Dear Colleagues:

The purpose of this letter is to provide you with important guidance for laboratories and tuberculosis control programs considering or currently performing assays for the molecular detection of mutations associated with resistance to antituberculosis drugs. With our partner, the Association of Public Health Laboratories (APHL), we have focused 2010 end-of-fiscal-year supplemental cooperative agreement funding on one-time enhancements targeting increased patient access to molecular diagnostic testing.

We recommend that laboratories continue to ensure that conventional drug susceptibility testing is performed along with molecular testing. Rapid molecular tests should be used to supplement, but not replace culture and conventional drug susceptibility testing1. Because the diagnosis of multidrug-resistant tuberculosis has serious clinical and public health implications, laboratories are encouraged to use molecular tests, and also to expedite conventional testing. When resistance is detected, drug susceptibility information for a full panel of first and second line drugs, along with clinical patient information, is needed for health care providers to design an effective treatment regimen. Additional molecular testing should be considered to confirm the results when a rapid molecular assay indicates resistance to rifampin. Laboratories should report preliminary molecular results as soon as possible while awaiting confirmation.2

As you are aware, the Laboratory Branch of the Division of Tuberculosis Elimination (DTBE) has offered the Molecular Detection of Drug Resistance (MDDR) service since September of 2009 for rapid DNA sequence analysis of isolates known or suspected of drug resistance3. The MDDR service is available at no cost to laboratories as both a primary means of rapid detection of drug resistance and as a secondary confirmatory method for those laboratories performing similar assays in-house. We encourage submission of specimens or isolates found to have mutations associated with rifampin resistance.

1 National Plan for Reliable Tuberculosis Laboratory Services Using a Systems Approach, MMWR, April 15, 2005/54(RR06):1-12; The Future of TB Laboratory Services, APHL, 2004; Updated Guidelines for the Use of Nucleic Acid Amplification Tests in the Diagnosis of Tuberculosis, January 16, 2009/58(01): (7-10); Core TB Laboratory Service for Public Health Laboratories, APHL Steering Committee, December 2009.
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In addition, isolates with discordant results are also relevant submissions, i.e., the molecular results are negative but the isolate is later found to be resistant by conventional methods.

Furthermore, our laboratory is collaborating with APHL to develop a one-year shipping contract for use by public health laboratories to get material to CDC for MDDR analysis. With APHL, we will continue to support our public health laboratory and tuberculosis control program partners through ensuring adequate accessibility to confirmatory testing. DTBE supports medical consultation to tuberculosis programs and medical providers through the Regional Training and Medical Consultation Centers⁴.

I want to take this opportunity to thank APHL for their work in ensuring the success of the recent funding announcement targeting increased patient access to molecular diagnostic testing. In closing, I am sure 2011 will provide ample opportunity for us to advance laboratory systems capacity and public health function, despite resource constraints. Please contact us if you have any questions regarding this communication. We welcome your ideas and suggestions as we work together to ensure rapid and reliable tuberculosis testing.

Sincerely,

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