Capital Health

MEMORANDUM

TO: **Clinicians and Provincial Laboratories**

FROM: Dr. Todd Hatchette / Dr. Jason LeBlanc
Directors Immunology / Virology Section

DATE: January 4, 2013

RE: Changes in HIV and Syphilis testing

Effective January 7, 2013 fourteen Microbiology serology tests will be performed using a new methodology. Clinicians should be aware of the following changes for HIV and Syphilis testing.

Changes in HIV Testing

Our current HIV screening assay detects only antibodies to HIV. The new Abbott Architect HIV Enzyme Immunoassay (EIA) screen detects both antibodies to HIV **and** the presence of p24 antigen. The p24 antigen is detected early in HIV infection, before a serologic response can be measured. Therefore, this new EIA shortens by five days the period before an acute HIV infection can be detected (from 22 to 17 days). Specimens that have a reactive EIA screen will continue to be further tested with the Western blot. However, the Western blot confirms only the presence of antibody and does not detect p24 antigen.

> **Clinical Significance:** A patient with a reactive HIV EIA screening test and negative Western blot could have an acute infection, **OR** a falsely reactive screening test. For tests with a positive EIA screen and a negative Western blot, the report will say that a repeat specimen should be submitted for testing in 2 weeks. If the patient is truly infected, the Western blot would then show evidence of infection. Although the repeat Western blot will unlikely be "positive", it should show an "indeterminate" result in the setting of acute infection. Clinicians should review the risk factors for infection with the patient to better understand whether the reported result could indicate an acute infection. Until repeat testing is done, patients should be counseled to use barrier methods of protection, and refrain from donating blood, tissues, and organs.

During our validation of this assay, the laboratory found a reduced rate of false-positive screening results. Therefore, any specimen referred in for confirmatory testing from provincial laboratories that currently use 3rd generation assays for their HIV screening will be retested with the 4th generation assay. If positive with the 4th generation assay, a Western blot will be performed.

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Changes in Syphilis Testing

Currently, syphilis testing relies on screening with the rapid plasma reagin (RPR) test. When the laboratory transitions to the Abbott Architect, we will use a treponemal specific EIA that detects both IgG and IgM. Positive results will be confirmed using the RPR and, if necessary, our current syphilis confirmatory test, the *Treponema pallidum* antibody assay (TP-PA).

> **Clinical Significance:** While this will improve our ability to detect early primary infections, false-positive EIAs can occur. In some situations it may be difficult to confirm infections and further supplemental testing may be necessary. Positive predictive value of any laboratory test is dependent on the pretest probability or prevalence in the population being tested. Clinicians should review the risk factors for syphilis with the patient and interpret the test results accordingly.

If there are any questions regarding the results they can be directed to Drs. Hatchette and LeBlanc (473-6885/7698).

Sincerely,

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