Abstract

Tuberculosis (TB) and multidrug and extensively drug-resistant (DR) TB are important public health problems that are spreading worldwide. The aims of this study were to determine the sensitivity and specificity of the GenoType® MTBDRplus assay from smear-positive clinical specimens and isolates and to explore its possible application in routine work. Clinical samples were previously decontaminated using NaOH-N-acetyl-L-cystein or NaOH-ClNa hypertonic solution for Ziehl-Neelsen staining and cultures. The leftover sediments of smear-positive samples were stored at –20 ºC, 70 of which were selected to be included in this study according to their DR profile. Thirty DR Mycobacterium tuberculosis isolates were also assessed. Sequencing was used as gold standard to detect mutations conferring isoniazid (INH) and rifampicin (RIF) resistance. Valid results were obtained in 94.0% of the samples and 85.5% (53/62) of the INH-R samples were properly identified. Mutations in the katGS315T gene and inhA C-15T gene promoter region were present in 59.7% (37/62) and 25.8% (16/62) of the INH-R samples, respectively. The system could also identify 97.7% (41/42) of the RIF-R samples; the mutations found were rpoBS531L (66.7%, 28/42), D516V (19.0%, 8/42), H526Y and S531P/W (4.8%, 2/42 each one), and S522L/Q (2.4%, 1/42). A 98.8% concordance between the GenoType assay and sequencing was obtained. GenoType® MTBDRplus has demonstrated to be easy to implement and to perform in clinical laboratories and useful for a rapid detection of DR M. tuberculosis from decontaminated sputa and clinical isolates. Therefore, this assay could be applied as a rapid tool to predict INH-R and/or RIF-R in DR risk cases.

Keywords

Molecular detection, multidrug-resistant tuberculosis, GenoType® MTBDRplus.