

MLS Laboratory Update: MDH-PHL adds Diphtheria Toxin Multiplex PCR Testing

OCTOBER 14, 2026

Purpose of this Message:

To inform MLS laboratories that the Minnesota Department of Health Public Health Laboratory (MDH-PHL) is introducing a new assay for detection of the diphtheria toxin gene in *Corynebacterium* species effective October 1, 2026.

Action Item:

Please forward information regarding the new available testing to Laboratory staff, especially Laboratory Information System (LIS) staff, Infectious Disease clinicians, and Infection Prevention and Control partners.

Background:

MDH-PHL has added the diphtheria multiplex PCR test. This test identifies *Corynebacterium diphtheriae* and *Corynebacterium ulcerans/pseudotuberculosis* in submitted isolates and detects the diphtheria toxin gene. The assay cannot confirm toxin gene expression or production. Isolates that test positive for the diphtheria toxin gene will be sent to the Centers for Disease Control and Prevention (CDC) for further testing to determine toxin production. Toxin production testing by the Elek test at the CDC may take up to 2 weeks for results. More information on toxin production testing can be found at [Laboratory Testing for Diphtheria \(https://www.cdc.gov/diphtheria/php/laboratories/index.html\)](https://www.cdc.gov/diphtheria/php/laboratories/index.html).

Submit isolates to MDH-PHL on media that support the growth of *Corynebacterium* spp. MDH-PHL test directory with additional information for submission can be found at the [Infectious Disease Laboratory \(IDL\) Test Catalog \(https://labinventory.web.health.state.mn.us/phl/lab-test-search#/\)](https://labinventory.web.health.state.mn.us/phl/lab-test-search#/)

MDH-PHL test results will be reported as such:

- ***C. diphtheriae* POSITIVE for toxin result** (example):
 - *Corynebacterium diphtheriae*: DETECTED
 - *Corynebacterium ulcerans/pseudotuberculosis*: Not detected
 - Diphtheria toxin gene: DETECTED
- ***C. diphtheriae* negative for toxin result** (example):
 - *Corynebacterium diphtheriae*: DETECTED
 - *Corynebacterium ulcerans/pseudotuberculosis*: Not detected
 - Diphtheria toxin gene: Not detected

- An FDA disclaimer will appear above the test results: “This test was developed and its performance characteristics determined by the MDH Public Health Laboratory. It has not been cleared or approved by the U.S. food and drug administration 21cfr 809.30(e). The FDA has determined that such clearance is not necessary.”
- The following disclaimer will appear for diphtheria toxin positive results: “PCR is not a confirmatory test for diphtheria toxin production. The Diphtheria Multiplex PCR detects the presence or absence of the diphtheria toxin gene. It cannot confirm toxin gene expression or production. In recent years, <20% of C. diphtheriae isolates with the tox gene produced toxin. This isolate will be sent to the Centers for Disease Control and Prevention for further testing to determine toxin production, and a separate report will follow. More information on testing for toxin production can be found at [Laboratory Testing for Diphtheria \(https://www.cdc.gov/diphtheria/php/laboratories/index.html\)](https://www.cdc.gov/diphtheria/php/laboratories/index.html).”
- If you would like an example report(s) please contact us at arlnmn@state.mn.us.

Questions: If you have any questions, please contact Paula Vagnone at 651-201-5581 or paula.snippes@state.mn.us or arlnmn@state.mn.us

Thank You,

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PLEASE FORWARD THIS TO ALL APPROPRIATE PERSONNEL WITHIN YOUR INSTITUTION AND HEALTH SYSTEM

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To obtain this information in a different format, call: 651-201-5200.