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Evaluation of the Amplified MTD® Test in respiratory specimens of human immunodeficiency virus patients

Laboratory assays for the detection of *Mycobacterium tuberculosis* have evolved significantly in the last decade. The Amplified MTD® Test (Gen-Probe, San Diego, CA, USA) can detect *M. tuberculosis* complex rRNA in approximately 3 h, is approved for use in respiratory samples and provides the greatest benefit for negative smear samples, as it allows early diagnosis and treatment. However, there are insufficient data to demonstrate the effectiveness of MTD in paucibacillary individuals, as the quality of the samples usually makes diagnosis by bacilloscopy and culture difficult.

We compared MTD with BACTEC™ MGIT™ (BD, Sparks, MD, USA) in human immunodeficiency virus (HIV) positive patients in a study of diagnostic accuracy in routine conditions at the Clinical Research Institute Evandro Chagas–Oswaldo Cruz Foundation, a reference center for infectious diseases with an out-patient clinic specializing in TB care and a level III mycobacterial laboratory.

All first respiratory samples provided by 118 HIV-positive patients (74.4% male, mean age 36.61 ± 10.6 years) being screened for pulmonary tuberculosis between January 2008 and June 2009 were processed and analyzed as per the manufacturers' instructions. Three non-tuberculous mycobacteria and one *Rhodococcus sp*. isolates were identified and excluded from the analysis. We estimated a sensitivity (95%CI) of 88.6% (73.3–96.8), specificity of 92.4% (84.2–97.2), a positive predictive value (PPV) of 83.8% (68.0–93.8), a negative predictive value (NPV) of 94.8% (87.2–98.6), a positive likelihood ratio (LR+) 11.66 (5.35–25.40), a negative LR (LR−) of 0.12 (0.05–0.31) and accuracy 91.2% (84.5–95.7). On a subset of smear-negative samples, we found sensitivity 70.8% (48.6–87.3), specificity 94.8% (87.2–98.6), PPV 81.0% (58.1–94.6) and PNV 91.3% (82.8–96.4).

The discordant results observed in MTD, i.e., MTD-positive, culture-negative, were due to laboratory contamination or the reference methodology used. MTD can detect dead or non-viable bacilli, i.e., those that barely grow on culture, and paucibacillary samples. Conversely, MTD-negative, culture-positive isolates indicate the possibility of inhibiting substances yielding negative results in MTD, as we did not check for the presence of inhibitors in our study.

This study found similar sensitivity and specificity to those found by others in non-exclusively HIV-infected patients.[1,2] Regardless of the smear results, MTD presented comparable sensitivity and specificity to reports in the literature.[3]

The greatest advantage of implementing a nucleic acid amplification technique in routine laboratory practise is the speed at which the results are available, enabling swift intervention where necessary. However, it should not replace culture, which is capable of detecting non-viable micro-organisms. These tests should always be interpreted in conjunction with conventional tests and clinical data.

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