

P1561 **Pre-validation of the BD Max MDR-TB assay for the rapid detection of MTBc DNA and mutations associated with rifampin and isoniazid resistance**

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**Background:** Tuberculosis is caused by *Mycobacterium tuberculosis* complex (MTBc) species and remains a major global health problem. The detection of resistance against commonly used drugs is a critical demand in clinical management. Understanding resistance to first line antimicrobials is key to improving patient management and potentially minimizing the risk of missing mono-resistance. The fully automated BD MAX™ MDR-TB assay (BD MAX) detects MTBc DNA and mutations conferring rifampin (RIF) and isoniazid (INH) resistance, the two major resistance markers in the first line of anti-TB therapy.

**Materials/methods:** At least 3 mL of sputum was collected and frozen from patients located in six countries. Each specimen was split in two portions. Portion A was processed with the NALC/NaOH. Fluorochrome and Ziehl-Neelsen microscopy, liquid culture (BD BBL™ MGIT™, BD MGIT™ TBc Identification test, and BACTEC™ MGIT™ 960 susceptibility test), Xpert® MTB/RIF assay, and BD MAX were performed from the sputum pellet. BD MAX testing was also performed on the raw specimen (portion B). The reference method (RM) for MTBc and resistance to RIF was a composite of MGIT and Xpert. Only one method needed to be positive for a positive RM. Both methods needed to be negative for a negative RM. Only MGIT was used as the INH RM.

**Results:** Combining raw and processed sputa, the sensitivity for MTBc in smear positive, smear negative, and RIF and INH resistance were 99.0% (377/381), 87.2% (245/281), 100% (69/69), and 100% (84/84) respectively. The specificity of BD MAX for MTBc, RIF and INH resistance were 96.4% (264/274), 98.9% (356/360), and 100% (341/341). The initial and final non-reportable results rates due to internal control or instrument failure was 3.6% (37/1018) and 0.1% (1/1014) respectively. For specimens for which MTBc DNA was detected but resistance metrics were not measurable ("MTB low pos" result), initial and final rates were 8.9% (91/1018) and 6.3% (64/1014) respectively. Initial and final unreportable resistance rates were 1.6% (10/639) and 0.9% (5/570) for RIF and were 1.7% (10/573) and 1.8% (10/571) for INH.

**Conclusions:** BD MAX MDR-TB is a promising assay for the detection of MTBc, RIF and INH resistance within 4 hours.