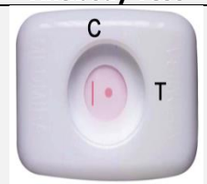
Rapid HIV tests suitable for use in clinical settings (CLIA-moderate complexity) [a]
[For use with blood, serum or plasma]

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	http://chembio.com/products/human-diagnostics/dpp-hiv-12-assay/
Clearview COMPLETE HIV 1/2	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	http://www.alere.com/us/en/product-details/clearview-complete-hiv-1-2.html
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	http://www.alere.com/us/en/product-details/clearview-hiv-1-2-stat-pak.html

Determine HIV-1/2 Ag/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	**http://www.alere.com/content/alere/us/en/product-details/determine-1-2-ag-ab-combo-us.html.html**
INSTI HIV-1 Antibody Test	<2 min	Validated for HIV-1 antibodies only but contains HIV-2 proteins	Plasma 99.9 (99.5-100)	Plasma 100 (99.7-100)	Plasma/whole blood[c] 50 µl	12 months	**http://www.biolyticalus.com/products.html**
 **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	**http://www.medmira.com/products/hiv/reveal-g3**
Multispot HIV-1/HIV-2 Rapid Test as a screening assay	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	**http://www.bio-rad.com/prd/en/US/CDG/SKU/25228/Multispot-HIV-1/HIV-2-Rapid-Test**

OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	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	http://www.orasure.com/products-infectious/products-infectious-oraquick.asp
Uni-Gold Recombigen HIV	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	http://www.unigoldhiv.com/
Rapid HIV supplemental tests suitable for use in clinical settings (CLIA-moderate complexity) [a]							
Geenius HIV 1/2 Supplemental Assay	20min	Antibodies to HIV-1 and HIV-2	Serum 99.3 (97.6-99.8) EDTA Plasma 99.3 (96.3-99.9) EDTA whole blood 100 (97.5-100) Fingerstick 100 (97.5-100)	Overall indeterminate rate in low risk population: 4.33% for all sample types	Serum/plasma 5 µL Whole blood 15 µL	12 months	http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/UCM420735.pdf **or** http://www.bio-rad.com/en-us/clinical-diagnostics/news/bio-rad-introduces-the-geenius-hiv-1-2-confirmatory-system
Multispot HIV-1/HIV-2 **As a supplemental test**	20 min	Discriminates antibodies to HIV-1 and 2	Serum/plasma See product insert for performance in a diagnostic algorithm	Serum/plasma See product insert for performance in a diagnostic algorithm	Serum/plasma 30 µl	12 Months	http://www.bio-rad.com/prd/en/US/CDG/SKU/25228/Multispot-HIV-1/HIV-2-Rapid-Test

[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 http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/CLIA_Regulations_and_Federal_Register_Documents.html.

[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.