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Room: Hall 3 (Posters & Exhibition)

Evaluation of the diagnostic performance of MTBDRplus VER 2.0 line probe assay for the detection of MDR-TB in sputum samples referred to National TB Reference Laboratory, Ethiopian Public Health Institute

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Background: Multi drug resistant tuberculosis(MDR-TB) is more difficult to diagnose and treat, leading to high mortality. Accurate and rapid detection of MDR-TB is critical for timely initiation of treatment. Evaluating new drug resistance diagnostic tools such as Genotype MTBDRplus VER 2.0 assay offer opportunity to scale up drug susceptibility testing(DST) capacity in Ethiopia.

Methods & Materials: A cross sectional study was conducted from December to August, 2015 on presumptive MDR-TB patients. Analysis of 72 smear positive and 197 smear negative sputum samples was done with Genotype MTBDRplus VER 2.0 assay and compared with the reference, BACTEC MGIT 960 culture and DST. Sensitivity, specificity, PPV and NPV of the MTBDRplus VER 2.0 assay was calculated, comparing the results with the reference method and results was interpreted based on 95% confidence interval, statistical significant was taken at p-value <0.05.

Results: The sensitivity, specificity, PPV and NPV of Genotype MTBDRplus VER 2.0 assay were 96.4, 100, 100 and 96.9%, respectively for the detection of MDR-TB from direct smear positive sputum samples. Only 14(54%) samples had valid results with LPA among the 26 smear negative culture positive samples. The remaining 8(30.6%) and 4(15.4%) were invalid and negative with LPA, respectively. The sensitivity and specificity of Genotype MTBDRplus VER 2.0 assay was 100% for the detection of MDR-TB among 14 direct smear negative and culture positive sputum samples. The most common mutations associated with RMP and INH resistance was S531L and S315TL, respectively. A single rare mutation (C15T/A16G) was also detected in this study.

Conclusion: The diagnostic performance of Genotype MTBDRplus VER 2.0 assay in direct smear positive sputum sample was highly sensitive and specific for early detection of MDR-TB. However, the diagnostic performance of Genotype MTBDRplus VER 2.0 assay in direct smear negative sputum sample was low and showed high level of invalid results so it is unlikely to implement Genotype MTBDRplus VER 2.0 assay for the detection of MDR-TB in direct smear negative sample in our routine settings until the method is optimized. Hence, large scale further studies are needed in direct smear negative samples.

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Insertion Sequence IS6110 mapping, a tool to characterise TB strains into genetic lineages

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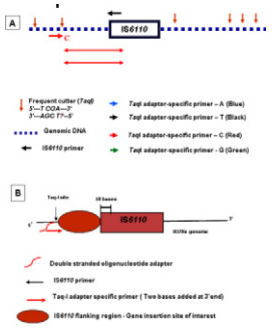
Background: Tuberculosis (TB) along with HIV infection is the major cause of mortality worldwide including the 29 million people in Nepal. The steady rise in the number of Multi-drug Resistant (MDR) TB cases in the last few years has increased the challenges facing the scientists and health professionals alike. With no previous epidemiological data available on transmission patterns of *Mycobacterium tuberculosis* complex (MTBC) in Nepal, the focus of this study is to categorise the TB samples for the first time using IS*6110* fluorescent amplified fragment length polymorphism (FAFLP) PCR into different genetic lineages.

Methods & Materials: The bacterial DNA from clinical isolates of 176 TB patients in Nepal along with the reference strain H37Rv were extracted using the CTAB method and subjected to FAFLP PCR, using four differentially labelled selective primers. The samples separated on the ABI Genetic Analyser 3730xl were then analysed using the PeakScanner software and were identified using their fluorescent tag. The 4-dye FAFLP data collected from the different profiles were later recorded in the BioNumerics software v6.1and compared with the reference global collection of TB samples.



Method schematic of 4-dye IS6110 FAFLP PCR. In the example shown above (A), red fragment is generated as TaqI -C anneals to the C base in the DNA where base C is amplified and in example (B) exact insertion of IS6110 in the Mtb genome is identified using

Results: Out of 176 samples analysed, 64 samples belong to the Central Asian (CAS) lineage or principal genetic group 1(PGG1), 33 samples belong to the Beijing lineage (PGG1) and the rest of the samples belong to other genetic groups – LAM, Haarlem, X (PGG2) and T (PGG3). Also, all but two of the sixteen insertion sites of H37Rv were mapped using this technique.