




Rapid HIV tests suitable for use in clinical settings (CLIA-moderate complexity) ^a [For use with blood, serum or plasma]

Test Name	Time to test result	Indications for use	Sensitivity for established HIV-1 infection % (95% CI) ^b	Specificity % (95% CI) ^b	Approved specimen types for CLIA-moderate settings and specimen volume	Shelf life	Manufacturer web site
 ChemBio DPP HIV-1/2	15 min	Antibodies to HIV-1 and 2	Serum/plasma 99.9 (99.4-99.9)	Serum/plasma 99.9 (99.7-99.9)	Serum/plasma/whole blood ^c 10 µl or oral fluid swab ^c	23 months	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	Serum/plasma 99.7 (98.9-100.0)	Serum/plasma 99.9 (99.6-100.0)	Serum/plasma/whole blood ^c 2.5 µL	24 months	Link to ChemBio
 Clearview HIV 1/2 STAT-PAK	15 min	Antibodies to HIV-1 and 2	Serum/plasma 99.7 (98.9-100.0)	Serum/plasma 99.9 (99.6-100.0)	Serum/plasma/whole blood ^c 5 µL	24 months	Link to ALERE



Determine HIV-1/2 Aq/Ab Combo Test

20 min	Antibodies to HIV-1 and HIV-2, Detects HIV-1 p24 Antigen	Serum/plasma 99.9 (99.4-100)	Serum: Low risk subjects 100 (99.6-100) High-risk subjects 98.9 (97.7-99.5) Plasma: Low risk subjects 100 (99.6-100) High-risk subjects 99.2 (98.2-99.7)	Serum/plasma/whole blood ^c 50 µL	14 months	Link to ALERE
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INSTI HIV-1/HIV-2 Rapid Antibody Test

<2 min	Antibodies to HIV-1 and 2	Plasma 99.9 (99.5-100)	Plasma 100 (99.7-100)	Plasma/whole blood ^c 50 µL	12 months	Link to BioLytical
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MedMira Reveal G3 Rapid HIV-1 Antibody Test

<2 min	Antibodies to HIV-1	Serum 99.8 (99.2-100) Plasma 99.8 (99.0-100),	Serum: 99.1 (99.8-99.4) Plasma 98.6 (98.4-98.8),	Serum/plasma 30 µL	12 months	Link to Medmira
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Multispot HIV-1/HIV-2 Rapid Test
(This test is no longer manufactured)

20 min	Discriminates antibodies to HIV-1 and 2	Serum/plasma 100 (99.9-100)	Serum/plasma 99.9 (99.8-100)	Serum/plasma 30 µL	12 Months	Link to Bio-Rad
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	20 min	Antibodies to HIV-1 and 2	Plasma 99.6 (98.9-99.8)	Plasma 99.9 (99.6-99.9)	Plasma/whole blood ^c 5µl	12 months	Link to OraSure Technologies
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test							
	10 min	Antibodies to HIV-1	Serum/plasma 100 (99.5-100.0)	Serum/plasma 99.8 (99.3-100)	Serum/plasma/whole blood ^c 50 µL	12 months	Link to Trinity BioTech
Uni-Gold Recombigen HIV							

^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 [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.

^c This specimen type for this test is also approved for use in CLIA-Waived settings.