Classification Headers

Antigen/Antibody Laboratory Tests

Antibody Laboratory Tests

Antigen/Antibody Rapid Tests

Antibody Self-Tests

Antibody Rapid Tests: Point-of-care

Diagnostic Nucleic Acid Laboratory Tests

Supplemental Antibody Laboratory Tests

Nucleic Acid Monitoring Tests – Not for Diagnosis

AGAB Lab 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	Least complex b CLIA category	FDA product inserts
HIV Ag/Ab Combo (CHIV) Assay Siemens Medical Solutions	ADVIA Centaur	Aid in the diagnosis of HIV-1 and HIV-2 infection in pediatric and adult populations, including pregnant women	<1 hour	Antibodies to HIV-1 & HIV-2 & HIV-1 p24 antigen	NO	IgG and IgM	Plasma, serum: 100 µL	8 hours on system	Moderate	ADVIA Centaur HIV Ag/Ab
HIV Ag/Ab Combo Assay Abbott Diagnostics	ARCHITECT system (Alinity I)	Aid in the diagnosis of HIV-1 and HIV-2 infection, including acute infection in adult and pediatric populations and pregnant women	<30 mins	Antibodies to HIV-1 & HIV-2 & HIV-1 p24 antigen	NO	IgG and IgM	Plasma, serum: 150 µL	Once every 24 hours	Moderate	Abbott ARCHITECT HIV Ag/Ab Combo
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 mins	Antibodies to HIV-1 & HIV-2 & HIV-1 p24 antigen	YES	IgG and IgM	Plasma, serum: 350 µL	At least once every 24 hours, and after each calibration	Moderate	BioPlex 2200 HIV Ag-Ab Assay

AGAB Lab Tests, continued

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	Least complex b CLIA category	FDA product inserts
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 mins	Antibodies to HIV-1 & HIV-2 & HIV-1 p24 antigen	NO	IgG and IgM	Plasma, 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
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 hours	HIV-1 Ab & HIV-2 Ab & HIV-1 p24 Ag	NO	IgG and IgM	Plasma, serum: 75 µL	Run with each plate	High	GS HIV Combo Ag/Ab EIA

AGAB Lab Tests, continued

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	Least complex b CLIA category	FDA product inserts
HIV Combo Test Ortho Clinical Diagnostics	VITROS ECi/ ECiQ, 3600, 5600, XT 7600	For the simultaneous qualitative detection of antibodies to HIV types 1, including group M and O, and/or 2 (anti-HIV-1 and anti-HIV-2) and HIV p24 antigen in human serum and plasma (heparin and EDTA) in adults, including pregnant women, adolescents, and children (as young as 2 years of age). As an aid in the diagnosis of infection with HIV-1 or HIV-2	48 mins	Antibodies to HIV-1 & HIV-2 & HIV-1 p24 antigen	NO	IgG and IgM	Plasma, serum: 80 µL	After calibration and at least once every 24 hours	Moderate	VITROS Immuno-diagnostic Products HIV Combo Reagent Pack
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 mins	HIV-1 Ab & HIV-2 Ab & HIV-1 p24 Ag	YES	IgG and IgM	Plasma, serum: 60 µL	After calibration and at least once every 24 hours	Moderate	Elecsys HIV Duo

Ab Lab 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	Least complexb CLIA category	FDA product inserts
Siemens Medical Solutions USA, Inc.	ADVIA Centaur	Qualitative determination of antibodies to HIV type 1, including Group O, and/or type 2	< 1 hour	Antibodies to HIV-1 & HIV-2	No	IgG and IgM	Plasma/serum: 50 µl	Before and after a specimen or group of specimens	Moderate	ADVIA Centaur HIV 1/O/2 Enhanced ReadyPack Reagents | FDA
Avioq, Inc.	open	Aid in diagnosis of infection with HIV-1	>3 hours	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
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 hours	Antibodies to HIV-1 & HIV-2	No	IgG and IgM	Plasma, serum and cadaveric serum: 75 µl	Each plate	High	GS HIV-1/2 Plus O
Ortho Clinical Diagnostics	VITROS	For the in vitro detection of antibodies to Human Immunodeficiency virus types HIV-1 and/or HIV-2 in human serum and plasma. As an 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 hour	Antibodies to HIV-1 & HIV-2	No	IgG and IgM	Plasma, serum: 80 µl	After calibration and at least once every 24 hours	High	VITROS Immuno-diagnostics Products Anti-HIV 1+2 | FDA

AGAB Rapid 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	Least complexb CLIA category	FDA product inserts
Determine HIV-1/2 Ag/Ab Combo Abbott	N/A	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 mins	Antibodies to HIV-1 & HIV-2 & HIV-1 p24 antigen	YES	IgG and IgM	Whole blood, serum, plasma: 50 µL	Prior to testing patient specimens when a new operator performs testing, a new test kit lot is to be used, a new shipment of test kits received	Waived for fingerstick whole blood; moderate for venous whole blood, serum and plasma samples.	Alere Determine HIV-1/2 Ag/Ab Combo

Ab 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	Least complexb CLIA category	FDA product inserts
OraQuick In-Home HIV Test OraSure Technologies, Inc.	N/A	Over the counter; in-vitro diagnostic home-use test	20 mins	Antibodies to HIV-1 & HIV-2	NO	IgG and IgM	Oral fluid: oral swab	No external controls	N/A	OraQuick In-Home HIV Test

Ab rapid tests POC

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	Least complexb CLIA category	FDA product inserts
DPP HIV-1/2 Assay Chembio Diagnostics Inc.	N/A	Point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2	10 mins WB/25 mins OF	Antibodies to HIV-1 & HIV-2	NO	IgG and IgM	Whole blood, oral fluid: 10 µL oral swab	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 CLIA moderate complexity for venous whole blood and plasma	Chembio DPP HIV 1/2 Assay
HIV 1/2 STAT-PAK Assay Chembio Diagnostics Inc.	N/A	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 mins	Antibodies to HIV-1 & HIV-2	NO	IgG and IgM	Whole blood: 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 and plasma	Chembio HIV 1/2 STAT-PAK Assay

Ab rapid tests POC, continued

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	Least complexb CLIA category	FDA product inserts
INSTI HIV-1/HIV-2 Antibody Test bioLytical	N/A	Aid in the diagnosis of HIV-1 and/or HIV-2 infection in point-of-care settings	<2 mins	Antibodies to HIV-1 & HIV-2	NO	IgG and IgM	Fingerstick whole blood, venous whole blood and 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
OraQuick ADVANCE Rapid HIV-1/2 Antibody Test OraSure Technologies	N/A	Point-of-care test to aid in the diagnosis of infection with HIV-1 or HIV-2	20 mins	Antibodies to HIV-1 & HIV-2	NO	IgG and IgM	5 µL of whole blood, plasma, or oral fluid swab	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 temperature of the test kit storage area falls outside of 2C to 27C (35 to 80°F), if the temperature of the testing area falls outside of 15C to 37C (59 to 99°F), and at periodic intervals as dictated by the user facility	CLIA waived for fingerstick whole blood CLIA moderate complexity for venous whole blood and plasma	OraQuick ADVANCE Rapid HIV-1/2 Antibody Test

Ab rapid tests POC, continued

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	Least complexb CLIA category	FDA product inserts
Reveal G4 Rapid HIV-1 Antibody Test MedMira Laboratories, Inc.	N/A	Point-of-care test to aid in the diagnosis of infection with HIV -1	<2 mins	Antibodies to HIV-1	NO	IgG	1 drop whole blood, serum, plasma	Each run	Moderate	Reveal G4 Rapid HIV-1 Antibody Test (Reveal G4)
SURE CHECK HIV 1/2 Assay Chembio Diagnostics Inc.	N/A	As a point-of-care test to aid in the diagnosis of infection with HIV-1 and HIV-2.	15 mins	Antibodies to HIV-1 & HIV-2	NO	IgG and IgM	Whole blood: 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	Waived	Chembio SURE CHECK HIV 1/2 Assay
Uni-Gold Recombigen HIV-1/2 Trinity Biotech	N/A	For use in point of care settings as an aid in diagnosis of infection with HIV-1 or HIV-2	10 mins	Antibodies to HIV-1 & HIV-2	NO	IgG and IgM	Plasma, serum, 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)	Waived	Uni-Gold Recombigen HIV-1/2 | FDA

Ab rapid tests POC, continued

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	Least complexb CLIA category	FDA product inserts
DPP HIV-Syphilis System Chembio Diagnostics Inc.	N/A	Aid in the diagnosis of HIV and syphilis infection	10 mins	Antibodies to HIV-1 & HIV-2 or Treponema pallidum	NO	IgG and IgM	Fingerstick whole, venous blood or 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	Waived	CLIA – Clinical Laboratory Improvement Amendments (fda.gov) enter CW210001 into 'Document Number'

Diagnostic NA Lab 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	Least complexb CLIA category	FDA product inserts
HIV-1/HIV-2 Qualitative, MPX 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		LTR/gag (HIV-1) LTR (HIV-2)	N/A	EDTA Plasma Serum: 0.65 mL	On-board max 8 hours for HIV-1/HIV-2 Qualitative control kit	Moderate	cobas HIV-1/HIV-2 Qualitative
Aptima HIV-1 Quant Dx Assay Aptima® HIV-1 Quant Dx Assay | Hologic	Hologic Panther	Aid in diagnosis for 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. Aid in monitoring the effects of antiretroviral therapy	Approximately 3 hours (including reagent preparation time and quality control processing time)	LTR/pol	N/A	EDTA/ACD Plasma Serum: 0.7 mL	On-board max 24 hours for Controls and Calibrators	High	Aptima HIV-1 Quant Dx Assay
Alinity m HIV-1 Alinity m HIV 1Assay	Alinity m	Aid in the clinical management of HIV-1 infected individuals in conjunctions with clinical presentation and other laboratory markers. It is not intended for use in screening blood, blood products, tissue, or organ donors for HIV	< 2 hours to first result	LTR/pol	N/A	Serum or Plasma (ACD, K2 EDTA, K3 EDTA, and PPT): 0.75-1.4mL Serum for diagnosis; viral load requires plasma	On-board Three level controls at least once every 24 hours	Moderate	Alinity m HIV-1

Supplemental Ab Lab 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	Least complexb CLIA 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	Whole blood, serum /plasma: 5 uL serum or plasma, 15 uL whole blood	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	Moderate	Geenius HIV 1/2 Supplemental Assay
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, serum, dried blood spots: 10 µL or ¼" punch	Each run	High	–
VioOne HIV Profile Supplemental Assay Avioq, 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, serum: 20 µL	Each strip	High	VioOne HIV Profile Supplemental Assay
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

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.

Nucleic Acid Monitoring Tests

Test Name and Manufacturer	Instrument platform(s)	Indication	Run	Target analyte	Detects antigen/ antibody	Specimen types and volume for initial run	Frequency of external controls	Least complexb CLIA category	FDA product inserts
Cobas HIV-1 cobas® HIV-1 Test (roche.com)	cobas 5800, 6800, 8800	As a supplemental test, when reactive, to confirm HIV-1 infection in individuals whose plasma or serum was also reactive an approved screening assays. Is not intended as aid in diagnosis or to confirm HIV-1 infection	Approximately 3 hours for first result (including reagent preparation time and quality control processing time)	LTR/gag	N/A	EDTA Plasma:0.65 mL	Three level controls on each plate	Moderate	cobas HIV-1
AmpliPrep/COBAS TaqMan HIV-1 Test, version 2.0 COBAS® AmpliPrep/ COBAS® TaqMan® HIV-1 Test, v2.0 (roche.com)	COBAS TaqMan/ COBAS TaqMan 48 Analyzer	Aid in the clinical management of HIV-1 infected individuals in conjunctions with clinical presentation and other laboratory markers It is not intended as aid in diagnosis or to confirm HIV-1 infection.	>3 hours (including reagent preparation time and quality control processing time)	LTR/gag	N/A	EDTA Plasma: 1.0 mL	Three level controls in ever run	Moderate	MS – COBAS AmpliPrep/ COBAS TaqMan HIV-1 Test, version 2.0 IVD, Lot J04272 (08/23), #05212308190 (roche.com) COBAS AmpliPrep/ COBAS TaqMan HIV-1 Test, 48 Tests; COBAS AmpliPrep/ COBAS TaqMan Wash Reagent, 5.1 L | FDA

Nucleic Acid Monitoring Tests, continued

Test Name and Manufacturer	Instrument platform(s)	Indication	Run	Target analyte	Detects antigen/	Specimen types and volume for initial run	Frequency of external controls	Least complexb CLIA category	FDA product inserts
Aptima HIV-1 Quant Dx Assay Aptima® HIV-1 Quant Dx Assay | Hologic	Hologic Panther	Aid in diagnosis for 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. Aid in monitoring the effects of antiretroviral therapy	>3 hours (including reagent preparation time and quality control processing time)	LTR/pol	N/A	EDTA Plasma: 0.7 mL	On-board max 24 hours for Controls and Calibrators	High	Aptima HIV-1 Quant Dx Assay
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 conjunctions with clinical presentation and other laboratory markers. It is not intended as aid in diagnosis or to confirm HIV-1 infection	>3 hours (including reagent preparation time and quality control processing time)	*pol* (integrase	N/A	Plasma (ACD-A and EDTA): 0.2- 1.0 mL	Three level controls in each run	High	Abbott RealTime HIV-1 Amplification