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Evaluation of new diagnostic methodology for the detection of second-line drug resistance in Mycobacterium tubercolosis clinical isolates

Gardee, Yasmin

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APPENDIX B: Data Analysis of Study Objectives

Objectives	Methodology – how?	Methodology – when?	Data needed	Statistical method/analysis
Phase 1: a) To determine the accuracy sensitivity, specificity, PPV & NPV of Genotype MTBDRsl VER 2.0 LPA b) To compare MTBDRsl VER 2.0 LPA with SL* phenotypic DST c) To compare Genotype MTBDR*sl* v2 LPA with sequencing results on characterised *M. tuberculosis* strains	Perform of Genotype MTBDRsl VER 2.0 LPA using characterized *M. tuberculosis* strains with (1) good representation of phenotypic resistance (2) well distributed genetic mutations to 2nd-line anti-TB agents	July – Dec 2015	**Method A**: Presence / absence of mutations in (FLQ) gyrA, gyrB & (SLID)** rrs, eis genes (categorical data) **Method B:** Resistance/Susceptibility to KM, AK, CAP (SLID), OFX, MOX (FLQ) (categorical data) **Method C:** Presence / absence of mutations in sequence results of strains	Contingency (2X2) Table - Sensitivity, Specificity, NPV, PPV k-Correlation between Method A & B k-Correlation between Method A & C
Phase 2: d) To verify the performance by selected NHLS TB labs of Genotype MTBDRsl VER 2.0 LPA e) To compare MTBDRsl VER 2.0 LPA with SL phenotypic DST	Selected NHLS Labs to perform Genotype MTBDRsl VER 2.0 LPA and phenotypic DST on standardized BD 2nd-line anti-TB agents using sub-set of characterized *M. tuberculosis* strains	Sept 2015 – July 2016	**Method A**: Presence / absence of mutations in (FLQ) gyrA, gyrB & (SLID) rrs, eis genes (categorical data) **Method B** Resistance/Susceptibility to KM, AK, CAP (SLID), OFX, MOX (FLQ) (categorical data)	Contingency (2X2) Table -, Sensitivity, Specificity, NPV, PPV k-Correlation between Method A & B
Phase 3: Prospective study f) To determine the accuracy of Genotype MTBDRsl LPA g) To compare MTBDRsl VER 2.0 LPA with routine-SL phenotypic DST in residual sputum sediment	Selected NHLS Labs to perform Genotype MTBDRsl VER 2.0 LPA and compare with phenotypic DST	Nov 2016 – Mar 2017	**Method A**: Presence / absence of mutations (FLQ) gyrA, gyrB & (SLID) rrs, eis genes (categorical data) **Method B** Resistance/Susceptibility to KM, AK, CAP (SLID), OFX, MOX (FLQ) (categorical data	Contingency (2X2) Table - Specificity, Sensitivity, NPV, PPV k-Correlation between Method A & B

*SL= second-line drugs; **SLID= second-line injectable drugs