Test Definition: HIVSP

HIV-1/-2 Ag and Ab Prenatal Scrn, P

Overview

Useful For

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

This test is **not offered** 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
HIQNP	HIV-1 RNA Detect/Quant Prenatal, P	Yes	No

Testing Algorithm

This test begins with HIV-1/-2 antigen and antibody screen by chemiluminescence 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 HIV-1/-2 antibody confirmation/differentiation test is negative for both HIV-1 antibody and HIV-2 antibody, or indeterminate/negative for HIV-1/HIV-2 antibody, or indeterminate/indeterminate for HIV-1/ HIV-2 antibody, then HIV-1 RNA prenatal will be performed at an additional charge.

The following algorithms are available in Special Instructions:

-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

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

Chemiluminescent Microparticle Immunoassay

NY State Available

Yes

Specimen

Specimen Type

Plasma

Ordering Guidance

If specimen is from either 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.

Specimen Required

Collection Container/Tube: Lavender top (EDTA)

Submission Container/Tube: Plastic vial

Specimen Volume: 4 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. Transfer plasma into a plastic vial.

Specimen Minimum Volume

1.2 mL

Reject Due To

Gross hemolysis	Reject
Gross lipemia	Reject
Gross icterus	Reject

Specimen Stability Information

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

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 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.

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 infection is suspected, detection of HIV-1 RNA (HIQNP / HIV-1 RNA Detection and Quantification, 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 reflexed on 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 in Special Instructions:

-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

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.

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

-Grossly hemolyzed (hemoglobin level of >500 mg/dL)

-Grossly lipemic (triolein level of >1,250 mg/dL)

-Grossly icteric (total bilirubin level of >20 mg/dL)

-Heat-inactivated specimens

-Cadaveric specimens

-Presence of particulate matter

Clinical Reference

1. Bennett B, Branson B, Delaney K, et al: HIV testing algorithms: a status report. A publication from the Association of Public Health Laboratories and the Centers for Disease Control and Prevention. APHL; April 2009. Accessed June 15, 2020. Available at https://stacks.cdc.gov/view/cdc/5696/cdc_5696_DS1.pdf

2. Chavez P, Wesolowski L, Patel P, Delaney K, Owen SM: Evaluation of the performance of the Abbott ARCHITECT HIV Ag/Ab Combo assay. J Clin Virol. 2011 Dec;52(Suppl 1):S51-S55. doi: 10.1016/j.jcv.2011.09.010

3. 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 May 3, 2021. Available at http://stacks.cdc.gov/view/cdc/23447

4. Centers for Disease Control and Prevention: 2018 Quick reference guide: Recommended laboratory HIV testing algorithm for serum or plasma specimens. CDC; January 2018. Accessed May 3, 2021. Available at https://stacks.cdc.gov/view/cdc/50872

5. 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 May 3, 2021. Available at https://stacks.cdc.gov/view/cdc/48472

Performance

Method Description

The Abbott Architect HIV Ag/Ab Combo assay for use on the Architect *i* System is a 2-step immunoassay to determine the presence of HIV-1 p24 antigen, antibodies to HIV-1 (groups M and O), and antibodies to HIV-2 in human serum or plasma using chemiluminescent microparticle immunoassay (CMIA) technology. First, patient's specimen, Architect *i* wash buffer, assay diluent, and paramagnetic microparticles are combined in a single reaction well. HIV-1 p24 antigen and HIV-1/HIV-2 antibodies present in the patient's specimen bind to the HIV-1 antigen, HIV-2 antigen, and HIV-1 p24 monoclonal (mouse) antibody-coated microparticles. After washing, the bound HIV-1 p24 antigen and HIV-1/HIV-2 antibodies bind to the acridinium-labeled conjugates. Following another wash cycle, pretrigger and trigger solutions are added to the reaction mixture. The resulting chemiluminescent reaction is measured as relative light units (RLU). The amount of HIV antigen and antibodies present in the patient's specimen is directly proportionate to the RLU detected by the Architect *i* System optics. The presence or absence of HIV-1 p24 antigen or HIV-1/HIV-2 antibodies in the specimen is determined by comparing the chemiluminescent signal in the reaction to the cutoff signal determined periodically by assay calibration. Patients' specimens with signal-to-cutoff (S/CO) values greater than or equal to 1.00 are considered reactive for HIV-1 p24 antigen or HIV-1/HIV-2 antibodies. Specimens with S/CO values less than 1.00 are considered nonreactive or negative.(Package insert: HIV Ag/Ab Combo. Abbott Laboratories; 10/2017)

PDF Report

No

Day(s) Performed

Monday through Saturday

Report Available

1 to 2 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

87389

G0475

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