
syphilis	for detection of Treponema (T.)	the detection of antibodies to both HIV-1/2		
detection	pallidum antibodies (treponemal test)	and T. pallidum (treponemal test) using		
	using finger stick whole blood	fingerstick whole blood		
Accuracy <sup>2</sup>	Syphilis: PPA ~96%; NPA ~97%	Syphilis: PPA ~90%; NPA ~96%		
	HIV: sensitivity 98-100%; specificity: 99-			
		100%		
Test	Please refer to the package insert	Please refer to the package insert		
Sample volume	20 microliters	10 microliters		
Time to test	10 minutes	15 minutes		
result	20 million	20 1111000		
Test	15 to 30°C (59 to 86°F)	18 to 25°C (64 to 77°F)		
temperature	. ,			
Result	Results are positive, negative, or	The results of HIV-Syphilis System are read		
interpretation	invalid. and interpreted only by a DPP Micro Reade			
	Positive: colored bands in both with dedicated software. Results should no			
	the test (T) area AND control (C) be read manually. Results may include:			
	area			
	<ul> <li>Negative: 1 colored band in the</li> </ul>	HV.NR: HIV		
	control area only	A HV PLUV reactive		
	<ul> <li>Invalid: no distinct colored bands in either area OP 1 colored bands</li> </ul>	TP NPL T pallidum		
	in test area and no band in control	non-reactive		
	area	• TP.B: T. pallidum		
		reactive		
		INV: invalid result		
	POSITIVE NEGATIVE INVALID			



## First to Know<sup>®</sup> Syphilis Test

- The first at-home, over-the-counter (OTC) syphilis test; manufactured by NOWDiagnostics
- Cost: \$28-29 over-the-counter; \$17.50 public health pricing or \$210 per case of 12 tests (no shipping charge)
- OTC designation: the test can be performed in healthcare settings without a CLIA waiver, but all steps must be performed by the patient – staff can only coach the patient through the process
  - Patient may choose to report their results to staff





## First to Know<sup>®</sup> Syphilis Test

- Detects T. pallidum antibodies with a lateral-flow, visuallyread, chromatographic immunoassay using 40uL of fingerstick capillary whole blood
  - No software, instruments, or accessories required (except timer)
- Results in **15 minutes**; must be read by 30 minutes
- No lower age limit

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- Accuracy compared to a combination of FDA-cleared serologic tests:
  - Positive percent agreement: 93%
  - Negative percent agreement: 99%





#### **Negative Result**

с	
т	

#### **Invalid Result**

C T	C T	

#### **Please provide feedback!**



