Rifampicin (RMP) and Isoniazid (INH) and are important first-line drugs for the treatment of tuberculosis and resistance to these drugs often results in treatment failure and fatal clinical outcome. Until now, the drug susceptibility testing of Mycobacterium tuberculosis complex (MTBC) strains using liquid culture media takes around 7 to 10 days to complete. The most rapid results could be achieved by application of fast molecular methods. These methods are based on the knowledge that resistance to RMP and INH in M. tuberculosis is most often attributed to specific mutations in the rpoB, katG, and inhA genes. DNA strip assays targeting rpoB (INNO-LiPA Rif; Innogenetics N.V., Ghent, Belgium) or rpoB plus katG (GenoType® MTBDR; Hain Lifescience, Nehren, Germany) are available for MTBC cultures and smear-positive specimens. In order to enlarge the detection capacity, the new GenoType® MTBDRplus assay was developed including a broader variety of rpoB and additionally inhA regulatory region gene mutations.

The aim of the study was to determine the sensitivity and accuracy of the new MTBDRplus assay. In total, 106 RMP<sup>r</sup>/INH<sup>r</sup>, 10 RMP<sup>s</sup>/INH<sup>r</sup>, and 80 RMP<sup>s</sup>/INH<sup>s</sup> MTBC strains were comparatively analyzed with the new and the old MTBDR assay. No discrepancies were obtained compared with results from real time PCR or DNA sequencing. In comparison to conventional drug susceptibility testing both assays were able to identify RMP resistance correctly in 104 of the 106 strains (98.7%). Misidentification as RMP resistant was obtained in 2 strains containing rpoB P533L mutations. Compared to the old MTBDR assay the new GenoType® MTBDRplus assay enhanced the detection of isoniazid resistance from 102 (87.8%) to 106 (90.2%) of 116 INH resistant strains. Thus, the new GenoType® MTBDRplus assay represents an upgraded tool for the detection of INH and RMP resistance in MTBC strains and smear-positive sputum specimens.