

MEMORANDUM #143

TO:

UNC Hospitals Attending Physicians, Housestaff, Nursing Coordinators,

Department Heads and Supervisors

FROM:

John L. Schmitz, PhD, Associate Director, Clinical Microbiology/Immunology Laboratories

Peter Gilligan, PhD, Director, Clinical Microbiology/Immunology Laboratories

Herbert C. Whinna, MD, PhD, Director, McLendon Clinical Laboratories

DATE:

May 7, 2013

SUBJECT: Change in HIV Testing Results

Effective immediately the Clinical Microbiology/Immunology (CMI) Laboratories will include an "indeterminate" result category in addition to the current negative and positive result categories (see below) in the HIV testing algorithm. This change has been made as a result of a recent modification to the FDA approval of the Multispot HIV-1/2 test.

With this modification, Multispot supplemental samples will be tested and reported according to the following algorithm:

- 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 and will be reflexed for HIV RNA PCR to detect acute HIV infection.
- 5. Multispot reactive sera will be reported as either HIV-1 or HIV-2 reactive.
- 6. Multispot indeterminate sera will be reported as indeterminate for HIV-1 antibody and will be reflexed to HIV RNA PCR testing.
- 7. 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.