Antigen/Antibody Laboratory Tests

Name and Manufacturer	Instrument platform(s)	Indication	Run time	Target analyte	Reports Ag and Ab separately	Detects IgG and/or IgM	Specimen types and volume for initial run	Frequency of external controls	CLIA complexity category	FDA product inserts
HIV Ag/Ab Combo (CHIV) Assay, Siemens	ADVIA Centaur XP, XPT, Atellica	Aid in the diagnosis of HIV-1 and HIV-2 infection in pediatric and adult populations, including pregnant women.	<1 h	Antibodies to HIV-1 & HIV-2 & HIV-1 p24 antigen	No	IgG and IgM	Plasma or serum: 100 µL	8 hours on system	Moderate	ADVIA Centaur HIV Ag/Ab Combo (CHIV) Assay (FDA)
HIV Ag/Ab Combo Assay, Abbott Diagnostics	ARCHITECT system (Alinity i system)	Aid in the diagnosis of HIV-1 and HIV-2 infection, including acute infection in adult and pediatric populations and pregnant women.	<30 min	Antibodies to HIV-1 & HIV-2 & HIV-1 p24 antigen	No	IgG and IgM	Plasma or serum: 150 µL	Once every 24 hours	Moderate	Abbott ARCHITECT HIV Ag/Ab Combo (FDA)
HIV Ag/Ab Combo Assay, Abbott Diagnostics	Alinity s	To screen individual human donors, including volunteer donors of whole blood and blood components, and other living donors for the presence of anti-HIV-1/HIV-2 and HIV-1 p24 antigen.	<30 min	Antibodies to HIV-1 & HIV-2 & HIV-1 p24 antigen	No	IgG and IgM	Plasma or serum: 300 µL	Not available	Moderate	Alinity s HIV Ag/Ab Combo assay (FDA)
HIV Ag-Ab, Bio-Rad Laboratories, Inc.	BioPlex 2200	Aid in the diagnosis of infection with HIV-1 and/or HIV-2, including acute or primary HIV 1 infection; may also be used as an aid in the diagnosis of infection with HIV-1 and/or HIV-2 in pediatric subjects as young as two years of age, and pregnant women.	45 min	Antibodies to HIV-1 & HIV-2 & HIV-1 p24 antigen	Yes	IgG and IgM	Plasma or serum: 350 µL	At least once every 24 hours, and after each calibration	Moderate	BioPlex 2200 HIV Ag-Ab Assay (FDA)
Elecsys HIV combi PT, Roche Diagnostics	Cobas e602	Aid in the diagnosis of HIV-1 and/or HIV-2 infection, including acute or primary HIV-1 infection; may also be used as an aid in the diagnosis of HIV-1 and/or HIV-2 infection in subjects greater than 2 years of age and in pregnant women.	<30 min	Antibodies to HIV-1 & HIV-2 & HIV-1 p24 antigen	No	IgG and IgM	Plasma or serum: 39 µL	Once every 24 hours when the test is in use, once per reagent kit, and following each calibration.	Moderate	Elecsys HIV combi PT (FDA)
GS HIV Combo Ag/Ab EIA, Bio-Rad Laboratories, Inc.	Open	Aid in the diagnosis of HIV-1 or HIV-2 infection, including acute or primary HIV-1 infection. Aid in the diagnosis of HIV-1 or HIV-2 infection in pediatric subjects as young as two years of age.	>3 h	Antibodies to HIV-1 & HIV-2 & HIV-1 p24 antigen	No	IgG and IgM	Plasma or serum: 75 µL	Run with each plate	High	GS HIV Combo Ag/Ab EIA (FDA)

Name and Manufacturer	Instrument platform(s)	Indication	Run time	Target analyte	Reports Ag and Ab separately	Detects IgG and/or IgM	Specimen types and volume for initial run	Frequency of external controls	CLIA complexity category	FDA product inserts
HIV Combo Test, Ortho Clinical Diagnostics	VITROS ECi/ECiQ, 3600, 5600, XT 7600	Aid in the diagnosis of infection with HIV-1 and/or HIV-2 infection in adults, including pregnant women, adolescents, and children (as young as 2 years of age).	48 min	Antibodies to HIV-1 & HIV-2 & HIV-1 p24 antigen	No	IgG and IgM	Plasma or serum: 80 µL	After calibration and at least once every 24 hours	Moderate	VITROS HIV Combo (FDA)
Elecsys HIV Duo, Roche Diagnostics	Cobas e801	Aid in the diagnosis of HIV-1 and/or HIV-2 infection, including acute and primary HIV-1 infection.	<30 min	Antibodies to HIV-1 & HIV-2 & HIV-1 p24 antigen	Yes	IgG and IgM	Plasma or serum: 60 µL	After calibration and at least once every 24 hours	Moderate	Elecsys HIV Duo (FDA)
MUREX HIV Ag/Ab HT (Ag/Ab), Diasorin	LIASON® X , LIASON® XS	Aid in the diagnosis of HIV-1/HIV-2 infection, including acute or primary HIV-1 infection. As an aid in the diagnosis of HIV-1 and/or HIV-2 infection in pediatric subjects (2-21 years) and in pregnant women.	Not available	Antibodies to HIV-1 & HIV-2 & HIV-1 p24 antigen	No	IgG and IgM	Plasma or serum: 350 µL	Run with each batch	Moderate	LIAISON MUREX HIV Ab-Ag HT (FDA)

Antibody Laboratory Tests

Name and Manufacturer	Instrument platform(s)	Indication	Run time	Target analyte	Reports Ag and Ab separately	Detects IgG and/or IgM	Specimen types and volume for initial run	Frequency of external controls	CLIA complexity category	FDA product inserts
ADVIA HIV 1/O/2 Enhanced Assay, Siemens	ADVIA Centaur	Aid in the diagnosis of infection with HIV-1 and/or HIV-2	< 1 h	Antibodies to HIV-1 & HIV-2	No	IgG and IgM	Plasma or serum: 50 µl	Before and after a specimen or group of specimens	Moderate	ADVIA Centaur HIV 1/O/2 Enhanced (FDA)
Avioq HIV-1 Microelisa System, Avioq, Inc.	Open	Aid in diagnosis of infection with HIV-1	>3 h	Antibodies to HIV-1	No	IgG and IgM	Plasma, serum, oral fluid: 15 µl; dried blood spots: ¼" punch	Each run	High	Avioq HIV-1 Microelisa System (FDA)
GS HIV-1/HIV-2 PLUS O EIA, BioRad Laboratories, Inc.	Open	Screening test for specimens from individual human donors Aid in the diagnosis of infection with HIV-1 and/or HIV-2	>3 h	Antibodies to HIV-1 & HIV-2	No	IgG and IgM	Plasma, serum or cadaveric serum: 75 µl	Each plate	High	GS HIV-1/2 Plus O (FDA)
Anti HIV-1+2 Assay, Ortho Clinical Diagnostics	VITROS	Aid in the diagnosis of infection with HIV-1 and/or HIV-2 in persons with signs or symptoms of, or at risk for, HIV infection	< 1 h	Antibodies to HIV-1 & HIV-2	No	IgG and IgM	Plasma or serum: 80 µl	After calibration and at least once every 24 hours	High	VITROS Immunodiagnostics Products Anti-HIV 1+2 (FDA)

Antigen/Antibody Rapid Tests (point-of-care or laboratory)

Test Name and Manufacturer	Instrument platform(s)	Indication	Run time	Target analyte	Reports Ag and Ab separately	Detects IgG and/or IgM	Specimen types and volume for initial run	Frequency of external controls	CLIA complexity category	FDA product inserts
Determine HIV-1/2 Ag/Ab Combo, Abbott	Not applicable	Point of care test to aid in the diagnosis of infection with HIV-1 and/or HIV-2, including an acute HIV-1 infection, and may distinguish acute HIV-1 infection from established HIV-1 infection.	20 min	Antibodies to HIV-1 & HIV-2 & HIV-1 p24 antigen	Yes	IgG and IgM	Whole blood, serum or plasma: 50 µL	Used prior to testing patient specimens when a new operator performs testing, and/or a new test kit lot is to be used, and/or a new shipment of test kits received.	CLIA waived for fingerstick whole blood; CLIA moderate complexity for venous whole blood, serum and plasma samples.	Alere Determine HIV-1/2 Ag/Ab Combo (FDA)

Antibody Rapid Tests (point-of-care or laboratory)

Test Name and Manufacturer	Instrument platform(s)	Indication	Run time	Target analyte	Reports Ag and Ab separately	Detects IgG and/or IgM	Specimen types and volume for initial run	Frequency of external controls	CLIA complexity category	FDA product inserts
DPP HIV-1/2 Assay, Chembio Diagnostics Inc.	Not applicable	Point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms	10 min (25 min for oral fluid)	Antibodies to HIV-1 & HIV-2	No	IgG and IgM	Oral fluid swab or fingerstick whole blood, serum, or plasma (citrate, heparin or EDTA): 10 µL	Each new operator; new test kit lot; new shipment of test kits received; if the temperature of the test storage area falls outside of 2 to 30°C (36 to 86°F); if the temperature of the testing area falls outside of 18 to 30°C (64 to 86°F; at periodic intervals as indicated by the user facility	CLIA waived for fingerstick whole blood and oral fluid; CLIA moderate complexity for venous whole blood, serum and plasma samples.	Chembio DPP HIV 1/2 Assay (FDA)
HIV 1/2 STAT-PAK Assay, Chembio Diagnostics Inc.	Not applicable	Point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2. This test is suitable for use in multi-test algorithms designed for the statistical validation of rapid HIV test results. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms	15 min	Antibodies to HIV-1 & HIV-2	No	IgG and IgM	Fingerstick whole blood, venous whole blood, serum or plasma: 5 µL	Each new operator; new test kit lot; new shipment of test kits received; if the temperature of the test storage area falls outside of 8 to 30°C (46 to 86°F); if the temperature of the testing area falls outside of 18 to 30°C (64 to 86°F)	CLIA waived for fingerstick whole blood; CLIA moderate complexity for venous whole blood, serum and plasma	Chembio HIV 1/2 STAT-PAK Assay (FDA)
INSTI HIV-1/HIV-2 Antibody Test, bioLytical	Not applicable	Aid in the diagnosis of HIV infections. If multiple rapid HIV tests are available, this test is suitable for use in appropriate multi-test algorithms	<2 min	Antibodies to HIV-1 & HIV-2	No	IgG and IgM	Fingerstick whole blood, venous whole blood or plasma: 50 µL	For new INSTI operator verification prior to performing testing on patient specimens; when switching to a new lot number of INSTI test kits; whenever a new shipment of kits is received; when temperature during storage of the kit falls outside of 15° to 30°C (59° to 86°F); when the temperature of the test area falls outside of 15° to 30°C (59° to 86°F); at regular intervals as determined by the user facility	CLIA waived for fingerstick whole blood; CLIA moderate complexity for venous whole blood and plasma	INSTI HIV-1/HIV-2 Antibody Test (FDA)
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test, OraSure Technologies	Not applicable	Point-of-care test to aid in the diagnosis of infection with HIV-1 and/or HIV-2. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms	20 min	Antibodies to HIV-1 & HIV-2	No	IgG and IgM	Oral fluid swab or fingerstick whole blood, venous whole blood or plasma: 5 µL	Each new operator prior to performing testing on patient specimens, when opening a new test kit lot, whenever a new shipment of test kits is received, if the tempearature of test kit storage area falls outside of 2C to 27°C (35 to 80°F), if the tempearature of the testing area falls outside of 15C to 37°C (59 to 99°F), and at periodic intervals as dictated by the user facility	CLIA waived for fingerstick and venous whole blood and oral fluid; CLIA moderate complexity for plasma	OraQuick ADVANCE Rapid HIV-1/2 Antibody Test (FDA)

Test Name and Manufacturer	Instrument platform(s)	Indication	Run time	Target analyte	Reports Ag and Ab separately	Detects IgG and/or IgM	Specimen types and volume for initial run	Frequency of external controls	CLIA complexity category	FDA product inserts
Reveal G4 Rapid HIV-1/2 Antibody Test, MedMira Laboratories, Inc.	Not applicable	Point-of-care test to aid in the diagnosis of infection with HIV-1 and/or HIV-2 restricted to settings with quality assurance program	<2 min	Antibodies to HIV-1 & HIV-2	No	IgG	Fingerstick whole blood, venous whole blood, serum or plasma: drop auto-fill pipette	Each run	Moderate	Reveal G4 Rapid HIV-1 Antibody Test (FDA)
SURE CHECK HIV 1/2 Assay, Chembio Diagnostics Inc.	Not applicable	Point-of-care test to aid in the diagnosis of infection with HIV-1 and/or HIV-2. When multiple rapid HIV tests are available, this test should be used in appropriate multi-test algorithms	15 min	Antibodies to HIV-1 & HIV-2	No	IgG and IgM	Fingerstick whole blood, venous whole blood, serum or plasma: 2.5 µL	Each new operator; new test kit lot; new shipment of test kits received; if the temperature of the test storage area falls outside of 2 to 30°C (36 to 86°F); if the temperature of the testing area falls outside of 18 to 30°C (64 to 86°F; at periodic intervals as indicated by the user facility	CLIA waived for fingerstick and venous whole blood; CLIA moderate complexity for venous whole blood, serum and plasma	Chembio SURE CHECK HIV 1/2 Assay (FDA)
Uni-Gold Recombigen HIV-1/2, Trinity Biotech	Not applicable	Point-of-care test to aid in the diagnosis of infection with HIV-1 or HIV-2. It is suitable for use in appropriate multi-test algorithms	10 min	Antibodies to HIV-1 & HIV-2	No	IgG and IgM	Plasma, serum or whole blood: premeasured pipette	All new operators; each new kit lot; new shipment of test kits; if the temperature of the test kit storage area falls outside of 2 to 27°C (35.6 to 80.6°F); if the temperature of the testing area falls outside of 15 to 27°C (59.0 to 80.6°F)	CLIA waived for fingerstick and venous whole blood; CLIA moderate complexity for serum and plasma	Uni-Gold Recombigen HIV-1/2 (FDA)
DPP HIV-Syphilis System, Chembio Diagnostics Inc.	DPP Micro Reader	Aid in the diagnosis of HIV and syphilis infection. Intended to be used with the DPP Micro Reader.	15 min	Antibodies to HIV-1 & HIV-2 or Treponema pallidum	No	IgG and IgM	Fingerstick whole, EDTA venous blood or EDTA plasma: 10 µL	Each new operator prior to performing tests on patient samples; when opening a new test kit lot; whenever a new shipment of test kits is received; if the temperature of the test storage area falls outside of 2 to 30°C (36 to 86°F); if the temperature of the testing area falls outside of 18 to 30°C (64 to 86°F); at periodic intervals as indicated by the user facility	CLIA waived for fingerstick whole blood; CLIA moderate complexity for venous whole blood and plasma	DPP HIV-Syphilis System (FDA)

Antibody Self-Tests

Test Name and Manufacturer	Instrument platform(s)	Indication	Run time	Target analyte	Reports Ag and Ab separately	Detects IgG and/or IgM	Specimen types and volume for initial run	Frequency of external controls	CLIA complexity category	FDA product inserts
OraQuick HIV Self-test, OraSure Technologies, Inc.	Not applicable	Over-the-counter consumer; in-vitro diagnostic self-test	20 min	Antibodies to HIV-1 & HIV-2	No	IgG and IgM	Oral fluid swab	No external controls	Waived	OraQuick HIV Self-Test (FDA)
INSTI HIV Self Test, bioLytical	Not applicable	Over-the-counter consumer; in-vitro diagnostic self-test	1 min	Antibodies to HIV-1 & HIV-2	No	IgG and IgM	Fingerstick whole blood	No external controls	Waived	https://www.fda.gov/vaccines-blood-biologics/insti-hiv-self-test

Antibody Supplemental Laboratory Tests

Test Name and Manufacturer	Instrument platform(s)	Indication	Run time	Target analyte	Reports Ag and Ab separately	Detects IgG and/or IgM	Specimen types and volume for initial run	External quality control required	CLIA complexity category	FDA product inserts
Geenius HIV 1/2 Supplemental System, Bio-Rad Laboratories, Inc.	Geenius Reader	As an aid in the diagnosis of infection with HIV-1 and/or HIV-2; test to confirm the presence of antibodies to HIV-1 and HIV-2 for specimens found to be repeatedly reactive by diagnostic screening procedures; adults	20 mins	Differentiates HIV-1 and HIV-2 antibodies	No	IgG	Fingerstick whole blood, venous whole blood (EDTA, heparin or sodium citrate): 15 uL; serum or plasma (EDTA, heparin, sodium citrate): 5 uL	When opening a new test kit lot and when a new shipment of test kits is received; If the temperature of the test storage area falls outside of 2 to 30°C (36 to 86°F); If the temperature of the testing area falls outside of 18 to 30°C (64 to 86°F), at periodic intervals as dictated by the user facility	Moderate	Geenius HIV 1/2 Supplemental Assay (FDA)
Genetic Systems HIV-1 Western Blot, Bio-Rad Laboratories, Inc.	Open	Supplemental assay for the detection and identification of antibodies to HIV-1	3 hrs	Antibodies to HIV-1	No	IgG and IgM	Plasma or serum: 10 µL; dried blood spot: ¼" punch	Each run	High	Not found on FDA website
VioOne HIV Profile Supplemental Assay, Aviog, Inc	Open	Confirmation and differentiation of individual antibodies to HIV-1 and Type 2	>2 hours	Antibodies to HIV-1 and HIV-2	No	IgG	Plasma or serum: 20 µL	Each strip	High	VioOne HIV Profile Supplemental Assay (FDA)
Cambridge Biotech HIV-1 Western Blot Urine Kit, Maxim Biomedical, Inc.	Open	Supplemental test; as an aid in clinical diagnosis of HIV infection	~24 hrs	Antibodies to HIV-1	No	IgG	Urine: 1ml	Each run	High	Cambridge Biotech HIV-1 Western Blot Kit (FDA)

Footnote: Discontinued tests: OraSure HIV-1 Western Blot; Murex HIV Ab/Ag HT Assay; Cambridge Biotech HIV-1 Serum Western Blot; Aptima HIV-1 RNA Qualitative Assay (last reagents available Sept 2021); Multispot HIV 1/HIV 2 Rapid Test, LIAISON XL Murex HIV Ab/Ag HT; Cambridge Biotech HIV 1 Serum; Fluorognost HIV 1 IFA.

Diagnostic Nucleic Acid Laboratory Tests

Test Name and Manufacturer	Instrument platform(s)	Indication	Run time	Target analyte	Detects antibody/antigen	Specimen types and volume for initial run	Frequency of external controls	CLIA complexity category	FDA product inserts
HIV-1/HIV-2 Qualitative, Roche Molecular Systems, Inc.	cobas 5800, 6800, 8800	Aid in diagnosis of HIV-1/HIV-2 infection. Detection of HIV-1 or HIV-2 nucleic acid is indicative of HIV-1 or HIV-2 infection, respectively.	Not available	LTR/gag (HIV-1)	Not applicable	Serum or EDTA plasma: 0.65 mL	On-board max 8 h for HIV-1/HIV-2 Qualitative control kit	Moderate	cobas HIV-1/HIV-2 Qualitative (FDA)
Aptima HIV-1 Quant Dx Assay, Hologic	Hologic Panther	Aid in diagnosis of HIV-1 infection using appropriate HIV testing algorithms. The presence of HIV-1 nucleic acid in the plasma or serum of individuals without antibodies to HIV-1 is indicative of acute or primary Infection. As a supplemental test to confirm HIV-1 infections when reactive screening assays.	Approximately 3 h (including reagent preparation time and quality control processing time)	LTR/pol	Not applicable	Serum or plasma (EDTA, ACD): 0.7 mL	On-board max 24 h for Controls and Calibrators	High	Aptima HIV-1 Quant Dx Assay (FDA)
Alinity m HIV-1, Abbott Molecular, Inc.	Alinity m	For use as a supplemental test to confirm HIV-1 infection in individuals who have reactive results with HIV immunoassays. It is not intended for use in screening blood, blood products, tissue, or organ donors for HIV.	< 2 h to first result	LTR/pol	Not applicable	Serum or plasma (ACD, K2 EDTA,K3 EDTA, PPT): 0.75- 1.0 mL	On-board 3 level controls at least once every 24	Moderate	Alinity m HIV-1 (FDA)

Quantification Nucleic Acid Laboratory Tests

Test Name and Manufacturer	Instrument platform(s)	Indication	Run time	Target analyte	Detects antibody/antigen	Specimen types and volume for initial run	Frequency of external controls	CLIA complexity category	FDA product inserts
Cobas HIV-1, Roche Diagnostics	cobas 5800, 6800, 8800	For use in conjunction with clinical presentation and other laboratory markers for the clinical management of HIV-1 infected patients. It can be used to assess patient prognosis by measuring the baseline HIV-1 level or to monitor the effects of antiretroviral therapy by measuring changes in HIV-1 RNA levels during treatment. Is not intended as aid in diagnosis or to confirm HIV-1 infection.	Approximately 3 h for first result (including reagent preparation time and quality control processing time)	LTR/gag	Not applicable	EDTA plasma: 0.65 mL	Three level controls on each plate	Moderate	cobas HIV-1 (FDA)
Aptima HIV-1 Quant Dx Assay, Hologic	Hologic Panther	For use in conjunction with clinical presentation and other laboratory markers for disease prognosis and for use as an aid in monitoring the effects of antiretroviral treatment, as measured by changes in plasma HIV-1 RNA levels.	>3 h (including reagent preparation time and quality control processing time)	LTR/pol	Not applicable	EDTA plasma: 0.7 mL	On-board max 24 hours for Controls and Calibrators	High	Aptima HIV-1 Quant Dx Assay (FDA)
RealTime HIV-1 RealTime HIV-1 Viral Load Assay, Abbott Molecular	*m2000*	Aid in the clinical management of HIV-1 infected individuals in response to antiretroviral therapy in conjunction with clinical presentation and other laboratory markers. It is not intended as aid in diagnosis or to confirm HIV-1 infection.	>3 h (including reagent preparation time and quality control processing time)	*pol (integrase)*	Not applicable	Plasma (ACD-A and EDTA): 0.2- 1.0 mL	Three level controls in each run	High	Abbott RealTime HIV-1 Amplification (FDA)
Alinity m HIV-1, Abbott Molecular	Alinity m	For use to monitor disease prognosis by measuring baseline plasma HIV-1 RNA level and to assess response to antiretroviral treatment by measuring changes in plasma HIV-1 RNA levels.	< 2 h to first result	LTR/pol	Not applicable	Plasma (ACD, K2 EDTA, K3 EDTA, PPT): 0.75- 1.0 mL	On-board Three level controls at least once every 24 hours	Moderate	Alinity m HIV-1 (FDA)

Footnote: Discontinued test: Roche COBAS AmpliPrep/COBAS TaqMan HIV-1 Test, v2.0