



**MLS Laboratory Update
Changes in the MDH TB Laboratory
November 1, 2011**



Purpose of this Message:

To inform MLS laboratories about four changes MDH-PHL has recently implemented in the Mycobacteriology (TB) Laboratory.

1. New direct PCR test for *Mycobacterium tuberculosis* complex (MTBC)
2. New schedule for running of MTB Complex and *M. avium* Complex DNA probes
3. New rejection criteria for swab specimens
4. New look to paper reports

1. New Direct PCR Test for MTB Complex

“CDC recommends that nucleic acid amplification testing be performed on at least one respiratory specimen from each patient with signs and symptoms of pulmonary TB for whom a diagnosis of TB is considered but has not yet been established, and for whom the test result would alter case management or TB control activities, such as contact investigations.” [Updated Guidelines for the Use of Nucleic Acid Amplification Test in the Diagnosis of Tuberculosis; MMWR Weekly, January 16, 2009/58(01); 7-10]

Because of these recommendations, MDH PHL is now performing PCR for the direct detection of *Mycobacterium tuberculosis* complex DNA in patient specimens using an assay developed in-house. This assay is currently validated for AFB smear positive respiratory specimens (e.g. sputum, bronchoscopy, etc.) and is always performed in conjunction with culture. Work continues to evaluate use of this test for other specimen types and AFB smear negative respiratory specimens.

WHEN THE TEST IS BEING PERFORMED: Currently this test is being used when a submitted respiratory specimen is found to be smear positive for acid-fast bacilli on a patient where the diagnosis of TB has not yet been established (i.e. no previous positive AFB smear or culture). The specimen will automatically be reflexed to the direct PCR test with the goal of results within 48 business hours after smear result is determined. Consultation with the Microbiology Supervisor is required prior to approval of this test under any other circumstances.

2. New Schedule for *M. tuberculosis* complex and *M. avium* complex DNA probes

Many of our submitters have grown accustomed to our schedule of running DNA probes on Tuesdays and Fridays. However, due to changes in staffing and workflow, we will now be running probes at different times during the week based on workload. Our goal is to attain a 48 hour, or in most cases, faster turn-around-time. For those laboratories processing and growing mycobacteria cultures, please send us specimens for DNA probe testing as soon as you have an eligible specimen.

3. New Rejection Criteria for Swabs

Swabs are a discouraged specimen type because they are not optimal for the recovery of *Mycobacterium* sp. therefore we will no longer accept swabs submitted in transport medium or commercial swab transport devices. If a swab is the ONLY specimen available, then it must be submitted in 2-3 mL of sterile saline as per the Clinical and Laboratory Standards Institute (CLSI) guidelines [Laboratory Detection and Identification of Mycobacteria; Approved Guideline. N48-A, Vol. 28, No. 17, May 2008]. Because swabs are not optimal specimens, a disclaimer will continue to accompany a negative report.

4. **New Look To Paper Reports**

You will soon notice that we have changed the look of reports generated by our TB laboratory. The goal is to provide all results for a specimen on a single report. Please provide feedback if you have any questions or comments.

Questions

If you have any questions or comments about these changes in the MDH TB Laboratory, please contact Paula Vagnone (information below).

Thank you,

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