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An Evaluation of the Performance, Patient Acceptability and Feasibility of a Point-of-Care HIV-Syphilis Assay in an Urban Emergency Department

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Abstract

Background: Point-of-care (POC) tests for sexually transmitted infections (STIs) permit delivery of results during the patient's emergency department (ED) encounter. We evaluated performance, patient acceptability, and feasibility of a new duplex POC test, Chembio DPP® HIV-Syphilis Assay in an urban ED setting.

Methods: Convenience sampling approach prioritizing those considered at increased risk for an STI and/or with a history of HIV. For the performance evaluation, participants were tested for HIV/syphilis with the Chembio POC assay, and the reference laboratory tests; sensitivity and specificity were determined. For the patient acceptability evaluation, participants completed pre- and post-user surveys. For the feasibility evaluation, ED clinical technicians completed a survey evaluating their perceptions regarding feasibility of use of this POC test.

Results: 327 patients were consented and enrolled. The diagnostic sensitivity and specificity of the Chembio POC assay for HIV was 96.5% (95% CI: 90.1%, 99.3%) and 99.6% (95% CI: 97.7%, 100.0%), respectively, and for syphilis was 93.9% (95% CI: 85.0%, 98.3%) and 99.6% (95% CI: 97.9%, 100.0%), respectively. Regarding patient acceptability: 87% trusted the result; and 93%

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reported they were more likely to seek treatment if they received a positive STI test result in the ED rather than after the ED visit. Regarding feasibility: 90% of the technicians reported they would recommend using the test in EDs.

Conclusions: The Chembio DPP® HIV-Syphilis POC assay had excellent performance characteristics when evaluated in an ED population, as well as high perceived acceptability from patients, and feasibility for ED use from clinical technicians. The test may have utility for HIV-syphilis screening among high-risk ED patients.

Summary:

We found that the recent FDA-cleared Chembio DPP® HIV-Syphilis POC Assay demonstrated good overall performance, a high-level patient acceptability, and technician feasibility for potential use for ED HIV-syphilis screening.

Keywords

HIV; Syphilis; Sexually Transmitted Infection; Point-of-Care Test; Emergency Department; Diagnostics; Linkage to Care

Introduction

The diagnosis and treatment of sexually transmitted infections (STIs) continue to pose a significant burden on the healthcare systems. Use of centralized reference laboratory standard-of-care (SOC) assays for STI testing, typically does not allow results to be reported during the patient encounter. These diagnostic delays drive empiric syndromic-based STI treatment strategies, particularly in episodic emergency and urgent care settings, occasionally leading to inappropriate antimicrobial treatment, and/or missed opportunities for treating STIs, including HIV and syphilis (1).

Emergency Departments (EDs) serve populations at high risk for STIs. Recent studies demonstrate a high prevalence of HIV-syphilis co-infections among high-risk groups, such as men who have sex with men (MSM) (2, 3). This further highlights the need for improved approaches to testing and screening for those infections, which are often clinically difficult to recognize due to their indolent clinical course. Currently, rates of HIV and syphilis testing and recognition in EDs remain low, even amongst those receiving STI (chlamydia and gonorrhea) testing (4). One frequently cited concern by ED clinicians and administrators is that the burden of follow-up for positive results remains a barrier to ordering tests at all in the ED (5).

Point-of-care (POC) tests have the potential to improve STI diagnosis and treatment in the ED setting by increasing the likelihood of appropriate treatment and linkage to follow-up care when needed (3, 6). Given the emergence of newer POC tests, we sought to explore the utility of a novel HIV and syphilis assay in the ED setting. The Chembio Dual Path Platform® (DPP) HIV-Syphilis POC Assay is a rapid HIV and syphilis FDA cleared antibody test which deliver results in 15 minutes (7). Our aim was to evaluate the performance, patient acceptability, and feasibility of utilizing the Chembio Dual Path Platform® (DPP) HIV-Syphilis POC Assay, in an urban ED in Baltimore, Maryland.

Methods

Study Design and Participant Selection

This evaluation was conducted in the Johns Hopkins Hospital Adult ED (JHHED) in Baltimore City from October 2019-March 2020 and January 2021-March 2022 (clinical research was paused in 2020 due to the COVID-19 pandemic). Both ED patients and clinical staff were included to evaluate the feasibility of POC STI testing from both patient and ED staff perspectives.

ED patients aged 18 years or older were screened for eligibility and enrollment via convenience sampling. Eligible patients included all patients 18–70 years old with priority given to those with one or more of the following risk criteria: HIV or HCV positive, had a suspected STI, received STI testing in the ED, history of an STI, MSM, pregnant without prenatal care, and/or a history of drug use. Overall, 3112 ED patients were screened; 330 patients were enrolled; 3 patients withdrew from the study for a total of 327 evaluable participants (Figure 1).

ED technicians were enrolled as potential future users of the Chembio POC assay; they currently perform POC testing (stat glucose testing) as part of ED workflow, and frequently interact with ED patients in triage and during the screening process (drawing blood for clinical testing and performing EKGs). Ten ED technicians were recruited via convenience sampling by sending a recruitment email to all JHHED technicians (n=53). The email described the voluntary study opportunity. The first 10 respondents were selected for participation in the study. The study was approved by The Johns Hopkins University School of Medicine Institutional Review Board (IRB00194434) and conducted by the ethical standards of the Helsinki Declaration of the World Medical Association.

Data Collection and Study Procedures

Participants received standard of care (SOC) HIV and syphilis testing in accordance with JHH institutional laboratory algorithms. For HIV: the initial SOC assay was the 4th generation HIV Ag/Ab test, Elecsys® HIV combi PT (Roche Diagnostics, Indianapolis, IN); if positive, the confirmatory Bio-Rad Geenius™ HIV 1/2 Assay (Bio-Rad, Hercules, CA) was performed. If discordant results were obtained, the COBAS AmpliPrep/COBAS Taqman HIV-1 test, v2.0 (Roche, Diagnostics, Indianapolis, IN) was performed. For syphilis: the initial SOC test was the *T. pallidum* specific LIAISON® Treponema Assay (DiaSorin, Stillwater, MN); if positive, the non-treponemal SURE-VUE™ RPR Card Test (Fisher Scientific, Pittsburgh, PA) was performed. If the RPR was non-reactive, a Serodia® *T. pallidum* particle agglutination [TP-PA] test (Fujirebio, Tokyo, Japan) was performed to resolve. An expert panel was convened to perform chart review in order to determine the stage of syphilis infection (primary, secondary, latent, and tertiary) for those with active syphilis infection.

Following SOC testing, participants completed a ‘pre-POC’ survey which included demographic information and patient acceptability data. The survey asked questions regarding the participant’s STI risk factors, STI history, and perceptions of POC STI testing.

Participants then received POC HIV and syphilis testing with the Chembio DPP HIV-Syphilis test. The POC test was completed by a research coordinator using finger-stick whole blood. POC results, which were recorded based on the manufacturer reader's electronic results, were not disclosed to the patient or clinical staff. After administering the POC test, the participants completed a 'post-POC' survey to re-evaluate their attitudes and perceptions after their experience with POC testing.

Three participants were unable to provide SOC blood samples for laboratory-based HIV/syphilis testing due to limited venipuncture access and were excluded from performance analysis (n=324) but remained in the patient acceptability analysis based on survey results (n=327).

ED Technician Study Procedures

The ED technicians watched a 5-minute video demonstration, provided by the Chembio manufacturer which described the purpose and how to perform the Chembio POC assay including step-by-step instructions; each technician then completed a survey evaluating their prior experience with POC assays and their assessment of their perceived utility and the feasibility of using the Chembio POC assay in the ED setting.

Data Analysis

Assay performance of the Chembio POC assay for the detection of HIV and syphilis infection was determined by the point estimates of sensitivity and specificity with corresponding 95% confidence intervals (CIs) as compared to HIV and syphilis SOC testing, respectively. A sensitivity analysis was performed to determine the sensitivity and specificity of Chembio POC assay for syphilis after excluding those with documented syphilis treatment history. Descriptive analyses were performed to assess perceived acceptability and feasibility regarding the assay from ED patients' and technicians' perspective, respectively. Data analyses were performed using SAS V.9.4 (SAS Institute Inc., Cary, North Carolina).

Results

Participants Characteristics

Of the 327 participants, 51% were male and 49% were female (sex assigned at birth); median age was 39 years (interquartile range 30–52 years) (Table 1). Based on survey responses, 87% of participants reported STI testing in the past, 55% reported history of an STI, 64% reported currently sexually active, and 14% reported to the ED with STI concerns. Based on EMR chart review, 5% of participants were pregnant, 15% reported a history of drug use, 9% identified as MSM, and 26% reported positive HIV status (Table 1).

Chembio Performance Evaluation (n=324)

Of the 324 participants tested, institutional SOC test positivity for HIV and syphilis was 26.5% (n=86) and 20.1% (n=65), respectively. There were 13.9% (45/324) participants who tested positive for both HIV and syphilis by SOC testing.

The diagnostic sensitivity and specificity of the Chembio POC assay for HIV was 96.5% (83/86) (95% CI: 90.1%, 99.3%) and 99.6% (237/238) (95% CI: 97.7%, 100.0%) respectively, and for syphilis was 93.9% (61/65) (95% CI: 85.0%, 98.3%) and 99.6% (258/259) (95% CI: 97.9%, 100.0%), respectively. Excluding the 4 syphilis cases that were initially categorized as 'false-negative' from individuals who were previously treated (and thus had non-reactive SOC RPRs), the sensitivity of the Chembio POC assay for syphilis was 100% (95% CI: 94.2%, 100%). A sensitivity analysis that excluded 49 patients with documented history of syphilis treatment found that the diagnostic sensitivity and specificity of the Chembio POC assay for syphilis was 94.1% (16/17) (95% CI: 71.3%, 99.9%) and 100% (258/258) (95% CI: 98.6%, 100.0%) discordant results included 3 false negatives and 1 false positive (for HIV) and 4 false negatives and 1 false positive (for syphilis). For HIV: Of the 3 Chembio POC false negative tests, 2 were from patients known to be HIV positive on antiretrovirals (ART), and 1 was from a patient determined by SOC testing of acute HIV (such that a 3rd generation HIV antibody testing such as Chembio POC test would not be able to detect). Regarding the lone Chembio POC false-positive HIV test result, the patient self-reported having had a prior blood transfusion (potentially confounding the test result). Of those 4 patients with a false negative Chembio POC result for syphilis (i.e., reactive treponemal antibodies and nonreactive RPR titers by SOC testing), all 4 patients had documented histories of prior syphilis diagnosis and treatment. Regarding the sole false positive Chembio POC result for syphilis (i.e., a non-reactive result for SOC *T. pallidum* specific LIAISON® Treponema Assay), the patient was a known HIV positive patient, but had no known history of syphilis diagnosis.

Newly diagnosed HIV and Syphilis Infections and Active Syphilis Infections

With regard to the intake history that each patient filled out and EMR review, there were 240 participants in this study with no prior history of having an HIV positive test result. Amongst these one tested positive with both the Chembio POC assay and the SOC test; another tested positive by SOC testing only (and was determined to have an acute HIV infection). Both were successfully linked to an HIV care specialist.

There were 264 participants in this study who had no prior history of having had a positive syphilis test. Amongst these, 5 (1.9%) were newly diagnosed with syphilis by both Chembio POC assay and the SOC treponemal antibody testing (with confirmatory RPR testing). Of the 60 participants who had previously been diagnosed with syphilis, 56 tested reactive by both Chembio POC assay and SOC treponemal antibody testing; 4 tested reactive by the SOC test only (i.e., false negative by Chembio). Of the 56 Chembio POC and SOC positive cases, 26 were confirmatory RPR positive including; 15 with a greater than 4-fold decline in RPR compared to historical test results (indicating previous successful treatment based on CDC guidelines) and 11 with a documented history of having syphilis in the EMR with an elevated, reactive confirmatory RPR (indicating either undertreatment and/or potential re-infection, i.e., active syphilis infections). The remaining 30 patients had non-reactive RPR results, including successful treatment for syphilis. These results are summarized in Figure 2.

In total, there were 16 participants with active syphilis infections based on expert review on the charts; including 1 primary infection, 6 secondary infections and 9 latent stage infections (as determined by an infectious disease expert's review (AMR) of EMR historical test results and clinical course). All 16 infections were identified by the Chembio POC assay, and all 16 patients were treated either in the ED, while admitted as inpatients, or via linkage to care from the ED to an outside clinic.

Patient Acceptability Evaluation (n=327)

Survey results demonstrated that prior to testing, the majority of participants indicated that they would be 'comfortable with using a fingerstick test' (70%) and 'confident in the result' (81%); those rates increased to 95% and 87%, respectively, after the patients had experienced having had the Chembio POC testing in the ED (Table 2). Additionally, following having the Chembio POC test done in the ED, 93% of participants reported they would be 'more likely to seek treatment if they received a positive test result during their ED visit', versus receiving the result after discharge from the ED. The majority of participants indicated they would purchase the Chembio POC test over the counter (86%) and would feel confident performing the test at-home (87%) if it were available.

Feasibility Evaluation by Technicians (n=10)

All ED technician participants reported prior experience performing a POC test (100%) and most preferred using a POC HIV and syphilis test over SOC laboratory testing (70%). After reviewing the video and learning about the Chembio POC assay, 90% reported they would recommend using the Chembio POC test in the ED setting (Table 3).

Discussion

We evaluated the performance, patient acceptability and feasibility of the Chembio Dual Path Platform® HIV-Syphilis POC assay to accurately diagnose HIV, syphilis, and HIV-syphilis co-infections in the ED setting. Previous evaluations of the Chembio DPP HIV-Syphilis POC assay have been limited to laboratory evaluations and field evaluations in low-resource settings where SOC testing may not be feasible (8–15). This evaluation is novel in that we explored the performance and potential utility of the assay in an urban, ample-resource setting, inclusive of patient and ED staff perspectives regarding POC STI testing.

We found that the Chembio HIV-syphilis POC assay demonstrated good overall performance, accurately identifying the vast majority of ED patients with HIV and/or syphilis infections (HIV sensitivity and specificity: 96.5% and 99.6% respectively, syphilis sensitivity and specificity: 93.9% and 99.6% respectively). The performance of the Chembio POC assay in our ED setting was similar to what has been reported in prior clinical settings, which also found that sensitivity for detection of HIV antibodies was greater than that for syphilis (treponemal) antibodies (8, 10, 12, 13, 15).

The Chembio POC HIV component of the assay included three false-negative cases; one of these who determined by SOC testing to be an acute HIV infection (where the 3rd generation HIV Chembio Ab screening assay would not be expected to yield a positive

result); one patient (who was known positive and on ART) had a visible HIV-positive line on the Chembio POC device from coordinator who was performing the test, yet was not detected by the manufacturer DPP reader in spite of three repeat runs (utilizing the same blood sample); and the third was from another patient who was known to be HIV positive and on ART. For the latter two cases, the impact of long-term ART on performance of rapid HIV tests has been discussed previously and proposed to be related to down-regulating anti-HIV antibody production (16). There were also 4 false-negative results from the Chembio syphilis test observed here, all of which were from patients with documented diagnosis and treatment of syphilis over 20 years ago (with subsequent nonreactive RPR SOC laboratory test results). Regardless, false negative HIV and syphilis cases did occur with the Chembio POC assay; although they may potentially be attributable to prior treatment, further investigation is required. Further, the optimal cutoff of the Chembio DPP reader to detect low levels of HIV infection and antibody production (yet producing visible lines on the device) requires further investigation and potential further refinement of the reader.

Our findings suggest the Chembio POC assay has potential to serve as an HIV/syphilis screening tool in the ED setting (and could be most practically applied with a targeted testing strategy). Real-world utility in the ED (for patients in whom clinical suspicion exists, with no documented history of HIV and/or syphilis) would however require follow-up confirmatory testing for individuals who test positive. Notably, even though we tested relatively few (<300) patients who did not have a history of HIV and/or syphilis - we identified 1 patient with a new HIV infection, and 5 with new syphilis infections, successfully linking them all to care. The POC platform may be especially useful for low acuity ED or urgent care center patients who are not otherwise getting blood drawn for clinical care, but have increased risk for either HIV and/or syphilis.

A potential benefit of the Chembio POC assay is the capacity to screen for both HIV and syphilis infections with a single easy to use bedside test, which could have particular utility in urban ED settings serving high-risk populations. Despite the increasing rates of HIV and syphilis co-infections (2, 3, 17), overall rates of HIV and syphilis co-testing in EDs are known to be extremely low (<1.5%) even amongst patients considered at risk (i.e. those receiving chlamydia and gonorrhea testing) (4, 18). Notably, in our study, 13.9% of all participants (45/324) had HIV-syphilis co-infections, of which 15.5% (7/45) had untreated syphilis infections. Additionally, 9% (28/324) of participants identified as MSM, of which 75% (21/28) had HIV/syphilis co-infections. While our cohort is biased in that we oversampled HIV and/or syphilis positive patients, our findings still highlight the importance of co-testing for both infections. Further, given the indolent clinical courses of both infections, screening is particularly relevant among high-risk asymptomatic patients, as only approximately 20% (3/16) of participants with untreated syphilis infections reported STI-related concerns in the ED. ED patients with a history of syphilis but without documented treatment history may potentially benefit from a POC testing platform as suggested in our sensitivity analysis (when centralized co-testing for HIV and syphilis is not available or feasible). While further evaluation is warranted, POC assays such as the Chembio POC assay may serve to bridge gap in care, and help to reach underserved, high-risk populations.

For patients with known HIV and/or syphilis the utility of the Chembio assay may be more nuanced. For those who are known to be HIV positive, repeating antibody testing has no clinical utility. However, for those with a known history of syphilis infection, repeat syphilis testing (with follow-up RPR) might have value in selected cases, as we found here, where 42.3% (11/26) of patients who had a history of syphilis infections, were discovered to have either untreated infections (or incompletely treated infections) and/or have re-infections - based on RPR titres following a positive Chembio screening test. Research to identify optimal screening strategies for those with prior syphilis infection is needed.

We found that patients reported very high rates of acceptability for use of the Chembio POC assay in the ED, with patients reporting both a high level of comfort with us and trust in test results. Survey of the clinical technicians who represent the likely users of the POC assay also reported that they felt the test was highly feasible for use in the ED. In practice, EDs that are interested in use of the test would need to establish and integrate approaches to optimize meaningful use of the Chembio HIV-syphilis POC assay including approaches to exclude patients with a known history of either HIV and/or active syphilis infections, and approaches to integrate screening into triage workflows, the EMR, and /or best practice advisories (BPAs). Further implementation studies of the Chembio HIV-syphilis POC assay are needed to evaluate the true impact of the assay compared to the current, standard of care practices for HIV and syphilis testing in the ED.

This study has several limitations. Given the primary focus of our study was to evaluate the performance of the assay in the ED setting, we oversampled ED patients with previously diagnosed HIV and syphilis infections. Therefore, the population studied here was significantly biased (due to the high proportion of participants reporting previous HIV and/or syphilis infection) as well as the fact that we also focused on testing on those with self-disclosed high risk; further there are very high rates of HIV-syphilis co-infection in the ED where this study was conducted, i.e. Baltimore City (19). Additionally, given this was not an implementation study, patients did not receive their Chembio POC results during their ED visit, but rather required call-backs. This limits our ability to assess the true utility and impact of the Chembio POC assay on HIV and syphilis diagnosis, and management in the ED.

In conclusion, the Chembio DPP® HIV-Syphilis POC Assay demonstrated good overall performance, a high-level patient acceptability, and technician feasibility for use for HIV-syphilis screening among ED patients. We found high rates of co-infection, which support the need for an easy-to-use HIV and syphilis combination test in the ED. While the turnaround times of confirmatory tests remain a barrier to immediate treatment, utilizing the Chembio HIV-syphilis POC may provide a pathway for quickly identifying patients with new HIV and/or syphilis infections who might otherwise go undetected (particularly for those who are not having blood drawn). Future studies should evaluate optimal strategies for integrating POC STI testing (vs centralized laboratory testing) for HIV and syphilis in EDs with attention to individual ED workflow, resources, and populations being served.

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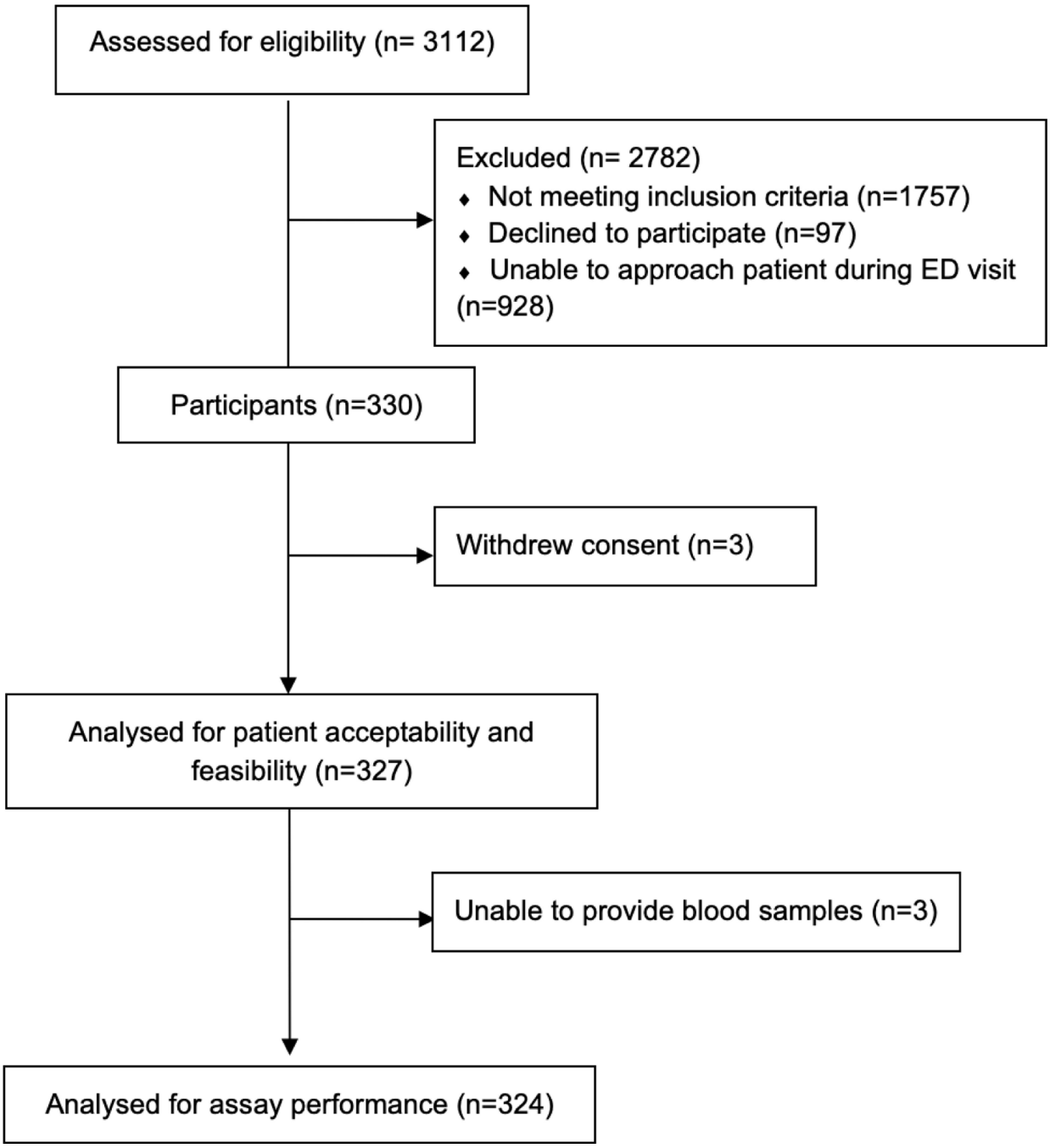

Figure 1.
Study Enrollment in the Johns Hopkins Hospital Adult Emergency Department

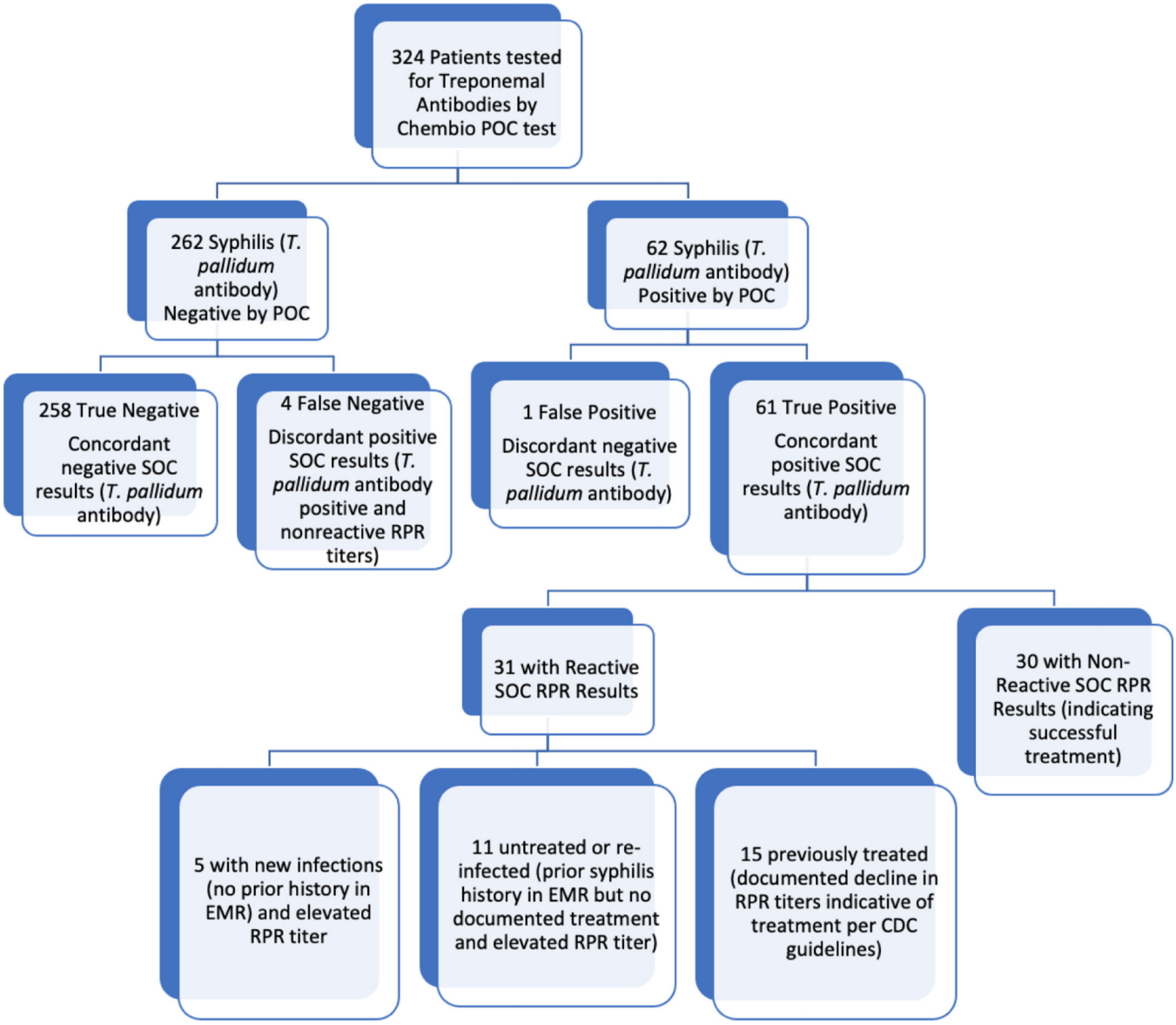

Figure 2.

Syphilis Results of Chembio Dual Path Platform® (DPP) HIV-Syphilis Assay and Standard of Care Syphilis Testing Algorithm among 324 Emergency Department Participants

Table 1.

Demographics and Self-reported Sexually Transmitted Infection (STI) Risk Factors among 327 Emergency Department Patient Participants

Characteristics	Category	Number (%) n=327
Biological sex		
	Male	167 (51)
	Female	160 (49)
Gender Identity		
	Male	164 (50)
	Female	160 (49)
	Transgender (male-to-female)	3 (1)
Age		
	18–24	28 (9)
	25–34	104 (32)
	35–44	63 (19)
	45–54	62 (19)
	≥55	70 (21)
Race		
	Asian	3 (1)
	Black or African American	227 (69)
	White	85 (26)
	Other or more than 1 race	12 (4)
Ethnicity		
	Hispanic or Latinx	9 (3)
	Non-Hispanic or Latinx	308 (94)
	Declined or unknown	10 (3)
STI Risk Factors		
	Reported to the ED with STI concerns or received STI testing	47 (14)
	Reported STI/acute HIV symptoms over the past 7 days	185 (57)
	Reported being tested for an STI in the past	285 (87)
	Reported having a partner with an STI in the past	130 (40)
	Reported STI history	179 (55)
	Reported currently sexually active (sex in past 3 months)	208 (64)
	Reported having a new partner in the past 3 months	61 (19)
	Reported no condom use over the past 3 months	117 (36)
	Reported some condom use over the past 3 months	50 (15)
	Reported pregnant at time of enrollment	17 (5)
	Men who have sex with men (per EMR)	28 (9)
	Current or previous drug use (per EMR)	50 (15)
	Known HIV positive status (per EMR)	84 (26)

EMR: electronic medical record

Table 2.

Results of the Acceptability Survey on Chembio Dual Path Platform® (DPP) HIV-Syphilis Assay among 327 Emergency Department Patient Participants

Acceptability Relevant Questions		Percentage
A. Pre-POC Test Survey		
Reported somewhat to extremely comfortable with a finger-stick test		70%
Reported they extremely agree the POC test is as good as the lab test:		81%
	Extremely agree	50%
	Somewhat agree	31%
B. Post-POC Test Survey		
Reported somewhat to extremely comfortable with a finger-stick test		95%
Reported they extremely agree the POC test is as good as the lab test:		87%
	Extremely agree	60%
	Somewhat agree	27%
Reported they are more likely to seek further treatment if they receive a positive test result during their ED visit		93%
Reported that it would reduce their stress/anxiety if they receive a negative test result during their ED visit		83%
Reported that they would be confident to perform this test at home by themselves		87%
Reported that they would use this test at-least once per year in the next 5 years (if it were available)		84%
Reported that they would purchase this POC test over the counter		86%
Reported they would prefer to use this POC test at home vs. a clinical setting		40%
Reported they would prefer to use this POC test in a clinical setting vs. at home		30%

POC: point-of-care

Table 3.

Survey Results of 10 Emergency Department Technicians on Chembio Dual Path Platform® (DPP) HIV-Syphilis Assay

Survey Questions	Percentage
Reported they have worked as an ED Technician for over 6 months	90%
Reported they have experience preforming a POC test in the past	100%
Reported they would feel comfortable performing the Chembio POC test	100%
Reported they prefer POC tests over SOC tests due to their fast turn-around-time and/or simplicity	70%
Reported they would recommend using the Chembio POC test in the study ED	90%

POC: point-of-care; SOC: standard of care