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Title: Xpert MTB/RIF assay for rapid detection of Mycobacterium tuberculosis and rifampicin resistance

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Body: Introduction: Xpert MTB/RIF is a novel molecular diagnostic point of care test for rapid detection of MTB and its susceptibility to rifampicin (RIF). Objective: This study was performed to evaluate the performance of Xpert MTB/RIF assay in detection of MTB and resistance to rifampicin from sputum specimens taking positive culture for MTB and phenotypic resistance to rifampicin as reference standards. Materials and Methods: 126 consecutive patients of pulmonary tuberculosis presenting to the hospital from December 2010 to January 2012 were enrolled for the study. Their sputum samples were subjected to concentrated ZN microscopy, culture on solid (LJ) and liquid (MGIT) media. All positive cultures were identified as MTB complex using SD TB Ag MPT 64 Rapid immunochromatographic test and indirect drug susceptibility testing performed by MGIT SIRE. Result: Of the 126 cases included in the study, 83 were smear-positive and 43 were smear-negative. Of patients with culture positive samples, 20 of 126 (15.9%) were found to have multidrug resistance on indirect drug susceptibility testing with MGIT SIRE. With positive culture as the reference standard, MTB/RIF assay when done detected 98.7% of smear positive cases and 72.1% of smear negative cases. The test correctly identified all 20 of rifampicin resistant culture isolates and 105 of 106 rifampicin susceptible isolates for a sensitivity, specificity, positive predictive value and negative predictive value of 100%, 99%, 95.2% and 100% respectively. Conclusion: Xpert MTB/RIF assay is a reliable technique for rapid detection of Mycobacterium tuberculosis and Rifampicin resistance from pulmonary specimens.