Overview

Useful For

Screening cadaveric or hemolyzed serum specimens for HIV-1 and/or HIV-2 infection in non- symptomatic patients with or without risk factors for HIV infection

This test is **not offered** as a screening or confirmatory test for blood donor specimens.

Highlights

Indicated for testing **non-symptomatic** individuals (screening purposes) with or without risk factors for HIV infection.

Reflex Tests

Test ID	Reporting Name	Available Separately	Always Performed
HIVDI	HIV Ab Confirm / Differentiation, S	No	No

Testing Algorithm

This test begins with HIV-1/-2 antibody enzyme immunoassay (EIA). If HIV-1/-2 antibody EIA is reactive, then HIV antibody confirmation/differentiation by immunochromatographic method is performed at an additional charge.

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

Special Instructions

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

Method Name

Enzyme Immunoassay (EIA)-Screening Procedure

NY State Available

Yes

Specimen

Specimen Type

Serum

Ordering Guidance

1. This test is **not intended for** testing **symptomatic** individuals (ie, diagnostic purposes). For testing hemolyzed specimens from such patients with or without risk factors for HIV infection, order HV1CD / HIV-1 and HIV-2 Antibodies for Cadaveric or Hemolyzed Specimens, Serum.

2. 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.

Additional Testing Requirements

If the initial enzyme immunoassay (EIA) result is negative and this test was ordered as a follow-up evaluation of a specimen with a reactive rapid HIV antibody test result, clients must call 800-533-1710 or 507-266-5700 to request supplemental testing for HIV antibody confirmation/differentiation by immunochromatography (HIVDI). The HIVDI / HIV-1 and HIV-2 Antibody Confirmation and Differentiation, Serum test is not FDA-approved for testing cadaveric specimens. If performed, test results will be reported with a disclaimer.

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: 1.5 mL

Collection Instructions:

1. Centrifuge blood collection tube per collection tube manufacturer's instructions (eg, centrifuge 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	Reject
Gross icterus	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Serum	Frozen (preferred)	30 days	
	Ambient	7 days	
	Refrigerated	7 days	

Clinical and Interpretive

Clinical Information

Epidemiological data indicate that AIDS is caused by at least 2 types of HIV. The first virus, HIV-1, has been isolated from patients with AIDS, AIDS-related complex, and asymptomatic infected individuals at high risk for AIDS. HIV-1 is transmitted by sexual contact, exposure to infected blood or blood products, or from an infected mother to her fetus or infant. A second HIV virus, HIV-2, was isolated from patients in West Africa in 1986. HIV-2 appears to be endemic only in West Africa, but it also has been identified in individuals who have lived in West Africa or had sexual relations with individuals from that geographic region. HIV-2 is similar to HIV-1 in its morphology, overall genomic structure, and its ability to cause AIDS.

Antibodies against HIV-1 and HIV-2 are usually not detected until 6 to 12 weeks following exposure and are almost always detected by 12 months. They may fall into undetectable levels in the terminal stage of AIDS.

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

Reference Values

Negative

Interpretation

A reactive HIV-1/-2 antibody screen result obtained by enzyme immunoassay (EIA) suggests the presence of HIV-1 and/or HIV-2 infection. However, it does not differentiate between HIV-1 and HIV-2 antibody reactivity. Diagnosis of HIV infection must be based on results of supplemental tests, such as HIV antibody confirmation/differentiation test (automatically reflexed on all samples with reactive screen test results at an additional charge).

All presumptive antibody-positive test results should be verified by submitting a second serum specimen for retesting.

A negative HIV-1/-2 antibody EIA screen result usually indicates the absence of HIV-1 or HIV-2 infection. However, for specimens that are reactive by the rapid HIV antibody tests, confirmatory testing is recommended even if the EIA results are negative.

Cautions

The predictive value of a reactive (or positive) test is highly dependent on the prevalence of HIV infection in the population tested; the lower the prevalence of HIV infection, the lower the positive predictive value of the test.

A person who has participated in an HIV vaccine study may develop antibodies to the vaccine and may or may not be infected with HIV. Clinical correlation is indicated with appropriate counseling, medical evaluation, and possibly additional testing to decide whether a diagnosis of HIV infection is accurate.

Negative results should be evaluated cautiously if the patient has clinical symptoms and/or a history of high-risk behavior for HIV infection. The Centers for Disease Control and Prevention recommends confirmatory testing on serum specimens that are reactive by the rapid HIV antibody tests, even if the initial EIA results are negative.

Screening and confirmatory tests for HIV-1/-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 of age). Reactive and confirmed positive antibody test results in infants during this period may indicate passive transfer of maternal HIV antibodies. Diagnosis of HIV infection in newborns and infants up to 2 years should be made by virologic tests, such as detection of HIV-1 DNA or RNA (HIVP / HIV-1 DNA and RNA Qualitative Detection by PCR, Plasma) or HIV-1 RNA (HIVQN / HIV-1 RNA Detection and Quantification, Plasma).

A reactive screen and confirmed HIV antibody test result should be reported by the health care provider to the State

Department of Health in accordance with the legislation in some states.

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

-Lipemic

-Icteric

-Containing particulate matter

Clinical Reference

1. Constantine N: HIV antibody assays In: HIV InSite Knowledge Base (online textbook). Regents of the University of California; May 2006. Available at http://hivinsite.ucsf.edu/InSite?page=kb-00&doc=kb-02-02-01

2. Centers for Disease Control and Prevention (CDC), Association of Public Health Laboratories: Laboratory testing for the diagnosis of HIV infection. CDC; Updated June 27, 2014. Available at: stacks.cdc.gov/view/cdc/23447

3. Centers for Disease Control and Prevention (CDC), Association of Public Health Laboratories: 2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens. CDC; January 2018. Available at https://stacks.cdc.gov/view/cdc/50872

4. Hariri S, McKenna MT: Epidemiology of human immunodeficiency virus in the United States. Clin Microbiol Rev. 2007;20:478-4884

5. Owen SM, Yang C, Spira T, et al: Alternative algorithms for human immunodeficiency virus infection diagnosis using tests that are licensed in the United States. J Clin Microbiol. 2008;46:1588-1595

Performance

Method Description

The Genetic Systems HIV-1/HIV-2 PLUS O enzyme immunoassay (EIA) is based on the principle of direct antibody sandwich technique. Microwell-strip plates (solid-phase) are coated with purified HIV antigens: gp160 and p24 recombinant proteins derived from HIV-1, gp36 peptide representing the immunodominant region of the HIV-2 transmembrane glycoprotein, and a synthetic polypeptide mimicking an artificial (not encoded by any existing virus) HIV-1 group O-specific epitope.

Serum samples and assay controls are added to the antigen-coated wells of the microwell-strip plate along with specimen diluent. The specimen diluent contains a dye which changes color from purple to blue when combined with a specimen or control. The wells are incubated and then washed. The next step is the addition of a colored conjugate solution (green) which contains the peroxidase-conjugated antigens. The wells are then incubated. If HIV-1 and/or HIV-2 antibody is present, it will bind to the antigen coated on the well and to the peroxidase-conjugated antigens in the conjugate solution. The antigen-antibody-antigen complexes remain bound to the well during the subsequent wash step, which will remove any unbound materials. Working chromogen solution (TMB) is added to the plate wells and allowed to incubate. A blue or blue-green color develops in proportion to the amount of HIV antibody present in the sample. Color development is stopped by the addition of acid, which changes the blue-green color to yellow. The optical absorbance of specimens and controls is determined spectrophotometrically at a wavelength of 450 nm.(Package insert: Genetics Systems HIV-1/HIV-2 PLUS O EIA. Bio-Rad Laboratories; 02/2019)

PDF Report

No

Day(s) Performed

Tuesday, Friday

Report Available

1 to 7 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

86703

G0432

86701 (if appropriate)

86702 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC Value
HV1CM	HIV-1/-2 Ab Screen Hemolyzed, S	31201-7

Result ID	Test Result Name	Result LOINC Value
60357	HIV-1/-2 Ab Screen Hemolyzed, S	31201-7