



October 2008

Amplified Mycobacterium Tuberculosis Direct Test (AMTD) - Update re Testing Guidelines

To Health Care Providers

The Amplified Mycobacterium Tuberculosis Direct test (AMTD) from GenProbe is a target-amplified nucleic probe test that detects *M. tuberculosis* complex (MTBC) rRNA directly from respiratory specimen concentrates. The AMTD test has been in use at the Ontario Public Health Laboratories since 1997 and is approved for use with acid-fast bacilli smear positive and negative respiratory specimens (sputum, bronchoalveolar lavage (BAL), bronchial aspirate or tracheal aspirate).

Recent laboratory data indicates that for the AMTD test, the sensitivity and specificity for smear-positive respiratory specimens are 98.0% and 98.0%, respectively. For smear-negative respiratory specimens, the sensitivity is much lower.

In order to ensure appropriate and optimal utilization of the AMTD, the following changes will take effect November 1st:

The AMTD test will be performed under the following conditions:

Respiratory Specimens:

- Only sputum, BAL or tracheal aspirate will be tested
- Only one specimen per patient will be tested
- All smear positive specimens from new, previously untreated patients will be tested routinely
- Smear-negative specimens will not be tested routinely. For special requests, the clinician should contact the Medical Microbiologist prior to submission of the specimens. (Indicate on the requisition that the test is requested and contact the office at 416-235-5712 to reach the Microbiologist)

Mycobacteriology and TB Lab – AMTD Update and Submission Information
(continued)

Non-Respiratory Specimens: (includes cerebrospinal fluid and pleural fluid)

- The AMTD test is not approved for use in non-respiratory specimens
- AMTD test will not be performed on non-respiratory specimens that are smear negative
- Smear-positive specimens will be tested routinely with the following note: “investigational / research use only” (Note: a minimum of 2 mL is required for CSF specimens).

The AMTD test will not be performed under the following conditions:

- Grossly bloody specimens
- Non respiratory smear negative specimens
- From patients currently on antituberculous therapy or who have been treated for TB within the preceding 12 months (AMTD cannot be used to monitor response to therapy for TB).

The AMTD test is performed Monday, Wednesday and Friday routinely, and results are reported to the submitter by 2 pm on the same day as testing.

Note:

A negative AMTD test does not exclude a positive MTBC culture.

A false negative AMTD may be the result of inhibitors in the specimen, blood in the specimen, low numbers of MTBC in the presence or absence of nontuberculous mycobacteria in the specimen, or if the patient is already on treatment for TB.

For Further Information:

- Contact the Medical Microbiologist through the Bacteriology office at **416-235-5712**
- Contact the TB and Mycobacteriology laboratory at **416-235-5928**
- Contact the laboratory manager at **416-235-5993**