

# Rapid HIV tests suitable for use in non-clinical settings (requires CLIA-waiver certificate)<sup>a</sup>

**[For use with finger stick or venipuncture whole blood or oral fluid]**

Test Name	Time to test result	Indications for use	Sensitivity for established HIV-1 infection, % (95% CI) <sup>b</sup>	Specificity % (95% CI) <sup>b</sup>	Approved specimen types and volumes	Test kit shelf life	Manufacturer web site
 <b>Chembio HIV 1/2 STAT-PAK</b>	15 min	Antibodies to HIV-1 and 2	Finger stick or venous whole blood 99.7 (98.9-100)	Finger stick or venous whole blood 99.9 (99.6-100.0)	Finger stick or venous whole blood 5 µL	24 months	<a href="http://chembio.com/products/human-diagnostics/hiv-12-stat-pak-assay/">http://chembio.com/products/human-diagnostics/hiv-12-stat-pak-assay/</a>
 <b>Clearview COMPLETE HIV 1/2</b>	15 min	Antibodies to HIV-1 and 2	Finger stick or venous whole blood 99.7 (98.9-100.0)	Finger stick or venous whole blood 99.9 (99.6-100.0)	Finger stick or venous whole blood 2.5 µL	24 months	<a href="http://www.alere.com/us/en/product-details/clearview-complete-hiv-1-2.html">http://www.alere.com/us/en/product-details/clearview-complete-hiv-1-2.html</a>
 <b>INSTI HIV-1 Antibody Test</b>	<2 min	Antibodies to HIV-1	Finger stick whole blood 99.8 (99.3-99.9), venous whole blood 99.9 (99.5-100)	Finger stick whole blood 99.0 (97.9-99.6), venous whole blood 100 (99.7-100)	Finger stick or venous whole blood 50 µl	12 months	<a href="http://www.biolyticalus.com/products.html">http://www.biolyticalus.com/products.html</a>

	20 min	Antibodies to HIV-1 and 2	Oral fluid 99.3 (98.4-99.7) finger stick whole blood (venous whole blood not evaluated) 99.6 (98.5-99.9)	Oral fluid 99.8 (99.6-99.9), finger stick whole blood (venous whole blood not evaluated) 100 (99.7-100)	Finger stick or venous whole blood 5µl or oral fluid swab	12 Months	<a href="http://www.orasure.com/products-infectious/products-infectious-oraquick.asp">http://www.orasure.com/products-infectious/products-infectious-oraquick.asp</a>
	10 min	Antibodies to HIV-1 and HIV-2	Finger stick or venous whole blood 100 (99.5-100.0)	Finger stick or venous whole blood 99.7 (99.0-100)	Finger stick or venous whole blood 50 µL	12 months	<a href="http://www.unigoldhiv.com/">http://www.unigoldhiv.com/</a>

<sup>a</sup> CLIA-waived rapid tests can be used in settings such as: community-based organizations, field testing, outreach activities, STD or other clinics, mobile clinics, non-traditional testing, or community/college clinics. The Clinical Laboratory Improvement Amendments (CLIA) sets criteria based on complexity levels of tests. Briefly, there are three levels of complexity: 1) Waived – simple, low-risk tests that can be performed with minimal training that do not require centrifugation of specimens for testing, 2) Moderate Complexity – simple tests that use plasma or serum specimens (must participate in an external proficiency testing program), 3) High Complexity – tests that require trained laboratory personnel, involve multiple-step protocols, frequent quality control, and participation in an external proficiency testing program. For more information about CLIA regulations go to [http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA\\_Regulations\\_and\\_Federal\\_Register\\_Documents.html](http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Regulations_and_Federal_Register_Documents.html).

<sup>b</sup> Sensitivity is a measure of the test's ability to correctly identify persons with a disease. Specificity is the test's ability to correctly identify persons without the disease.