

Overview

Useful For

Confirmation and differentiation of HIV-1 and HIV-2 antibodies in plasma specimens that show reactive results with third-(HIV-1/-2 antibody only) and 4th-generation (HIV antigen and antibody) HIV serologic assays

This test is **not useful** as a screening test for HIV infection in symptomatic or asymptomatic individuals.

This test is **not to be used** as a screening or confirmatory test for blood donor specimens.

Testing Algorithm

This test is for confirmation and differentiation of HIV-1/2 antibodies. If the following result types are obtained, HIV-1 RNA detection and quantification will be performed at an additional charge:

- HIV-1 and HIV-2 both negative
- Indeterminate for HIV-1 and negative for HIV-2
- Negative for HIV-1 and indeterminate for HIV-2
- HIV-1 and HIV-2 both indeterminate

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

Special Instructions

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

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
HIVQN	HIV-1 RNA Detect/Quant, P	Yes	No

Method Name

Rapid Immunochromatographic Assay

NY State Available

Yes

Specimen

Specimen Type

Plasma

Ordering Guidance

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 2 years). Diagnosis of HIV infection in newborns and infants up to 2 years should be made by virologic tests, such as detection of HIVQN / HIV-1 RNA Detection and Quantification, Plasma.

This test is **not** suitable for follow-up testing of patients with reactive results from any rapid HIV tests, regardless of specimen type tested, with the exception of patients who were reactive by the Determine HIV-1/-2 Ag/Ab Combo rapid point-of-care test on serum or plasma (but not whole blood). Per the latest CDC recommended HIV testing algorithm, the patients with reactive results from any rapid HIV tests 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.

If specimens are autopsy or cadaver blood sources, the proper FDA-licensed assay is HV1CD / HIV-1 and HIV-2 Antibodies for Cadaveric or Hemolyzed Specimens, Serum.

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

Supplies: Aliquot Tube, 5 mL (T465)

Collection Container/Tube: Lavender top (EDTA)

Submission Container/Tube: Plastic vial

Specimen Volume: 1 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 plasma into plastic vial.

Reject Due To

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

Specimen Minimum Volume

0.8 mL

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Plasma	Frozen (preferred)	30 days	
	Refrigerated	6 days	

Clinical & Interpretive

Clinical Information

AIDS is caused by 2 known types of HIV. HIV type 1 (HIV-1) is found in patients with AIDS or AIDS-related complex and in 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 and/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, supplemental or confirmatory testing should be requested only for specimens that are repeatedly reactive by these methods according to assay manufacturers' instructions for use.

Reference Values

Negative

Interpretation

Negative results for both HIV-1 and HIV-2 antibodies usually indicate the absence of HIV-1 and 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 infection. In this situation, the HIVQN / HIV-1 RNA Detection and Quantification, Plasma reflex test will be performed. 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.

Positive HIV-1 antibody, but negative HIV-2 antibody results, indicates the presence of HIV-1 infection. Together with reactive initial combined HIV-1/-2 antigen and antibody test results, individuals with such 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 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 be submitted also for 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 patients' specimens and HIV-1 antigens on the assay strip. In this situation, the HIVQN / HIV-1 RNA Detection and Quantification, Plasma reflex test will be performed.

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

Positive results for both HIV-1 and HIV-2 antibodies suggest probable presence of HIV-1 and HIV-2 coinfection. However, such results may be rarely due to: a) HIV-1 infection with HIV-2 antibody cross-reactivity; or b) 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 a new whole blood specimen 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). In this situation, the HIVQN / HIV-1 RNA Detection and Quantification, Plasma reflex test will be performed.

Negative HIV-1 antibody but positive HIV-2 antibody results indicates 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 newly submitted whole blood specimen for 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 be rarely 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 whole blood specimen for FHV2Q / HIV-2 DNA/RNA Qualitative Real-Time PCR. If the patient is at risk for HIV-1 infection (based on patient's clinical and epidemiologic history), a plasma specimen should be submitted also 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, by submitting a whole blood specimen for FHV2Q / HIV-2 DNA/RNA Qualitative Real-Time PCR. However, such 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 plasma specimen should be submitted also for detection of HIV-1 RNA (HIVQN / HIV-1 RNA Detection and Quantification, Plasma).

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

Cautions

A negative result for both HIV-1 and HIV-2 antibodies does not rule-out acute HIV infection.

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.

Participation in the 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 the vaccine giving a positive, indeterminate, or unreadable HIV-1 antibody result, while they 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

1. Branson BM, Owen SM, Wesolowski LG, et al: Laboratory testing for the diagnosis of HIV infection: Updated recommendations. Centers for Disease Control and Prevention; June 27, 2014. Accessed June 15, 2020. Available at <https://stacks.cdc.gov/view/cdc/23447>
2. 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
3. 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
4. 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
5. 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
6. Centers for Disease Control and Prevention: 2018 Quick Reference Guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens. CDC; January 2018. Accessed June 15, 2020. Available at <https://stacks.cdc.gov/view/cdc/50872>

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 or purple lines. When there are no HIV antibodies, there are no pink or purple lines in the test area. The sample continues to migrate through the membrane and a pink or 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

Specimen Retention Time

14 days

Performing Laboratory Location

Rochester

Fees & Codes

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

86701

86702

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
HVDIP	HIV Ab Confirm / Differentiation, P	89365-1

Result ID	Reporting Name	LOINC®
91947	HIV-1 Ab Differentiation, P	68961-2
91951	HIV-2 Ab Differentiation, P	81641-3