

ABSTRACT

substantial human morbidity and mortality globally. About 10.4 million TB cases and 1.4 million deaths worldwide were reported in 2015. Kenya is among the 22 countries with highest TB burden. Microscopy is routinely used for *Mycobacterium tuberculosis bacilli* (*Mtb*) detection; however its sensitivity has been reported to be as low as 60% posing a problem for case detection. Rifampicin (RIF) is one of the major drugs for first line TB treatment; however, most patients tend to develop resistance thus making treatment a challenge. Culture method, which is the gold standard for diagnosis of *Mtb* and drug resistance, is time-consuming, limited and technically involving, thus delaying initiation treatment of TB. GeneXpert MTB/RIF and Line Probe assay (LPA) have been recommended by World Health Organization (WHO) for rapid diagnosis of *Mtb* and RIF mono resistance but their performance tend to differ from region to region. The study aimed at determining the sensitivity, specificity, positive and negative predictive values of GeneXpert MTB/RIF and LPA in *Mtb* detection; determining the sensitivity, specificity, positive and negative predictive values of GeneXpert MTB/RIF and LPA in RIF mono resistance detection and test the agreement between GeneXpert MTB/RIF, LPA with culture in *Mtb* and RIF mono-resistant detection. This was a cross-sectional study with sample size of 131 at 95% confidence level, done between November, 2016 and March, 2017. In the laboratory culture, drug susceptibility testing and molecular analysis using GeneXpert MTB/RIF and LPA was done. The sensitivity, specificity and predictive values were calculated using MGIT culture and an agreement was done by Cohen kappa values (0.01-0.20 indicating none to slight, 0.21-0.40 as fair, 0.41-0.60 as moderate, 0.61-0.80 as good and 0.81-1.0 as very good agreement). GeneXpert MTB/RIF showed sensitivity and specificity of 76% and 66% while positive and negative predictive values were 57% and 82% respectively while, LPA showed sensitivity and specificity of 98% and 71%, with positive and negative predictive values of 67% and 98% respectively in detection of *Mtb*. Regarding RIF mono-resistance, Gene Xpert MTB/RIF had a sensitivity and specificity of 33% and 96%, with positive and negative predictive values of 33% and 94% respectively, whereas LPA reported a sensitivity and specificity of 100% and 100% with positive and negative predictive values of 100% and 100% respectively. In regards to diagnosis, there was a fair agreement in GeneXpert MTB/RIF and culture (Kappa value, 0.388) with LPA and culture reporting (Kappa value, 0.628). There was a fair agreement between GeneXpert MTB/RIF and culture (Kappa value, 0.275) as compared to a very good agreement between LPA and culture (Kappa value, 1.00) for detection of RIF mono-resistance. In conclusion, LPA diagnostically outperformed GeneXpert MTB/RIF in both *Mtb* and RIF mono-resistance diagnosis and that LPA is a good alternative to culture with regards to detection of RIF mono resistance in facilities without culture. The study recommends the up-scaling of LPA for both *Mtb* detection and RIF mono resistance, and development of country specific probes for local population in *Mtb* and RIF mono resistance detection.