2011 ESPID Meeting Abstract
June 7-11, The Hague, The Netherland

# A RAPID, COLLECTION-TO-DETECTION PCR SYSTEM FOR THE UNIVERSAL DETECTION OF *M. TUBERCULOSIS*

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**Background/aims:** *Mycobacterium tuberculosis* (MTB) is a highly transmissible bacterial pathogen with significant morbidity and mortality, particularly in HIV-infected patients. Emergence of multidrug resistant MTB strains has made diagnosis and treatment a high priority, particularly in Africa and developing countries. The 'gold standard' for MTB diagnostics is culture, a method requiring 4-8 weeks for detection. In previous studies, PrimeStore Molecular Transport Medium (MTM) rapidly killed MTB in sputum and facilitated DNA extraction and PCR detection. A rapid, real-time PCR detection assay was: 1) developed for universal species detection of MTB-strains, and 2) evaluated with MTB samples preserved in PrimeStore for DNA preservation at ambient temperature during prolonged shipment. **Methods:** A PCR assay was designed from the highly conserved IS6110 gene and integrated into PrimeMix, an all-inclusive, PCR blend. PCR detection was assessed from *M. tuberculosis* DNA preserved/stabilized in PrimeStore MTM from samples collected/shipped from Pretoria, South Africa to San Antonio, Texas, USA. **Results:** The PrimeMix Universal-MTB assay is highly specific, detecting 6 of 6 different spoligotyped strains of *M. tuberculosis,* with no cross-reactivity to 5 of 5 non-tuberculosis Mycobacterial strains. The assay is highly sensitive with a limit of detection of 1-10 template copies. Furthermore, MTB DNA and an Internal Positive Control DNA piece present in PrimeStore were preserved/detected by PCR (Ave $C_T$=15.29 and 28.2, respectively) from samples shipped at ambient temperature for 72 hours. **Conclusion:** This Universal-MTB assay could offer significant utility for rapid, point-of-care screening arising from TB infection in patients from rural areas and developing countries worldwide.