Utility of GeneXpert MTB/RIF assay for the diagnosis of pulmonary and extra-pulmonary tuberculosis, A report from Egypt

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مكان النشر:

Novel Research in Microbiology Journal Article 8, Volume 5, Issue 1, January and February 2021, Page 1146-1161

Published date: February, 2021

## **Abstract**

Early diagnosis of tuberculosis continues to be a challenge for clinicians. The World Health Organization (WHO) guidelines recommend the application of GeneXpert MTB/RIF in extra-pulmonary tuberculosis (EPTB) diagnosis. This study aimed to test and compare the accuracy of the GeneXpert MTB/RIF assay to diagnose pulmonary tuberculosis (PTB) and EPTB, compared to bacterial culture and to composite reference standard (CRS). The GeneXpert assay diagnosed tuberculosis (TB) in 19.5 % of patients. With reference to bacterial culture, the sensitivity of this assay for detection of the pulmonary and extrapulmonary specimens was perfect. For pulmonary specimens, on using CRS; the detected sensitivity and specificity of the GeneXpert assay were 78.3 % and 99.1 %, respectively. However, for extra-pulmonary specimens, the sensitivity and specificity of the GeneXpert assay were 37.1 % and 99 %, respectively. In the current study, the GeneXpert assay showed almost perfect agreement with the bacterial culture for TB diagnosis. The diagnostic accuracy of the GeneXpert assay was high in ruling in, but not in ruling out of EPTB.