INTRODUCTION

- Tuberculosis (TB) is the top infectious disease killer worldwide, with 9.6 million people with TB disease and 1.5 million TB-related deaths in 2014.
- Over 95% of TB deaths occur in low- and middle-income countries.
- TB is a leading killer of HIV-positive people in 2015; 1 in 3 HIV deaths was due to TB.
- The Millennium Development Goal target of halting and reversing the TB epidemic by 2015 has been met globally. TB incidence has fallen by an average of 1.5% per year since 2000 and is now 18% lower than the level of 2000.
- A major obstacle to the effective treatment of individuals with TB disease is the accurate identification of Mycobacterium tuberculosis (MTB) and the presence of drug-resistant strains in an environment safe for the laboratory personnel.

AIM: Evaluate the Abbott RealTime MTB (qualitative MTB assay) and Abbott RealTime MTB RIF/INH Resistance assays (which detects Rif and INH resistance targeting rpoB, katG and inhA upstream stream promoter regions [Fig. 3 and 4]).

METHODS

- 100 adults provided sputum specimens; 17 were previously diagnosed with Rif resistant MTB on a non-study XpertMTB RIF/INH (GeneXpert); 44 were suspected of having drug sensitive TB disease based on the absence of Rif resistance on the non-study GeneXpert or clinical evaluation, and 39 were selected because they were considered not to have pulmonary TB (healthy controls).
- The lab was blind to the participants TB status.
- 3ml of sputum was collected and the following assays performed: Study GeneXpert, Abbott RealTime MTB, Abbott RealTime MTB RIF/INH Resistance assay and Hain GenoType MTBDRplus assay (Hain). Liquid Culture using the Mycobacterial Growth Indicator Tube (MGIT) system (Becton Dickinson) and indirect DST were the gold standards.
- Figure 1 and 2 show the algorithm used for TB detection and resistance identification, respectively.

RESULTS

Evaluate the Abbott RealTime MTB

For the detection of MTB compared to MGIT the diagnostic sensitivity was 100% and specificity was 95% (Table 1). There were 6 discrepancies that were positive on Abbott RealTime MTB assay, but Negative on MGIT Culture. Of these six, five were positive by either GeneXpert and/or Hain (Table 2):

- 6 subjects with discrepant results, 5 were HIV positive and had clinical TB diagnosis
- 2 had started TB treatment (1 and 2 days before testing).

Evaluate the Abbott RealTime MTB RIF/INH Resistance assay

- Of the 32 MGIT positive samples RIF and INH resistance was compared on the Abbott RealTime MTB RIF/INH Resistance assay to indirect DST.
- Between the two method there were 5 discrepancies for Rif resistance and 2 discrepancies for INH (Table 3).

CONCLUSION

- The Abbott RealTime MTB and Abbott RealTime MTB RIF/INH Resistance assays detected more MTB compared to culture and have a high level of sensitivity and specificity for detection of MTB and the diagnosis of Rif and INH resistance.
- The different resistance patterns observed between the genotypic and phenotypic assays is most likely a result of mutations not targeted for in the genotypic assay/probe primer mismatches or compensatory mutations in other areas of the TB gene that give the bacteria some selective advantage over the antibacterial presc.