bioLytical LABORATORIES

CLIA WAIVED

INSTI®

HIV-1/HIV-2 Antibody Test

Introducing The World's Fastest Point-of-Care Test

- + Easy to use, early detection[1]
- + Clear and accurate results
- + Enhances patient flow
- + Expedites linkage to care
- + Simple reimbursement

Is 60 seconds quick enough?

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Guidelines support routine HIV testing[2, 3, 4]

CDC Centers for Disease Control and Prevention

"CDC recommends that diagnostic HIV testing and opt-out HIV screening be a part of routine clinical care in all healthcare settings... The recommendations are intended for providers in all health-care settings, including hospital EDs, urgent-care clinics, inpatient services, STD clinics or other venues offering clinical STD services, tuberculosis (TB) clinics, substance abuse treatment clinics, other public health clinics, community clinics, correctional healthcare facilities, and primary care settings...

In all healthcare settings, screening for HIV infection should be performed routinely for all patients aged 13–64 years... All patients seeking treatment for STDs, including all patients attending STD clinics, should be screened routinely for HIV during each visit for a new complaint, regardless of whether the patient is known or suspected to have specific behavior risks for HIV infection...

All women should receive HIV screening consistent with the recommendations for adults and adolescents. HIV screening should be a routine component of preconception care, maximizing opportunities for all women to know their HIV status before conception..."

U.S. Preventive Services TASK FORCE

Population	Recommendation	Grade
Adolescents and Adults (15–65 years old)	"Clinicians screen for HIV infection in adolescents and adults aged 15 to 65 years. Younger adolescents and older adults who are at increased risk should also be screened."	A
Pregnant Women	"Clinicians screen all pregnant women for HIV, including those who present in labor who are untested and whose HIV status is unknown."	A

ACP American College of Physicians Leading Internal Medicine, Improving Lives

"ACP recommends that clinicians adopt routine screening for HIV and encourage patients to be tested, and that clinicians determine the need for repeat screening on an individual basis."

Statistics[5, 6]

1.2M

People in the US living with HIV infection

50K

People become infected every year
(1 person every 9.5 minutes)

12.8%

Percentage of people who do not know they are infected with HIV
(1 in 8 people)

Early diagnosis is critical.

59
YEARS

Average life expectancy with late stage diagnosis

72%

Percentage of people with late stage diagnosis

1
MINUTE

Time it takes to screen patients for HIV, wherever they receive care

Clinical Data[7, 8]

INSTI® exceeds the FDA recommended performance targets for HIV-1/HIV-2 detection.

Sensitivity of a test is defined as the percentage of results that will be positive when HIV is actually present. Lower rates of sensitivity will produce more false negative results.

Specificity of a test is defined as the percentage of results that will be negative when HIV is not present. Lower rates of specificity will produce more false positive results.

Detection of Antibodies to HIV-1 in specimens from HIV-1 Infected Individuals

Study Design

A sensitivity study was performed at 14 US sites using freshly obtained matching fingerstick whole blood, EDTA whole blood, and EDTA plasma specimens collected from 1076 individuals known to be infected with HIV-1. Additionally, matching fingerstick whole blood, EDTA whole blood, and EDTA plasma specimens were collected from 782 previously unscreened individuals from populations at high risk for HIV-1 from which 22 were confirmed seropositive by an FDA licensed test.

A specificity study was performed in the same 14 sites using matching fingerstick whole blood, EDTA whole blood, and EDTA plasma specimens collected from 1410 low or unknown risk and high risk individuals. Of the 1386 eligible fingerstick specimens, 1376 gave a Non-Reactive result with INSTI® and 4 were invalid. Within the high risk group, 22 specimens were confirmed seropositive by Western Blot and of those, 21 were Reactive with INSTI®; an additional high risk specimen (1/782) was INSTI® false reactive.

Conclusions

INSTI was shown to have over 99.8% sensitivity and 99.5% specificity.

Sample Type	Sensitivity	Specificity
Venous Whole Blood	99.9%	100%
Plasma	99.9%	100%
Fingerstick Blood	99.8%	99.5%

95% CI for samples was > 98%.

Evaluation of the accuracy and ease of use of a rapid HIV-1 Antibody Test performed by untrained operators at the point of care

CLIA WAIVED

Study Design

The performance of the INSTI® HIV-1 Antibody Test was evaluated in a prospective study conducted over 4 months at 3 sites located in Arizona, Pennsylvania and Florida. At each site, INSTI® testing was conducted by operators who had no laboratory experience and were representative of users at CLIA waived testing sites. The 11 operators who participated in the study were not given any training on the use of the test. 905 subjects with unknown HIV status and 483 subjects known to be HIV positive were included in the study.

Results

Of the 517 HIV positive subjects (34 new positives and 483 known positives) the concordance between INSTI® performed by untrained operators and reference method performed by trained laboratory professionals was 100% (95% CI = 99.3–100%). Concordance for HIV negative results (n = 871) was 99.8% (95%CI = 99.2–99.9%).

Sample Type	Sensitivity	Specificity
Fingerstick Blood	100%	99.8%

Untrained operators with no laboratory background were able to perform and interpret the results of INSTI® on fingerstick blood specimens with a high degree of accuracy by following the manufacturer's written instructions.

Additional Published Studies[1, 9]

Sensitivity of a rapid point of care assay for early HIV antibody detection is enhanced by its ability to detect HIV gp41 IgM antibodies

Anti-HIV-1 IgM antibody is an important immunoassay target for early HIV antibody detection. The objective of this study was to determine if the early HIV antibody sensitivity of the 60 second INSTI® test was due to detection of anti-HIV-1 IgM in addition to IgG.

Study Design

To demonstrate HIV gp41 IgM antibody capture by the INSTI® HIV-1 gp41 recombinant antigen, an HIV-IgM ELISA was conducted with commercial HIV-1 seroconversion samples. To demonstrate that the INSTI® dye-labelled Protein A-based colour developer (CD) has affinity to human IgM, commercial preparations of purified human immunoglobulins (IgM, IgD, IgA, IgE, and IgG) were blotted onto nitrocellulose (NC) and probed with the CD to observe spot development. To determine that INSTI® is able to detect anti-HIV-1 IgM antibody, early seroconversion samples were tested for reduced INSTI® test spot intensity following IgM removal.

Results

The gp41-based HIV-IgM ELISA results for 6 early seroconversion samples that were INSTI® positive determined that the assay signal was due to anti-HIV-1 IgM antibody capture by the immobilized gp41 antigen. The dye-labelled Protein-A used in the INSTI® CD produced distinct spots for purified IgM, IgA, and IgG blotted on the NC membrane. Following IgM removal from 21 HIV-1 positive seroconversion samples with known or undetermined anti-HIV-1 IgM levels that were Western Blot negative or indeterminate, all samples had significantly reduced INSTI® test spot intensity.

Conclusion

The INSTI® HIV-1/HIV-2 Antibody Test detects anti-HIV-1 IgM antibodies, which can appear within 21–22 days after HIV infection, thus enhancing its utility in early HIV diagnosis.

Feasibility and success of HIV point-of-care testing in an emergency department in an urban Canadian setting

Study Design

Approximately 26% of Canadians living with HIV are unaware of their status. Point-of-care (POC) HIV tests have been introduced to simplify and expand HIV testing. A cross-sectional study of unselected adults presenting to an urban emergency department was performed. Study procedures included pre- and post-test counseling, administration of the INSTI® HIV-1/HIV-2 Antibody Test and a brief questionnaire. Venous blood samples were collected from participants for confirmatory testing on all reactive and indeterminate specimens.

Results

In total, 501 adults participated in the study. 49.1% of the participants had undergone previous HIV testing, although 63% of these tests were performed more than a year earlier. A total of seven individuals tested reactive with the POC test, all of whom were confirmed positive using serological testing (1.4%). All were linked to an HIV specialist within 24h. Nearly all of the participants (96%) reported satisfaction with the test and believed it belonged in the ED (93%).

Findings	Intervention with INSTI
No. of participants	501
% that had undergone previous HIV testing	49.1%
% of confirmed positives	1.4%
% reported satisfaction with test	96%

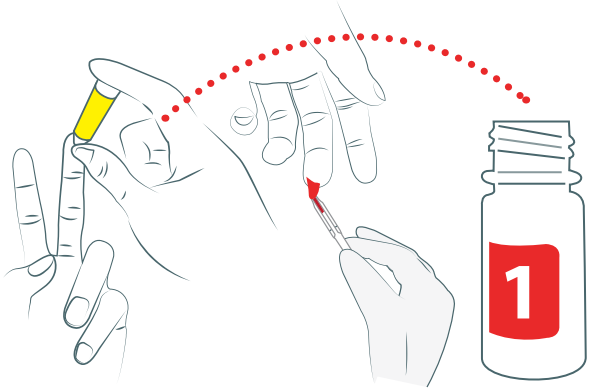
Conclusion

Of the participants tested, 1.4% tested reactive for HIV, which is significantly higher than the reported prevalence in the general population; furthermore, all individuals were immediately linked to care. The present study demonstrated that this particular busy tertiary care ED is an important and feasible location for HIV POC testing.

Test Procedure

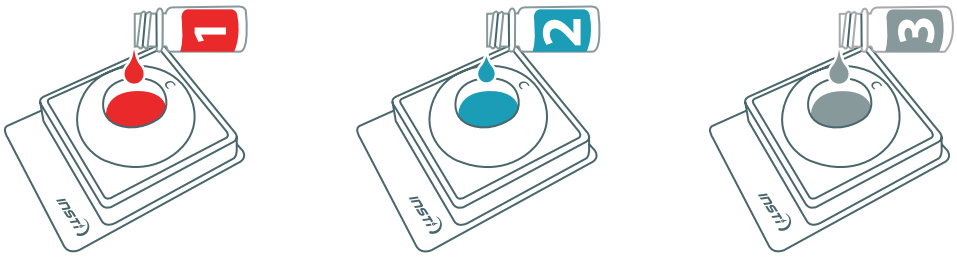
1

Collect blood and transfer into Solution 1



2

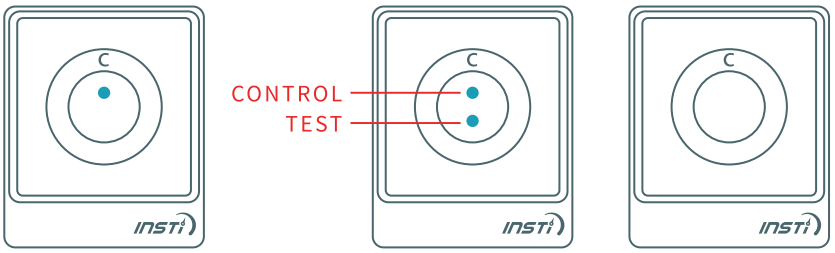
Mix and pour Solutions 1, 2 & 3



SAMPLE, POUR & READ RESULTS IMMEDIATELY!

3

Results interpretation



Non-reactive | HIV-reactive | Invalid

Always read results with INSTI® logo facing you

Product Information

Information Type	Product Details
Method	Flow-through
Time to results	As little as 60 seconds
Storage conditions	35.6–86 °F (2–30 °C)
Test shelf life	15 months
Sample type	Fingerstick, venous whole blood or plasma
CLIA complexity	Waived for fingerstick whole blood

Reimbursement

Type	Code
CPT & HCPCS Codes	86703 (CPT code) | G0433 (HCPCS code)
Modifiers	QW or 92

Additional elements physician should consider in their request for verification of the CPT code:

+ Patient background
+ Reported ICD-10-CM diagnosis codes
+ Description of the INSTI® POC diagnostic procedure
+ Who ordered and supervised the test
+ Where the test was administered (physician office setting, hospital emergency room)

Ensure appropriate evaluation and management services. Information provided is general reimbursement coding. It is neither legal or coding advice. It is the responsibility of the provider to contact the payer and/or carrier for official coding and coverage policities.

For ordering information & customer support, please contact:

1 866 674 6784 info@biolytical.com

References

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[2] Galli, RA., Green, KF., La Marca, A., et al. Evaluation of the accuracy and ease of use of a rapid HIV-1 Antibody Test performed by untrained operators at the point of care. J Clin Virol 2013;58 Suppl I:e65-9

[3] *Final Recommendation Statement: Human Immunodeficiency Virus (HIV) Infection: Screening. US Preventive Services Task Force.* May 2015. Retrieved March 23, 2016 from: http://www.uspreventiveservicestaskforce.org/Page/Document/RecommendationStatementFinal/human-immunodeficiency-virus-hiv-infection-screening

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[8] Galli RA, Green KR, La Marca A, et al. *Evaluation of the accuracy and ease of use of a rapid HIV-1 Antibody Test performed by untrained operators at the point of care.* J Clin Virol 2013; 58 Suppl 1:e65-9

[9] Becker ML, Thompson LH, Pindera C, et al. *Feasibility and success of HIV point-of-care testing in an emergency department in an urban Canadian setting. Can J Infect Dis Med Microbiol* 2013; 24(1):27–31

INSTI®

Trusted when it matters the most

The World's Fastest HIV Test

Ordering Information

Part	Product
90-1019	Box of 50 - INSTI® HIV-1/HIV-2 Antibody Test
90-1031	1 Set - INSTI® HIV-1/HIV-2 Controls

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biolytical Laboratories
406-13251 Delf Place, Richmond, BC, Canada V6V 2A2
1 604 204 6784 | bioLytical.com | insti.com

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