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Abstract (poster session)

Evaluation of the new HyBeacon-based PCR assay, FluoroType MTB, for the direct detection of Mycobacterium tuberculosis in respiratory and non-respiratory specimens

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Objectives: The performance of the new FluoroType (FT) MTB assay (Hain Lifescience, Nehren, Germany) for the direct detection of Mycobacterium tuberculosis in respiratory and nonrespiratory specimens was evaluated. Results were compared to conventional liquid and solid culture media. In addition a subgroup of the specimens were also tested with the Cobas TaqMan (CT) MTB test (Roche, Mannheim, Germany). **Methods:** In total 261 NALC-decontaminated specimens were investigated with the FT MTB assay. Microscopy was performed directly from the patient specimens. After decontamination 500µl of the phosphate-buffered suspension were taken for inoculation of BACTEC MGIT medium and 100µl each for solid media (Löwenstein-Jensen, Stonebrink). For DNA extraction 700 µl of the suspension was incubated at 70°C for 15 min. DNA purification was performed fully automated on the GenoXtract system and the GXT DNA/RNA extraction kit (Hain Lifescience). Identification of cultured acid fast bacteria was performed with the GenoType MTBC and GenoType Mycobacteria CM/AS strip assays (Hain Lifescience). The new FT MTB test is based on HyBeacon fluorescence-technology and is performed on the FluoroCycler (Hain Lifescience). After PCR amplification melting curves are created with HyBeacon probes at probe specific temperatures. The FT MTB and the CT MTB assay were performed according to manufacturer's instructions. **Results:** 80 of 261 specimens were culture-positive for M. tuberculosis. FT MTB correctly identified 39 of 40 smear-positive, 30 of 31 smear-negative and 9 of 9 smear-scanty specimens. 2 specimens (one abscess-swab and one sputum) were negative with the FT MTB assay. In 181 culture negative specimens, FT MTB showed 179 correct negative results. 82 specimens were utilized for CT MTB assay, 26 were culture-positive for M. tuberculosis. CT MTB correctly identified 6 of 7 smear-positive, 25 of 26 smear-negative and 7 of 7 smear-scanty specimens. In 42 culture-negative specimens, CT MTB showed 42 correct negative results. Overall sensitivity, specificity, NPV and PPV were 97.5%, 98.8%, 98.9% and 97.5% with the FT MTB assay and 95.0%, 100%, 95.4% and 100% with the CT MTB-PCR respectively. Sensitivity in smear-negative specimens was 96.7% with the FT MTB test and 96.1% with the CT MTB test. **Conclusion:** Both PCR-assays, the new FluoroType MTB and the Cobas TaqMan evaluated for the direct detection of Mycobacterium tuberculosis provide sensitive and specific results in about 3 hours.