MAYO
Mayo Medical Laboratories
1-800-533-1710

NEW TEST ANNOUNCEMENT
MML NEW ENGLAND
NOTIFICATION DATE: April 18, 2014
EFFECTIVE DATE: May 19, 2014

HIV-1 AND HIV-2 ANTIBODY DIFFERENTIATION, SERUM
Test ID: HIVDI

USEFUL FOR:
- Detection and differentiation of HIV-1 and HIV-2 antibodies.
- Supplemental serologic testing of specimens that are reactive by FDA-approved HIV-1/-2 antigen and antibody combination tests.

METHODOLOGY: Membrane Immunoconcentration

REFLEX TESTS:

Test ID	Reporting Name	Available Separately	Always Performed
HV1WB	HIV-1 Ab Confirm by Western Blot, S	Yes	No
HIV2L	HIV-2 Ab Confirmation, S	Yes	No

TESTING ALGORITHM:
This HIV-1 and HIV-2 Antibody Differentiation test begins with the Bio-Rad Multispot HIV-1/HIV-2 Rapid Test, with the following reflex testing:
1. Specimens with indeterminate HIV-1 antibody but negative HIV-2 antibody results: HIV-1 Ab Confirm by Western Blot, S, is performed at an additional charge.
2. Specimens with reactive or unreadable results for both HIV-1 and HIV-2 antibodies: HIV-1 Ab Confirm by Western Blot, S, and HIV-2 Ab Confirmation, S, are performed at additional charges.
3. Specimens with negative HIV-1 antibody but reactive HIV-2 antibody results: HIV-2 Ab Confirmation, S, is performed at an additional charge.

No reflex testing is performed on specimens with a) positive HIV-1 antibody but negative HIV-2 antibody results, or b) negative HIV-1 and HIV-2 results.

REFERENCE VALUES: Negative

SPECIMEN REQUIREMENTS:
Collection Container/Tube:
Preferred: Serum gel
Acceptable: Red top
Submission Container/Tube: Plastic vial
Specimen Volume: 2 mL
Collection Instructions: Spin down and remove serum from clot within 24 hours.
Additional Information: If specimens are autopsy or cadaver blood sources, the proper FDA-licensed assay is HV1CD / HIV-1 and HIV-2 Antibodies for Cadaveric or Hemolyzed Specimens, Serum.
Forms: If not ordering electronically, submit a General Request Form (Supply T239) with the specimen.

SPECIMEN STABILITY INFORMATION:

Specimen Type	Temperature	Time
Serum	Frozen (preferred)	30 days
	Ambient	24 hours
	Refrigerated	7 days

CAUTIONS:

- This test should not be used as a screening test for HIV infection in symptomatic or asymptomatic individuals. It should not be used as a screening or confirmatory test for blood donor specimens.
- This test is not offered for maternal/newborn HIV screening for specimens originating in New York State.
- Negative results for both HIV-1 and HIV-2 antibodies do not rule out acute HIV infection. If acute HIV-1 infection is suspected, detection of HIV-1 RNA (HIVQU / HIV-1 RNA Quantification, Plasma) or HIV proviral DNA (PHIV / HIV-1 Proviral DNA Qualitative Detection by PCR, Blood) is recommended. For patients at risk for HIV-2 infection (eg, having lived in West Africa or have sexual partners from West Africa), testing for HIV-2 DNA / RNA (FHV2Q / HIV-2 DNA/RNA Qualitative Real-Time PCR) is recommended.
- All initially positive supplemental or confirmatory HIV test results should be verified by submitting a second 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.
- 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 18 months). Diagnosis of HIV infection in newborns and infants up to 18 months should be made by virologic tests, such as detection of HIV RNA (HIVQU / HIV-1 RNA Quantification, Plasma) or HIV proviral DNA (PHIV / HIV-1 Proviral DNA Qualitative Detection by PCR, Blood).
- Participation as a recipient of a HIV-1 vaccine (eg, participants in HIV-1 vaccine study trials) may develop vaccine-specific antibodies that may cross-react with this test and yield to the vaccine giving a positive, indeterminate, or unreadable HIV-1 antibody result while they may or may not be infected with HIV-1.

CPT CODE:
86701-HIV-1 Antibody
86702-HIV-2 Antibody

DAY(S) SET UP: Monday through Friday; Varies **ANALYTIC TIME**: 1 day

QUESTIONS: Contact your Mayo Medical Laboratories' Regional Manager or
Brandon DeBoom, MML Laboratory Technologist Resource Coordinator
Telephone: 800-533-1710