MAYO CLINIC LABORATORIES

Test Definition: HIVSP

HIV Antigen and Antibody Prenatal Routine Screen, Plasma

Overview

Useful For

Screening for HIV-1 and HIV-2 infection in nonsymptomatic pregnant patients

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

Reflex Tests

Test Id	Reporting Name	Available Separately	Always Performed
HVDSP	HIV Ab Differentiation Prenatal, P	Yes	No
HPP12	HIV-1/HIV-2 RNA Detect Prenatal, P	Yes	No
HIQNP	HIV-1 RNA Detect/Quant Prenatal, P	Yes	No

Testing Algorithm

This test begins with HIV-1/-2 antigen and antibody (Ab) screen by electrochemiluminescence immunoassay. If the screen result is reactive, then HIV-1/-2 antibody confirmation/differentiation test by immunochromatographic method is performed at an additional charge.

If the following result types are obtained from the HIV-1/-2 confirmation/differentiation test, HIV-1/HIV-2 RNA detection will be performed at an additional charge:
-Negative for both HIV-1 Ab and HIV-2 Ab
-Indeterminate for HIV-1 Ab but negative for HIV-2 Ab
-Negative for HIV-1 Ab but indeterminate for HIV-2 Ab
-Indeterminate for both HIV-1 Ab and HIV-2 Ab
-Positive for both HIV-1 Ab and HIV-2 Ab

If the following result types are obtained from the HIV-1/-2 confirmation/differentiation, HIV-1 RNA detection and quantification will be performed at an additional charge:
-Positive for HIV-1 Ab and negative for HIV-2 Ab
-Positive for HIV-1 Ab and indeterminate for HIV-2 Ab

Special Instructions

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

Method Name

Electrochemiluminescence Immunoassay (ECLIA)

NY State Available
No

Specimen

Specimen Type
Plasma EDTA

Ordering Guidance
If the specimen is obtained from either autopsy or cadaver blood sources, order HV1CD / HIV-1 and HIV-2 Antibodies for Cadaveric or Hemolyzed Specimens, Serum which is the US Food and Drug Administration-approved assay for these specimen types.

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.

Specimen Required
Supplies: Sarstedt Aliquot Tube, 5 mL (T914)
Collection Container/Tube: Lavender top (EDTA)
Submission Container/Tube: Plastic vial
Specimen Volume: 1.5 mL Plasma
Collection Instructions:
1. Centrifuge blood collection tube per manufacturer's instructions (eg, centrifuge and aliquot within 2 hours of collection for BD Vacutainer tubes).
2. Transfer plasma into a plastic vial.

Forms
If not ordering electronically, complete, print, and send Infectious Disease Serology Test Request (T916) with the specimen.

Specimen Minimum Volume
Plasma: 1 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject
Heat-inactivated specimen	Reject

Specimen Stability Information

Specimen Type	Temperature	Time	Special Container
Plasma EDTA	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 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, but HIV p24 antigen should be detectable and yield reactive results with the HIV antigen-antibody combination detection assays.

Routine serologic screening of patients at risk for HIV-1 or HIV-2 infection usually begins with an HIV-1/-2 antigen and/or antibody screening test, which may be performed by various US Food and Drug Administration-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.

Reference Values

Negative

Interpretation

Negative HIV-1/-2 antigen and antibody screening test results usually indicate absence of HIV-1 and HIV-2 infection. However, such negative results do not rule out acute HIV infection. If acute HIV-1 or HIV-2 infection is suspected, detection of HIV RNA (HPP12 / HIV-1/HIV-2 RNA Detection Prenatal, Plasma) is recommended.

Reactive HIV-1/-2 antigen and antibody screening test results suggest the presence of HIV-1 and/or HIV-2 infection, but it is not diagnostic for HIV infection and should be considered preliminary. A reactive result does not differentiate among reactivity with HIV-1 p24 antigen, HIV-1 antibody, and HIV-2 antibody. Diagnosis of HIV infection must be based on results of supplemental tests, such as HIV antibody confirmation/differentiation test (automatically added to all samples with reactive screen test results at an additional charge).

All initially positive supplemental or confirmatory HIV test results (by serologic or molecular test methods) should be verified by submitting a second plasma 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.

The following algorithms are available:
-HIV Prenatal Testing Algorithm, Including Follow-up of Reactive Rapid Serologic Test Results
-HIV Testing Algorithm (Fourth Generation Screening Assay), Including Follow-up of Reactive Rapid Serologic Test Results

Cautions

This assay has not been licensed by the US Food and Drug Administration for the screening of blood, plasma, cells, tissues, and cellular and tissue-based product donors.

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

A reactive result of this assay does not differentiate among reactivity with HIV-1 p24 antigen, HIV-1 antibody, and HIV-2 antibody.

A reactive screening test result is not diagnostic for HIV infection and should be considered preliminary.

The positive predictive value of a reactive screening test result 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 and higher the false-positive rate of the test. Diagnosis of HIV infection must be based on positive results of the supplemental or confirmatory serologic or molecular tests.

Recipients of experimental HIV-1 vaccines may have false-reactive HIV antibody test results due to the presence of vaccine-induced, HIV-1-specific antibodies without actual HIV infection.

Negative serologic or molecular HIV screening test results should be evaluated with caution in patients with clinical symptoms or a history of high-risk behavior for HIV infection. Repeat testing in 1 to 2 months is recommended in these at-risk individuals.

Uninfected individuals undergoing antiretroviral therapy or taking pre-exposure prophylaxis or post-exposure prophylaxis may produce non-reactive or delayed reactive test results during early stages of infection when prophylaxis fails.

Individuals who have received mouse monoclonal antibodies for diagnosis or therapy may contain human anti-mouse antibodies which may interfere in assays that employ mouse monoclonal antibodies, causing false-positive test results with this assay.

This assay has no biotin interference with serum concentrations up to 1200 ng/mL. Pharmacokinetic studies have shown that serum concentrations of biotin can reach up to 355 ng/mL within the first hour after biotin ingestion for subjects consuming supplements of 20 mg biotin per day. and up to 1160 ng/mL for subjects after a single dose of 300 mg biotin.

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

-Grossly hemolyzed (hemoglobin level of >500 mg/dL)
-Grossly lipemic (intralipid level of >2000 mg/dL)
-Grossly icteric (total bilirubin level of >66 mg/dL)
-Heat-inactivated specimens
-Cadaveric specimens
-Presence of particulate matter
-Specimen types other than plasma

Clinical Reference

1. Centers for Disease Control and Prevention. 2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens. CDC; January 2018. Accessed October 16, 2023. Available at https://stacks.cdc.gov/view/cdc/50872
2. Centers for Disease Control and Prevention. Technical update: Use of the Determine HIV 1/2 Ag/Ab combo test with serum or plasma in the laboratory algorithm for HIV diagnosis. CDC; October 4, 2017. Accessed October 16, 2023. Available at https://stacks.cdc.gov/view/cdc/48472
3. Muhlbacher A, Sauleda S, Piron M, et al. A multicentre evaluation of the Elecsys HIV Duo assay. J Clin Virol. 2019;112:45-50
4. Duncan D, Duncan J, Kramer B, et al. An HIV diagnostic testing algorithm using the cobas HIV-1/HIV-2 Qualitative Assay for HIV type differentiation and confirmation. J Clin Microbiol. 2021;59(7):e03030-20. doi:10.1128/JCM.03030-20

Performance

Method Description

The Elecsys HIV DUO assay is performed with the fully automated cobas e 801 electrochemiluminescence immunoassay analyzer. Initially, HIV-1 p24 antigen (Ag) present in patient's sample reacts with biotinylated monoclonal anti-p24 antibodies and ruthenylated monoclonal anti-p24 antibodies, to form a sandwich complex. In a separate reaction vessel, HIV-1 and HIV-2 antibodies (Ab) present in the same sample react with biotinylated HIV-specific recombinant antigens/peptides and ruthenylated HIV-specific recombinant antigens/peptides, to form a sandwich complex. After addition of streptavidin-coated microparticles to each reaction vessel, the complexes become bound to the solid phase via interaction of biotin and streptavidin. The reaction mixtures are then each aspirated into the measuring cell where the microparticles are magnetically captured onto the surface of the electrode. Unbound substances are then washed away, and application of a voltage to the electrode then induces chemiluminescent emission which is measured by a photomultiplier. Test result for each patient's sample is determined automatically by the assay-specific software program by comparing the electrochemiluminescence signal obtained from the sample with the cutoff index value set from reagent lot-specific assay calibrations for HIV-1 p24 Ag and HIV Ab.(Package insert: Elecsys HIV DUO. Roche Diagnostics; v1.0, 12/2020)

PDF Report

No

Day(s) Performed

Monday through Friday, Sunday

Test Definition: HIVSP

HIV Antigen and Antibody Prenatal Routine Screen, Plasma

Report Available
1 to 3 days

Specimen Retention Time
14 days

Performing Laboratory Location
Mayo Clinic Jacksonville Clinical Lab

Fees & 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 account representative. 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
87389
G0475 (if appropriate)

LOINC® Information

Test ID	Test Order Name	Order LOINC® Value
HIVSP	HIV-1/-2 Ag and Ab Prenatal Scrn, P	56888-1

Result ID	Test Result Name	Result LOINC® Value
HIVC5	HIV-1/-2 Ag and Ab Prenatal Scrn, P	56888-1