

**TO:** Wisconsin Mycobacteriology Laboratories, Wisconsin Public Health Departments, Wisconsin Infection Control Practitioners

**FROM:** Dr. Dave Warshauer, PhD, Deputy Director, CDD  
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 Wisconsin State Laboratory of Hygiene (WSLH)

**DATE:** June 24, 2013

**RE:** **New MAC PCR Assay for Detection of *M. avium* complex**

WSLH will be implementing a real-time PCR assay for the detection of *M. avium* complex (MAC) in **smear-positive** respiratory specimens as of August 1, 2013. The MAC PCR will be incorporated into the *M. tuberculosis* complex (TB) PCR testing algorithm with no need for the submitter to order testing. The assay targets the 16S-23S internal transcribed spacer (ITS) region and detects all current members of MAC including *M. avium*, *M. avium* subsp. *avium*, *M. avium* subsp. *paratuberculosis*, *M. intracellulare*, *M. chimaera*, *M. arosiense*, *M. colombiense*, *M. marseillense*, *M. bochedurhonense*, and *M. timonense*. This assay was developed and its performance characteristics determined by the WSLH. This assay has not been cleared by the U.S. Food and Drug Administration.

The WSLH will perform same-day, fee-exempt concurrent TB/MAC PCR Panel testing on initial smear-positive diagnostic respiratory specimens. MAC PCR testing will not be performed on smear negative specimens because of the limited sensitivity of the assay. WSLH will continue to perform fee-exempt TB PCR testing on smear-negative specimens from patients considered to be TB suspects with pre-approval from the Wisconsin Division of Public Health Tuberculosis Program (DPHTBP). DPHTBP can be reached at (608) 261-6319. The approval criteria are listed below.

Test	Specimen Type	Billing	Notes
<b>TB/MAC PCR Panel</b> Test codes MM00256 and MM00260	Initial smear-positive respiratory specimens (sputum, tracheal aspirate, bronchial washings, BAL)	Same-day, fee-exempt testing*	Primary patient specimens or decontaminated sediments may be submitted.  If a specimen from a non-sterile site has not been decontaminated, WSLH will perform decontamination and the submitter will be billed.
<b>TB PCR alone</b>  Test code MM00256	Smear-negative specimens  Respiratory and non-respiratory specimens	Fee-exempt testing is performed with pre-approval from DPHTBP. Same-day testing may not be available.	
<b>MAC PCR alone</b>  Test code MM00260	By special request on initial smear positive respiratory specimens for patients in which TB has been ruled out.	\$100 (CPT code 87556)	Specimens with visible blood will be accepted.  PCR testing should be performed within 7 days of specimen collection.

\*For Same Day Service: Primary specimens must arrive at WSLH by 10:00 AM. Specimens that have been decontaminated (for non-sterile sites) and cultured must arrive by 12:00 noon.



**PATIENT CRITERIA for TB/MAC PCR Panel (MAC testing performed only on smear-positive respiratory specimens):**

PCR testing at WSLH is supported by state funding; patients must meet the following criteria established by the Wisconsin TB Control Program to qualify for fee exempt testing:

- Patient must have signs and symptoms of pulmonary TB
- Patient must be reported to the local or state public health department as a suspect TB case
- Patient must be in respiratory isolation
- Patient must not have been diagnosed with TB or a non-tuberculous mycobacterial infection within the last 12 months
- Patient must have received  $\leq 7$  days of anti-mycobacterial therapy or no such treatment within the last 12 months

**Submission of Specimens for TB/MAC PCR Panel (MAC testing performed only on smear-positive respiratory specimens):**

- For primary respiratory specimens (sputum, tracheal aspirate, bronchial washing, BAL): Submit 3-10 ml of specimen in a leak-proof container. Decontamination, smear and culture will also be performed at WSLH.
- For decontaminated sediments: submit 0.5 ml of sediment in a leak-proof container.
- Specimens should be stored at 2-8°C degrees before and during transport. Specimens should be transported to WSLH as soon as possible.
- Notify the DPH Tuberculosis Program (608) 261-6319, or Local Public Health Department of a new TB suspect and for approval for fee-exempt testing.
- It is recommended that you notify the WSLH TB Laboratory (608) 262-1618 before submitting specimens for PCR.
- For no-charge **next-day** courier service, call Dunham Express for delivery to WSLH. Dial 1-800-236-7127 to reach the Dunham Express dispatcher. The WSLH-TB account number is 7271.

**REFERENCE:**

CDC. Updated guidelines for the use of nucleic acid amplification tests in the diagnosis of tuberculosis. MMWR 2009; 58: 7-10.

Ngan, G.J.Y., Ng, L.M., Jureen, R., Lin, R.T.P., and Teo, J.W.P. 2011. Development of multiplex PCR assays based on the 16S-23S rRNA internal transcribed spacer for the detection of clinically relevant nontuberculous mycobacteria. Letters in Applied Microbiology. 52(5): 546-554.

