

From: Angela Starks

Date: Friday, November 20, 2020 at 1:16 PM

Subject: Dear Colleague Letter: Laboratory reagent shortage for MTB identification

Dear Colleagues,

We have learned that the Hologic AccuProbe culture identification tests are on backorder as a result of a shortage in the supply chain system. AccuProbe is one of the primary or secondary identification methods for *Mycobacterium tuberculosis* (MTB) from culture used by many clinical, commercial, and public health laboratories in the United States. Shortage of this test could result in increased turnaround time for the identification of (MTB) and some nontuberculous mycobacteria from culture.

Rapid identification of MTB is critical for patient care and public health response. Given the slow growth rate of MTB, growth-based tests have a lengthy turnaround time; this timeframe could be extended given the current situation. CDC therefore reiterates the importance of routine performance of nucleic acid amplification tests (NAAT) for direct detection of MTB in clinical specimens in the diagnosis of tuberculosis (TB) for patients with signs and symptoms of pulmonary TB ([CDC guidelines for use of NAAT](#)) ([Diagnostic guidelines](#)).

The Division of TB Elimination (DTBE) and the Association of Public Health Laboratories (APHL) are working to better understand the severity of this shortage and when it may be resolved. In the meantime, we suggest that laboratories that had been using AccuProbe consider the following solutions:

- Transition to use of secondary or replacement identification methods such as multiplex PCR, MALDI-TOF, HPLC, line probe assays, or DNA sequencing. Review current test algorithms to determine if efficiencies could be achieved in reducing redundant identification practices that could save resources.
- For public health laboratories without secondary or replacement identification methods, please reach out to your CDC DTBE Laboratory Consultant and APHL (Infectious.Diseases@aphl.org) for assistance. We are working closely with APHL to try and identify potential interim solutions through establishment of temporary referral networks.
- For low-volume public health laboratories enrolled in the National Drug Susceptibility Testing Reference Center at the California Microbial Diseases Laboratory, some capacity for interim support of identification from AFB positive cultures may be available. APHL will communicate with these laboratories as soon as it has more information on how this process might work.

We encourage communication among all stakeholders as we navigate this situation. This year has been trying on many levels, but the continued dedication and commitment of our public health partners never ceases to amaze. Thank you for all that you are doing and please let us

know how we might be of assistance. We will keep you all updated as additional information becomes available.

Sincerely,
Angela

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