28th ECCMID EUROPEAN CONGRESS OF CLINICAL MICROBIOLOGY AND INFECTIOUS DISEASES
Madrid, Spain
21 – 24 April 2018

P1559 Performance of genotype MTBDRplus ver 2.0 assay for the detection of rifampin and isoniazid resistance in Mycobacterium tuberculosis complex: Eleven years experience

Fanourios Kontos*[1], Kiriaki Paraskevi[1], Athanasios Tsakris[2], Spyros Pournaras[1 2]

[1]National and Kapodistrian University of Athens, Medical school, Attikon University Hospital , Laboratory of Clinical Microbiology, Athens , , [2]Medical School, National and Kapodistrian University of Athens, Department of Microbiology, Athens,

Background: Rapid determination of drug resistance among *Mycobacterium tuberculosis complex* (MTBC) strains to isoniazid (INH) and rifampin (RIF), is critical for effective patient treatment and to prevent further spread of resistant isolates. The aim of the study was to determine the diagnostic accuracy of the commercially available molecular assay Genotype MTBDRplus ver 2.0 (Hain-Lifescience), performed on clinical isolates and directly on smear-positive clinical specimens.

Materials/methods: A total of 320 MTBC clinical strains recovered during an 11-year period 1/2007 to 10/2017 were studied. Also, 158 directly processed clinical specimens, derived from different patients which had positive Ziehl-Neelsen stain, were included. In the recovered MTBC strains and the clinical samples, we performed the MTBDRplus assay which is a reverse-hybridization-based assay that identifies molecularly the MTBC and mutations conferring resistance to INH (*katG* and *inhA* genes) and RIF (*rpoB* gene). MTBC identification was performed by Mycobacterium CM (Hain-Lifescience) tests and drug susceptibility testing (DST) by the MGIT960 system (Becton-Dickinson) according to CLSI recommendations.

Results: In all cases of isolated strains and clinical samples, the MTBDRplus assay produced valuable results. By DST, 23 (7.2%) and 7 (2.2%) of the 320 MTBC strains were INH-resistant (INH-R) and RIF-resistant (RIF-R), respectively. MTBDRplus assay detected all 7 RIF-R strains and 19/23 INH-R strains. All RIF-R strains carried the mutation rpoB-S531L. Twelve INH-R strains, carried the mutation *katG*-S315T, 6 strains carried the mutation *inhA* (-15 C→T) in the *inhA* promoter region and finally a strain carried both mutations. There was 4 INH-R strains that had no mutations in *katG and* inhA genes, indicating other resistance mechanisms. The sensitivity, specificity, positive and negative predictive values of MTBDRplus for INH were 82.6, 100, 100 and 98.7% respectively and for RIF 100%.

Conclusions: The Genotype MTBDRplus assay is easy to perform with a turnaround time of only 6 hours and is a useful tool for the management of tuberculosis, as it allows the detection of INH and RIF resistance in MTBC strains and, importantly, in clinical samples. On the other hand, DST with reference method is still required to reveal resistance/susceptibility to INH, RIF and the remaining anti-tuberculosis drugs.