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Clinical Evaluation of the FASTPlaqueTB for the Rapid Diagnosis of Pulmonary Tuberculosis

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Abstract: The reliability of the FASTPlaqueTB (FPTB) test (Biotec Ltd.) for the rapid diagnosis of pulmonary tuberculosis was evaluated and its diagnostic performance was compared with the Amplified Mycobacterium Tuberculosis Direct (MTD) test (Gen-Probe) by testing 80 sputum samples obtained from 77 patients. The results were compared to those of mycobacterial culture, smear and clinical course. After a chart review 14 culture-negative patients who had been on antituberculosis therapy before the study began were excluded from the final analysis. Of the remaining 63 patients, 33 were considered to have tuberculosis; 29 of them were both smear and culture positive, for whom FPTB gave a sensitivity of 27% and a specificity of 97%. MTD exhibited a sensitivity and a specificity of 91% and 93%, respectively. In patients with a specimen storage and antituberculosis therapy period of < 7 days, FPTB sensitivity increased up to 53% (8/15). These data suggest that even under optimal conditions the sensitivity of FPTB is lower than that of MTD, smear and culture tests. It could be said, therefore, that FPTB for the direct detection of M. tuberculosis complex in respiratory specimens did not add an adjunct value to smears and culture. Thus, we conclude that the sensitivity of FPTB needs to be improved in order to be used for a rapid diagnosis of pulmonary tuberculosis.

Key Words: Phage amplification, transcription mediated amplification, and pulmonary tuberculosis

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