Rapid HIV tests suitable for use in non-clinical settings (CLIA-waived) [a]

Test Name	Time to test result	Indications for use	Sensitivity for established HIV-1 infection, % (95% CI)[b]	Specificity % (95% CI)[b]	CLIA-Waived approved specimen types and volumes	Test kit shelf life/ storage temperature range/Testing area temperature range	Manufacturer web site
 **Chembio DPP HIV-1/2**	Blood: between 10 and 25 min Oral fluid: 25-40 min for reactive results and 40 min for non-reactive results	Antibodies to HIV-1 and 2	Finger stick whole blood 99.8 (99.2-99.9) oral fluid 98.9 (98.0-99.4) Venous whole blood 99.9 (99.4-99.9)	Finger stick whole blood 100 (99.8-100) oral fluid/ venous whole blood 99.9 (99.7-99.9)	Finger stick or venous whole blood 10 µl Or oral fluid swab	23 months; 36 to 86°F / 64 to 86°F	Link to Chembio
 **June 1, 2016: Clearview COMPLETE is now Chembio SURE CHECK HIV 1/2 Assay**	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; 46 to 86°F/ 64 to 86°F	Link to Chembio
 **Clearview HIV 1/2 STAT-PAK**	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; 46° to 86° F/ 64 to 86°F	Link to Chembio

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 **Determine HIV-1/2 Ag/Ab Combo Test**	20 min	Antibodies to HIV-1 and HIV-2, Detects HIV-1 p24 Antigen	Finger stick whole blood 99.9 (99.4-100)	Finger stick whole blood: Low risk subjects 100 (99.5-100), High risk subjects 99.7 (98.9-100)	Finger stick whole blood 50 µL	15 months; 36-86°F/ 59-86°F	Link to ALERE now Abbott
 **INSTI HIV-1/HIV-2 Antibody Test**	<2 min	Antibodies to HIV-1 and 2	Finger stick whole blood 99.8 (99.3-99.9)	Overall from low, high and unknown risk individuals Finger stick whole blood 99.5 (99.0.9-99.8)	Finger stick whole blood 50 µl	15 months; 59-86°F/ 59-86°F	Link to bioLytical
 **OraQuick ADVANCE Rapid HIV-1/2 Antibody Test**	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; 36-80°F/ 59-99°F	Link to OraSure

Test Name	Time to test result	Indications for use	Sensitivity for established HIV-1 infection, % (95% CI)[b]	Specificity % (95% CI)[b]	CLIA-Waived approved specimen types and volumes	Test kit shelf life/ storage temperature range/Testing area temperature range	Manufacturer web site
 **Uni-Gold Recombigen HIV-1/2**	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; 35.6-80.6°F/ 59-80.6°F	**Link to Trinity Biotech**

[a] 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 Link to CLIA Regulations.

[b] 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.