Centers for Disease Control and Prevention
***Mycobacterium tuberculosis* and Non-tuberculous Mycobacteria**
Drug Susceptibility Testing 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 process for drug-resistance stains of *Mycobacterium tuberculosis* and non-tuberculous mycobacteria. Benefits of laboratory participation include the opportunity to conduct a free, self-assessment that will improve testing processes and will prepare laboratories to satisfy mandatory requirements.

Clinical mycobacteriology laboratories play a key role in combating this public health problem. By participating in this program developed by CDC's National Center for Preparedness, Detection, and Control of Infectious Diseases, Division of Laboratory Systems, laboratories can use this self-assessment tool to help optimize their skills in susceptibility testing in mycobacteriology. Participation in the program is voluntary and is conducted in a non-regulatory environment. Laboratories will not be identified in any publication.

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 mechanisms for performing self-assessment for improvement of laboratory susceptibility testing performance;
- Detection of problems with test systems and reagents;
- Receipt of well-characterized 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 isolates with *M. tuberculosis* isolates 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 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. Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5TH EDITION, 2007 which can be found at:
http://www.cdc.gov/od/ohs/biosfty/bmbl5/BMBL_5th_Edition.pdf

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

Enrollment information can be found at: http://wwwnl.cdc.gov/mpep/mtbenroll.aspx

If you have questions about enrollment and would like to participate, please contact:

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If you have questions concerning the performance evaluation program contact:

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