Advantages and Disadvantages of FDA-Approved HIV Assays Used for Screening, *by test category*

Test Category [a]	HIV Screening Tests	Run Time	Instrument	Report Ag and Ab separately	Detects IgG	Detects IgM	Uses whole blood (WB) specimens	Uses oral fluid (OF) specimens	Uses dried blood spot specimens	Least complex[b] CLIA category	External quality control not required in each run
Nucleic acid laboratory test	Aptima HIV-1 RNA Qualitative Assay[c]	>3 hours	semi-automated							high	
Ag/Ab laboratory test	ADVIA Centaur HIV Ag/Ab Combo (CHIV) Assay	<1 hour	automated		✓	✓				moderate	✓
	Architect HIV Ag/Ab Combo Assay	<30 mins	automated		✓	✓				moderate	✓
	BioPlex 2200 HIV Ag-Ab	45 mins	automated	✓	✓	✓				moderate	✓
	GS HIV Combo Ag/Ab EIA	>3 hours	semi-automated		✓	✓				high	
Ag/Ab rapid test	Determine HIV-1/2 Ag/Ab Combo	20 mins	single-use	✓	✓	✓	✓			waived	✓
Ab laboratory test	ADVIA Centaur HIV 1/O/2 Enhanced (EHIV) Assay	<1 hour	automated		✓	✓				moderate	
	Avioq HIV-1 Microelisa System	<3 hours	semi-automated		✓	✓		✓	✓	high	
	GS HIV-1/2 Plus O	>3 hours	semi-automated		✓	✓				high	
	Vitros Anti-HIV 1+2	<1 hour	automated		✓	✓				moderate	✓
Ab rapid test	DPP HIV-1/2 Assay	10 mins WB/ 25 mins OF	single-use		✓		✓	✓		waived	✓
	HIV 1/2 STAT-PAK	15 mins	single-use		✓		✓			waived	✓
	INSTI HIV-1/HIV-2 Antibody Test	<2 mins	single-use		✓	✓	✓			waived	✓
	OraQuick ADVANCE Rapid HIV-1/2 Antibody Test	20 mins	single-use		✓	✓	✓	✓		waived	✓
	Reveal G4 Rapid HIV-1 Antibody Test	<2 mins	single-use		✓		✓			moderate	✓
	SURE CHECK HIV 1/2 Assay	15 mins	single-use		✓		✓			waived	✓
	Uni-Gold Recombigen HIV	10 mins	single-use		✓	✓	✓			waived	✓

HIV-1 Nucleic Acid Laboratory-Based Test[c]

Hologic Aptima HIV-1 RNA Qualitative Assay: *CLIA-high complexity*

Advantages

- The most sensitive test available for diagnostic use capable of detecting HIV-1 RNA during acute HIV infection.

Disadvantages

- Test may be cost-prohibitive for individual screening.

Antigen/Antibody (Ag/Ab) Laboratory-Based Tests

Abbott Architect HIV Ag/Ab Combo Assay: *CLIA-moderate complexity*
Siemens ADVIA Centaur HIV Ag/Ab Combo (CHIV) Assay: *CLIA-moderate complexity*

Advantages

- CDC recommends initial testing with an FDA-approved Ag/Ab assay[d].
- Detects HIV-1 p24 antigen during early HIV infection.
- Requires minimal technician time to process specimens.
- Quality control is run once daily.
- Fully automated; capable of testing for comorbid pathogens.

Disadvantages

- Requires specialized equipment and trained technicians to conduct testing.
- Does not differentiate between the HIV-1 p24 antigen and the HIV-1/2 antibody results.

Bio-Rad BioPlex 2200 HIV Ag-Ab Assay: *CLIA-moderate complexity*

Advantages

- CDC recommends initial testing with an FDA -approved Ag/Ab assay[d].
- Detects HIV-1 p24 antigen during early HIV infection.
- Provides separate results for: HIV-1 p24 antigen, HIV-1 antibody, and HIV-2 antibody.
- Requires minimal technician time to process specimens.
- Quality control is run once daily.
- Fully automated; capable of running tests for comorbid pathogens.

Disadvantages

- Requires specialized equipment and trained technicians to conduct testing.

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Bio-Rad GS HIV Combo Ag/Ab EIA: *CLIA-high complexity*

Advantages

- CDC recommends initial testing with an FDA-approved Ag/Ab assay[d].
- Detects HIV-1 p24 antigen during early HIV infection.
- Can be run manually in low-volume settings.
- Quality control is included in each run.

Disadvantages

- More labor-intensive than fully automated platforms.
- Long turnaround time (>3 hours); reduces the likelihood that the person tested will receive the result in the same day.
- Does not differentiate between the HIV-1 p24 antigen and the HIV-1/2 antibody results.

Ag/Ab Rapid Lateral Flow Test

Alere Determine HIV–1/2 Ag/Ab Combo: *CLIA-waived when used with whole blood*

Advantages

- Detects HIV-1 p24 antigen during early HIV infection.
- Test is portable; if performed at point-of-care, high likelihood that person will receive test result.

Disadvantages

- When used with fingerstick whole blood specimens, not as sensitive near the time of infection as Ag/Ab lab tests performed on plasma.

IgM/IgG Antibody Laboratory-Based Tests

Siemens ADVIA Centaur HIV 1/O/2 Enhanced Assay: *CLIA-moderate complexity*

Advantages

- Fully automated; capable of testing for comorbid pathogens.
- Turnaround time for initial result is <1 hour.

Disadvantages

- Requires specialized equipment and trained technicians to conduct testing.
- Specimens must be bracketed with quality controls in each run.

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Avioq HIV-1 Microelisa System: *CLIA-high complexity*

Advantages

- Can also be used with dried blood spots or with oral fluid collected using the OraSure collection device.

Disadvantages

- Long turnaround time (>3 hours); reduces the likelihood that the person tested will receive the result in the same day.
- Semi-automated HIV immunoassay; more labor-intensive than fully automated platforms.
- FDA-approved for HIV-1 only.
- When used with plasma, less sensitive in detecting near the time of infection than other IgM/IgG tests and Ag/Ab tests.
- Results from specimens collected using the OraSure oral fluid collection device have reduced sensitivity and specificity compared with blood specimens[4].

Bio-Rad GS HIV-1/2 Plus O: *CLIA-high complexity*

Advantages

- Can be run manually in low-volume settings.

Disadvantages

- Long turnaround time (>3 hours); reduces the likelihood that the person tested will receive theresult in the same day.
- Semi-automated HIV immunoassay; more labor -intensive than fully automated platforms.

Ortho Clinical Diagnostics Vitros Anti-HIV 1+2: *CLIA-high complexity*

Advantages

- Fully automated; capable of testing for comorbid pathogens.
- Turnaround time for initial result is <1 hour.
- Only borderline-reactive specimens need to be repeated.
- Quality control is run once daily.

Disadvantages

- Requires specialized equipment and trained technicians to conduct testing.

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IgM/IgG Antibody Flow-Through Rapid Test

bioLytical INSTI HIV-1/HIV-2 Antibody Test: *CLIA-waived for whole blood*

Advantages

- Quick run time (<2 minutes) and can be read immediately after adding reagents.
- Test is portable; if performed at point-of-care, high likelihood that person will receive test result.

Disadvantages

- When used with fingerstick whole blood specimens it is not as sensitive near the time of infection as Ag/Ab lab tests performed on plasma.

IgM/IgG Antibody Lateral-Flow Rapid Test

Trinity Biotech Uni-Gold Recombigen HIV: *CLIA-waived when used with whole blood*
OraSure OraQuick ADVANCE Rapid HIV-1/2 Antibody Test: *CLIA-waived when used with whole blood or oral fluid*

Advantages

- Quick run time (≤ 20 minutes).
- Test is portable; if performed at point-of-care, high likelihood that person will receive test result.

Disadvantages

- When used with fingerstick whole blood specimens it is not as sensitive near the time of infection as IgM/IgG or Ag/Ab lab tests performed on plasma.
- Rapid tests used with oral fluid, which has lower antibody concentrations, are less sensitive when antibody concentrations are low (e.g., closer to time of infection or with long term effective therapy) and less specific than when used with blood[1,2,3].

IgG Antibody Flow-Through Rapid Test

MedMira Reveal G4 Rapid HIV-1 Antibody Test: *CLIA-moderate complexity*

Advantages

- Quick run time (<2 minutes) and can be read immediately after adding reagents.

Disadvantages

- Test is FDA-approved for detection of HIV-1 only.
- Not as sensitive as IgM/IgG or Ag/Ab lab tests when performed with plasma.

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IgG Antibody Lateral-Flow Rapid Tests

Chembio HIV 1/2 STAT-PAK Assay: *CLIA-waived when used with whole blood*

Chembio SURE CHECK HIV 1/2 Assay: *CLIA-waived when used with whole blood*

Advantages

- Quick run time (15 minutes).
- The tests are portable; if performed at point -of-care, high likelihood that person will receive test result.

Disadvantages

- Less sensitive near the time of infection than IgM/IgG or Ag/Ab tests performed on plasma.

IgG Antibody Sensitive Dual-Path Platform Rapid Test

Chembio DPP HIV 1/2 Assay: *CLIA-waived when used with whole blood or oral fluid*

Advantages

- Quick run time when performed with whole blood (10 minutes).
- Test is portable; if performed at point-of-care, high likelihood that person will receive test result.

Disadvantages

- Less sensitive in detecting near the time of infection than Ag/Ab or IgM/IgG tests performed on plasma.
- When performed on oral fluid the run time is 25 minutes.
- Rapid tests used with oral fluid, which has lower antibody concentration, are less sensitive and specific than when used with blood[1,2,3].

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a. For more information about window period and test sensitivity during early/acute infection **(click here)**.

b. Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), tests are categorized by the complexity of the test. The more procedural steps and requirements for user interpretation, the more restrictions are placed on who can perform the test. CLIA-waived tests are simple laboratory tests where the likelihood of erroneous test results is negligible. More information on **HIV CLIA-waived testing** and **laboratory-based testing** information can be found on **CDC's HIV testing website**.

c. The APTIMA HIV-1 RNA Qualitative Assay is currently the only HIV-1 RNA assay intended for use as an aid in the diagnosis of HIV-1 infection including acute or primary infection. Presence of the HIV-1 RNA in the plasma or serum of patients without antibodies to HIV-1 is indicative of acute or primary HIV-1 infection. When used as a screening test, the specimen must also be tested with an antibody test to verify the absence of antibodies. Additional information about APTIMA can be found in the **APTIMA package insert**. Laboratories are not authorized to use HIV-1 RNA viral load assays as a screening test without a written order from a physician.

d. For information about using HIV tests in multitest laboratory algorithms, see **Laboratory testing for the diagnosis of HIV infection: updated recommendations**, and the **2018 Quick reference guide**. For other testing in nonclinical settings see chapter 5 of **Planning and implementing HIV testing and linkage programs in non-clinical settings: a guide for program managers.**

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4. Avioq, Inc. Avioq HIV-1 Microelisa System [package insert]. 2009; **http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/PremarketApprovalsPMAs/ucm185249.htm**. Accessed March 22, 2018.

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