**Overview**

**Useful For**

Confirmation and differentiation of HIV-1 and HIV-2 antibodies in serum specimens that show reactive results with third- (HIV-1/-2 antibody only) and fourth- (HIV antigen and antibody) generation HIV serologic assays.

This test is **not useful** as a screening test for HIV infection in symptomatic or asymptomatic individuals. It is not to be used as a screening or confirmatory test for blood donor specimens.

This test is **not useful** for maternal or newborn HIV screening for specimens originating in New York State.

This test is **not useful** for follow-up testing of patients with reactive results from any rapid HIV tests. These patients should be tested subsequently with laboratory-based HIV antigen and antibody combination immunoassays, such as HIVDX / HIV-1 and HIV-2 Antigen and Antibody Diagnostic Evaluation, Plasma, per the latest CDC recommended HIV testing algorithm.

**Testing Algorithm**

Only orderable as a reflex. For more information see:

- HV1CD / HIV-1 and HIV-2 Antibodies for Cadaveric or Hemolyzed Specimens, Serum

- HV1CM / HIV-1 and HIV-2 Antibody Screen for Hemolyzed Specimens, Serum

This HIV-1 and HIV-2 antibody confirmation and differentiation test begins with Geenius HIV-1/2 Supplemental Assay (Bio-Rad Laboratories).

See HIV Testing Algorithm (Fourth Generation Screening Assay) including Follow-up of Reactive HIV Rapid Serologic Test Results in Special Instructions.

**Special Instructions**

- HIV Testing Algorithm (Fourth-Generation Screening Assay), Including Neonatal Testing and Follow-up of Reactive Rapid Serologic Test Results

**Method Name**

Only orderable as a reflex. For more information see:

- HV1CD / HIV-1 and HIV-2 Antibodies for Cadaveric or Hemolyzed Specimens, Serum

- HV1CM / HIV-1 and HIV-2 Antibody Screen for Hemolyzed Specimens, Serum

Rapid Immunochromatographic Assay

**NY State Available**

Yes

**Specimen**

**Specimen Type**

Serum
Advisory Information
If testing is needed for autopsy or cadaver blood sourced specimens, order the FDA-licensed assay: HV1CD / HIV-1 and HIV-2 Antibodies for Cadaveric or Hemolyzed Specimens, Serum.

Necessary Information
Date of collection is required.

Specimen Required
Only orderable as a reflex. For more information see:

HV1CD / HIV-1 and HIV-2 Antibodies for Cadaveric or Hemolyzed Specimens, Serum

HV1CM / HIV-1 and HIV-2 Antibody Screen for Hemolyzed Specimens, Serum.

Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 1.5 mL

Collection Instructions:
1. Centrifuge blood collection tube per collection tube manufacturer's instructions.
2. Aliquot serum into plastic vial.

Specimen Minimum Volume
0.1 mL

Reject Due To

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Hemolysis</td>
<td>Mild OK; Gross OK</td>
</tr>
<tr>
<td>Lipemia</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Icterus</td>
<td>Mild OK; Gross reject</td>
</tr>
<tr>
<td>Other</td>
<td>NA</td>
</tr>
</tbody>
</table>

Specimen Stability Information

<table>
<thead>
<tr>
<th>Specimen Type</th>
<th>Temperature</th>
<th>Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>Frozen (preferred)</td>
<td>30 days</td>
</tr>
<tr>
<td></td>
<td>Refrigerated</td>
<td>14 days</td>
</tr>
<tr>
<td></td>
<td>Ambient</td>
<td>48 hours</td>
</tr>
</tbody>
</table>
Clinical and Interpretive

Clinical Information

AIDS is caused by 2 known types of HIV. HIV type 1 (HIV-1) is found in patients with AIDS, AIDS-related complex, and asymptomatic infected individuals at high risk for AIDS. The virus is transmitted by sexual contact, by exposure to infected blood or blood products, or from an infected mother to her fetus or infant. HIV type 2 (HIV-2) infection is endemic only in West Africa, and it has been identified in individuals who had sexual relations with individuals from that geographic region. HIV-2 is similar to HIV-1 in viral morphology, overall genomic structure, and its ability to cause AIDS.

Antibodies against HIV-1 and HIV-2 are usually not detectable until 6 to 12 weeks following exposure and are almost always detectable by 12 months. They may fall to undetectable levels (ie, seroreversion) in the terminal stage of AIDS when the patient's immune system is severely depressed.

Routine serologic screening of patients at risk for HIV-1 or HIV-2 infection usually begins with a HIV-1/-2 antigen or antibody screening test, which may be performed by various FDA-approved assay methods, including rapid HIV antibody tests, enzyme immunoassays, and chemiluminescent immunoassays. In testing algorithms that begin with these methods, per manufacturers' instructions, supplemental or confirmatory testing should only be requested for specimens that are repeatedly reactive.

Reference Values

Only orderable as a reflex. For more information see:

HV1CD / HIV-1 and HIV-2 Antibodies for Cadaveric or Hemolyzed Specimens, Serum

HV1CM / HIV-1 and HIV-2 Antibody Screen for Hemolyzed Specimens, Serum

Negative

Interpretation

Negative results for both HIV-1 and HIV-2 antibodies usually indicate the absence of HIV-1 and HIV-2 infection. However, negative results do not rule-out acute or early HIV infection in patients with reactive initial combined HIV-1/-2 antigen and antibody test results. If acute or early HIV infection is suspected, detection of HIV-1 RNA (HIVQN / HIV-1 RNA Detection and Quantification, Plasma) and/or HIV-2 DNA/RNA (FHV2Q / HIV-2 DNA/RNA Qualitative Real-Time PCR) is recommended, based on the patient's clinical and epidemiologic exposure history.

Positive HIV-1 antibody but negative HIV-2 antibody results indicate the presence of HIV-1 infection. Together with reactive initial combined HIV-1/-2 antigen and antibody test results, individuals with these results are presumed to have HIV-1 infection. Verification of a first-time positive test result is recommended for the diagnosis of HIV-1 infection. Additional testing with a newly submitted plasma specimen for HIV-1 RNA (HIVQN / HIV-1 RNA Detection and Quantification, Plasma) is recommended to verify and confirm the diagnosis of HIV-1 infection prior to initiating antiretroviral treatment.

Positive HIV-1 antibody but indeterminate HIV-2 antibody results indicate the presence of HIV-1 infection, with probable cross-reactivity of HIV-1 antibodies with HIV-2 antigens on the assay strip. Verification of a first-time positive test result is recommended for the diagnosis of HIV-1 infection. Submit a new plasma specimen for detection of HIV-1 RNA (HIVQN / HIV-1 RNA Detection and Quantification, Plasma). However, such result patterns may rarely indicate early HIV-2 infection (ie, HIV-2 coinfection) in HIV-1-infected individuals. For individuals at risk for HIV-2
infection (based on epidemiologic exposure history), a whole blood specimen should also be submitted for HIV-2 DNA/RNA (FHV2Q / HIV-2 DNA/RNA Qualitative Real-Time PCR).

Indeterminate HIV-1 antibody but negative HIV-2 antibody results suggest either very early HIV-1 infection (in individuals with risk factors) or the presence of nonspecific cross-reactivity between the patient specimens and HIV-1 antigens on the assay strip. If a patient has known risk factors for HIV-1 infection, submit a new plasma specimen for detection of HIV-1 RNA (HIVQN / HIV-1 RNA Detection and Quantification, Plasma).

Negative HIV-1 antibody but indeterminate HIV-2 antibody results may be due to acute HIV-1 infection or suggest either very early HIV-2 infection (in individuals with risk factors) or the presence of nonspecific cross-reactivity between the patient specimens and HIV-2 antigens on the assay strip. A new plasma specimen for HIVQN / HIV-1 RNA Detection and Quantification, Plasma should be submitted. If the subsequent HIV-1 RNA test result is negative and the patient has known risk factors for HIV-2 infection (based on patient's clinical and epidemiologic history), a new whole blood specimen should be submitted for FHV2Q / HIV-2 DNA/RNA Qualitative Real-Time PCR.

Positive results for both HIV-1 and HIV-2 antibodies suggest the probable presence of HIV-1 and HIV-2 coinfection. However, such results may rarely be due to either HIV-1 infection with HIV-2 antibody cross-reactivity or HIV-2 infection with HIV-1 antibody cross-reactivity (eg, absence of HIV-1 p24 and p31 bands). Verification of a first-time positive test result is recommended for the diagnosis of HIV infection. Based on the patient's clinical and epidemiologic history, a new plasma specimen should be submitted for detection of HIV-1 RNA (HIVQN / HIV-1 RNA Detection and Quantification, Plasma) and/or a whole blood specimen submitted for detection of HIV-2 DNA/RNA (FHV2Q / HIV-2 DNA/RNA Qualitative Real-Time PCR).

Indeterminate results for both HIV-1 and HIV-2 antibodies indicate either very early HIV infection (in individuals with risk factors) or the presence of nonspecific cross-reactivity between the patients' specimens and HIV antigens on the assay strip. Nonspecific cross-reactivity may be due to recent non-HIV infections, hypergammaglobulinemic states, connective tissue disorders, or pregnancy (alloantibodies). For individuals at risk for HIV infection, a new plasma specimen should be submitted for detection of HIV-1 RNA (HIVQN / HIV-1 RNA Detection and Quantification, Plasma) and/or a whole blood specimen submitted for detection of HIV-2 DNA/RNA (FHV2Q / HIV-2 DNA/RNA Qualitative Real-Time PCR), depending on the epidemiologic exposure history.

Negative HIV-1 antibody but positive HIV-2 antibody results indicate the presence of HIV-2 infection. Together with a reactive initial HIV-1/-2 antigen and antibody screening test results, individuals with such results are presumed to have HIV-2 infection. Additional testing with a new whole blood specimen for HIV-2 DNA/RNA (FHV2Q / HIV-2 DNA/RNA Qualitative Real-Time PCR) is recommended to verify and confirm the diagnosis of HIV-2 infection prior to initiating antiretroviral treatment.

Reactive HIV-1 antibody but positive HIV-2 antibody results usually indicate the presence of HIV-2 infection with HIV-1 antibody cross-reactivity (eg, presence of only HIV-1 gp41 and/or gp160 band). However, such results may rarely be due to HIV-1 and HIV-2 coinfection. Verification of a first-time positive test result is recommended for the diagnosis of HIV-2 infection, by submitting a new whole blood specimen for HIV-2 DNA/RNA (FHV2Q / HIV-2 DNA/RNA Qualitative Real-Time PCR). If the patient is at risk for HIV-1 infection, based on the patient's clinical and epidemiologic history, a new plasma specimen should also be submitted for detection of HIV-1 RNA (HIVQN / HIV-1 RNA Detection and Quantification, Plasma).

Indeterminate HIV-1 antibody but positive HIV-2 antibody results indicate the presence of HIV-2 infection with probable cross-reactivity of HIV-2 antibodies with HIV-1 antigens on the assay strip. Verification of a first-time positive test result is recommended for the diagnosis of HIV-2 infection. Submit a new whole blood specimen for FHV2Q / HIV-2 DNA/RNA Qualitative Real-Time PCR. However, these result patterns may rarely indicate early HIV-1 infection (ie, HIV-1 coinfection) in HIV-2-infected individuals. For individuals at risk for HIV-1 infection, based on epidemiologic exposure history, a new plasma specimen should also be submitted for detection of HIV-1 RNA (HIVQN / HIV-1 RNA Detection and Quantification, Plasma).
See HIV Testing Algorithm (Fourth Generation Screening Assay) Including Follow-up of Reactive HIV Rapid Serologic Test Results in Special Instructions.

**Cautions**

A negative result for both HIV-1 and HIV-2 antibodies does not rule-out acute HIV infection. If acute HIV-1 infection is suspected, detection of HIV-1 RNA (HIVQN / HIV-1 RNA Detection and Quantification, Plasma) is recommended. For patients at risk for HIV-2 infection (eg, having lived in West Africa or have sexual partners from West Africa), testing for HIV-2 DNA/RNA (FHV2Q / HIV-2 DNA/RNA Qualitative Real-Time PCR) is recommended.

All initially positive supplemental or confirmatory HIV test results should be verified by submitting a second specimen for repeat testing. Such positive HIV test results are required under laws in many states in the United States to be reported to the departments of health of the respective states where the patients reside.

Screening, supplemental, or confirmatory serologic tests for HIV-1 or HIV-2 antibodies cannot distinguish between active neonatal HIV infection and passive transfer of maternal HIV antibodies in infants during the postnatal period (up to 18 months). Diagnosis of HIV infection in newborns and infants up to 18 months should be made by virologic tests, such as detection of HIV RNA (HIVQN / HIV-1 RNA Detection and Quantification, Plasma).

Recipients of HIV-1 vaccine (eg, participants in HIV-1 vaccine study trials) may develop vaccine-specific antibodies that may cross-react with this test and yield to a positive, indeterminate, or unreadable HIV-1 antibody result. However, the patient may or may not be infected with HIV-1.

Assay performance characteristics have not been established for the following specimen characteristics:

- Heat-inactivated specimens
- Cadaveric specimens
- Presence of particulate matter

**Clinical Reference**


**Performance**

**Method Description**
The Geenius HIV 1/2 Supplemental Assay cassette contains antibody-binding protein A, which is conjugated to colloidal gold dye particles, and HIV-1 and HIV-2 antigens, which are bound to the membrane solid phase. The sample is applied to the sample and buffer well. After the sample and buffer have migrated onto the test strip, additional buffer is added to the buffer well. The buffer causes the specimens and reagents to flow laterally and facilitates the binding of antibodies to the antigens. In a reactive sample, the antibodies are captured by the antigens immobilized in the test area.

The protein A-colloidal gold binds to the captured antibodies, causing development of pink/purple lines. When there are no HIV antibodies, there are no pink/purple lines in the test area. The sample continues to migrate through the membrane and a pink/purple line develops in the control (C) area, which contains Protein A. This built-in procedural control provides evidence that the test was performed properly and that the sample and reagents have migrated through the cassette. (Package insert: Geenius HIV 1/2 Supplemental Assay; Bio-Rad Laboratories, Redmond, WA; September 2017)

PDF Report
No

Day(s) and Time(s) Test Performed
Monday through Friday; Varies

Analytic Time
1 day

Maximum Laboratory Time
3 days

Specimen Retention Time
14 days

Performing Laboratory Location
Rochester

Fees and Codes

Fees
- Authorized users can sign in to Test Prices for detailed fee information.
- Clients without access to Test Prices can contact Customer Service 24 hours a day, seven days a week.
- Prospective clients should contact their Regional Manager. For assistance, contact Customer Service.

Test Classification
This test has been cleared or approved by the U.S. Food and Drug Administration and is used per manufacturer’s instructions. Performance characteristics were verified by Mayo Clinic in a manner consistent with CLIA requirements.

CPT Code Information
86701
86702

LOINC® Information
### Test Definition: HIVDI
HIV Ab Confirm / Differentiation, S

<table>
<thead>
<tr>
<th>Test ID</th>
<th>Test Order Name</th>
<th>Order LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIVDI</td>
<td>HIV Ab Confirm / Differentiation, S</td>
<td>89365-1</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result ID</th>
<th>Test Result Name</th>
<th>Result LOINC Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>36112</td>
<td>HIV-1 Ab Differentiation, S</td>
<td>68961-2</td>
</tr>
<tr>
<td>36113</td>
<td>HIV-2 Ab Differentiation, S</td>
<td>81641-3</td>
</tr>
</tbody>
</table>