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National Tuberculosis Reference Laboratory Experience in Multi Center Quality Control Programs for Molecular Diagnostics of Tuberculosis

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Abstract: Nucleic acid amplification methods to detect Mycobacterium tuberculosis complex (MTBC) in clinical specimens are increasingly used to diagnose tuberculosis. A number of nucleic acids amplification assays have been developed to detect MTBC DNA in clinical material. These assays differ in their requirements for sample volume and sample preparation, methods of amplification, and methods of detection. There are advantages and disadvantages of all assays; thus, there is probably no assay which is best suited to all situations. Quality control programs for molecular diagnostics (QCMD) based on nucleic acid amplification have not been widely implemented in clinical laboratories and remain limited to a few tests. Development of specific QCMD trials based on methodologic proficiency testing and directed to the evaluation of analytical aspects common to the majority of PCR -based tests may be valuable. The purpose of this study was to evaluate the specifity and sensitivity of molecular amplification methods for MTBC detection and our laboratory performance. Proficiency panel specimens were obtained from QCMD 2002 TB Proficiency Panel for the Assessment of Mycobacterium tuberculosis Nucleic Acid Detection Methodologies Program, Scotland, UK. The proficiency panel consisted of 12 (8 sputum and 4 diluted samples) samples containing a range of concentrations of cultured Mycobacterium bovis BCG in either pooled sputum or presented as a decontaminated and washed cell pellet . Negative samples were also included in the panel. In the present study, all samples sent in the framework of QCMD 2000, were evaluated using three different diagnostic methods, namely COBAS Amplicor MTB, Gen Probe MTD, Taq Man RT-PCR / Gene Amp 7700 sequence detection system. All steps of the tests used during the study were made in accordance with standard protocols and instructions of the manufacturer. According to these results, COBAS Amplicor MTB test yielded consistent results in 10 (83.3%), Gen Probe MTB test in 8 (66.66%) ve RT-PCR test in 6 (50%). Our success rates were 100 % (8/8), in sputum samples and 50 % (2/4) in diluted samples. Multicenter quality control programs are quite illuminating for the determination of laboratory efficacy and the performance of the tests. It is our suggestion that nucleic acid amplification methods employed for rapid diagnosis of M. tuberculosis should be subjected to internal and external controls and made routine accordingly.

Key Words: Tuberculosis, Quality Control, Molecular Diagnosis, PCR

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