

Overview

Useful For

Confirmation of the presence of HIV-2 antibodies in patients with repeatedly reactive combined HIV-1 and HIV-2 antibody or HIV-2 antibody-only screening test results

Diagnosis of HIV-2 infection

Testing Algorithm

The following algorithms are available in Special Instructions:

[-HIV-2 Testing Algorithm: Screening \(Nonsymptomatic\) and Diagnostic \(Symptomatic\)](#)

[-HIV Testing Algorithm \(Fourth-Generation Screening Assay\), Including Follow-up of Reactive Rapid Serologic Test Results](#)

Special Instructions

- [HIV-2 Testing Algorithm: Screening \(Nonsymptomatic\) and Diagnostic \(Symptomatic\)](#)
- [HIV Testing Algorithm \(Fourth-Generation Screening Assay\), Including Follow-up of Reactive Rapid Serologic Test Results](#)

Method Name

Rapid Immunochromatographic Assay

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

This confirmatory assay should be ordered only on specimens that are repeatedly reactive by HIV-2 antibody screening immunoassay.

Screening, supplemental, or confirmatory serologic tests for HIV-2 antibodies cannot distinguish between active HIV-2 infection and passive transfer of maternal HIV-2 antibodies in infants during the postnatal period (up to 2 years). Diagnosis of HIV-2 infection in newborns and infants of less than 2 years old should be made by consistently positive nucleic acid test results, such as the presence of HIV-2 DNA/RNA (FHV2Q / HIV-2 DNA/RNA Qualitative Real-Time PCR).

New York State clients: This test should not be requested for maternal/newborn HIV screening on specimens originating in New York State, due to state regulatory requirements for expedited result reporting.

Necessary Information

Date of collection is required.

Specimen Required

Collection Container/Tube:

Preferred: Serum gel

Acceptable: Red top

Submission Container/Tube: Plastic vial

Specimen Volume: 0.5 mL

Collection Instructions:

1. Centrifuge blood collection tube per collection tube manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).

2. Aliquot serum into plastic vial.

Specimen Minimum Volume

0.2 mL

Reject Due To

| | |
|-----------------|----|
| Gross hemolysis | OK |
| Gross lipemia | OK |
| Gross icterus | OK |

Specimen Stability Information

| Specimen Type | Temperature | Time | Special Container |
|---------------|--------------------|----------|-------------------|
| Serum | Frozen (preferred) | 30 days | |
| | Refrigerated | 14 days | |
| | Ambient | 48 hours | |

Clinical and Interpretive
Clinical Information

Human immunodeficiency virus type 2 (HIV-2) is a lentivirus, a retrovirus in the same genus (Lentiviridae) as HIV-1. It was first isolated in 1986 in West Africa, where it is currently endemic. As of June 2010, CDC has reported a total of 166 cases that met the CDC case definition of HIV-2 infection in the United States. Most of these cases were found in the northeastern United States, and the majority had a West African origin or connection.

Compared to HIV-1 infection, HIV-2 infection is associated with slower rate of progression, low viral load (which may not be reliably measured with current methods), slower rates of decline in CD4 cell count, and lower rates of transmission (sexually or vertically). Up to 95% of HIV-2-infected individuals are long-term nonprogressors, and individuals with undetectable HIV-2 viral load have similar survival rates as that of the uninfected population. However, HIV-2 does cause immunosuppression as well as AIDS with the same signs, symptoms, and opportunistic infections seen in HIV-1. Due to the rarity of HIV-2, there are scant data from controlled trials to inform management

decisions.

Although there are several FDA-approved screening assays to detect combined HIV-1 and HIV-2 antibodies or HIV-2 antibodies alone, currently there is only one FDA-approved supplemental (confirmatory) HIV-2 serologic assay for clinical use in the United States.

Reference Values

Negative

Interpretation

Negative results for HIV-2 antibodies usually indicate the absence of HIV-2 infection. However, in patients with reactive initial combined HIV-1/-2 antigen and antibody test results, such negative results do not rule-out acute or early HIV-2 infection. If acute or early HIV-2 infection is suspected, detection of 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-2 antibody results indicate the presence of 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.

Indeterminate HIV-2 antibody results may be due to acute HIV-1 infection or very early HIV-2 infection (in individuals with risk factors). If acute HIV-1 infection or early HIV-2 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 HIV-2 DNA/RNA Qualitative Real-Time PCR) is recommended, depending on the epidemiologic exposure history.

Cautions

A negative HIV-2 antibody supplemental (confirmatory) test result does not exclude the possibility of acute or early (<60 days from time of exposure) HIV-2 infection. Individuals suspected of having acute or early HIV-2 infection should be tested for qualitative HIV-2 DNA/RNA (FHV2Q / HIV-2 DNA/RNA Qualitative Real-Time PCR) or quantitative HIV-2 RNA.

The US Association of Public Health Laboratories recommends verification of all first-time positive supplemental test results for the definitive diagnosis of HIV infection. A second serum specimen should be obtained from the patient and submitted for repeat testing to verify all first-time positive test results.

Although a positive HIV-2 antibody supplemental test result indicates HIV-2 infection, a diagnosis of AIDS can only be made based on the case definition established by the CDC. In many US states, positive HIV-2 antibody supplemental test results are required to be reported to the state department of health.

Individuals at risk for HIV-2 infection with indeterminate or negative HIV-2 antibody supplemental test results should be retested in 2 to 4 weeks or have qualitative HIV-2 DNA/RNA (FHV2Q) testing performed.

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

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

Clinical Reference

1. Campbell-Yesufu OT, Gandhi RT: Update on human immunodeficiency virus (HIV)-2 infection. 2011 Mar

15;52(6):780-787

2. Centers for Disease Control and Prevention and Association of Public Health Laboratories. Laboratory testing for the diagnosis of HIV infection: Updated recommendations. June 27, 2014. Accessed June 15, 2020. Available at <https://stacks.cdc.gov/view/cdc/23447>

3. Malloch L, Kadivar K, Putz J, et al: Comparative evaluation of the Bio-Rad Geenius HIV-1/2 confirmatory assay and the Bio-Rad Multispot HIV-1/2 rapid test as an alternative differentiation assay for CLSI M53 algorithm-I. J Clin Virol. 2013 Dec;58(Suppl. 1):e85-e91

4. Montesinos I, Eykmans J, Delforge ML: Evaluation of the Bio-Rad Geenius HIV-1/2 test as confirmatory assay. J Clin Virol. 2014 Aug;60(4):399-401

5. Mor O, Milequir F, Michaeli M, Levy I, Mendelson E: Evaluation of the Bio-Rad Geenius HIV 1/2 assay as an alternative to the INNO-LIA HIV 1/2 assay for confirmation of HIV infection. J Clin Microbiol. 2014 Jul;52(7):2677-2679

6. Abbate I, Pergola C, Pisciotta M, et al: Evaluation in a clinical setting of the performances of a new rapid confirmatory assay for HIV-1/2 serodiagnosis. J Clin Virol. 2014 Sep;61(1):166-169

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; 07/2019)

PDF Report

No

Day(s) Performed

Monday through Friday

Report Available

1 to 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, approved, or is exempt by the US 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

86689

LOINC® Information

| Test ID | Test Order Name | Order LOINC Value |
|---------|--------------------------|-------------------|
| HIV2L | HIV-2 Ab Confirmation, S | 81641-3 |

| Result ID | Test Result Name | Result LOINC Value |
|-----------|--------------------------|--------------------|
| 61785 | HIV-2 Ab Confirmation, S | 81641-3 |