

Evaluation of the performance and acceptability of mailed dried blood spots for HIV and syphilis screening

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DIVISION OF INFECTIOUS DISEASES

APHL ID Lab Con 2025
Pasadena, CA
March 27, 2025



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IWTK I WANT THE KIT

Take Control, Know Your Status

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

Read More

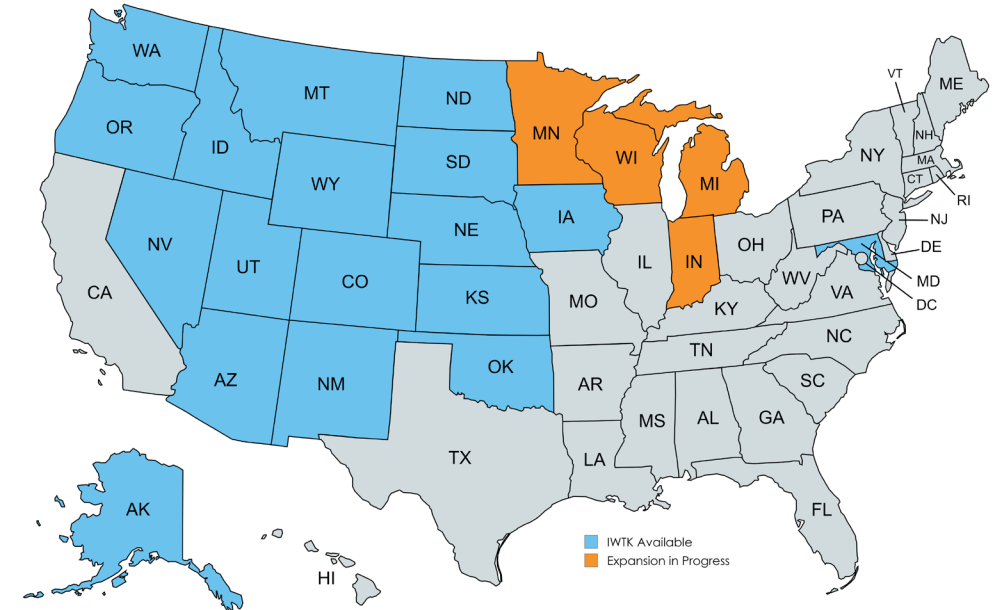
IWantTheKit (IWTK)

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

Take Control, Know Your Status. Order your test kit today.

2004 - present

States served as of January 2025



Due to federal funding issues, kit orders and testing have been paused for all states except residents of Baltimore City, MD. At this time, we advise using the CDC [clinic finder](#) to find an STI clinic near you.

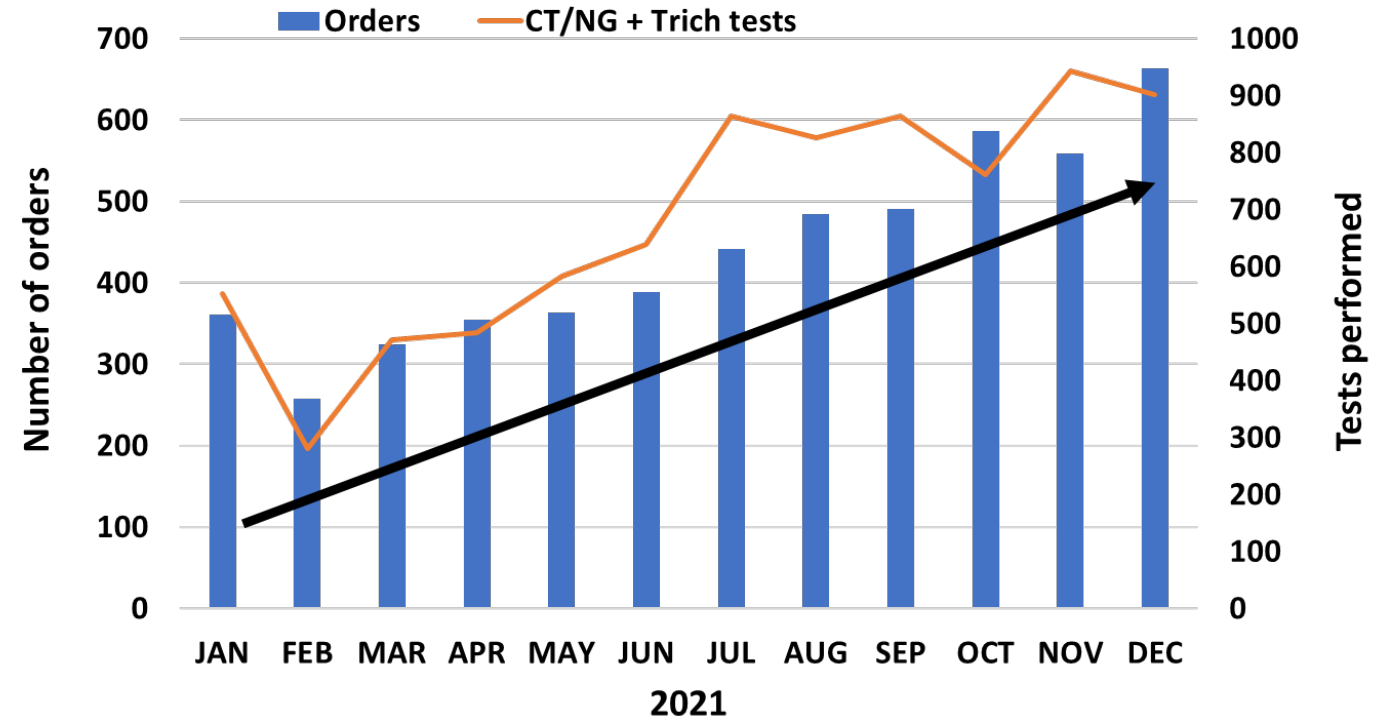
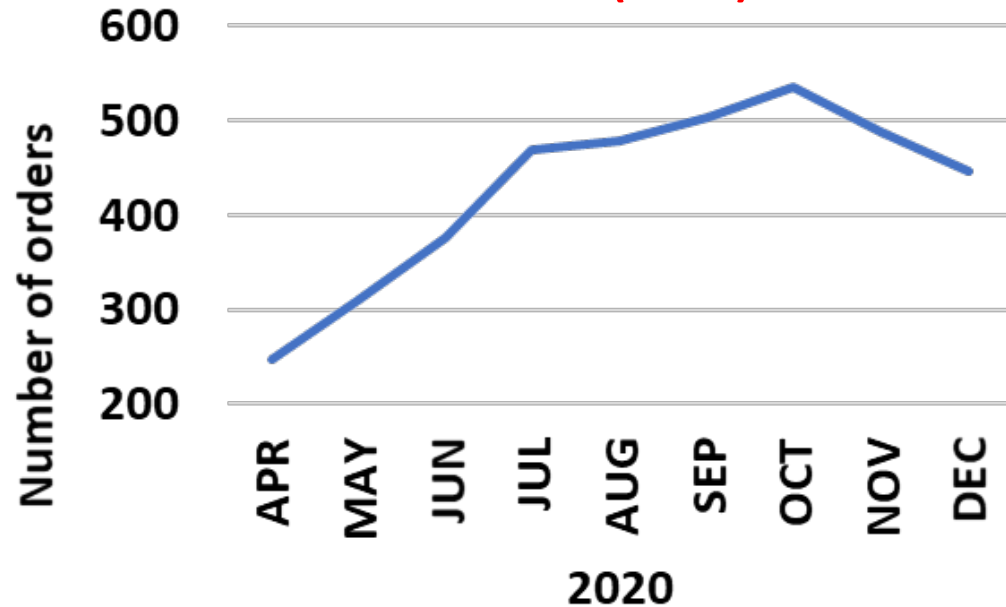
Increase and sustained demand for online STI testing

Pre-COVID (2019 – 2020)

Number of orders: 121

Number of tests: 165

COVID (2020)



Data from Maryland, Alaska, and Washington, DC

Online kit ordering

Mailing of collection kit

Home collection of swab samples

Mail-in sample return

Testing at accredited laboratory

Online results notification

Treatment (if needed)

First to know syphilis test



If possible, call or text a healthcare provider to discuss syphilis testing and/or OraQuick for at home testing; if no previous syphilis infection)

Home collection of blood, urine, and/or swab samples

4) Begin PrEP and Doxy PEP discussions
5) Make follow-up phone call within 1-2 weeks

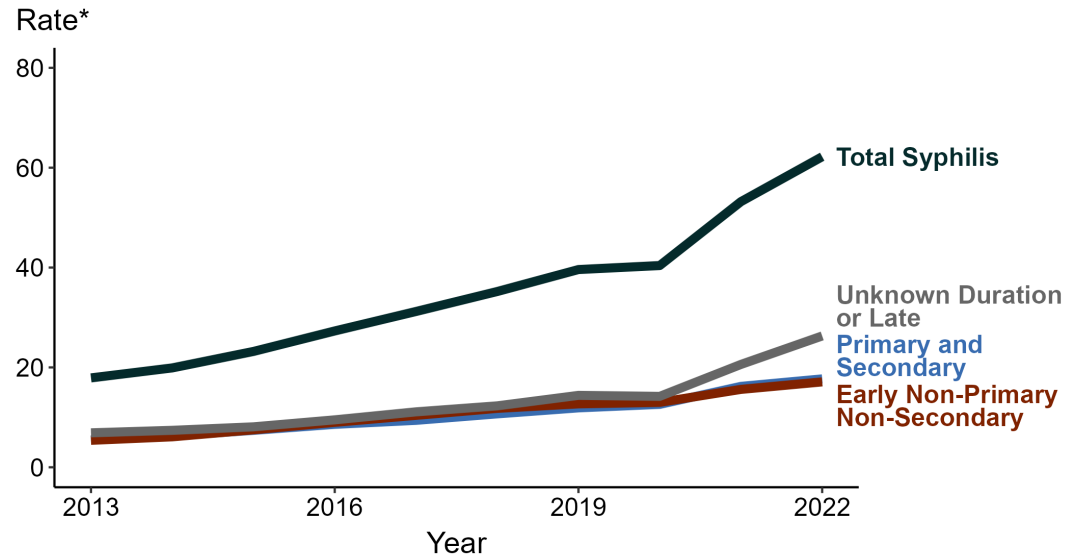


HIV confirmatory testing and Syphilis testing

Linkage to care

- **Not offered through Johns Hopkins Laboratory**
- **Offered through partner laboratory – Preventx**
 - **Low return rates of blood samples**
 - **High rate of invalid results**
 - **Preventx - no longer performing testing in the US**

Increasing rates of syphilis and need for testing



* Per 100,000

NOTE: Includes all stages of syphilis and congenital syphilis

2021 to 2022

Syphilis – 17.0 % increase

Congenital syphilis – 30.6 % increase

- FDA-approved, at home, over-the-counter test for *T. pallidum* antibodies
- Access to testing – at-risk and underserved populations remains a challenge
- Implementation of online programs for testing using self-collected lab-processed samples
- Limited data on performance and acceptability HIV/syphilis testing using self-collected samples

Overarching goals

**Laboratory-developed tests
(LDT) for HIV screening, viral
load testing, syphilis screening,
and syphilis confirmatory
testing testing using dried blood
spots (DBS)**

Evaluation of DBS for HIV and syphilis screening

Evaluation using mail-in

❖ Spiked DBS samples

❖ Prospectively-collected DBS samples

Dual Path Platform (DPP) HIV and Syphilis test

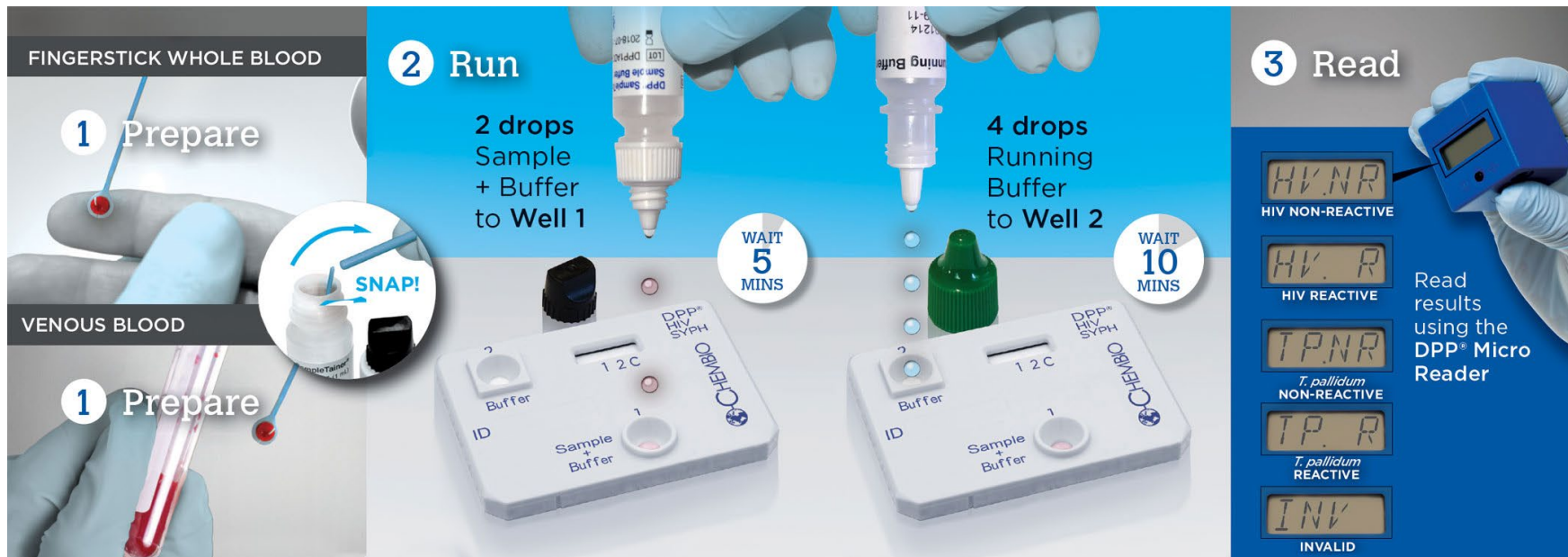
- FDA-approved HIV and syphilis rapid test
- Sensitivity: 100% for HIV and 97.4% for *T. pallidum*
- Specificity: 98.7% (HIV) and 99.7% (*T. pallidum*)
- Fingerstick whole blood, venous whole blood, or plasma specimens

Not approved for use with DBS

The DBS study nested within a larger study assessing the utility of using the Chembio test in the Emergency

Department

Maliszewski et al. An Evaluation of the Performance, Patient Acceptability and Feasibility of a Point-of-Care HIV-Syphilis Assay in an Urban Emergency Department.
Sex Transm Dis. 2024; 51(10):648-653



Evaluation # 1 – blinded analysis – 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 (JH)

Set # 1
Tested same
day

Set # 2
Mailed to JH
laboratory

Set # 3
Mailed to
Chembio

DBS samples mailed through national mail carrier

HIV and syphilis results from mailed DBS
results were compared to results from DBS
tested the same day

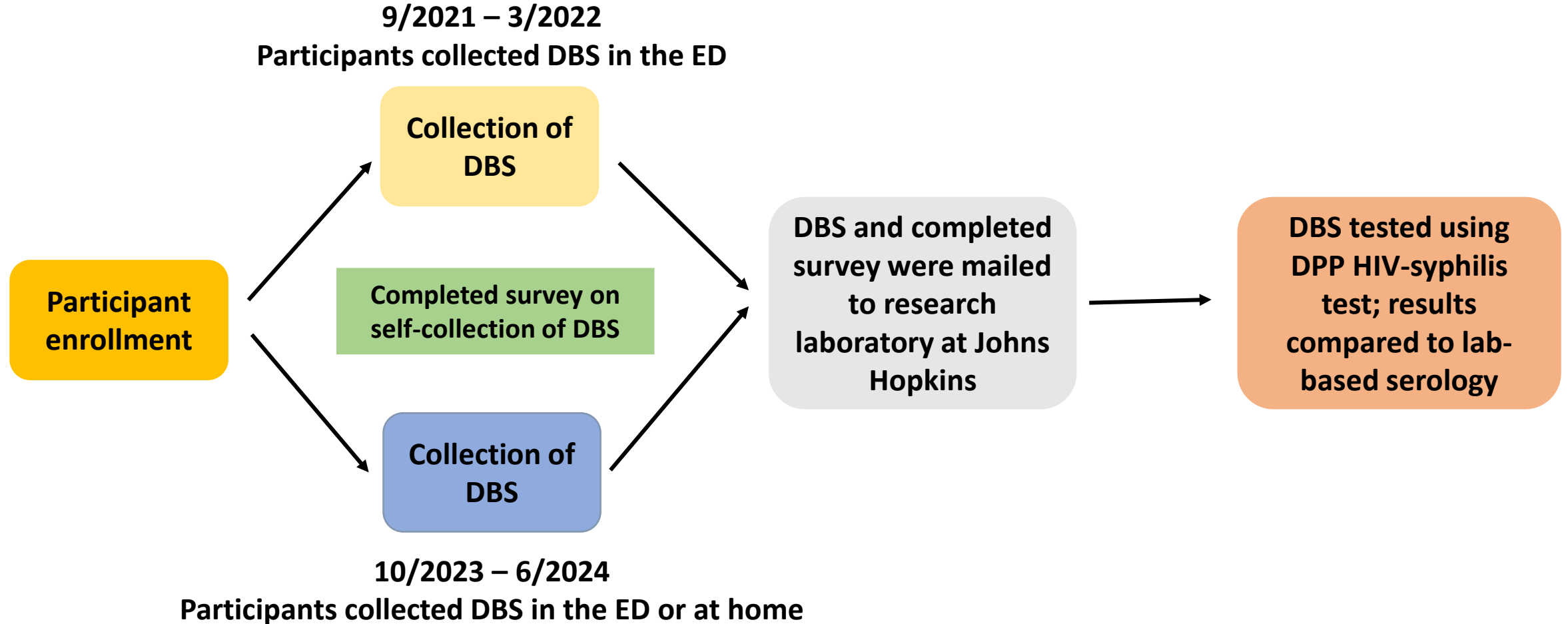
Concordance of mailed DBS compared
to DBS tested the same day

Testing location	HIV	Syphilis
Johns Hopkins Lab	100%	100%
Chembio Lab	100%	93.4%*

*One syphilis false-negative

Mailing DBS does not affect DPP
HIV-syphilis test performance

Evaluation # 2 – prospectively-collected DBS samples



Who is willing to self-collect a DBS?

		Enrolled* (N = 57) n (%)	Not enrolled (N =37) n (%)
Gender	Female	30 (52.6)	10 (27.0)
	Male	27 (47.4)	24 (64.9)
	Transgender (Male-to-Female)	0	3 (8.1)
Age (years)	18-34	5 (8.8)	4 (10.8)
	25-34	21 (36.8)	7 (18.9)
	35-44	12 (21.1)	6 (16.2)
	45-55	11 (19.3)	8 (21.6)
	>55	8 (14.0)	12 (32.4)
Race	Black	41 (71.9)	26 (70.3)
	White	16 (28.1)	8 (21.6)
	American Indian/Alaska Native	0	1 (2.7)
	Other	0	2 (5.4)
Serology results	HIV positive	7 (12.3)	17 (45.9)
	Syphilis positive	4 (7.0)	14 (37.8)
	HIV and syphilis positive	18 (31.6)	12 (32.4)
	HIV and/or syphilis positive	29 (50.9)	19 (51.4)
	HIV and syphilis negative	28 (49.1)	18 (48.6)

- 2 participants enrolled but not included in analysis.
- One participant could not collect DBS
- One DBS lost in the mail for two months

DBS collection



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 FINGER. 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 FINGER. 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**

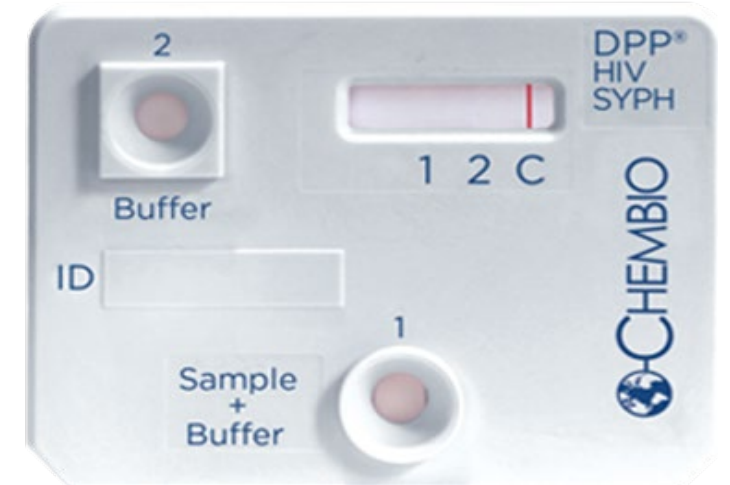
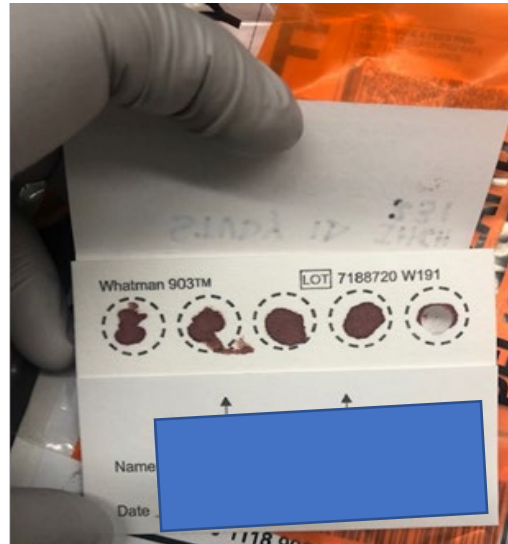
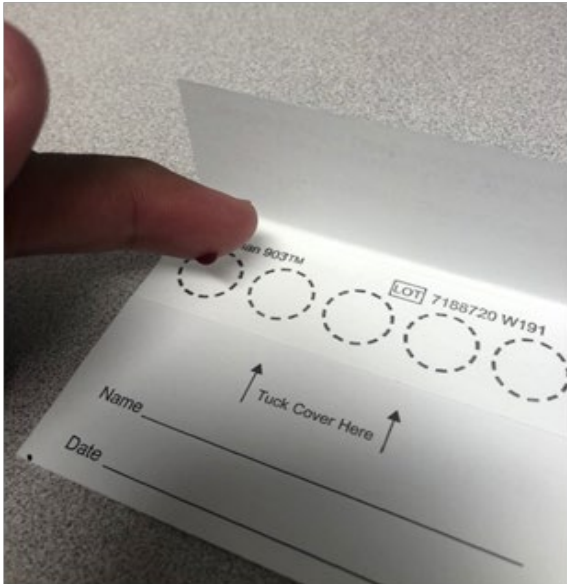
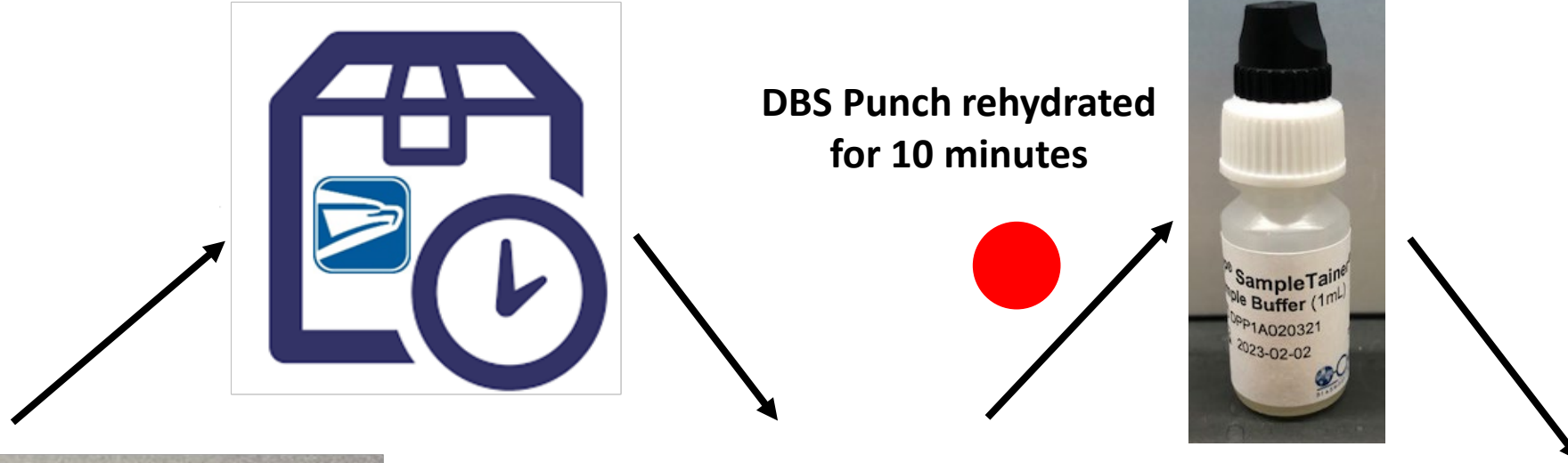
After 15 minutes have passed and the card is dry, close up the card by tucking in the flap.
- 10**

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.

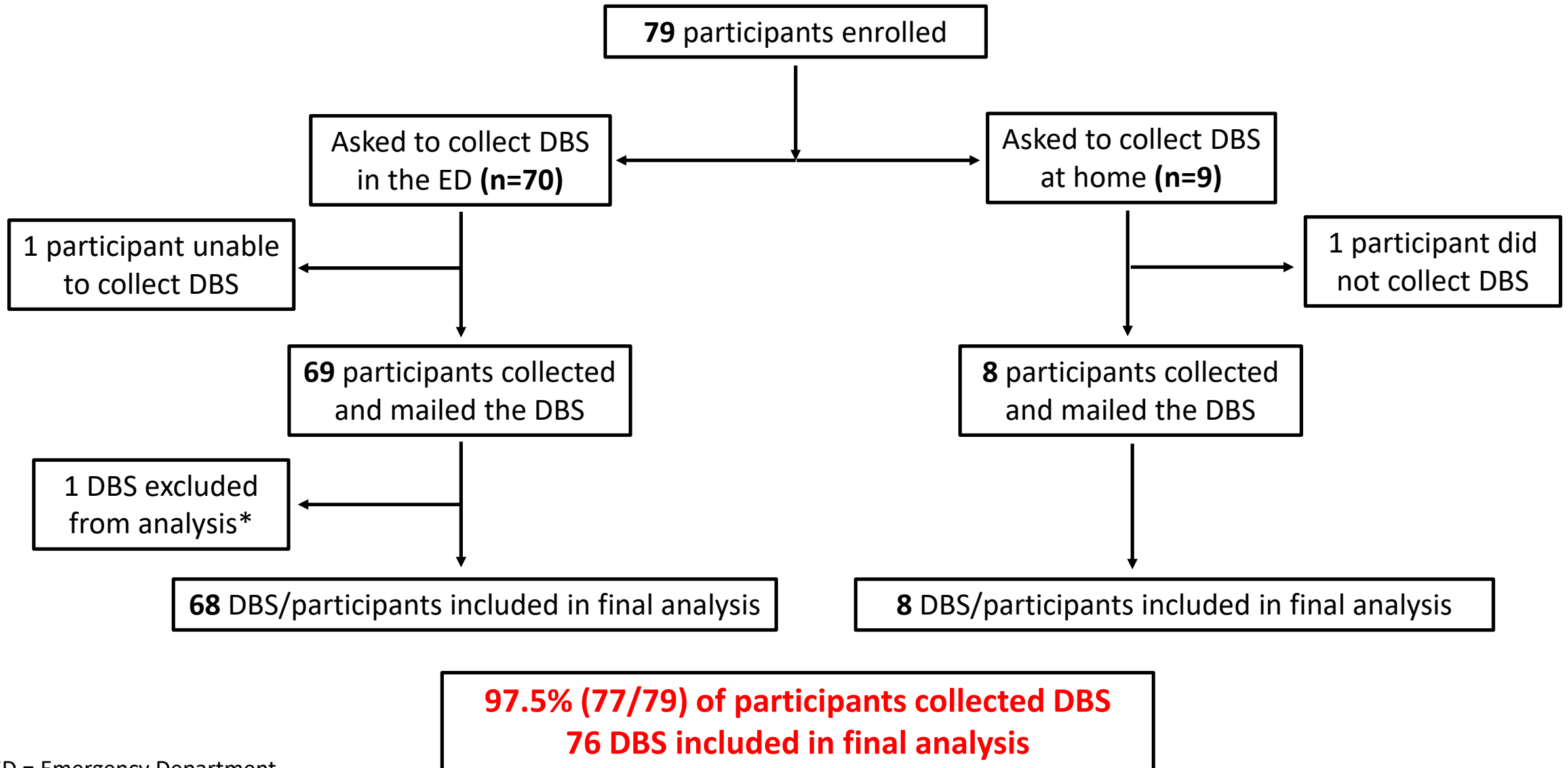
Instructions for self-collection

DBS collection, transport, and testing



DPP HIV-syphilis test

Participant recruitment and collection of DBS samples



ED = Emergency Department

*DBS mailed on 2/9/2022; Received in lab on 4/8/2022

Participants Demographics

		All participants (N= 76) n (%)
Gender	Female	38 (50.0)
	Male	36 (47.4)
	Transgender (Male-to-Female)	1 (1.3)
	Other	1 (1.3)
Age	18-24	7 (9.2)
	25-34	28 (36.8)
	35-44	18 (23.9)
	45-55	11 (14.5)
	>55	12 (15.8)
Race	Black	50 (65.8)
	White	21 (27.6)
	Asian	1 (1.3)
	Other	3 (3.9)
	Declined to answer	1 (1.3)

Serology results - blood

N = 76 participants	Number of participants (%)
HIV or syphilis positive	33 (43.4)
HIV and syphilis positive (n=74)	18 (24.3)
HIV positive only (n=75)	9 (12.0)
HIV positive and syphilis unknown	1 (1.3)
Syphilis positive only (n=74)	5 (6.8)
HIV and syphilis negative (n=74)	42 (56.8)
HIV negative and syphilis unknown	1 (1.3)

- **HIV+ participants – all aware of their status**
- **23 participants positive for syphilis antibodies**
- **Two new syphilis diagnosis (RPR = 1:64; 1:32)**
- **Previous syphilis diagnosis (n=21)**
 - **18 previously treated**
 - **1 untreated (RPR = 1:64)**
 - **2 re-infected (RPR = 1:512; RPR = 1024)**

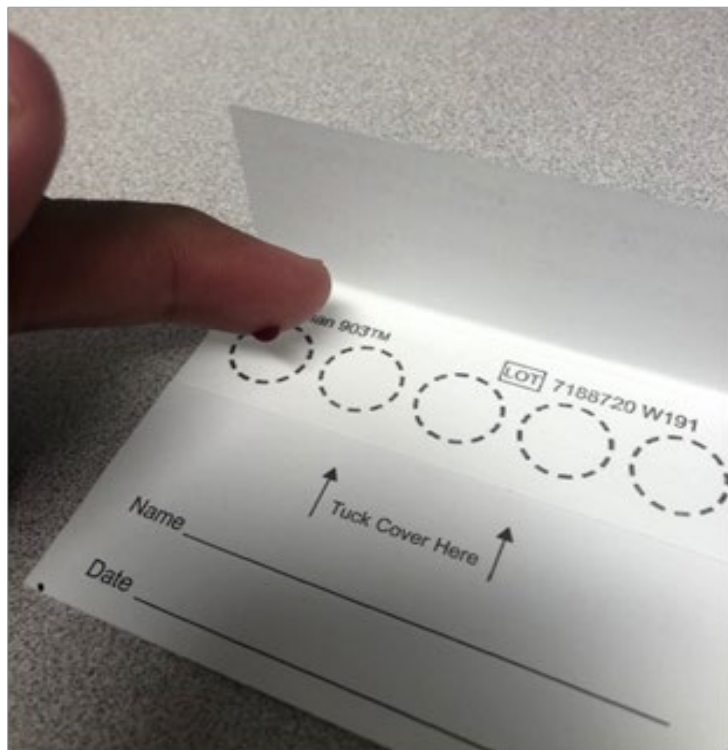
Performance characteristics of mailed DBS samples

	Sensitivity % (95% CI)	Specificity % (95% CI)
HIV	96.4 (82.3-99.4)	100 (92.6-100)
Syphilis	95.7 (79.0-99.2)	98.0 (89.7-99.7)

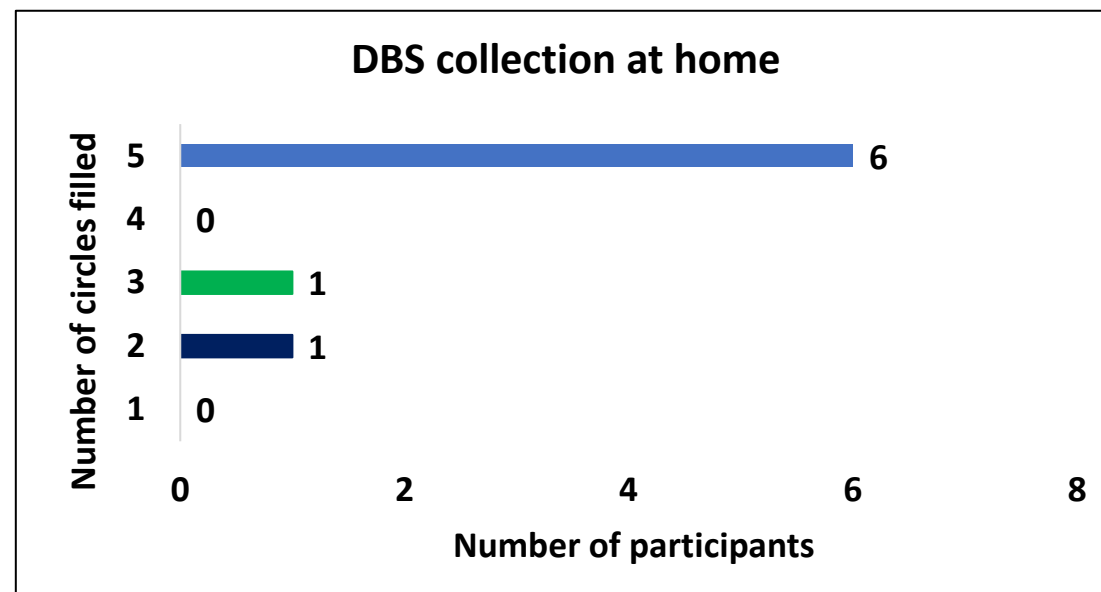
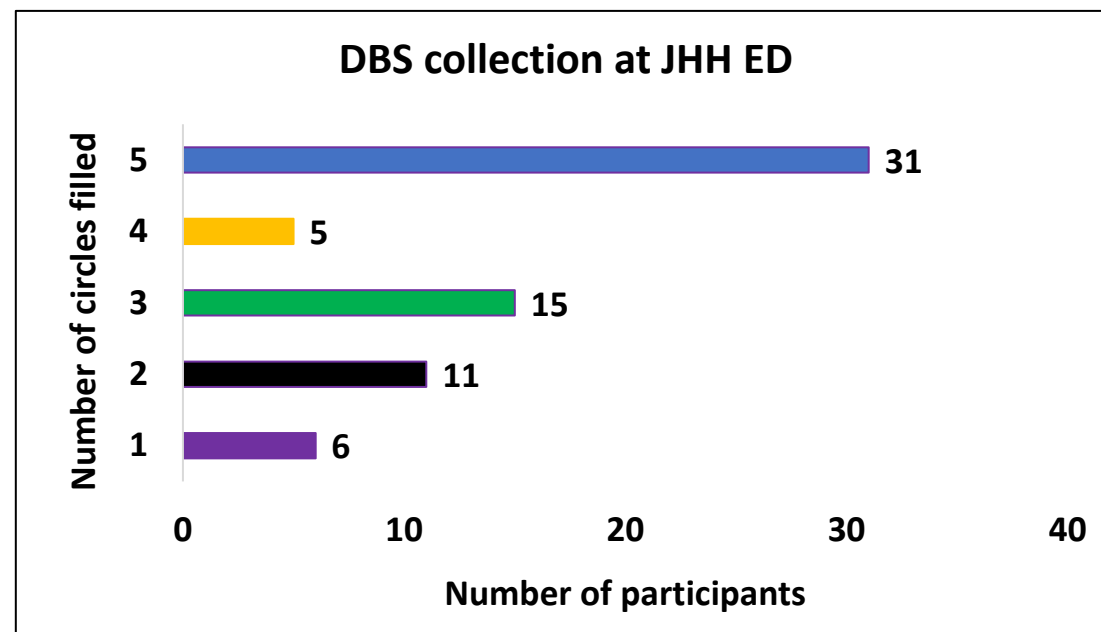
Study ID	Chembio DPP assay results				Serology				
	Mailed DBS		Blood		Blood				Comments
	HIV	Syphilis	HIV	Syphilis	HIV	Syphilis	RPR	TPPA	
JHCH330	NR	R	NR	R	R	R	NR	R	DBS = positive for HIV after re-test
JHCH279	NR	NR	NR	R	NR	R	NR	R	Insufficient blood on DBS
JHCH243	NR	R	NR	NR	NR	NR	N/A	N/a	DBS positive for syphilis antibodies

NR – non-reactive; R – reactive; TPPA - *Treponema pallidum* particle agglutination

Ability to self-collect DBS



Participants asked to fill up all five circles or as many as possible



76% (n=58) of participants filled ≥ 3 circles

Participants' attitudes towards DBS

Participants' responses	%
Somewhat to very comfortable with DBS collection procedures	91
Somewhat or very confident to collect DBS at home	95
Would use DBS to test for HIV and syphilis at home at least once every 6 months	82
Would consider using this method to test for other bloodborne infectious diseases	93
Trust the result of the Chembio test using DBS would be as good as standard lab tests	93
Availability of at-home HIV/syphilis testing is moderately or extremely important to them	84

All participants (n=74)

Participants' attitudes towards DBS

Participants' responses – collected DBS in the ED (n=66)	%
Somewhat to very comfortable with DBS collection procedures	89
Somewhat or very confident to collect DBS at home	94
Would use DBS to test for HIV and syphilis at home at least once every 6 months	83
Would consider using this method to test for other bloodborne infectious diseases	94
Trust the result of the Chembio test using DBS would be as good as standard lab tests	94
Availability of at-home HIV/syphilis testing is moderately or extremely important to them	83

Participants' responses – collected DBS at home (n=8)	%
Somewhat to very comfortable with DBS collection procedures	100
Somewhat or very confident to collect DBS at home	100
Would use DBS to test for HIV and syphilis at home at least once every 6 months	75
Would consider using this method to test for other bloodborne infectious diseases	88
Trust the result of the Chembio test using DBS would be as good as standard lab tests	88
Availability of at-home HIV/syphilis testing is moderately or extremely important to them	88

RPR testing using spiked DBS

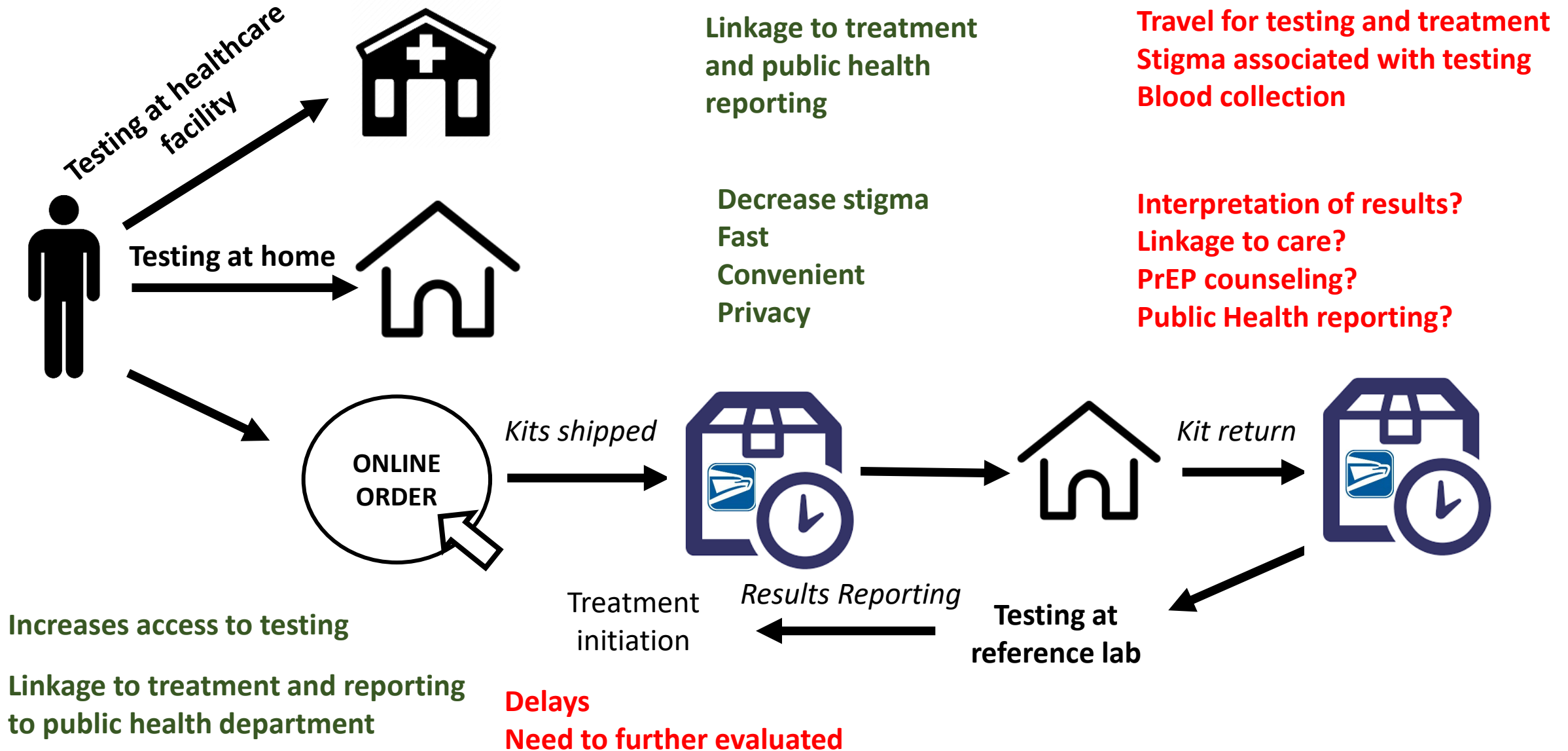
- Protein saver card (DBS collection) – Chembio assay and RPR testing
- Perform RPR from blood; no need for serum separation
- Overnight elution of DBS
- Detection of 1:8 RPR titer using DBS
- Spiked DBS samples: 1 – 2 fold lower titer (RPR blood: **64**; DBS titer: **16-32**)
 - Evaluation of prospectively-collected DBS

RPR = rapid plasma reagin

Conclusions and next steps

- **Mailed DBS can be used with Chembio assay**
- **Participants can self-collect DBS; favorable opinion about home collection**
- **Mailed DBS – excellent sensitivity and specificity for screening of HIV/syphilis**
- **Mail-in of DBS and testing by a reference laboratory – suitable approach to expand testing capacity; increase patients' choices**
- **Future – perform HIV viral load and RPR testing from DBS**

Take home message – many approaches – one goal



Acknowledgements

Study participants

Yuka C. Manabe
Gretchen Armington
Yu-Hsiang Hsieh
Kendall Maliszewski
Nyah Johnson
Gaby Dashler
Matthew M. Hamill
Richard E. Rothman



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HPTN
HIV Prevention
Trials Network

**Life isn't about waiting
for the storm to pass
but learning how to
dance in the rain**

Vivian Greene