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TEST UPDATE
HIV CONFIRMATORY TESTING

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This change will take effect **April 28, 2014**

OVERVIEW AND CLINICAL UTILITY:

PathGroup Labs will begin confirmatory testing for a positive HIV screen utilizing the Bio-Rad MultiSpot HIV1/HIV2 discriminatory assay and will discontinue confirmatory testing by Western Blot **effective April 28, 2014**. It is strongly recommended that patients whose positive screen is followed by a negative confirmatory assay be tested by Nucleic Acid Testing.

Screening for infection with human immunodeficiency virus (HIV) has improved dramatically in the last 10 years. Screening tests used routinely in clinical laboratories now are more sensitive than the confirmatory test by western blot. The Centers for Disease Control (CDC) have updated recommendations for HIV screening and confirmatory testing.

The CDC recommendations are as follows:

1. An FDA-approved 4th generation HIV-1/2 immunoassay (IA) should be used as the initial test to screen for acute HIV-1 infection and for established infections with HIV-1 or HIV-2.
2. Specimens with a reactive 4th generation IA (or repeatedly reactive, if repeat testing is recommended by the manufacturer) should be tested with an FDA-approved 2nd generation antibody IA that differentiates HIV-1 antibodies from HIV-2 antibodies.
3. Persons whose specimens give positive results on the initial IA and HIV-1/HIV-2 antibody differentiation IA should be considered positive for HIV-1 or HIV-2 antibodies and should initiate medical care that includes laboratory tests (such as viral load, CD4 determinations, and antiretroviral resistance assays) to confirm the presence of HIV infection, to stage HIV disease, and to assist in the selection of an initial antiretroviral drug regimen. *[DHHS Guidelines]*
4. Specimens that are reactive on the initial assay and negative on the HIV-1/HIV-2 antibody differentiation IA should be tested with an FDA-approved nucleic acid test (NAT) for HIV-1 RNA. Under these circumstances, a reactive NAT result indicates the presence of acute HIV-1 infection. A negative result indicates the absence of HIV-1 infection, either a false-positive result on the initial IA or rarely, recent HIV-2 infection. If HIV-2 infection is a possibility, a NAT for HIV-2 DNA can be considered. However, HIV-2 infection is rare in the United States, and there is no FDA-approved NAT for HIV-2.
5. This same testing algorithm beginning with a 4th generation immunoassay should be followed for specimens from persons with a preliminary positive rapid HIV test result.

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Alternatives for use with other FDA-approved HIV tests:

3rd generation HIV-1/2 IA used as the initial test: Perform subsequent testing as specified in the recommended algorithm. This alternative will miss some acute HIV infections in antibody-negative persons.

An algorithm describing these recommendations may be found on the Directory of Services (DOS).

TEST METHODOLOGY: Multispot Qualitative Immunoassay

ORDERING: (REFLEX FROM POSITIVE SCREEN ONLY)

NEW TEST	NEW TEST NAME	CPT	PREVIOUS TEST	PREVIOUS TEST NAME	CPT
HIVRT	Multispot HIV-1/HIV-2 Rapid Test	86701 86702	**HIV1B**	HIV Confirmation by Western Blot	86689

REFERENCE RANGE: Negative

SPECIMEN COLLECTION AND STORAGE:

	IF ORDERING:
Serum	1) Collect specimen in an SST /serum separator tube a) Allow serum tube to clot for 30 minutes. b) Spin serum separator tube 10-15 minutes @ 3500 rpm. 2) Serum specimens are stable refrigerated for 7 days. 3) Transport specimen refrigerated. 4) Unacceptable: Severely hemolyzed or heat-inactivated specimens.

For further questions, please contact Client Services at 615-562-9300 or 888-474-5227