Department of Pathology & Laboratory Medicine

UNIVERSITY of ROCHESTER MEDICAL CENTER

MEDICINE of THE HIGHEST ORDER

TO: Clients of URMC Labs

FROM: Marilyn A. Menegus, Ph.D.
Associate Director, Clinical Microbiology Laboratories & Professor of Microbiology and Immunology,
Department of Pathology and Laboratory Medicine
Phone: (585) 275-7735
E-mail: Marilyn_Menegus@URMC.Rochester.edu

SUBJECT: NEW HIV TESTING ALGORITHM

DATE: 4/29/2013

Beginning May 5th 2013, we will be changing both our routine HIV screening assay and our HIV confirmatory algorithm.

What change was made and why?
The Association of Public Health Laboratories (APHL) in collaboration with the Centers for Disease Control and Prevention (CDC) is now advocating a new approach to HIV testing as a replacement for the algorithm that has been in place since 1989. Our variant of this new approach includes a next generation HIV screening assay, and an entirely new and more definitive approach to confirmatory testing described below. Our new screening assay will be the Abbott HIV-1/2 Antigen/ Antibody Combo assay (4th generation assay) and it will be performed on the Abbott ARCHITECT instrument. The Combo assay simultaneously detects the presence of HIV-1& HIV-2 antibodies and p24 antigen. The primary advantage of the HIV combo assay is that the p24 antigen component significantly improves our ability to detect acute HIV infection in patients who have not yet mounted a detectable HIV antibody response. In addition, the combo assay remains >99% sensitive for detecting established or chronic HIV infections.

How does the change affect confirmation of results?
The current HIV testing algorithm includes an initial antibody screen for HIV-1 and HIV-2. If the screen is positive, reflex testing is performed using a confirmatory Western blot for HIV-1 performed at a reference laboratory. The HIV-1 Western blot will no longer be used as the routine method of HIV confirmation. In its place, we will now perform the BioRad Multispot as our primary confirmatory test. The Multispot assay will be done in our own laboratory soon after the positive screen results are detected thus providing same day confirmatory results. As well as being rapid, the Multispot confirmatory test is more sensitive than the Western blot and it also distinguishes between HIV-1 and HIV-2 antibodies. All individuals with reactive HIV-1 and HIV-2 Combo assay samples that are also positive on the Multispot should be considered HIV infected. NYSDOH requires that all providers promptly link HIV infected individuals to appropriate HIV care.

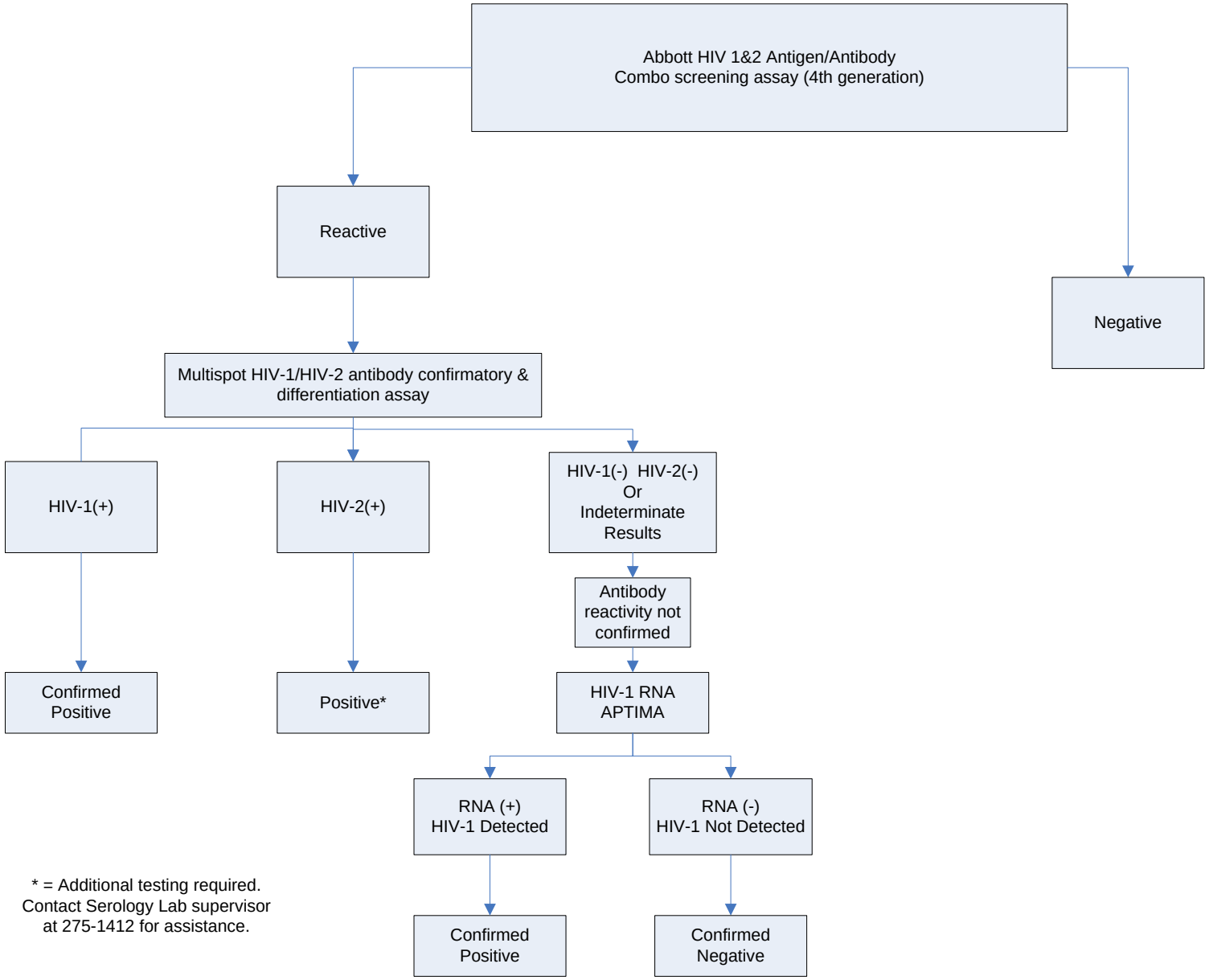
What happens in the uncommon situation where a screen is positive with a negative confirmatory test?
Patient samples that are repeatedly reactive on the HIV-1/2 Combo assay and either negative or indeterminate on the Multispot will be sent to the NYS Bloodborne Virus Laboratory Wadsworth Center for diagnostic nucleic acid amplification testing (NAAT) by the HIV-1 Aptima assay. This assay detects the presence or absence of virus in the specimen and thus it provides the final answer regarding HIV infection status. Please see page 2 of this memo for a flow chart of the new algorithm.

Can I still get a rapid (medically urgent) HIV test?
In those settings where rapid (<2hr) HIV results are required (eg. Occupational Medicine, Labor and Delivery, medically urgent cases), please continue to order the rapid (medically urgent) HIV test as you have in the past. Any positive findings will be followed up with the 4th generation assay and the new diagnostic algorithm. In cases where a rapid HIV test is negative and acute or early HIV infection is suspected, the HIV-1/2 Antigen/ Antibody Combo assay can be added by contacting the Serology Lab.

Sample requirements: No changes. Continue to draw an SST tube for testing.
Test turnaround time: Screening and antibody confirmation assays performed 7 days/week.

For questions or additional information, please contact the Serology Lab supervisor, Daniel Wheeler.
Phone: (585) 275-7801 E-Mail Daniel_Wheeler@urmc.rochester.edu

NEW HIV TESTING ALGORITHM



* = Additional testing required.
Contact Serology Lab supervisor at 275-1412 for assistance.