

## Utility of Point-of-Care Xpert MTB/XDR assay in detection of isoniazid and second-line anti-tubercular drug resistance at a tertiary care hospital in India

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**Introduction and Objectives:** The Xpert MTB/XDR assay enables rapid, automated detection of *Mycobacterium tuberculosis* and resistance to key first and second-line anti-tubercular drugs. This is one of the first studies conducted in India to evaluate the Xpert MTB/XDR assay in detecting extensive drug resistance in MDR-TB patients, focusing on its sensitivity, specificity and diagnostic accuracy across various sample types.

**Methods:** This retrospective cross-sectional study was conducted in the Department of Microbiology, AIIMS Gorakhpur over a period of six months. It included 80 suspected TB patients tested by Xpert MTB/RIF Ultra. Data were sourced from hospital records and diagnostic reports. Samples such as sputum, BAL fluid, pleural fluid, pus, CSF and tissue were sent to the mycobacteriology laboratory where they were tested by Xpert MTB/RIF Ultra and Xpert MTB/XDR. AFB microscopy and Xpert MTB/RIF Ultra tests were performed on all 80 samples initially and those which showed rifampicin resistance were again subjected to Xpert MTB/XDR as per manufacturer guidelines. A structured register was used to record data.

**Results:** This retrospective analysis included 80 clinical samples tested using the Xpert MTB/RIF Ultra assay. *M. tuberculosis* (MTB) was detected in 61 of the 80 cases with 33 showing resistance to rifampicin. A significant number of these rifampicin-resistant cases also exhibited resistance to isoniazid (15) and fluoroquinolones (13) indicating pre-XDR and XDR-TB patterns. However, most remained susceptible to second-line injectable agents such as amikacin, kanamycin and capreomycin. Ethionamide resistance was seen in a few cases. The most common sample type was sputum, followed by BAL fluid, pleural fluid, and FNAC.

**Conclusion:** The Xpert MTB/XDR assay will prove to be a game changer in TB diagnostics as it will detect resistance to both INH and most of the second line anti-TB drugs, which when tested by other methods take a long time. As there is no national data of second line resistance to TB drugs using this novel point of care modality, these findings will help to integrate molecular testing into TB management to guide effective treatment and prevent transmission of drug-resistant strains.

**Keywords:** Xpert MTB/XDR, Drug-resistant tuberculosis, Molecular diagnostics

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