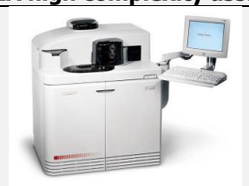
FDA-Approved HIV screening tests for laboratory use only (CLIA Moderate or High Complexity Tests)[a,b] [For use with: serum, plasma, oral fluid or dried blood spots]

p24 Antigen (Ag)/IgM/IgG antibody sensitive assays recommended for laboratory-based screening

Test Name	Time to test result	Target analyte	Sensitivity for established HIV-1 and HIV-2 infection (%) (95% CI)	Specificity for established HIV-1 infection (%) (95% Confidence Interval)	Approved specimen types and volume[c]	Assay format[d]	Manufacturer web site FDA product inserts
 **Abbott Architect HIV Ag/Ab Combo Assay (fully automated CLIA moderate assay)**	<30 min	HIV-1 p24 antigen and antibodies to HIV-1/2	Plasma/serum HIV-1: 100 (99.63-100) HIV-2: 100 (98.2-100) HIV-1 p24: 100 (94.3-100) at 18.1 pg/ml (range 17.8-19.7).	Plasma/serum 99.8 (99.6-99.9)	Plasma/serum 150 µl	Chemiluminescent microparticle immunoassay (CMIA)	**Link to Abbott** **Link to FDA-Approved product insert**
 **ADVIA Centaur HIV Ag/Ab Combo (CHIV) (fully automated CLIA moderate assay)**	<1 hour	Antibodies to HIV p24 Ag, HIV-1 including group O, and/or HIV-2	Serum HIV-1 100.00 (99.61-100.00) HIV-2 100.00 (98.18-100.00)	Serum HIV-1 99.72 (99.56-99.84)	Serum/Plasma	Chemiluminescent microparticle immunoassay (CMIA)	**Link to Siemens** **Link to FDA-Approved product insert**

 **BioPlex® 2200 HIV Ag-Ab**	45 minutes	Simultaneously detects and reports: HIV Ag-Ab overall result with HIV-1 p24 Ag HIV-1 Ab (groups M & O) HIV-2 Ab	Plasma/serum HIV-1 100 (99.72-100) HIV-2 100 (98.12-100) HIV-1 p24 Ag 5.2 pg/ml (5.0-5.4)	Plasma/serum HIV-1 99.92 (99.82-99.97), HIV-2 99.97 (99.89-99.99) HIV-1 p24 Ag 99.91 (99.80-99.96)	Plasma (K2 EDTA, K3 EDTA), lithium heparin, sodium heparin, serum	Multiplex flow immunoassay	**Link to Bio-Rad** **Link to FDA-Approved product insert**
 **Bio-Rad GS HIV Combo Ag/Ab EIA (manual or semi-automated CLIA high complexity assay)**	>3 hours	HIV-1 p24 antigen and antibodies to HIV-1/2	Plasma/serum HIV-1: 100 (99.7-100) HIV-2: 100 (98.1-100) HIV-1 p24: 100% at 14.8 pg/ml (range 13.2-15.9)	Plasma/serum 99.9 (99.8-99.9)	Plasma/serum 75 µl	Enzyme immunoassay micro-well format (EIA)	**Link to Bio-Rad** **Link to FDA-Approved product insert**

IgM/IgG antibody sensitive assays

 **ADVIA Centaur HIV 1/O/2 Enhanced (EHIV) (fully automated CLIA moderate assay)**	<1 hour	Antibodies to HIV-1/2	Plasma/serum HIV-1: 100 (99.7-100) HIV-2: 100 (98.5-100)	Plasma/serum 99.9 (99.8-100)	Plasma/serum 50 µl	Chemiluminescent microparticle immunoassay (CMIA)	**Link to Siemens** **Link to FDA-Approved produce insert**
 **Bio-Rad GS HIV-1/2 Plus O (manual or semi-automated CLIA high complexity assay)**	>3 hours	Antibodies to HIV-1/2	Plasma/serum HIV-1: 100 (99.8-100) HIV-2: 100 (99.8-100)	Plasma/serum 99.9 (99.8-100)	Plasma/serum 75µl	Enzyme immunoassay micro-well format (EIA)	**Link to Bio-Rad** **Link to FDA-Approved product insert**
 **Ortho Vitros ECi/ECiQ Anti-HIV 1+2 Reagent pack (fully automated CLIA high complexity assay)**	<1 hour	Antibodies to HIV-1/2	Plasma/serum HIV-1: 100 (99.7-100) HIV-2: 100 (98.2-100)	Plasma/serum 99.6 (99.1-99.9)	Plasma/serum 80µl	Chemiluminescent immunoassay (CIA)	**Link to Ortho Diagnostics and then follow directions below** **Select: 1. United States, 2. English, 3. Vitros Microwell, 4. Click on "instructions for use" across the top of page and then click "submit" and scroll down.**

IgG antibody sensitive assay							
 **Avioq HIV-1 Microelisa System (manual CLIA high complexity assay)**	>3 hours	Antibodies to HIV-1	Plasma/serum/ dried blood spots: 100 (99.6-100), oral fluid: 99.1[f]	Plasma/serum/ dried blood spots: 100 (99.9-100), oral fluid: 99.6	Plasma/serum, DBS or oral fluid collected with the OraSure HIV-1 oral fluid collection device, 15µl plasma, serum, or oral fluid; dried blood spot ¼" punch	Enzyme-linked immunosorbent assay (ELISA)	**Link to Avioq** **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 Criteria for Laboratory Testing and Diagnosis of Human Immunodeficiency Virus Infection; Approved Guideline (M53-A) available for purchase at http://www.clsi.org/source/orders/Product_Display.cfm?section=Shop&task=3&CATEGORY=MI&PRODUCT_TYPE=SALES&SKU=M53A.

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

d As antibody assays evolved with different mechanisms of detection the terminology to describe this group of tests is now commonly referred to as "Immunoassays" or "IAs".