

Notification Date: March 27, 2023 Effective Date: May 9, 2023

HIV-1 and HIV-2 Antigen and Antibody Diagnostic Evaluation, Serum

Test ID: HIVDS

Useful for:

Diagnosing HIV-1 and/or HIV-2 infection in <u>symptomatic</u> patients more than 2 years old.

Follow-up testing of individuals with reactive rapid HIV test results.

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
HIVDI	HIV Ab Confirm / Differentiation, S	Yes	No
HIS12	HIV-1/HIV-2 RNA Detect, S	Yes	No

Method:

Chemiluminescent Microparticle Immunoassay

Reference Values:

Negative

Specimen Requirements:

Collection Container/Tube: Serum gel

Submission Container/Tube: Plastic vial - Sarstedt Aliquot Tube, 5 mL (T914)

Specimen Volume: 2 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 serum into a plastic vial.

Minimum Volume: 1.2 mL

Specimen Stability Information:

Specimen Type	Temperature	Time
Serum	Refrigerated (preferred)	6 days
	Frozen	30 days

Cautions:

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.

CPT Code:

87389

Day(s) Performed: Monday through Saturday Report Available: 1 to 2 days

Questions

Contact James Conn, Laboratory Resource Coordinator at 800-533-1710.