
Centers for Disease Control and Prevention
***Mycobacterium tuberculosis* and Non-tuberculous Mycobacteria**
Drug Susceptibility Performance Evaluation Program Description

The Centers for Disease Control and Prevention (CDC) is conducting a voluntary performance evaluation program to assess the laboratory's susceptibility testing probes for drug-resistance stains of *Mycobacterium tuberculosis* and non-tuberculous 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 requirements.

Clinical mycobacteriology laboratories have a key role in combating this public health problem. By participating in this program developed by CDC's Public Health Practice Program Office, Division of Laboratory Systems, laboratories can use this self assessment tool to help maximize skills in mycobacteriology. Participation in the program is voluntary and anonymity of individual laboratory contributions to the program will be maintained.

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 aggregates data of all participating laboratories. Other benefits of laboratory participation are:

- Analysis of characterized and referenced cultures with attributes closely resembling those of cultures 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 *M. tuberculosis* and non-tuberculous 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 *M. tuberculosis* and non-tuberculous mycobacteria strains with *M. tuberculosis* strains exhibiting patterns of resistance to the primary antituberculosis drugs (e.g., isoniazid, rifampin, ethambutol and pyrazinamide). Laboratories will submit testing results and provide CDC with information about the methods used. Shipment dates for the performance evaluation panels will be announced.

One month after CDC receives all responses each participant laboratory will be provided with a preliminary report laboratory will be provided with a preliminary report reflecting

the susceptibility testing results for each culture. A detailed aggregate report of result and methods reported by all participants (without identification of individual laboratories) for each panel culture will be mailed before shipment of the next panel of *M. tuberculosis* and non-tuberculous 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), 4TH EDITION, 1999 Publication No.017-040-00547-4. For information, call the U.S. Government Printing Office (1-866-512-1800).

International participation is limited to laboratories which have public health responsibilities for tuberculosis drug susceptibility testing and approval by their National Tuberculosis Program.

CDC will contract with an independent scientific service organization to assist in collecting enrollment information. If you have questions about enrollment and would like to participate, please contact:

Name
Project Coordinator
Coordinator to be determined
1-800-xxx-xxxx
Address

If you have questions concerning the performance evaluation program contact:

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