Centers for Disease Control and Prevention
Mycobacterium tuberculosis Nucleic Acid Amplification 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 testing process for nucleic acid amplification (NAA) tests for *Mycobacterium tuberculosis*. Benefits of laboratory participation include the opportunity to conduct a free, anonymous self-assessment that promote sharing of information for improving the testing processes.

Culture identification of *M. tuberculosis*, even with the recommended rapid methods, requires a minimum of 14-21 days. The FDA has approved two commercial NAA tests that offer the opportunity to provide early confirmation of *M. tuberculosis* infection. Although these tests provide rapid results, questions remain about appropriate guidance for infection control, patient management, and tuberculosis control.

Clinical mycobacteriology laboratories have a key role in slowing the spread of *M. tuberculosis*. 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 with NAA tests. CDC has contracted with the Wisconsin State Laboratory of Hygiene (WSLH) a university-based public health service organization, to collect enrollment information, develop and ship test samples, and forward aggregate results to CDC for analyses. 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 the regulatory requirement for participation in a proficiency testing program. Results will be reported solely on aggregate data. Individual performance reports will not be provided.

Other benefits of laboratory participation are:

Analysis of reference samples with attributes resembling those of specimens encountered in routine clinical testing;

Evaluation of aggregate methods and results Reported by other participant laboratories for NAA tests for *M. tuberculosis*;

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

Detection of problems with test systems and reagents; Contribution to a system to improve or maintain the high quality of the testing process.

Program participants will conduct periodic testing of performance evaluation samples in the same manner that they evaluate patient isolates. Panels consist of *M. tuberculosis* and other mycobacteria in samples that mimic pre-treated (decontaminated/concentrated) patient specimens. Laboratories will submit testing results and provide CDC with information about the methods used. Shipment dates for the performance evaluation panels will be announced.

Each participant laboratory will be provided with a preliminary report reflecting the reference testing results for each test sample one month after CDC receives all responses. A detailed aggregate report of results and methods reported by all participants (without identification of individual laboratories) for each sample will be mailed before shipment of the next panel of test samples.

Only laboratories following at a minimum, Biosafety Level 2 practices are eligible for participation. CDC requests that participant laboratories follow guide-lines described in the *CDC Biosafety Manual*, 1999, 4th edition, Publication No. CDC-99-8395.

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

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