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Title: Substantial time reduction in diagnosis of Mycobacterium tuberculosis rifampicin and isoniazid resistance by the application of a DNA strip hybridization assay in clinical samples

Dr. Panayotis 20646 Ioannidis reflabtsotiria@yahoo.gr¹, Dr. Dimitrios 20647 Papaventsis reflabtsotiria@yahoo.gr MD¹, Dr. Simona 20648 Karabela reflabtsotiria@yahoo.gr MD¹, Ioanna 20649 Marinou reflabtsotiria@yahoo.gr MD¹, Dr. Euthemia 20650 Konstantinidou reflabtsotiria@yahoo.gr MD¹, Ms. Marina 20651 Panagi reflabtsotiria@yahoo.gr¹, Mr. Anastasios 20655 Skourogrou reflabtsotiria@yahoo.gr¹, Georgios 20668 Dionellis dionellisgeorgios@hotmail.com MD², Prof. Dr Nikolaos 20674 Koulouris koulunik@med.uoa.gr MD² and Dr. Evangelos 20675 Vogiatzakis vogia1@otenet.gr MD¹. ¹ Microbiology Laboratory-National Reference Center for Mycobacteria, Sotiria Chest Diseases Hospital, Athens, Greece, 11527 and ² 1st Dept of Respiratory Medicine, University of Athens, Sotiria Chest Diseases Hospital, Athens, Greece, 11527 .

Body: The MTBDRplus (Hain Lifescience, Nehren, Germany) is a molecular assay detecting mutations involved in M. tuberculosis rifampicin (RMP) and isoniazid (INH) resistance, approved for application on culture isolates and smear-positive (AFB+) specimens¹. We evaluated its performance as a routine diagnostic assay directly on clinical specimens. Methods: Consecutive AFB+ and selected AFB- specimens, from high risk patients for drug resistance, were assayed. The results were compared to conventional drug susceptibility testing (DST). For time reduction estimation we counted the days elapsed before patient's first positive culture was available. Results: 475 specimens were analyzed. Interpretable MTBDRplus results were obtained for 331/400 (82.7%) AFB+, 33/70 (47%) AFB- and 1/5 (20%) microscopically suspicious specimens. We identified: 13 MDR, 28 INH resistant, 2 RMP resistant, and 2 rpoB polymorphic strains. Disagreement between DST and MTBDRplus mainly involved strains with inhA mutations (6/8) conferring resistance to low INH concentrations². The sensitivity, specificity, PPV and NPV values for RMP and INH resistance detection were 100%, 99, 6%, 92, 8%, 100% and 86, 6%, 96, 9%, 79%, 94% respectively. Substantial reduction in drug susceptibility diagnosis was recorded (14.1 ± 6.2 days). Conclusions: The MTBDRplus assay was informative for the great majority of AFB+ cases, highly accurate for screening RMP and INH resistance and its application achieved considerable reduction in diagnostic delay. ¹Hillemann D. et al. J. Clin. Microbiol. 2007, 45: 2635–2640 ²Hongling G. et al. J. Med. Microbiol. 2006, 55: 1527-1531.