

# Validation and prospective evaluation of mailed dried blood spot (DBS) for dual detection of HIV and syphilis using the DPP<sup>®</sup> HIV-Syphilis test

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**POC**

**Technologies  
Research for**

**STDs**

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Chembio

Study participants

# IWantTheKit (IWTK)

Mail-in, self-collection, online platform for STI testing

Order a Free, Accurate, and Confidential STI/HIV Home-Test Kit

Read More

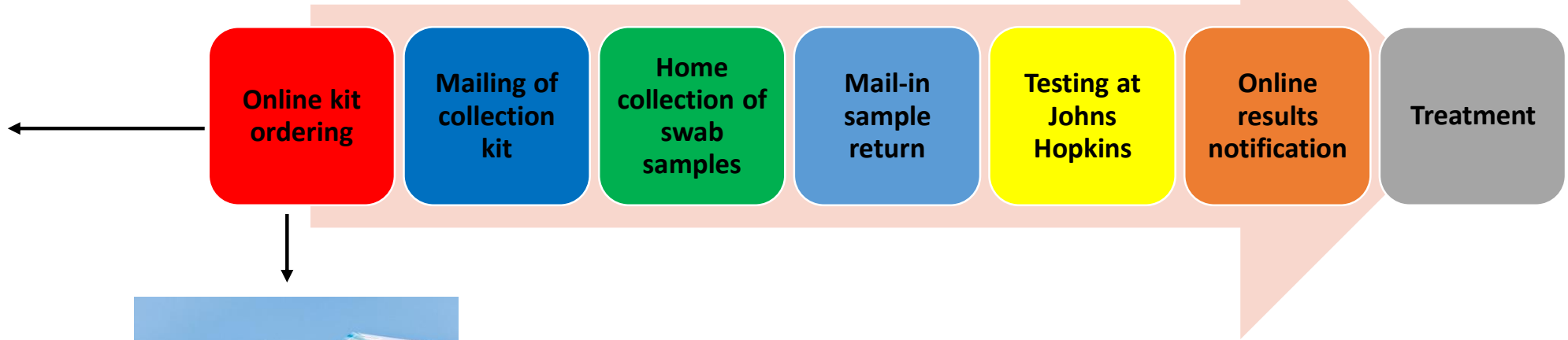


Home collection kit

Chlamydia,  
gonorrhea, and  
trichomonas



HIV home test

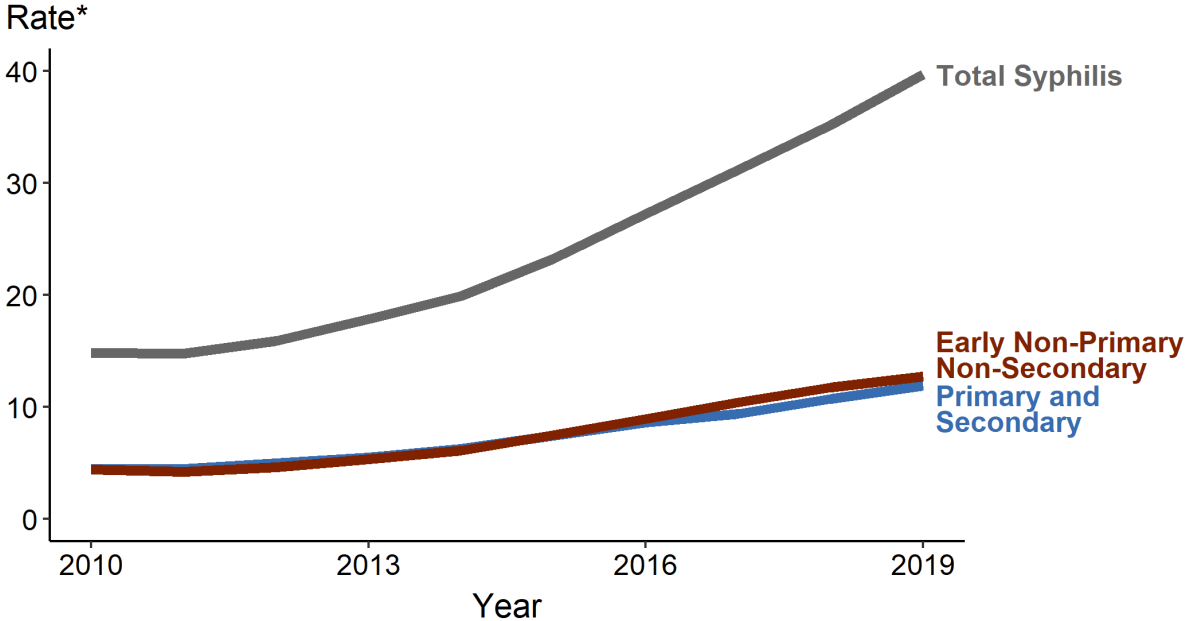


Currently not offered

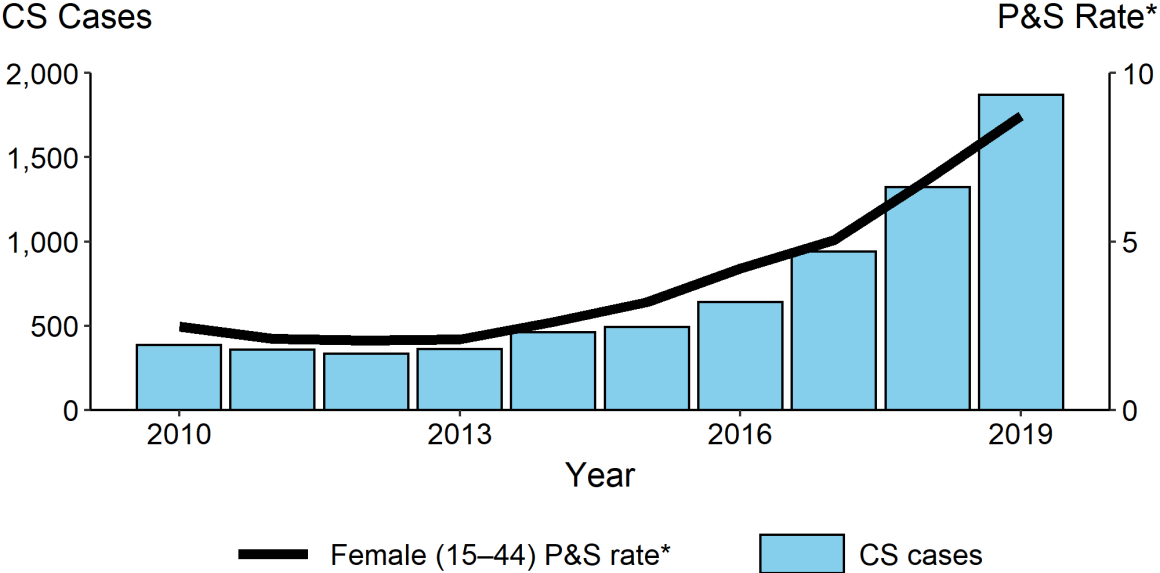
HIV confirmatory testing

Syphilis testing

# Increase in syphilis and congenital syphilis



\* Per 100,000



CS = Congenital syphilis; P&S = Primary and secondary syphilis



# Validation of the Chembio DPP HIV/syphilis assay using dried blood spot (DBS)

## Evaluation using mail-in

- ❖ **Spiked DBS samples**
- ❖ **Prospectively-collected DBS samples**

# Dual Path Platform (DPP) HIV and Syphilis test

- Only FDA HIV and syphilis rapid test
- Sensitivity: >99% for HIV and >94% for *T. pallidum*
- Fingertick whole blood, venous whole blood, or plasma specimens

**Not approved for use with DBS**

**1 Prepare**

FINGERSTICK WHOLE BLOOD

VENOUS BLOOD

**2 Run**

2 drops Sample + Buffer to Well 1

4 drops Running Buffer to Well 2

WAIT 5 MINS

WAIT 10 MINS

**3 Read**

Read results using the DPP® Micro Reader

HV.NR  
HIV NON-REACTIVE

HV.R  
HIV REACTIVE

TP.NR  
*T. pallidum* NON-REACTIVE

TP.R  
*T. pallidum* REACTIVE

INV  
INVALID



# Evaluation using spiked DBS samples

4 HIV-Pos/syphilis-Neg  
4 HIV-Neg/syphilis-Pos  
4 HIV-Pos/syphilis-Pos  
4 HIV-Neg/syphilis-Neg

3 sets of 16  
DBS

Tested same  
day

Mailed to JHU  
laboratory

Mailed to  
Chembio

Spiked DBS samples mailed through USPS

Mailed DBS sample results compared to  
same day testing results

## Concordance of mailed DBS samples to freshly-prepared DBS

Testing location	HIV	Syphilis
JHU	100%	100%
Chembio	100%	93.4%*

\*One syphilis false-negative

Mailed DBS samples can be  
used with Chembio assay

# Prospectively-collected DBS samples

## Participant recruitment

Nested within a larger Chembio evaluation (2019 – 2022) >300 participants  
Johns Hopkins Hospital Emergency Department

**DBS sub-study  
Sept 2021**

**Participants  
collected DBS  
and completed  
survey**

**DBS mailed to  
laboratory**

**DBS analyzed  
(blinded)  
Chembio assay**

**DBS results  
compared to  
serology and  
Chembio (ED)  
results**



# DBS collection using simulated living room environment

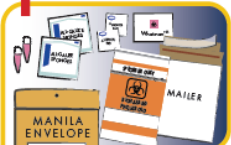



Collection kit

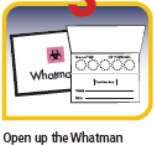



## INSTRUCTIONS FOR DRIED BLOOD SPOT (DBS) SPECIMEN COLLECTION


Disclaimer: For participation in this study, you will be pricking your finger in order to fill a DBS card with drops of blood. This card will be mailed to our lab for testing. It is recommended you complete this when hydrated to enhance blood flow and avoid difficulties obtaining blood. The blood collection procedures below will take 10-30 minutes.


- 

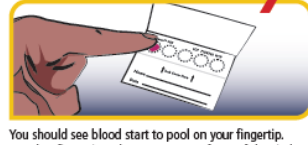
**1** Open up the manila envelope with the prepaid postage sticker on it and take everything out. You will see 2 pink lancets, 2 gauze sponges, 2 alcohol pads, 1 Whatman Protein Saver card, 1 biohazard bag and 1 small white envelope.
- 

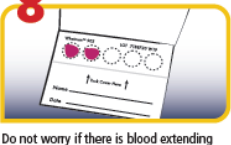
**2** Write your first and last name on the Whatman Protein Saver card next to where it says "Name". Write the date of your specimen collection next to where it says "Date".
- 


**3** Open up the Whatman Protein Saver card so that you can see all the circles on the paper. **DO NOT TOUCH THE PAPER WITH YOUR FINGERTIP AND TOUCH THE CIRCLES ON IT.**
- 


**4** Wash your hands thoroughly with soap and warm water for at least 30 seconds. After you are done washing and drying your hands, shake them forcefully for at least 15 seconds to stimulate blood flow to your fingers.
- 


**5** Open up one of the alcohol pads and take the pad out of the packaging. Using the pad, wipe clean the fingertip you intend to use. You should use the fingertip of your middle or ring finger on your non-dominant hand.
- 

**6** After you have wiped your fingertip and the alcohol has dried, pick up the pink lancet and twist off the cap. Each lancet can only be used once. Keeping your hand below your heart, firmly press the small tip of the lancet into the side of your fingertip. You should feel the needle eject and hear a clicking sound. Massage your finger from the base to stimulate blood flow.
- 

**7** You should see blood start to pool on your fingertip. Use that fingertip to hover over top of one of the circles and wait until the blood drops in the center of the circle. Please be patient as this process might take a few minutes. **DO NOT TOUCH THE PAPER WITH YOUR FINGERTIP AND DO NOT SQUEEZE YOUR FINGERTIP.** You will need to apply 2-3 drops of blood per circle. Once the first circle has 2-3 drops of blood in it and starts to dry, move on to the second circle and repeat steps 5-7 on a different finger.
- 

**8** Do not worry if there is blood extending beyond the outlines of each circle. Do not add any more blood to a circle once it is completed or dry. After you have filled 2 circles with 2-3 drops of blood each, let the card air dry on a flat surface for at least 15 minutes. Use the gauze sponges to soak up any extra blood from your fingertips.
- 

**9** After 15 minutes have passed and the card is dry, close up the card by tucking in the flap.
- 

**10** Place the closed Whatman Protein Saver card into the biohazard bag and seal the bag. Place the biohazard bag with the card inside of it into the small white envelope and seal it.
- 

**11** Place the white envelope into the larger manila envelope with the pre-paid postage on it and seal it. All of the other materials should be thrown away in the trash.

Instructions for self-collection

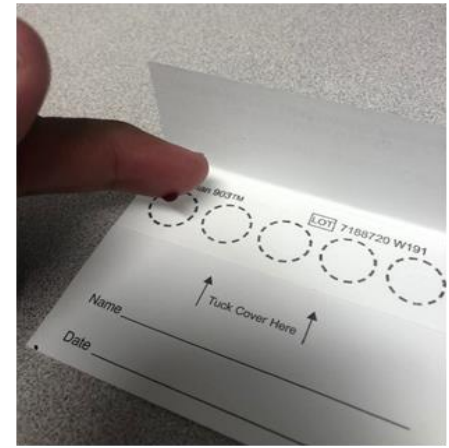
# DBS collection

## Participants

- 63.1% (53/84) – agreed to collect a DBS
- Simulated living room environment
  - 98.1% (52/53) – collected a DBS using written instructions; 71% required no assistance
- 98% filled at least one circle on DBS card; 73% filled three circles

## DBS

- 98.1% (51/52) – mailed DBS received in the laboratory (median = 3 days)
- 98.0% (50/51) – sufficient blood for analysis

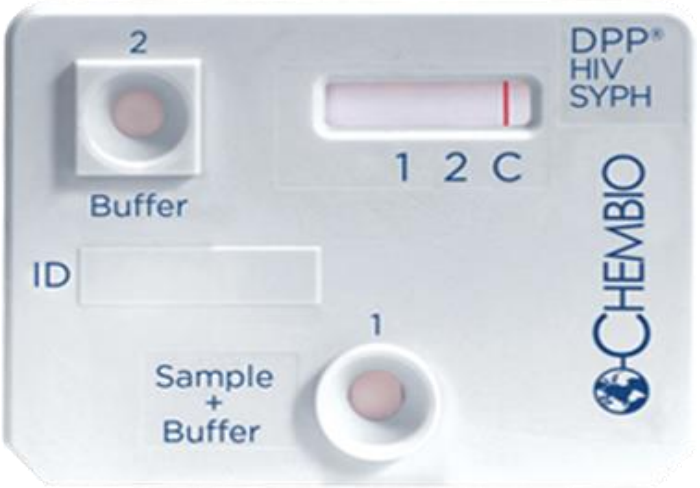
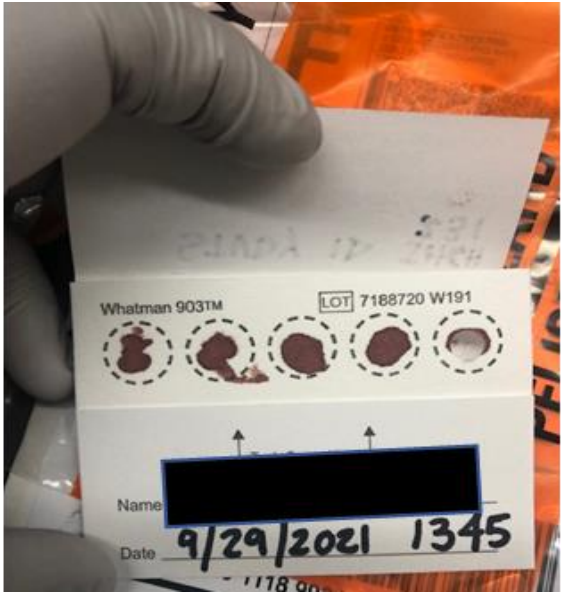
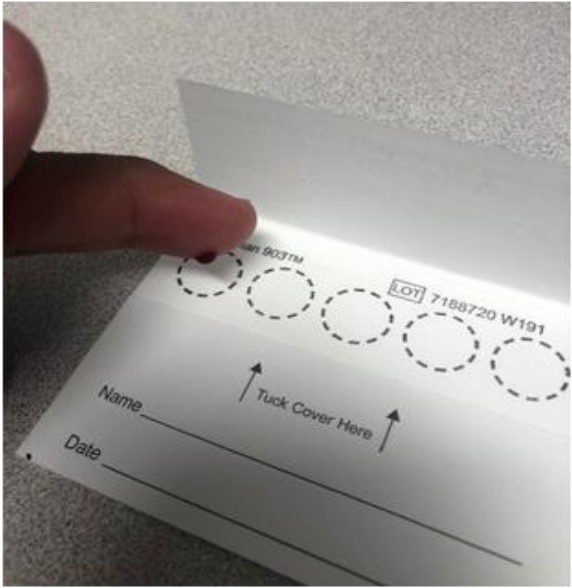
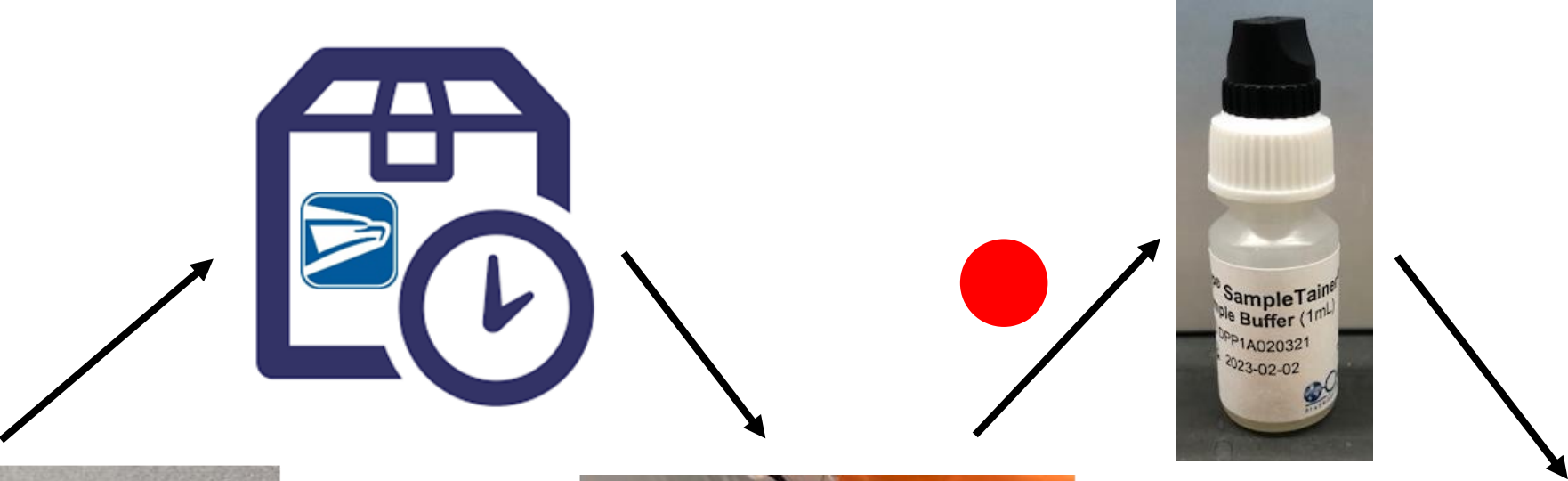


**DBS card**

# Participants demographics (N=53)

		N (%)
<b>Gender</b>		
	<b>Female</b>	<b>29 (54.7)</b>
	<b>Male</b>	<b>24 (45.3)</b>
<b>Age</b>		
	<b>18-24</b>	<b>5 (9.4%)</b>
	<b>25-34</b>	<b>21 (39.6%)</b>
	<b>35-44</b>	<b>10 (18.9%)</b>
	<b>45-55</b>	<b>9 (17.0%)</b>
	<b>&gt;55</b>	<b>8 (15.1%)</b>
<b>Race</b>		
	<b>Black</b>	<b>38 (71.7)</b>
	<b>White</b>	<b>15 (28.3)</b>

# DBS collection, transport, and testing



Johns Hopkins Hospital Emergency Room

6 mm punch ( $\approx 10 \mu\text{L}$  blood)

# Serology and Chembio DPP results - blood

<b>N = 51 participants</b>	<b>Number of participants (%)</b>
HIV positive	6 (11.8)
Syphilis positive	3 (5.9)
HIV and Syphilis	<b>14 (27.5)</b>
HIV and/or syphilis positive	<b>23 (45.1)</b>
HIV and syphilis negative	28 (54.9)

**100% concordance – serology and Chembio results (Emergency department)**

- **HIV+ participants – all aware of the status**
- **One new syphilis diagnosis (RPR = 1:64)**
- **Previous syphilis positive (n=16)**
  - **14 previously treated; 1 untreated (RPR = 1:64); 1 re-infected (RPR = 1:512)**

# DBS performance compared to serology results

## HIV

- Sensitivity – 100% (95% CI – 83.9%-100%)
- Specificity – 100% (89.0%-100%)

## Syphilis

- Sensitivity – 94.1% (73.0%-99.0%)
- Specificity – 97.1% (85.1%-99.5%)
- One false-negative DBS – less than 6 mm of blood on DBS
- One false-positive DBS

# Participants' attitudes towards DBS

- **DBS survey results**

- **95%** - somewhat to very comfortable with DBS collection procedures
- **93%** - somewhat or very confident to collect DBS at home
- **84%** - **they would use home-collection of DBS** at least once every 6 months
- **96%** - they would consider using DBS to test for other bloodborne infectious diseases
- **84%** - the availability of at-home HIV and syphilis testing is moderately important or extremely important to them
- **93%** - they **trust the result of the Chembio test using DBS**. Results “as good as standard lab tests”

# Conclusions

- **Mailed DBS can be used with Chembio assay**
- **Participants have favorable opinions about DBS, can collect them**
- **Mailed DBS – excellent sensitivity and specificity for detection of HIV/syphilis**
- **Mail-in of DBS and testing by a reference laboratory – suitable approach to expand testing capacity; increase patients' choices**



