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

FROM: Dr. Dave Warshauer, PhD, Deputy Director, CDD
Julie Tans-Kersten, MS, BS-MT (ASCP), TB Laboratory Program Coordinator
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. intracellularre, M. chimaera, M. arosiense, M. colombiense, M. marseillense, M. bouchedurhonense, 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.

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