Lab Dept: Serology

Test Name: FOR LAB USE ONLY * HIV-1 AND HIV-2 ANTIGEN AND ANTIBODY ROUTINE SCREEN, PLASMA (MAYO)

General Information

Lab Order Codes: HIV12

Synonyms: Anti-HIV; Anti-HIV-1/2; HIV Types 1 and 2 Antibodies; HIV-1/2; HIV-1/-2 Ab; HIV-1/2 Ag/Ab; HIV-1/-2 Antibodies; HIV-1/-2 Antigen; HIV combo; Human Immunodeficiency Virus (HIV)

CPT Codes: 87389 – HIV-1 antigen, with HIV1/2 antibodies, single result G0475

Test Includes: *This order is for lab back up use only. See in-house HIVI (HIV-1,2 COMBO EVALUATION REFLEX (ANTI-HIV-1,2)

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 the HIV-1/-2 antibody confirmation/differentiation test is negative for both HIV-1 antibody and HIV-2 antibody, or indeterminate/negative for HIV-1/-2 antibody, or indeterminate/indeterminate for HIV-1/HIV-2 antibody, then HIV-1 RNA detection and quantification is performed at an additional charge. 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 old). Diagnosis of HIV infection in newborns and infants up to 2 years old should be made by virologic tests, such as detection of HIV-1 DNA and RNA (HIVP / HIV-1 DNA and RNA Qualitative Detection by PCR, Plasma) or HIV-1 RNA (HIVQN / HIV-1 RNA Detection and Quantification, Plasma).

Logistics

Test Indications: Screening for HIV-1 and HIV-2 infection in nonsymptomatic, nonpregnant individuals older than 2 years. This test is not offered as a screening or confirmatory test for blood donor specimens.

Lab Testing Sections: Serology - Sendouts

Referred to: Mayo Medical Laboratories (Test: HVCOP)

Phone Numbers: MIN Lab: 612-813-6280
Test Availability: Monday through Saturday

Turnaround Time: 1 – 4 days, tests performed Monday - Saturday.

Special Instructions: This test is not offered as a screening or confirmatory test for blood donor specimens. See Patient HIV Testing Algorithm (https://www.mayocliniclabs.com/articles/resources/-/media/it-mmfiles/special%20instructions/hivtestingalgorithmfourthgenerationscreeningassayincludingfollowupofreactivehivrapidserologictests.pdf) for more information.

Specimen

Specimen Type: Blood

Container: Lavender (EDTA) top tube

Draw Volume: 12 mL (Minimum: 3.6 mL) blood

Processed Volume: 4 mL (Minimum 1.2 mL) plasma

Collection: Routine venipuncture

Special Processing: Lab Staff: Centrifuge specimen within 24 hours, remove plasma aliquot into screw-capped round bottom plastic vial. Store and ship at refrigerated temperatures. Forward promptly.

Specimen Stability Information:
Plasma Refrigerated (preferred) 6 days
Frozen 30 days

Patient Preparation: None

Sample Rejection: Specimens other than EDTA plasma as indicated; lithium heparin samples are unacceptable; mislabeled or unlabeled specimens; gross hemolysis; gross lipemia; grossly icteric

Interpretive

Reference Range: Negative

Critical Values: N/A

Limitations: 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 and/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

**Methodology:** Chemiluminescent Microparticle Immunoassay

**References:** [Mayo Medical Laboratories Web Page](https://www.mayoreferences.com)

**Updated:**
07/08/2022: Updated Title/Test Indications to clarify age requirements, aliases, testing algorithm information, collection volumes, and specimen storage information.

5/5/2023: The recommended test for HIV-1/2 Ag/Ab screen is the in-house HIVI. Updated this reference lab test order to clarify that it is intended for lab back up use.