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Title: The MTBDRplus 2.0 for rapid diagnosis of multidrug-resistant tuberculosis among patients with high risk of TB resistance

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Body: Background: Rapid diagnosis of multidrug-resistant tuberculosis (MDR-TB) is essential for the prompt initiation of effective second-line therapy to improve treatment outcome and limit transmission of TB resistance. The MTBDRplus ver.2 test is a commercially available line-probe assay (LPA) that rapidly detects M.tuberculosis (MTB) complex, as well as the most common mutations associated with Rifampicin and Isoniazid resistance. Objectives of this study were to evaluate the MTBDRplus 2.0 for rapid diagnosis of MDRTB between new and retreatment cases, with high risk of TB resistance. Method. A total of 1405 results of MTBDRplus 2.0 were analyzed, from these, the fourth part of specimens was performed directly from smear-negative (33,5%) and smear-positive (66,5%) sputum. The strains used for MTBDRplus 2.0 were isolated by liquid media (MGIT 960) and DST for first line drugs were performed and compared with LPA results. Results. The Rifampicin resistance was detected in total in 785 (55,9%) cases and 620 (44,1%) were sensitive. The Isoniazid was resistant in 939 (66,8%) and 466 (33,2%) cases were sensitive. The MDR TB were detected in 646 (46,0%) cases. The most common mutations for RIF resistance was rpoB MUT3 (86,8%) and for INH resistance katG MUT1 (97,7%). Conclusion. The MTBDRplus ver.2 assay is a sensitive and specific tool for diagnosis of RIF, INH resistance and MDR in sputum specimens and culture strains. The short turnaround times and the potential for rapid screening of large numbers of specimens make it suitable as a first-line screening assay for TB drug resistance.