

Mycobacterium tuberculosis and Nontuberculous mycobacteria Drug Susceptibility Testing Program Description

The Centers for Disease Control and Prevention (CDC) is conducting a voluntary performance evaluation program to assess the laboratory's susceptibility testing process for drug-resistant strains of *Mycobacterium tuberculosis* and nontuberculous mycobacteria. Benefits of laboratory participation include the opportunity to conduct a free, anonymous self-assessment that will improve testing processes and will prepare laboratories to satisfy mandatory testing requirements.

Clinical mycobacteriology laboratories have a key role in combating this public health problem. By participating in this program developed by CDC's Public Division of Laboratory Systems, laboratories can use this self-assessment tool to help maximize skills in mycobacteriology. Participation in the program is voluntary and individual laboratory will not be identified in the aggregate reports.

This is not a proficiency testing program. Therefore, the testing components of the program are not intended for use by a laboratory to satisfy any regulatory requirement for participation in a proficiency testing program. Results will be reported solely on aggregate data of all participating laboratories. Other benefits of laboratory participation are:

- Analysis of characterized and referenced cultures with attributes closely resembling those of cultures encountered in routine clinical testing;

- Summary of aggregate methods and results reported by all participant laboratories for drug susceptibility testing;

- Provision of a mechanism for performing self-assessment for improvement of laboratory performance;

- Detection of problems with test systems and reagents;

- Receipt of reference strains of *M. tuberculosis* and nontuberculous mycobacteria to be used for future quality control;

- Access to sources for technical consultations; and

- Contribution to a system to improve or maintain the high quality of drug susceptibility testing.

Program participants will conduct periodic testing of performance evaluation panels (Lowenstein-Jensen slants) in the same manner that they evaluate patient isolates. Panels consist of five *M. tuberculosis*, or four *M. tuberculosis* and one nontuberculous mycobacteria isolates, with *M. tuberculosis* strains exhibiting patterns of resistance to the primary anti-tuberculosis drugs (e.g., isoniazid, rifampin, ethambutol and pyrazinamide). Laboratories will submit testing results and provide CDC with information about the methods used. All response must be submitted online. Shipment dates for the performance evaluation panels will be announced. One month after CDC receives all responses, participants will receive an email containing a preliminary report reflecting the susceptibility testing results for each culture. A detailed aggregate report of results and methods reported by all participants (without identification of individual laboratories) for each panel culture will be emailed before shipment of the next panel of *M. tuberculosis* and nontuberculous mycobacteria isolates.

Only laboratories following Biosafety Level 3 practices are eligible for participation. Biosafety Level 2 facilities with Level 3 containment equipment are acceptable. CDC requests that participant laboratories follow guidelines described in the Biosafety in Microbiological and Biomedical Laboratories (BMBL 5th Edition, 2007):
http://www.cdc.gov/od/ohs/biosfty/bmb15/BMBL_5th_Edition.pdf Publication

International participation is limited to laboratories which have public health responsibilities for tuberculosis drug susceptibility testing and approval by their National Tuberculosis Program. However, at this time due to budgetary restraints, we are not enrolling International laboratories.

If you have any questions concerning enrollment information and would like to participate in the program, please contact:

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If you have questions concerning the performance evaluation program, contact:

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