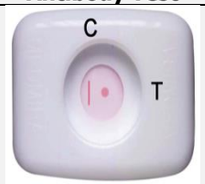
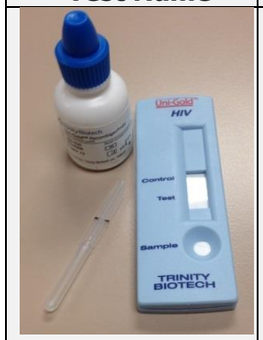
Rapid HIV tests suitable for use in clinical settings (CLIA-moderate complexity) [a]

[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	Finger stick whole blood 99.8 (99.2-99.9) oral fluid 98.9 (98.0-99.4) Venous whole blood/plasma/serum 99.9 (99.4-99.9)	Finger stick whole blood 100 (99.8-100) oral fluid/ venous whole blood/plasma/serum 99.9 (99.7-99.9)	Finger stick or venous whole blood/ plasma/serum 10 µl or oral fluid swab	23 months	**link to Chembio DPP HIV-1/2 Assay product information**
Clearview HIV 1/2 STAT-PAK	15 min	Antibodies to HIV-1 and 2	Serum or plasma 99.7 (98.9-100.0)	Serum or plasma 99.9 (99.6-100.0)	Serum or plasma 5 µL	24 months	**Link to Alere Clearview HIV 1/2 Stat Pak product information**
Clearview COMPLETE HIV 1/2	15 min	Antibodies to HIV-1 and 2	Serum or plasma 99.7 (98.9-100.0)	Serum or plasma 99.9 (99.6-100.0)	Serum or plasma 2.5 µL	24 months	**Link to Clearview Complete HIV 1/2 product information**

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
Determine HIV-1/2 Ag/Ab Combo Test	20 min	Antibodies to HIV-1 and HIV-2, Detects HIV-1 p24 Antigen	Serum, Plasma, Whole Blood HIV-1 Sensitivity is 99.9% 95% CI (99.4-100%)	HIV-1 Specificity for low risk subjects is 100.0%, HIV-1 Specificity high-risk subjects ranges from 98.9% (serum) to 99.7% (whole blood).	Serum, plasma or whole blood 50 µL	14 months	**Link to Alere Determine HIV-1/2 Ag/Ab Combo product information**
INSTI HIV-1 Antibody Test	<2 min	Antibodies to HIV-1	Plasma 99.9 (99.5-100)	Plasma 100 (99.7-100)	Plasma 50 µl	12 months	**Link to Biolytical INSTI HIV-1 product information**

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
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 5µl	12 months	**Link to Orasure OraQuick Advance HIV-1/2 product information**
 **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 or plasma 30 µl	12 months	**Link to Medmira REVEAL G3 product information**
Multispot HIV-1/HIV-2 Rapid Test	20 min	Discriminates antibodies to HIV-1 and 2	Serum or plasma 100 (99.9-100)	Serum or plasma 99.9 (99.8-100)	Serum or plasma 30 µl	12 Months	**Link to Bio-Rad Multispot product information**

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
 **Uni-Gold Recombigen HIV**	10 min	Antibodies to HIV-1	Serum or plasma 100 (99.5-100.0)	Serum or plasma 99.8 (99.3-100)	Serum or plasma 50 µL	12 months	**Link to Trinity Uni-Gold product information**

[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 and Federal Register Documents.

[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.