HHS Public Access

Author manuscript

J Clin Virol. Author manuscript; available in PMC 2024 March 21.

Published in final edited form as:

J Clin Virol. 2020 March ; 124: 104282. doi:10.1016/j.jcv.2020.104282.

Performance evaluation of four point-of-care HIV tests using unprocessed specimens*

Pollyanna R. Chavez[a,*], **Heather M. Bradley**[a], **Laura G. Wesolowski**[a], **Lauren R. Violette**[b], **David A. Katz**[c], **Lisa A. Niemann**[b], **Vanessa M. McMahan**[b], **Sarah McDougal**[b], **Andy M. Cornelius-Hudson**[b], **Steven F. Ethridge**[a], **Joanne D. Stekler**[b,c], **Kevin P. Delaney**[a]

[a]Centers for Disease Control and Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Division of HIV/AIDS Prevention, Atlanta, GA, United States

[b]Department of Medicine, University of Washington, Seattle, WA, United States

[c]Department of Global Health, University of Washington, Seattle, WA, United States

Abstract

Background: The performance of recently approved point-of-care (POC) HIV tests should be assessed using unprocessed specimens.

Objective: To evaluate the sensitivity and specificity of four POC HIV tests using whole blood (WB) and two using oral fluid (OF) among persons recruited from health clinics in Seattle, Washington, during September 2015-September 2017.

Study design: Participants were tested with the POC tests, additional plasma and serum were collected for laboratory testing, and participant- reported use of antiretroviral therapy (ART) or pre-exposure prophylaxis (PrEP) was recorded. Participants testing negative on all tests could reenroll every 90 days. Specimens from persons previously diagnosed with HIV infection as

---

The findings and conclusions in this manuscript are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

*Corresponding author at: Centers for Disease Control and Prevention, National Center for HIV, Viral Hepatitis, STD, and TB Prevention, Division of HIV/AIDS Prevention, Behavioral and Clinical Surveillance Branch, 1600 Clifton Road, Mailstop US8-4, Atlanta, GA, 30329, United States. geo5@cdc.gov (P.R. Chavez).

Disclosure of relationship

The Centers for Disease Control and Prevention (CDC) and our content experts wish to disclose that they have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters. Trade names are used for identification purposes only. Their use does not imply endorsement by CDC or the U.S. Department of Health and Human Services.

Ethical approval

Project DETECT received ethical approval from the University of Washington Human Subjects Division (STUDY#00001637).

CRediT authorship contribution statement

Pollyanna R. Chavez: Writing - original draft, Formal analysis, Visualization. **Heather M. Bradley:** Writing - original draft, Visualization. **Laura G. Wesolowski:** Writing - review & editing, Conceptualization. **Lauren R. Violette:** Writing - review & editing, Data curation, Investigation, Software. **David A. Katz:** Writing - review & editing, Methodology, Software. **Lisa A. Niemann:** Writing - review & editing, Data curation, Methodology. **Vanessa M. McMahan:** Writing - review & editing, Data curation, Methodology, Software. **Sarah McDougal:** Writing - review & editing, Data curation, Methodology. **Andy M. Cornelius-Hudson:** Investigation, Writing - review & editing. **Steven F. Ethridge:** Writing - review & editing. **Joanne D. Stekler:** Writing - review & editing, Supervision, Resources, Data curation, Conceptualization. **Kevin P. Delaney:** Conceptualization, Project administration, Supervision, Writing - review & editing.

Declaration of Competing Interest

None declared.

well as from those who were newly diagnosed during the study were included in the sensitivity estimate. Sensitivity and specificity were calculated based on HIV status determined by laboratory testing.

Results: Of 1,256 visits, 179 were from persons with HIV infection; 120 of these were taking ART. Among 1,077 visits from participants not diagnosed with HIV, PrEP use was reported at 155 (14.4%) visits. Sensitivity was similar among POC WB tests (95.53%−97.21%; p>0.05). Among participants on ART, sensitivity was lower for the same test performed on OF compared to WB ($p < 0.003$). Specificity was high for all tests (99.44%−100.00%); we did not detect specificity differences with PrEP use.

Conclusions: These POC tests displayed relatively high sensitivity and specificity using unprocessed specimens, suggesting their effectiveness in identifying HIV infections whenever laboratory-based testing is not feasible. Nonetheless, clients with recent risk should retest to rule out the possibility of a false-negative result.

Keywords

HIV; Point-of-care; Performance; Rapid test; Unprocessed specimens

1. Background

An estimated 14.2 % of people living with HIV in the U.S. are undiagnosed and consequently not receiving appropriate care and treatment [1]. Accurately diagnosing HIV infections in a variety of settings requires considering both logistical feasibility and test performance. Guidance from the Centers for Disease Control and Prevention (CDC) [2] emphasizes the importance of using point-of-care (POC) HIV tests when more sensitive laboratory-based testing is not feasible. POC tests are useful in identifying HIV infections in high-risk, hard-to-reach populations as they are acceptable, easy to use, and provide results expediently [3,4].

Since 2012, the U.S. Food and Drug Administration (FDA) has approved several POC tests aiming to identify HIV infections earlier (Table 1). Their performance has been evaluated using plasma, serum, and in some cases simulated whole blood [5–9] or unprocessed oral fluid (OF) or whole blood (WB) [10,11]. However, these newer tests have not all been evaluated in real-world settings, including among persons receiving HIV pre-exposure prophylaxis (PrEP).

2. Objective

To evaluate the sensitivity and specificity of four POC HIV tests using unprocessed OF and WB specimens.

3. Study design

A detailed description of Project DETECT, including POC and laboratory testing protocols, is available elsewhere [12]. Briefly, during 9/2015–9/2017, persons at risk for HIV infection and presenting for testing at the Public Health - Seattle & King County STD clinic; persons

recently diagnosed with HIV, including with acute HIV infection (AHI, as defined below); and persons in HIV care at referral sites were invited to participate. Participants with negative study HIV test results were allowed to reenroll every three months. At their study visit, receipt of antiretroviral therapy (ART) or PrEP was documented. We analyzed data from participants who were tested with four POC tests using unprocessed fresh WB and two POC tests using unprocessed fresh OF (Table 1) and who also had serum and plasma specimens processed for laboratory testing.

Sensitivity and specificity of the POC tests with exact 95 % confidence intervals were calculated based on the participant's HIV status at the time of their visit. The algorithm used to determine HIV status for this analysis (Fig. 1) was based on the CDC-recommended laboratory-based HIV testing algorithm [13]. A reactive antigen/antibody test (Ag/Ab), followed by a negative or indeterminate HIV-1/HIV-2 differentiation test (*Geenius*, Geenius™ HIV 1/2 Supplemental Assay) result and a negative nucleic acid test (NAT) or a non-reactive Ag/Ab, followed by a negative NAT, indicated that the participant did not have HIV infection. Participants with reactive Ag/Ab and HIV-1 positive Geenius results were considered to have HIV infection. Participants with reactive Ag/Ab result, negative or indeterminate Geenius result, and positive NAT were considered to have AHI. Participants with concordant negative POC tests, non-reactive or missing Ag/Ab results, and positive individual or pooled NAT results were also considered to have AHI. Participants with HIV infection but not AHI and with a negative HIV test documented through clinical records obtained with a release of information within the prior 180 days were classified as having early HIV infection (EHI) (Fig. 1). Other participants with HIV infection based on the algorithm described above and who did not meet criteria for EHI were classified as having established infection.

Analyses were performed using SAS 9.4 (SAS Institute, Cary, NC). The Agresti-Caffo test compared performance of tests among different participant populations. McNemar's test was used to determine differences in performance of tests on the same participant.

4. Results

We recruited 1004 participants who contributed 1256 visits. Of these, 179 participants had HIV infection, including six with AHI and 12 with EHI. Two-thirds (120/179) of them reported being on ART; three participants with established infection were missing ART data. Among 56 participants not taking ART, five (8.9 %) had AHI and eight (14.3 %) had EHI. The proportion of persons taking ART was higher among those with established infection (72.8 %; 115/158) compared to those with AHI (16.6 %; 1/6) and EHI (33.3 %; 4/12).

Sensitivity of WB POC tests ranged from 95.53 %–97.21 % (Table 2) with no differences across tests ($p > 0.05$ for all comparisons). Sensitivity point estimates were higher when excluding specimens from participants with AHI. Only three participants with AHI were correctly identified by any POC test: two by Determine and one by INSTI (Table 3). Among participants on ART, the sensitivities of DPP and OraQuick were significantly lower when performed on OF compared to WB (Table 4).

Specificity was high for all tests (range = 99.44 %–100.00 %); however, Determine had a significantly lower specificity than DPP OF, DPP WB, and OraQuick WB (p=0.031). Among 1,077 visits from 826 participants without HIV infection, participants reported PrEP use at 155 (14.4 %) visits; 50 visits were missing PrEP data (Table 5). PrEP use did not seem to affect test specificity. There were nine false-positive results; no specimen tested false positive on more than one test (Table 3).

5. Discussion

Project DETECT directly compared the performance of four POC HIV tests used with unprocessed specimens. The high specificity (> 99 %), high sensitivity (> 95 %) with WB, and > 89 % sensitivity with OF specimens, suggests that these POC tests can effectively identify HIV infections when laboratory–based testing is not feasible. Their specificity is similar to previous evaluations of POC tests on unprocessed specimens [10,11,14,15]. The higher proportion of AHI in this study likely accounts for the lower estimates of sensitivity reported here relative to previous reports [11,16,17].

This evaluation in a real-world setting provided important information about test performance when using unprocessed specimens among persons with acute infection and persons on PrEP. Testing programs might consider these reported performance characteristics, along with operational considerations, when choosing a test. We could not detect test specificity differences with PrEP. However, consistent with prior studies [14,18], ART compromised the sensitivity of OF tests, reinforcing the idea that they should not be used by persons on PrEP [19,20]. Despite the high specificity (> 99.44 %) of these POC tests, when used among PrEP patients–where true HIV incidence is low and testing should occur every 90 days– a low positive predictive value (PPV) and therefore a relatively high number of false-positive results should still be expected [21,22]. The possibility of false-positive results should prompt organizations to establish mechanisms for either additional HIV testing onsite (using a different rapid HIV test) or follow-up laboratory testing to confirm any positive result [23,24].

This study included a relatively high proportion of AHI (8.9 %) among participants with untreated HIV infection compared to prior studies where the proportion of AHI was around 5 % [14,25,26]. Only Determine and INSTI were able to detect any participants with AHI. Programs diagnosing a high number of patients with AHI (e.g. high-incidence populations with frequent testing) might experience lower sensitivity using POC tests than those diagnosing mostly patients with established infection.

Organizations should also consider counseling patients reporting a recent possible exposure about AHI and EHI and the need for retesting to minimize the effect of false-negative results [2].

Study limitations include the small sample size of participants with HIV infection that were treatment-naïve. However, some persons continue to test after starting treatment [27], so we were able to assess the impact of treatment on test sensitivity.

In conclusion, the relatively high specificity and sensitivity of these POC HIV tests should be reassuring to organizations implementing rapid HIV testing. However, organizations should acknowledge the limitations of these POC tests (e.g., lower sensitivity to identify AHI, effect of ART and PrEP on OF tests, low PPV among PrEP populations) and should have a plan to manage false results.

Acknowledgements

The authors would like to thank Ms. Hollie Clark, Mr. George Ure, Ms. Mandy Truong, Ms. Gabriella Veytsel, Mr. Dilpreet Kochhar, Mr. Jon Dimer, PHSKC STD Clinic Staff, Madison Clinic staff, and study participants.

Funding

This project was funded through a federal contract (# 200-2014-61285) with the Centers for Disease Control and Prevention. Additional support was provided by the University of Washington/Fred Hutch Center for AIDS Research (P30 AI027757) and the AIDS Clinical Trials Group (NIH UM AI069481).

References

[1]. Centers for Disease Control and Prevention, Estimated HIV Incidence and Prevalence in the United States, 2010–2016. HIV Surveillance Supplemental Report 2019; 24 (No.1), Available at http://www.cdc.gov/hiv/library/reports/hivsurveillance.html. Published February 2019. Accessed January 1 (2020).

[2]. Centers for Disease Control and Prevention, Implementing HIV Testing in Nonclinical Settings: A Guide for HIV Testing Providers, Available at: https://www.cdc.gov/hiv/testing/nonclinical/index.html. Published March 2016. Accessed September 3 (2019).

[3]. Spielberg F, Branson BM, Goldbaum GM, Kurth A, Wood RW, Designing an HIV counseling and testing program for bathhouses: the Seattle experience with strategies to improve acceptability, J. Homosex 44 (2003) 203–220. [PubMed: 12962183]

[4]. Keenan PA, Keenan JM, Branson BM, Rapid HIV testing. Wait time reduced from days to minutes, Postgrad. Med 117 (2005) 47–52.

[5]. Masciotra S, Price KA, Sprinkle P, Wesolowski L, Owen SM, Performance evaluation of the CHEMBIO DPP(R) (dual path platform) HIV-1/2 assay in early and established infections, J. Clin. Virol 70 (2015) 97–100. [PubMed: 26305829]

[6]. Masciotra S, Luo W, Westheimer E, Cohen SE, Gay CL, Hall L, et al. , Performance evaluation of the FDA-approved Determine HIV-1/2 Ag/Ab Combo assay using plasma and whole blood specimens, J. Clin. Virol 91 (2017) 95–100. [PubMed: 28372891]

[7]. Adams S, Luo W, Wesolowski L, Cohen SE, Peters PJ, Owen SM, et al. , Performance evaluation of the point-of-care INSTI HIV-1/2 antibody test in early and established HIV infections, J. Clin. Virol 91 (2017) 90–94. [PubMed: 28372890]

[8]. Masciotra S, Luo W, Youngpairoj AS, Kennedy MS, Wells S, Ambrose K, et al. , Performance of the Alere Determine HIV-1/2 Ag/Ab Combo Rapid test with specimens from HIV-1 seroconverters from the US and HIV-2 infected individuals from Ivory Coast, J. Clin. Virol 58 (Suppl 1) (2013) e54–8. [PubMed: 23911678]

[9]. Parker MM, Bennett SB, Sullivan TJ, Fordan S, Wesolowski LG, Wroblewski K, et al. , Performance of the Alere Determine HIV-1/2 Ag/Ab Combo Rapid test with algorithm-defined acute HIV-1 infection specimens, J. Clin. Virol 104 (2018) 89–91. [PubMed: 29803089]

[10]. Stekler JD, Ure G, O'Neal JD, Lane A, Swanson F, Maenza J, et al. , Performance of Determine Combo and other point-of-care HIV tests among SeattleMSM, J. Clin. Virol 76 (2016) 8–13. [PubMed: 26774543]

[11]. Cappello JM, Gunasekera A, Gunasekera D, Esfandiari J, Ippolito T, A multi-center performance evaluation of the DPP((R)) HIV-1/2 assay for the detection of HIV antibodies in various HIV testing algorithms, J. Clin. Virol 58 (Suppl 1) (2013) e59–64. [PubMed: 24342478]

[12]. Stekler JD, Violette LR, Clark HA, McDougal SJ, Niemann LA, Katz DA, et al. , Prospective evaluation of HIV testing technologies in a clinical setting: protocol for project DETECT, JMIR Res. Protoc (2020) (forthcoming/in press). DOI: 10.2196/16332. URL, https://preprints.jmir.org/preprint/16332.

[13]. Centers for Disease Control and Prevention and Association of Public Health Laboratories, Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations, Available at 10.15620/cdc.23447. Published June 2014. Accessed September 3 (2019).

[14]. Delaney KP, Branson BM, Uniyal A, Phillips S, Candal D, Owen SM, et al. , Evaluation of the performance characteristics of 6 rapid HIV antibody tests, Clin. Infect. Dis 52 (2011) 257–263. [PubMed: 21288853]

[15]. Stekler JD, O'Neal JD, Lane A, Swanson F, Maenza J, Stevens CE, et al. , Relative accuracy of serum, whole blood, and oral fluid HIV tests among Seattle men who have sex with men, J. Clin. Virol 58 (Suppl 1) (2013) e119–22. [PubMed: 24342471]

[16]. Bergman J, Gratrix J, Plitt S, Fenton J, Archibald C, Wong T, et al. , Feasibility and field performance of a simultaneous syphilis and HIV point-of-care test based screening strategy in at risk populations in Edmonton, Canada, AIDS Res. Treat (2013) 819593. [PubMed: 24527210]

[17]. Pant Pai N, Balram B, Shivkumar S, Martinez-Cajas JL, Claessens C, Lambert G, et al. , Head-to-head comparison of accuracy of a rapid point-of-care HIV test with oral versus whole-blood specimens: a systematic review and meta-analysis, Lancet Infect. Dis 12 (2012) 373–380. [PubMed: 22277215]

[18]. O'Connell RJ, Merritt TM, Malia JA, VanCott TC, Dolan MJ, Zahwa H, et al. , Performance of the OraQuick rapid antibody test for diagnosis of human immunodeficiency virus type 1 infection in patients with various levels of exposure to highly active antiretroviral therapy, J. Clin. Microbiol 41 (2003) 2153–2155. [PubMed: 12734265]

[19]. Suntharasamai P, Martin M, Choopanya K, Vanichseni S, Sangkum U, Tararut P, et al. , Assessment of oral fluid HIV test performance in an HIV pre-exposure prophylaxis trial in Bangkok, Thailand, PLoS One 10 (2015) e0145859. [PubMed: 26717405]

[20]. Centers for Disease Control and Prevention and Association of Public Health Laboratories, Technical Update: Use of the Determine HIV 1/2 Ag/Ab Combo Test with Serum or Plasma in the Laboratory Algorithm for HIV Diagnosis, Available at https://stacks.cdc.gov/view/cdc/48472. Published on October 2017. Accessed September 3 2019 (2017).

[21]. Stekler JD, Violette LR, Niemann L, McMahan VM, Katz DA, Baeten JM, et al. , Repeated false-positive HIV test results in a patient taking HIV pre-exposure prophylaxis, Open Forum Infect. Dis 5 (2018) ofy197. [PubMed: 30276221]

[22]. Smith DK, Switzer WM, Peters P, Delaney KP, Granade TC, Masciotra S, et al. , A strategy for PrEP clinicians to manage ambiguous HIV test results during follow-up visits, Open Forum Infect. Dis 5 (2018) ofy180. [PubMed: 30568989]

[23]. Centers for Disease Control and Prevention, HIV Testing in Nonclinical Settings, (2019) Accessed on September 3 https://www.cdc.gov/hiv/testing/nonclinical/index.html.

[24]. Centers for Disease Control and Prevention, HIV Basics: Testing, 2019 Accessed on September 3 https://www.cdc.gov/hiv/basics/testing.html.

[25]. Delaney KP, Heffelfinger JD, Wesolowski LG, Owen SM, Meyer WA 3rd, Kennedy S, et al. , Performance of an alternative laboratory-based algorithm for HIV diagnosis in a high-risk population, J. Clin. Virol 52 (Suppl 1) (2011) S5–10. [PubMed: 22019251]

[26]. Delaney KP, Ethridge SF, Adams S, Luo W, Masciotra S, Wesolowski LG, et al. , Evaluation of newly approved HIV antigen-antibody tests individually and when used in the CDC/APHL HIV diagnostic algorithm, HIV Diagnostics Conference. Atlanta GA, 2016 Available at: https://custom.cvent.com/BEED90636AE44DD0A76741F3CCF3692C/files/650b3c4a6987431e9a96e36ddacac677.pdf; Accessed on September 3 2019.

[27]. Duffus WA, Kintziger KW, Heffelfinger JD, Delaney KP, Stephens T, Gibson JJ, Repeat Western blot testing after receiving an HIV diagnosis and its association with engagement in care, Open AIDS J. 6 (2012) 196–204. [PubMed: 23049670]

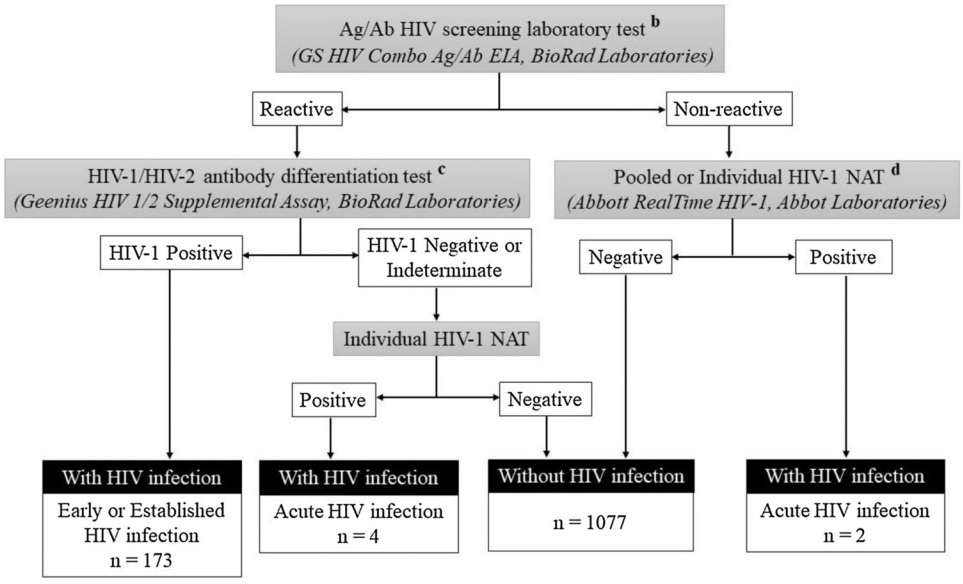

Fig. 1.

Algorithm used to determine HIV infection status[a].

Abbreviations: Ag/Ab, antigen/antibody; Ab, antibody; NAT, nucleic acid test; Geenius, Geenius™ HIV 1/2 Supplemental Assay.

Footnotes:

a There were several exceptions to this algorithm:

- One participant missing the laboratory screening test and with a negative pooled NAT was classified as not having HIV infection.
- One participant missing the screening laboratory test and with a negative Geenius result and a positive HIV-1 NAT result was classified as having acute HIV infection.
- One participant missing the screening laboratory test and with a positive Geenius result was classified as having established HIV infection.
- Three participants with non-reactive Ag/Ab results and with insufficient blood for NAT were classified as not having HIV infection.

b For 15 participants recruited early in the study, the Ag/Ab test was not available and the result of an Ab-only test (GS HIV-1/HIV-2 PLUS O EIA, BioRad Laboratories) performed on serum was used as the first step of the algorithm.

c During this period, there were no HIV-2 positive results from the HIV-1/HIV-2 antibody differentiation test.

d Individual NAT was performed when there was a record of a previous HIV-positive result or when one of the point-of-care tests conducted during the visit had a positive result or when the Ag/Ab screening test had a reactive result. Pooled NAT was conducted when all point-of-care tests resulted negative during the visit. Pooled NAT was originally performed on 27-member pools and after 10/12/2015 on 10-member pools.

Table 1

Point-of-care HIV screening tests used in Project DETECT.

POC Test	FDA Approval date	Specimen type used	Manufacturer
Chembio DPP® HIV-1/2	2012 – PMA approval	Oral fluid, Venous whole blood	Chembio Diagnostics System, Inc.
Determine™ HIV-1/2 Ag/Ab Combo	2013 – PMA approval	Venous whole blood	Abbott Laboratories
INSTI™ HIV-1/HIV-2 Rapid Antibody Test	2015 – PMA approval	Venous whole blood	bioLytical Laboratories, Inc.
OraQuick *ADVANCE*® Rapid HIV-1/2 Antibody Test	2004 – PMA approval 2015 – Approval of changes to raw material and manufacturing process to improve seroconversion detection.	Oral fluid, Venous whole blood	OraSure Technologies, Inc.

Abbreviations: POC, point of care; FDA, US Food and Drug Administration; PMA, premarket approval application.

Table 2

Sensitivity of point-of-care screening tests when used with specimens from participants with HIV infection by acute HIV infection status at time of study visit, Project DETECT, Seattle WA US, September 2015- September 2017.

POC test and specimen type	Specimens from participants with HIV infection (n = 179)			Specimens from participants with HIV infection, excluding those with AHI (n = 173)		
	TP	Sensitivity % (95 % CI)	p-value[a]	TP	Sensitivity % (95 % CI)	p-value[a]
DPP OF	161	89.94 (84.57–93.93)	**0.0002**	161	93.06 (88.20–96.36)	**0.001**
DPP WB	171	95.53 (91.38–98.05)	0.250	171	98.84 (95.89–99.86)	> 0.999
OraQuick OF	165	92.18 (87.23–95.66)	**0.012**	165	95.38 (91.09–97.98)	**0.039**
OraQuick WB	172	96.09 (92.11–98.41)	0.500	172	99.42 (96.82–99.99)	> 0.999
INSTI WB	173	96.65 (92.85–98.76)	> 0.999	172	99.42 (96.82–99.99)	> 0.999
Determine WB	174	97.21 (93.60–99.09)	ref	172	99.42 (96.82–99.99)	ref

Abbreviations: POC, point of care; AHI, acute HIV infection; TP, true positive; DPP, DPP HIV1/2 Assay; OraQuick, OraQuick Advance HIV-1/2; INSTI, INSTI HIV-1/HIV-2 Rapid Antibody Test; Determine, Determine HIV-1/2 Ag/Ab Combo; OF, oral fluid; WB, whole blood.

Footnotes:

[a]Compared to Determine performed on whole blood using McNemar's test.

Table 3

Line list of specimens with false-negative or false-positive results, Project DETECT, Seattle WA US, September 2015- September 2017.

ID	HIV Infection	Participant-reported treatment status	DPP OF	DPP WB	OraQuick OF	OraQuick WB	INSTI	Determine overall[a]	Determine p24 Ag	Determine Ab
1	Acute	Currently on ART	***Negative***	***Negative***	***Negative***	***Negative***	Positive	***Negative***	Negative	Negative
2	Acute	Not on ART	***Negative***	***Negative***	***Negative***	***Negative***	***Negative***	***Negative***	Negative	Negative
3	Acute	Not on ART	***Negative***	***Negative***	***Negative***	***Negative***	***Negative***	***Negative***	Negative	Negative
4	Acute	Not on ART	***Negative***	***Negative***	***Negative***	***Negative***	***Negative***	***Negative***	Negative	Negative
5	Acute	Not on ART	***Negative***	***Negative***	***Negative***	***Negative***	***Negative***	Positive	Positive	Negative
6	Acute	Not on ART	***Negative***	***Negative***	***Negative***	***Negative***	***Negative***	Positive	Positive	Positive
7	Early	Currently on ART	***Negative***	Positive	***Negative***	Positive	Positive	Positive	Negative	Positive
8	Early	Currently on ART	***Negative***	Positive	***Negative***	Positive	Positive	Positive	Negative	Positive
9	Early	Currently on ART	***Negative***	Positive	Positive	Positive	Positive	Positive	Negative	Positive
10	Early	Not on ART	***Negative***	Positive	***Negative***	Positive	Positive	Positive	Positive	Positive
11	Established	Currently on ART	***Negative***	Positive	***Negative***	Positive	Positive	Positive	Negative	Positive
12	Established	Currently on ART	***Negative***	Positive	***Negative***	Positive	Positive	Positive	Negative	Positive
13	Established	Currently on ART	***Negative***	Positive	***Negative***	Positive	Positive	Positive	Negative	Positive
14	Established	Currently on ART	***Negative***	Positive	***Negative***	Positive	Positive	Positive	Negative	Positive
15	Established	Currently on ART	***Negative***	***Negative***	***Negative***	Positive	Positive	Positive	Negative	Positive
16	Established	Currently on ART	***Negative***	Positive	Positive	Positive	Positive	Positive	Negative	Positive
17	Established	Currently on ART	***Negative***	Positive	Positive	Positive	Positive	Positive	Negative	Positive
18	Established	Not on ART	***Negative***	***Negative***	Positive	***Negative***	***Negative***	***Negative***	Negative	Negative
19	Uninfected	Missing	Negative	Negative	Negative	Negative	Negative	***Positive***	Negative	Positive
20	Uninfected	Not on PrEP	Negative	Negative	Negative	Negative	Negative	***Positive***	Negative	Positive
21	Uninfected	Currently on PrEP	Negative	Negative	Negative	Negative	Negative	***Positive***	Positive	Negative
22	Uninfected	Not on PrEP	Negative	Negative	Negative	Negative	Negative	***Positive***	Positive	Negative
23	Uninfected	Currently on PrEP	Negative	Negative	Negative	Negative	Negative	***Positive***	Positive	Negative
24	Uninfected	Not on PrEP	Negative	Negative	Negative	Negative	Negative	***Positive***	Positive	Negative
25	Uninfected	Not on PrEP	Negative	Negative	Negative	Negative	***Positive***	Negative	Negative	Negative
26	Uninfected	Not on PrEP	Negative	Negative	Negative	Negative	***Positive***	Negative	Negative	Negative
27	Uninfected	Not on PrEP	Negative	Negative	***Positive***	Negative	Negative	Negative	Negative	Negative

Abbreviations: ART, antiretroviral therapy; PrEP, Pre-exposure prophylaxis; Ag/Ab, antigen/antibody; Ag, antigen; Ab, antibody; n/a, data missing; OF, oral fluid; WB, whole blood; DPP, DPP HIV1/2 Assay; OraQuick, OraQuick Advance HIV-1/2; INSTI, INSTI HIV-1/HIV-2 Rapid Antibody Test; Determine, Determine HIV-1/2 Ag/Ab Combo.

Footnotes:

[a] Overall result of Determine antigen and antibody lines. If either was reactive, the overall result was considered positive.

Table 4

Comparison of the sensitivity of point-of-care screening tests when used with oral fluid versus whole blood from participants with HIV infection by treatment status[a] at time of study visit, Project DETECT, Seattle WA US, September 2015- September 2017.

Treatment Status	POC test	Oral fluid specimen		Whole blood specimen		p-value[b]
		TP	Sensitivity % (95 % CI)	TP	Sensitivity % (95 % CI)	
On ART (n = 120)	**DPP**	109	90.83 (84.19–95.33)	118	98.33 (94.11–99.80)	0.004
	OraQuick	112	93.33 (87.29–97.08)	119	99.17 (95.44–99.98)	0.016
Not on ART [c] (n = 56)	**DPP**	49	87.50 (75.93–94.82)	50	89.29 (78.12–95.97)	> 0.999
	OraQuick	50	89.29 (78.12–95.97)	50	89.29 (78.12–95.97)	> 0.999

Abbreviations: POC, point of care; ART, antiretroviral therapy; TP, true positive; DPP, DPP HIV1/2 Assay; OraQuick, OraQuick Advance HIV-1/2.

Footnotes:

[a] Of the 179 HIV infected specimens, 31.3 % (56/179) were not on treatment, 67 % (120/179) were on treatment, and 1.67 % (3/179) were missing treatment data.

[b] Comparison between oral fluid and whole blood using McNemar's test.

[c] There were 5 participants with acute HIV infection that were not on ART. They were all negative by DPP and OQ with both oral fluid and whole blood specimens. All 5 were also negative by INSTI and 3 of 5 were negative by Determine.

Table 5

Specificity of point-of-care (POC) screening tests when used with specimens from participants without HIV infection by PrEP use at time of first DETECT visit (n = 1,077), Project DETECT, Seattle WA US, September 2015- September 2017.

POC test and specimen type	Specimens[a] from all participants without HIV infection[b] (n = 1077)			Specimens[a] from participants without HIV infection[b], not on PrEP (n = 872)			Specimens[a] from participants without HIV infection[b], currently on PrEP (n = 155)			PrEP vs Not on PrEP p-value[d]
	TN	Specificity % (95 % CI)	p-value[c]	TN	Specificity % (95 % CI)	p-value[c]	TN	Specificity % (95 % CI)	p-value[c]	
DPP OF	1,077	100 (99.66–100.00)	0.031	872	100 (99.58–100.00)	0.250	155	100 (97.65–100.00)	0.500	0.418
DPP WB	1,077	100 (99.66–100.00)	0.031	872	100 (99.58–100.00)	0.250	155	100 (97.65–100.00)	0.500	0.418
OraQuick OF	1,076	99.91 (99.48–100.00)	0.125	871	99.89 (99.36–100.00)	0.625	155	100 (97.65–100.00)	0.500	0.533
OraQuick WB	1,077	100 (99.66–100.00)	0.031	872	100 (99.58–100.00)	0.250	155	100 (97.65–100.00)	0.500	0.418
INSTI WB	1,075	99.81 (99.33–99.98)	0.289	870	99.77 (99.17–99.97)	> 0.999	155	100 (97.65–100.00)	0.500	0.658
Determine WB	1,071	99.44 (98.79–99.80)	ref	869	99.66 (99.00–99.93)	ref	153	98.71 (95.42–99.84)	ref	0.193

Abbreviations: POC, point of care; PrEP, pre-exposure prophylaxis; TN, true negative; DPP, DPP HIV1/2 Assay; OraQuick, OraQuick Advance HIV-1/2; INSTI, INSTI HIV-1/HIV-2 Rapid Antibody Test; Determine, Determine HIV-1/2 Ag/Ab Combo; OF, Oral fluid; WB, whole blood.

Footnotes:

[a] Participants without HIV infection could have tested more than once and provided more than one specimen.

[b] 50 specimens from participants without HIV infection were missing data about PrEP use.

[c] Compared to Determine performed on whole blood using McNemar's test.

[d] Comparison between specimens from participants on PrEP with those not on PrEP using Agresti-Caffo test.