

P1171

Paper Poster Session VI

Tuberculosis - clinical issues

**Performance assessment of Anyplex plus MTB/NTM/MDR-TB detection kit for detection of mycobacteria and anti-tuberculosis drug susceptibility test**

T. Kim<sup>1</sup>, M. Lee<sup>1</sup>

<sup>1</sup>Chung-Ang University College of Medicine, Seoul, Korea

**Objectives:** Anyplex plus MTB/NTM/MDR-TB Detection kit (Seegene, Korea) is a real-time PCR assay for direct detection of *Mycobacterium tuberculosis* (MTB) and nontuberculous mycobacteria (NTM) and for identification of rifampin (RIF) and isoniazid (INH) resistance from various specimens. We evaluated the diagnostic performance of Anyplex plus MTB/NTM/MDR-TB Detection kit.

**Methods:** The target genes of Anyplex plus MTB/NTM Detection kit are *IS6110*, *MPB64*, and 16S rRNA. Anyplex plus MDR-TB Detection kit detects 15 mutations causing RIF resistance and 6 mutations causing INH resistance. To detect MTB/NTM, 557 samples were tested. The diagnostic performances of Anyplex plus MTB/NTM Detection kit were determined based on the overall results of culture, nucleic acid amplification tests (NAAT), radiologic, or clinical feature suggestive of mycobacterial infection. For drug susceptibility test (DST), 29 MTB isolates were tested. The diagnostic performances of Anyplex plus MDR-TB Detection kit were determined based on the conventional DST and sequence analysis.

**Results:** Sensitivity and specificity for MTB detection were 82.9% (63/76) and 99.4% (478/481). Those for NTM detection were 76.5% (13/17) and 89.6% (484/540). Sensitivity and specificity for RIF resistance detection were 100% (3/3) and 100% (26/26). Those for INH resistance detection were 83.3% (5/6) and 100% (23/23).

**Conclusions:** Anyplex plus MTB/NTM Detection kit showed good diagnostic performance for detection of MTB and NTM. In MTB positive cases, Anyplex plus MDR-TB Detection kit provided rapid and reliable results of drug resistance to RIF and INH.