# Advantages and disadvantages of FDA-approved HIV assays used for screening, by test category

<table>
<thead>
<tr>
<th>Test Category</th>
<th>HIV Screening Tests</th>
<th>Run time</th>
<th>Instrument</th>
<th>Reports Ag and Ab separately</th>
<th>Detects IgG</th>
<th>Detects IgM</th>
<th>Uses whole blood specimens</th>
<th>Uses oral fluid specimens</th>
<th>Uses dried blood spot specimens</th>
<th>Least complex CLIA category</th>
<th>External quality control not required in each run</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nucleic acid lab test</strong></td>
<td>Aptima HIV-1 RNA Qualitative Assay</td>
<td>&gt;3 hours</td>
<td>semi-automated</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Ag/Ab lab tests</strong></td>
<td>Architect HIV Ag/Ab Combo Assay</td>
<td>&lt;30 min</td>
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<td>✓</td>
<td>✓</td>
<td></td>
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<td>moderate</td>
</tr>
<tr>
<td></td>
<td>ADVIA Centaur HIV Ag/Ab Combo (CHIV) Assay</td>
<td>&lt;1 hour</td>
<td>automated</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
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<tr>
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<td>BioPlex 2200 HIV Ag-Ab</td>
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<td></td>
<td>moderate</td>
</tr>
<tr>
<td></td>
<td>GS HIV Combo Ag/Ab EIA</td>
<td>&gt;3 hours</td>
<td>semi-automated</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Ag/Ab rapid test</strong></td>
<td>Determine HIV-1/2 Ag/Ab Combo</td>
<td>20 min</td>
<td>single-use</td>
<td>✓</td>
<td>✓</td>
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<td>✓</td>
<td></td>
<td></td>
<td></td>
<td>waived</td>
</tr>
<tr>
<td><strong>Ab lab test</strong></td>
<td>ADVIA Centaur HIV 1/0/2 Enhanced (EHIV) Assay</td>
<td>&lt;1 hour</td>
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<td>✓</td>
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<td></td>
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</tr>
<tr>
<td></td>
<td>Vitros Anti-HIV 1+2</td>
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<td>✓</td>
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<tr>
<td></td>
<td>GS HIV-1/2 Plus O</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
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<tr>
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<td>Avioq HIV-1 Microelisa System</td>
<td>&gt;3 hours</td>
<td>semi-automated</td>
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<td>✓</td>
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<tr>
<td><strong>Ab rapid test</strong></td>
<td>INSTI HIV-1/HIV-2 Antibody Test</td>
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<tr>
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<td>Uni-Gold Recombigen HIV</td>
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<tr>
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<td>HIV 1/2 STAT-PAK</td>
<td>15 min</td>
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<tr>
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<td>SURE CHECK HIV 1/2 Assay</td>
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<td>waived</td>
<td>✓</td>
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<tr>
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<td>OraQuick ADVANCE Rapid HIV-1/2 Antibody Test</td>
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<td>single-use</td>
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<td>✓</td>
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<td>DPP HIV-1/2 Assay</td>
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<tr>
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<td>Reveal G4 Rapid HIV-1 Antibody Test</td>
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<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>moderate</td>
<td></td>
</tr>
</tbody>
</table>

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*July 2017*
HIV-1 nucleic acid laboratory-based test

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
- 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
- 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

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

Advantages
- CDC recommends initial testing with an FDA-approved Ag/Ab assay
- 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 1/2 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

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

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 the result in the same day
• Semi-automated HIV immunoassay; more labor-intensive than fully automated platforms
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

IgM/ IgG antibody flow-through rapid test

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

Advantages
- Quick run time (<5 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 IgM/IgG or 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

Advantages
- Quick run time (10 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

IgG antibody flow-through rapid test

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

Advantages
- Quick run time (<5 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
IgG antibody lateral-flow rapid tests

Chembio HIV 1/2 STAT-PAK: CLIA-waived when used with whole blood
Chembio SURE CHECK HIV 1/2 assay: 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)
- 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
- 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 sensitive dual-path platform rapid test

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

Advantages
- Quick run time when performed with whole blood (<20 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 40 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 (Note we will add this soon to the clinical testing page)

\(^b\) 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.
For information about using HIV tests in multistest algorithms, see Laboratory testing for the diagnosis of HIV infection: updated recommendations, the companion quick reference guide, and a technical update on HIV-1/2 differentiation assays.

References


