

Starting December 31, 2011, SHL is pleased to announce the implementation of a new nucleic acid amplification test (NAAT) for the detection of *Mycobacterium tuberculosis* complex DNA directly from clinical specimens.

Method: The new test is a semi-quantitative nested real-time PCR assay that detects the presence of *Mycobacterium tuberculosis* complex DNA and Rifampicin resistance associated with mutations of the rpoB gene directly from clinical specimens. This test will replace the Mycobacterium Tuberculosis Direct (MTD) test that is currently in use. It is only validated for the following specimen types: sputum, bronchial alveolar lavage, and transtracheal aspirates. In addition this test will detect mutations in the rpoB gene that codes for resistance to rifampicin. When *M. tuberculosis* complex is detected, a result for detection of rifampicin resistance will also be issued. This test is performed in conjunction with traditional culture and identification as well as growth dependent susceptibility testing on isolates of *M. tuberculosis* complex.

Acceptable specimens are:

- Initial smear positive specimen from a patient when the clinical specimen is sent to SHL for acid fast bacillus (AFB) smear and culture.
- Sediment from clinical specimens processed in other labs by the standard Nalc-NaOH digestion/decontamination procedure and the initial AFB smear is positive. There is no charge for this test. [New submission requirements](#) are now available for those laboratories submitting sediment for NAAT. Please review the documents carefully.
- Specimens or sediment when AFB smear negative and physician requests NAAT. There is a charge for this test.
- The new NAAT is not appropriate for test of cure. A culture must be done to determine if the *M. tuberculosis* organism has been eliminated.

Test Request Form (TRF):

- An updated [Bacteriology test request form](#) is now available. The new version must be used to order this test. When submitting sediment, please complete the information regarding your smear result and time since processing. Please destroy any copies of the old Bacteriology TRF that you may have and use only the new version.

Transport of Specimens:

- The sediment should no longer be sent to the Ankeny laboratory-all testing for this organism will occur in at the Iowa City laboratory.
- As always, all clinical specimens should reach SHL within 24 hours of collection for the most valid results. All clinical specimens should also be kept at 4 degrees C (range of 2-8 degree C) from time of collection through transport to SHL. SHL will now be documenting whether or not specimens are received on cold packs.

Please share this information on our new test and proper specimen transport conditions with your physicians. Many of them give specimen collection kits to patients in their office or clinics and they need this information prior to having a patient collect a sputum specimen.

Let us know if you have any questions. This new test will be implemented on December 31, 2011.