

Detection of resistance to second-line antituberculosis drugs using Genotype MTBDRs/ assay

Background

WHO has recommended that the Genotype MTBDRs/ assay be used as a rule in test for XDR-TB and can guide infection control precautions while waiting for confirmatory results from conventional phenotypic testing. In India XDR-TB is diagnosed by conventional phenotypic testing method at the level of national reference laboratories. The aim of this research is to study the feasibility of diagnosing XDR-TB in intermediate reference laboratories by using Genotype MTBDRs/ assay.

Methods

Damien TB Research Centre (DTRC), Nellore, India sends the samples from patients with presumptive XDR-TB to National Institute for Research in Tuberculosis (NIRT), Chennai for second line DST. In 2014, 83 samples were screened with MTBDRsl at DTRC, Nellore and the results were compared with conventional phenotypic results from NIRT, Chennai. The GenoType MTBDRs/ assay was done according to the instructions provided by manufacturer (Hain Lifescience, Germany). If all of the wild-type probes in an isolate showed positive staining and the mutant probes produced no staining, the isolate was considered susceptible. The isolate was considered resistant if at least one wild-type probe was absent or if any mutant probe was present.

Results

Conventional phenotypic and MTBDRsl assay results were available for 83 samples from patients with presumptive XDR-TB. Sensitivity and specificity for Ofloxacin resistance was 82% and 100% respectively. Sensitivity and specificity for Kanamycin resistance was 91% and 93.8% respectively. Positive predictive value for Ofloxacin and Kanamycin was found to be 100% and 98.4%. Negative predictive value for Ofloxacin and Kanamycin was 81.8% and 71.4%.

Conclusion

The results are consistent with WHO recommendation on the use of MTBDRs/ for ruling in XDR TB. Since there are no false positives in Genotype MTBDRs/ assay, it can be used to screen MDR-TB patients at the time of treatment initiation for diagnosing XDR-TB. This will help in preventing the transmission of XDR-TB by early diagnosis, treatment and following appropriate infection control precautions.