



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 1 st test result	Target analyte	Sensitivity (%) (95% CI)	Specificity (%) (95% CI)	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



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](#)

BioPlex® 2200 HIV Ag-Ab



>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](#)

Bio-Rad GS HIV Combo Ag/Ab EIA (manual or semi-automated CLIA high complexity assay)



48 minutes

HIV-1 p24 antigen and antibodies to HIV-1/2

Plasma/serum

HIV-1: 100 (99.6-100)
HIV-2: 100 (98.4-100)
HIV-1 p24:
96.2 (86.8-99.5)

Plasma/serum
99.6 (99.4-99.7)

Plasma/serum
80 µl

Immunometric 2-stage reaction

[Link to Ortho Diagnostics](#)
[Link to FDA-Approved product insert](#)

Ortho VITROS HIV Combo Test on the VITROS 3600 Immunodiagnostic System






**Roche Elecsys HIV combi PT
on the cobas e 602**

27 min	HIV-1 p24 antigen and antibodies to HIV-1/2	Plasma/serum HIV-1: 100 (99.7-100) HIV-2: 100 (98.3-100) HIV-1 p24: 96.3 (81.0-99.9)	Plasma/serum 99.9 (99.9-100)	Plasma/serum 39 µl	Electro-chemiluminescence Immunoassay (ECLIA)
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[Link to Roche](#)
[Link to FDA-Approved product insert](#)

IgM/IgG antibody sensitive assays on next page

IgM/IgG antibody sensitive assays

	<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 product insert
	>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
	<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 Clinical Diagnostics Link to FDA-Approved product insert

IgG antibody sensitive assay on next page

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".