*Datasheet*
CE-IVD

# Xpert® MTB/XDR

**Test Reagent Kit**: Xpert® MTB/XDR

**Catalog Number**: GXMTB/XDR-10 (10 tests)

**Technology**: Semi-quantitative nested PCR followed by high resolution melt technology

**Targets**

| Drug Resistance | Gene Target | Codon Regions | Nucleotide Interrogated |
|---|---|---|---|
| isoniazid | *inhA* promoter | NA | -1 to -32 intergenic |
| | *katG* | 311-319 | 939-957 |
| | *fabG1* | 199-210 | 597-630 |
| | *oxyR- ahpC* intergenic region | NA | -5 to -50 intergenic (or-47 to 92) |
| ethionamide | *inhA* promoter | NA | -1 to -32 intergenic |
| fluoroquinolones | *gyrA* | 87-95 | 261-285 |
| | *gyrB* | 531-544 (or 493-505) | 1596-1632 |
| amikacin, kanamycin, capreomycin | *rrs* | NA | 1396-1417 |
| | *eis* promoter | NA | -6 to -42 intergenic |

**Sample Type**: Sputum sediment and unprocessed sputum
BD-Mycobacteria Growth Indicator Tube (MGIT)

**Sample Extraction**: Automated/integrated

**Precision Pipetting**: Not required

**Turnaround time**: Less than 90 minutes

**Controls: Process**: Sample Processing Control (SPC) and Sample Volume Adequacy (SVA)

**Controls: Probe Function/Detection**: Probe Check Control (PCC)

**Sensitivity & Specificity**

| | vs phenotypic DST* | | vs sequencing | |
|---|---|---|---|---|
| | Sensitivity (%) | Specificity (%) | Sensitivity (%) | Specificity (%) |
| isoniazid | 91.4 | 99.1 | 98.8 | 98.7 |
| fluoroquinolones | 93.1 | 98.5 | 93.3 | 100 |
| amikacin | 91.9 | 99.4 | 96.4 | 100 |
| kanamycin | 87.9 | 99.6 | 96.7 | 100 |
| capreomycin | 84.0 | 100 | 96.3 | 100 |
| ethionamide | 64.7^ | 98.3 | 97.2 | 100 |

**Storage**

**Unprocessed Sputum**
**2-35 °C** up to 7 days

**Sputum Sediment**
**2-8 °C** up to 7 days

**Specimen treated with sample reagent**
**up to 35 °C** up to 2.5 hrs
**2-8 °C** up to 4 hrs

**Kit Storage**: 2-28 °C

* Drug susceptibility testing (DST) using MGIT™ liquid culture.
^ For ethionamide, Xpert and sequencing only target the *inhA* promoter region therefore have a higher discrepancy vs phenotypic DST.

CE IVD *In Vitro* Diagnostic Medical Device

Not available in all countries. Not available in the United States.


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