



Missouri Department of Health and Senior Services

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TO: Submitters of HIV Specimens to the Missouri State Public Health Laboratory

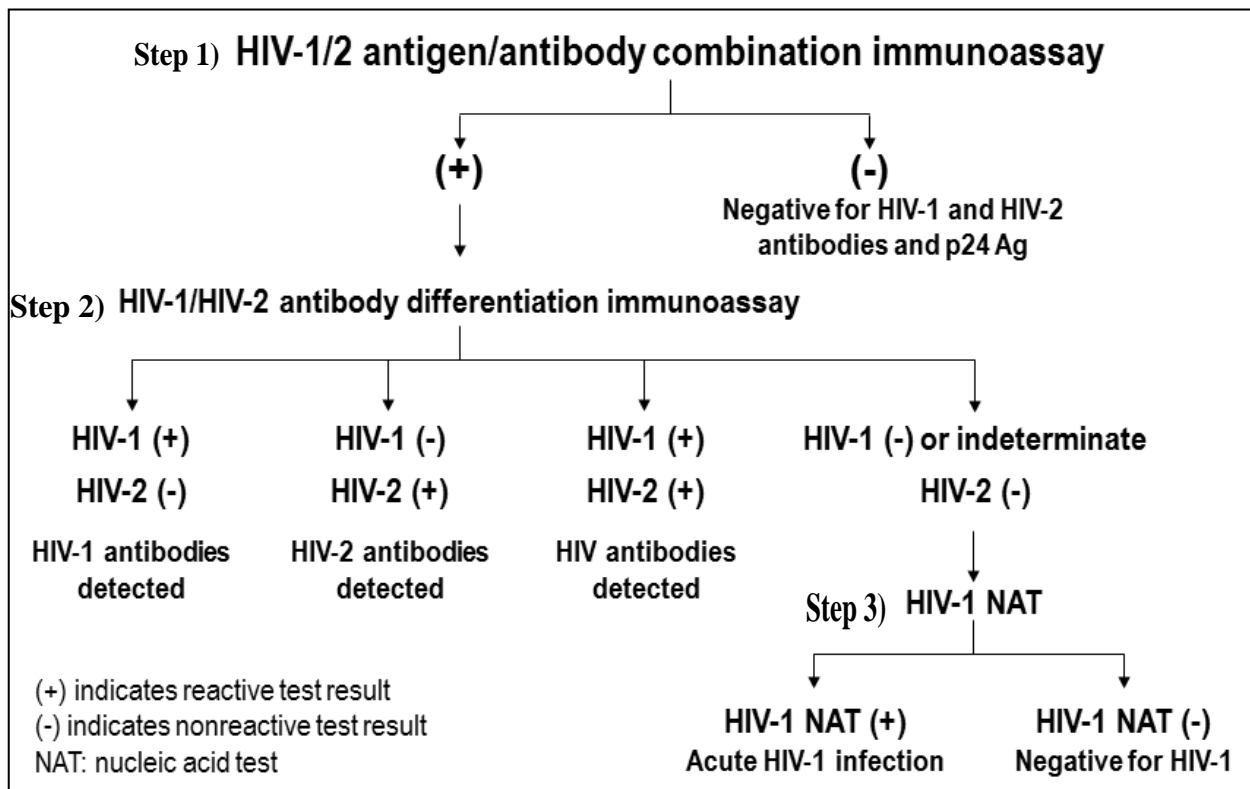
FROM: Bill Whitmar, Laboratory Director
Missouri State Public Health Laboratory

DATE: August 11, 2014

RE: Change in HIV Algorithm

During the month of September 2014, the Missouri State Public Health Laboratory (MSPHL) will begin following a new HIV Diagnostic Testing Algorithm that is recommended by CDC for diagnosis of HIV infection. The HIV Diagnostic Testing Algorithm is a multi-test algorithm, incorporating tests that detect HIV antigens, antibodies and RNA, and the final interpretation is based on a combination of test results rather than a single confirmatory test such as the Western blot.

In 2013, the MSPHL implemented 4th generation testing (Step 1) and the send out process for HIV-1 NAT testing (Step 3) according to the testing algorithm shown below. **This year, the MSPHL will be discontinuing the Western Blot test and in its place performing an antibody differentiation test (Multispot) that can differentiate between HIV-1 and HIV-2 antibodies (Step 2).**



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The new algorithm begins with the latest (4th) generation of HIV tests that offer greater sensitivity during early infection than previous tests by detecting the HIV-1 p24 antigen, which can be detected even before antibodies develop, as well as antibodies to both HIV-1 and HIV-2. It is critical to identify HIV infection as early as possible, so that individuals can receive maximum treatment benefits; live longer, healthier lives; and protect their partners. Recent studies show that HIV treatment can reduce the likelihood of transmission from an HIV positive person to their partner by 96%. This series of tests can detect an acute infection as well as chronic infection and differentiate between an HIV-1 infection and an HIV-2 infection. As new generations of screening tests, including rapid tests, become available, the HIV-1 Western Blot test, a first generation test, becomes less effective as a confirmatory test for HIV infection. This, in addition to new CDC guidance recommending laboratory use of the algorithm above, have led to the decision to discontinue the Western Blot in our testing process.

To help health care providers interpret the combinations of HIV test results, an attachment is enclosed listing the test methods, possible test results, and interpretations. The initial screening result and the differentiation result, if needed, will be reported by the MSPHL. The HIV-1 NAT will be sent to Wadsworth Center –New York State Health Department for testing. A separate report with this result will be sent to your facility.

All preliminary positive HIV rapid test samples received at the MSPHL will follow the HIV Diagnostic Testing Algorithm starting at Step 1 and then proceed through the cascade if necessary.

For all testing to be successfully completed, please collect a full tube of blood (6 mL red top vacutainer tube) and send to the MSPHL within 3 days of collection or as soon as possible. Specimens will be unsatisfactory for HIV screening 10 days after collection and will not be tested. To assist in transporting the specimen to the MSPHL, please visit our web site at www.health.mo.gov/lab/courierservices.php to find the closest courier drop off location to your facility.

The new HIV Diagnostic Testing Algorithm offers the opportunity to provide infected persons and their clinicians more accurate and timely information on HIV-1 and HIV-2 infection as well as the opportunity to improve capacity to detect acute HIV infection. We look forward to collaborating with you to continue the important work of prevention, diagnosis and treatment of HIV infection by incorporating the HIV Diagnostic Testing Algorithm into routine diagnostic testing.

Should you have any questions regarding the HIV Diagnostic Testing Algorithm please contact Nicole Ayres, HIV/Syphilis Supervisor, at Nicole.Ayres@health.mo.gov or Dana Strobe, Immunology Manager, at Dana.Strobe@health.mo.gov or by calling the laboratory at 573-751-3334.

Interpreting Laboratory Results from the HIV Diagnostic Testing Algorithm

Step 1	Step 2	Step 3	Interpretation for Laboratory Report	Further Action
HIV -1/2 Antigen/Antibody combination (CMIA)	HIV- 1/HIV- 2 Antibody Differentiation (MULTISPOT)	HIV-1 NAT (SEND OUT)		
Nonreactive	N/A	N/A	HIV-1 p24 antigen and HIV-1/HIV-2 antibodies not detected	Sample can be reported as nonreactive for HIV. If recent HIV exposure is suspected, redraw and repeat algorithm. If acute HIV infection is suspected, consider testing for HIV-1 RNA.
Reactive	HIV-1 Positive	N/A	Positive for HIV-1 antibodies. Laboratory evidence consistent with established HIV-1 infection is present.	Provide person tested with appropriate counseling and link to medical care
Reactive	HIV-2 Positive	N/A	Positive for HIV-2 antibodies. Laboratory evidence of HIV-2 infection is present.	Provide person tested with appropriate counseling and link to medical care
Reactive	HIV Positive (Undifferentiated)	N/A	Positive for HIV antibodies. Laboratory evidence of HIV infection is present. HIV antibodies could not be differentiated as HIV-1 or HIV-2.	Provide person tested with appropriate counseling and link to medical care and treatment. Additional testing for HIV-1 RNA or HIV-2 RNA should be performed if clinically indicated.
Reactive	Nonreactive or HIV-1 Indeterminate	Detected	Positive for HIV-1. Laboratory evidence consistent with an acute HIV-1 infection is present.	Provide person tested with appropriate counseling and link to medical care and treatment.
Reactive	Nonreactive or HIV-1 Indeterminate	Not detected	HIV antibodies were not confirmed and HIV-1 RNA was not detected. No laboratory evidence of HIV-1 infection.	Consider repeat testing if clinically indicated. If there is a reason to suspect recent HIV-2 infection, additional testing for HIV-2 RNA or DNA should be considered.
Reactive	Nonreactive or HIV-1 Indeterminate	Invalid or not performed	HIV-1 antibodies were not confirmed and HIV-1 RNA testing was not performed.	Testing of this specimen is incomplete. Follow-up testing for HIV antibodies and HIV-1 RNA is recommended as soon as possible.