TB/MAC PCR

Nucleic Acid Amplification for Direct Detection of *M. tuberculosis* complex (“TB”) and *M. avium* complex (MAC) from clinical specimens

The WSLH will perform same-day, fee-exempt TB/MAC PCR testing on initial smear-positive diagnostic specimens. WSLH also performs fee-exempt TB PCR testing with pre-approval from the Wisconsin Division of Public Health Tuberculosis Program (DPHTBP) on smear-negative specimens from patients considered to be TB suspects. MAC PCR testing will not be performed on smear negative specimens because of the limited sensitivity of the assay.

<table>
<thead>
<tr>
<th>Test</th>
<th>AFB Smear Result</th>
<th>Specimen Type</th>
<th>Billing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>TB/MAC PCR Panel</strong></td>
<td></td>
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</tr>
<tr>
<td>Test codes MM00256 and MM00260</td>
<td>Smear Positive</td>
<td>Initial respiratory or non-respiratory specimens£</td>
<td>Same-day, fee-exempt testing*</td>
</tr>
<tr>
<td><strong>TB PCR alone</strong></td>
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<tr>
<td>Test code MM00256</td>
<td>Smear Negative</td>
<td>Smear-negative respiratory specimens</td>
<td>Fee-exempt testing is performed with pre-approval from DPHTBP. Same-day testing may not be available.</td>
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<tr>
<td><strong>MAC PCR alone</strong></td>
<td></td>
<td></td>
<td>$100 (CPT code 87556)</td>
</tr>
<tr>
<td>Test code MM00260</td>
<td>Smear Positive</td>
<td>By special request on initial smear positive respiratory specimens for patients in which TB has been ruled out.</td>
<td></td>
</tr>
</tbody>
</table>

* For Same Day Service: Primary specimens must arrive at WSLH by 10:00 AM. Decontaminated sediments must arrive by 1:00 PM.

£ Respiratory specimens include sputum, tracheal aspirate, bronchial washings and BAL.

£ Non-respiratory specimens include tissue, sterile body fluid, CSF and urine.

PATIENT CRITERIA for TB/MAC PCR Panel:
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:

- 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 and/or concentrated 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. PCR testing should be performed within 7 days of specimen collection.
- 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.
- WSLH has contracted with Statmedex for free next-day delivery of TB specimens. To request a package pick-up by Statmedex, enter an on-line order before noon on the day you would like the specimen picked up. If you are not familiar with the on-line order process, please contact Statmedex Customer Service before noon at 763-233-0099.

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