



MEMORANDUM #138

TO: UNC Hospitals Attending Physicians, Housestaff, Department Heads,
Nursing Staff and Supervisors

FROM: John L. Schmitz, Ph.D., Associate Director, Clinical Microbiology/Immunology Laboratories *JL*
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DATE: February 29, 2012

SUBJECT: **Change in HIV Testing Algorithm**

Effective March 1, 2012 the Clinical Microbiology/Immunology (CMI) Laboratories will change the method for confirmation of reactive Abbott HIV-1/2 Combo (4th generation) HIV test results. Currently, the HIV-1 Western blot (WB) is used to confirm the presence of HIV-1 antibody in sera that are repeatedly reactive in the Abbott HIV-1/2 Combo assay. Based on guidance recently published by the Clinical and Laboratory Standards Institute and pending changes in the CDC recommended algorithm for HIV antibody testing, the CMI laboratories will replace the WB with the Multispot HIV-1/2 rapid test. Replacing WB with the rapid test for confirmation of reactive 4th generation result will reduce the turnaround time for positive results to 24 - 48 hours on samples received Monday thru Friday (previously, positive result reports could take up to 7 days). The Multispot test will also allow the laboratory to determine the HIV-2 serostatus of individuals. Finally, the cost of the Multispot test will be significantly less than the WB assay.

Several studies have documented comparable performance of the Multispot algorithm compared to the traditional WB algorithm. Our in house validation studies also demonstrate comparable sensitivity and specificity of the Multispot algorithm. With implementation of the Multispot supplemental test the following algorithm will be followed:

1. All sera for HIV antibody testing will be tested with the HIV-1/2 Ag/Ab Combo test. Negative sera will be reported as HIV-1/2 negative.
2. All reactive sera will be repeated in duplicate. Sera for which both replicates are negative will be reported as HIV-1/2 negative.
3. Repeatedly reactive sera will be reflexed to the Multispot HIV-1/2 test.
4. Multispot negative sera will be reported as supplemental test negative. HIV RNA PCR is recommended for these results to detect acute HIV infection.
5. Multispot reactive sera will be reported as either HIV-1 or HIV-2 reactive.
6. Some sera may react to both the HIV-1 and HIV-2 antigens. These sera will be reported as HIV positive undifferentiated. HIV RNA PCR testing is recommended on these sera.

HIV testing can be ordered in A2K by searching for "HIV Ag/AB Combo Screen", test code 8212.

Any questions about the HIV testing algorithm can be addressed to the Clinical Immunology Laboratory at 966-4058 or to Dr. John Schmitz at 966-8453.