

TITLE: PERFORMANCE EVALUATION OF THE GENEXPERT® MTB/RIF ASSAY FOR RAPID DIAGNOSIS TUBERCULOSIS IN SPUTUM SAMPLES

AUTORS: SAPUCCI, F.H.F.¹; D'ANDREA, L.A.Z.¹; SAEKI, E.K.¹; LIMA, P.E.S.¹; ALFREDO, M.X.¹; MIZUSAKI, S.¹; SILVA, M.C.M.F.¹; ROMÃO, M.M.¹

INSTITUTION: 1. INSTITUTO ADOLFO LUTZ - CENTRO DE LABORATÓRIO REGIONAL IAL PRESIDENTE PRUDENTE-V (Avenida Cel. José Marcondes, 2.357 – Jd. Paulistano – Presidente Prudente-SP CEP: 19013-050).

The *Mycobacterium tuberculosis* complex comprises eight species, among them the most important are: *M. tuberculosis*, *M. bovis* and *M. africanum*. *M. tuberculosis* is the main etiological agent of pulmonary tuberculosis in humans. The GeneXpert® MTB/RIF assay is used to simultaneously detect *M. tuberculosis* complex and to screen for strains resistant to the drug rifampicin, which was introduced in Brazil by the Ministry of Health in 2014. This work aimed at evaluating the results of GeneXpert® MTB / RIF and comparing against the results obtained in the culture for the diagnosis of pulmonary tuberculosis (TB). The types of errors, invalid and the utilization rate of cartridges were also evaluated. Between September 2014 and September 2015, the results of 1,614 samples of sputum from four prison patients with suspect of pulmonary tuberculosis were analyzed. The samples belonged to the Regional Health Division XI-RRAS 11 Presidente Prudente and were processed in the Regional Laboratory Center IAL of Presidente Prudente / SP. Methods GeneXpert® MTB/RIF (Cepheid) and automated MGIT culture of Becton Dickinson (BD) with decontamination through the Petroff method were used. Comparing the results obtained in GeneXpert® MTB/RIF against the "gold standard" Culture Bactec MGIT® 960° BD, we obtained 99.34% specificity, sensitivity of 71.83%, 98.10% and concordance index K = 0.76. The cartridge recovery rate was 98.23%. From 1,614 patients results obtained, 1,643 cartridges were used, of which 29 errors and invalid were identified. About the errors, five different types were identified. As for invalid cartridges, 17 have been identified. The GeneXpert® MTB/RIF assay, additionally to bringing greater flexibility to the diagnosis in about two hours, allowed the early treatment to take place and thus breaking the chain of transmission of TB. It is extremely important use this rapid assay in identifying individuals with TB, especially in prison system and HIV patients.

Keywords: *Mycobacterium tuberculosis*, real-time PCR, Tuberculosis.

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