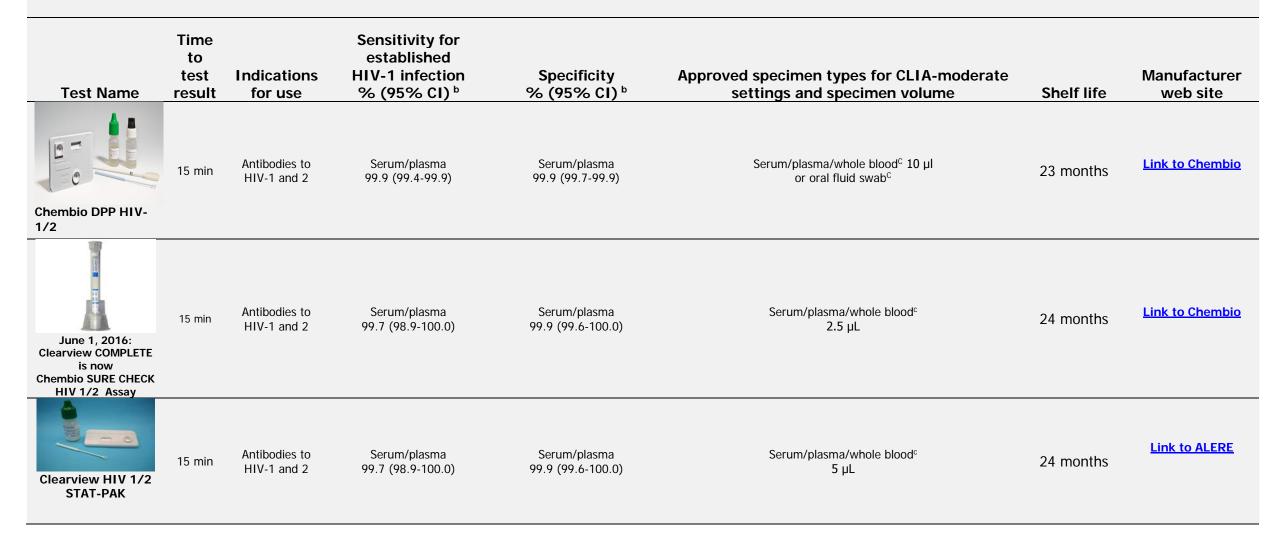
Rapid HIV tests suitable for use in clinical settings (CLIA-moderate complexity)^a [For use with blood, serum or plasma]



Determine HIV-1/2 Ag/Ab Combo Test		Antigen		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
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	<u>Link to BioLytical</u>
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
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

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	<u>Link to OraSure</u> <u>Technologies</u>
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	<u>Link to Trinity</u> <u>BioTech</u>

^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 <u>CLIA Regulations</u>.

^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.