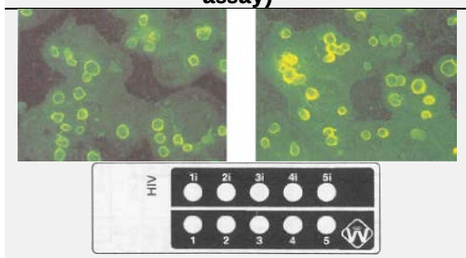
FDA-Approved HIV supplemental tests for laboratory use only (CLIA Moderate or High Complexity Tests)[a,b] [For use with: serum, plasma, oral fluid, dried blood spots or urine]

Test Name	Time to test result	Target analyte	Sensitivity for established HIV-1 infection (%) (95% Confidence Interval)	Specificity (%) (95% Confidence Interval)	Specimen types and volume[c]	Assay format	Manufacturer web site FDA product inserts
 **Geenius™ HIV 1/2 Supplemental System (CLIA moderate complexity)**	20 min	Differentiates HIV-1 and HIV-2 antibodies.	Serum 99.33(97.59-99.82) Fingerstick 100 (97.46-100) Whole Blood EDTA 100 (97.5-100) EDTA Plasma 99.34 (96.34-99.88)	Overall indeterminate rate for low risk population was 4.33% (18/416) for all matched sample types combined.	Whole Blood, Serum /plasma	Immuno-chromatographic. Assay results are read and interpreted by the Geenius Reader.	**Link to Bio-Rad** **Link to FDA-Approved product insert**
 **Aptima HIV-1 RNA Qualitative Assay (CLIA high complexity assay)**	> 3 hours	**HIV-1 Viral RNA: This is the only FDA-Approved HIV-1 NAT approved for Diagnostics use.**	Serum/plasma sensitivity at 100 copies/ml: 100 (99.6-100)	Serum/plasma (see product insert)	Serum/plasma 500 µl	Transcription-mediated amplification of nucleic acid	**Link to Hologic** **Link to FDA-Approved product insert**

 **Multispot HIV-1/HIV-2 Rapid Test CLIA moderate complexity** **(This test is no longer manufactured)**	20 min	Differentiates antibodies to HIV-1 and HIV-2, can be used as a screening test or as a supplemental test in a diagnostic algorithm	Serum/plasma 100 (99.9-100)	Serum/plasma 99.9 (99.8-100)	Serum/plasma 30 µl	ImmunoConcentration	**Link to Bio-Rad** **Link to FDA-Approved product insert**
Other HIV-1 Antibody Supplemental Diagnostic Assays							
 **Bio-Rad Genetic Systems HIV-1 Western Blot (CLIA high complexity assay)**	>3 hours	Antibodies to HIV-1	HIV-1 serum/plasma /dried blood spots (see product insert)	Serum/plasma /dried blood spots HIV-1 indeterminate rate in low risk populations that are EIA negative: 10.7% [g]	Serum/plasma or dried blood spots 10µl	Western blot electrophoresis (WB)	**Link to Bio-Rad** **Link to FDA-Approved product insert**
 **Fluorognost HIV-1 IFA (CLIA high complexity assay)**	1.5 hours	Antibodies to HIV-1	Serum/plasma /dried blood spot (see product insert)	Serum/plasma /dried blood spot (see product insert)	Serum/plasma 10 µl Dried blood Spot	indirect immunofluorescence (IFA)	**link to Sanochemia**

 **Cambridge Biotech HIV-1 Serum Western Blot (CLIA high complexity assay)**	> 3 hours	Antibodies to HIV-1	Serum/plasma (see product insert)	Serum/plasma (see product insert)	Serum/plasma 20 µl	Western blot electrophoresis (WB)	**Link to Cambridge Biotech** **Link to FDA-Approved product insert**
 **Cambridge Biotech HIV-1 Western Blot Urine Kit**	> 3 hours	Antibodies to HIV-1	Urine (see product insert)	Urine (see product insert)	Urine 1 ml	Western blot electrophoresis (WB)	**Link to Maxim Biomedical** **Link to FDA-Approved product insert**
 **OraSure HIV-1 Western Blot (only used with specimens collected with the OraSure HIV-1 oral fluid collection device) CLIA high complexity assay**	> 3 hours	Antibodies to HIV-1	Oral fluid (see product insert)	Oral fluid (see product insert)	Oral fluid 150 µl	Western blot electrophoresis (WB)	**Link to OraSure Technologies** **Link to FDA-Approved product insert**

a 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 external proficiency testing program) 3) High Complexity – tests that require trained lab personnel, involve multiple step protocols, frequent quality control, and participation in 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 For more information about using HIV tests in multi-test algorithms see "Laboratory Testing for the Diagnosis of HIV Infection: Updated Recommendations" Link to Recommendations and a companion quick reference graphic is available Link to Quick Reference Guide.

c Volume for initial test. Repeat testing of reactive tests may be required based on manufacturer's instructions.