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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.

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

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

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:

- <u>For primary respiratory specimens</u> (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.

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



[¥] Respiratory specimens include sputum, tracheal aspirate, bronchial washings and BAL.

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