

## **Advanced Diagnostic Laboratories**

October 17, 2018

Important Notice: New methodology for Nontuberculous Mycobacteria-Drug Resistance

Effective Date: December 17, 2018

Dear Valued Client,

We are pleased to announce the successful validation of a new methodology for nontuberculous mycobacteria (NTM) drug resistance and identification in our Mycobacteriology Laboratory.

- Assay is performed 7 days a week, with speciation and molecular drug resistance marker results available within 48 hours
- Results now include induced macrolide resistance for *Mycobacterium abscessus* subspecies *abscessus* and *M. abscessus* subsp. *bolletii*
- Identification for frequently encountered NTM species will be significantly shortened

Code	Test	СРТ	<b>CPT Units</b>
AFB4	Line Probe Assay Identification	87798	7
AFB6	Drug Resistance Markers of Various NTM	87798	2
AFB5	Differentiation within M. abscessus group	Discontinued	

The Nontuberculous Mycobacteria-Drug Resistance (NTM-DR) line probe assay from Hain Lifescience (Nehren, Germany) is an accurate test to identify from acid-fast bacilli (AFB) positive cultures several frequently encountered nontuberculous mycobacteria (NTM), including the slowly growing *Mycobacterium avium, Mycobacterium intracellulare, Mycobacterium chimaera* and the rapidly growing *M. abscessus* subsp. *abscessus*, *M. abscessus* subsp. *massiliense, M. abscessus* subsp. *bolletii,* and *Mycobacterium chelonae*.

In addition to species identification of frequently encountered NTM, this line probe assay is able to identify antimicrobial resistance markers for macrolide [*erm*(41) and *rrl*] and aminoglycoside (*rrs*) antimicrobials.

Based on the evaluation results using whole genome sequence data as a reference method, the following algorithm will be used in the laboratory:

- 1. **If an AFB positive culture** is from a patient without a history of NTM or the box 'tuberculosis ruled out' is not checked on the requisition form, tuberculosis is first ruled out.
- 2. If negative for *M. tuberculosis* complex, or the AFB positive culture is from a patient with a history of NTM, the new line probe assay (NTM-DR) is performed.
- 3. If the identification results in one of the following species (*M. avium, M. intracellulare, M. chimaera* or *M. abscessus* subsp. *abscessus, M. abscessus* subsp. *massiliense, M. abscessus* subsp. *bolletii, M. chelonae* the result will be released as final with one exception, *M. intracellulare* will be resulted as preliminary since these results will be confirmed with Sanger sequencing.
- 4. If the identification is not one of the seven line probe species and subspecies, the laboratory will perform Sanger sequencing as currently performed no change to the algorithm.
- 5. The molecular markers for drug resistance (*rrl* and *rrs*), ordered either with checking off the AFB6 box or the 'appropriate antimicrobial susceptibility testing' (AST) box, will be reported when the identification is considered final; *erm* (41) results will be only reported for *M. abscessus* subsp. *abscessus* and *M. abscessus* subsp. *bolletii.*
- 6. If only AFB6 is ordered, the submitter must provide an identification of the isolate.
- 7. Phenotypic MIC antimicrobial susceptibility testing for slowly growing and rapidly growing NTM will follow as currently performed no change to the algorithm; however, if the appropriate AST box is marked off, the laboratory will perform the NTM-DR assay and an additional charge will be invoiced.

Additional information available upon request, including a poster presented at the American Thoracic Society (ATS) 2018 international conference in San Diego, CA (May 2018) and an accepted poster abstract for the North American Cystic Fibrosis Conference (NACFC) in Denver, CO (October 2018).

Thank you for your continued support of National Jewish Health Advanced Diagnostic Laboratories. Please contact our client service team at 800.550.6227, if you have any questions.