



Evaluating the efficacy of stool sample on Xpert MTB/RIF Ultra and its comparison with other sample types by meta-analysis for TB diagnostics

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Abstract

Precise and timely detection of tuberculosis (TB) is crucial to reduce transmission. This study aims to assess the accuracy of Xpert MTB/RIF Ultra on stool samples and systematically review the performance of Xpert MTB/RIF Ultra with different sample types by meta-analysis. Stool samples of smear-negative pulmonary TB (PTB), cervical lymph node TB, and abdominal TB patients were tested on the Xpert MTB/RIF Ultra system. Meta-analysis was performed on a set of 44 studies. Data were grouped by sample type, and the pooled sensitivity and specificity of Xpert MTB/RIF Ultra were calculated. The sensitivity of Xpert MTB/RIF Ultra with stool samples was 100% for smear-negative PTB, 27.27% for cervical lymph node TB, and 50% for abdominal TB patients, with 100% specificity for all included TB groups. The summary estimate for all PTB samples showed 84.2% sensitivity and 94.5% specificity, and EPTB samples showed 88.6% sensitivity and 96.4% specificity. Among all sample types included in our meta-analysis, urine showed the best performance for EPTB diagnosis. This pilot study supports the use of stool as an alternative non-invasive sample on Xpert MTB/RIF Ultra for rapid testing, suitable for both PTB and EPTB diagnosis.

Keywords Xpert MTB/RIF Ultra · Stool · Pulmonary tuberculosis · Extra-pulmonary tuberculosis · Cervical lymph node TB · Abdominal TB · Meta-analysis

Introduction

Tuberculosis (TB) is an ancient disease that remains one of the deadliest infections, with an estimated 9.9 million newly diagnosed TB cases and 1.5 million TB deaths worldwide in 2020 [1]. This is despite the fact that directly observed treatment short-course (DOTS) can successfully cure drug-susceptible TB [2]. A major deterrent in eradicating this disease has been its timely diagnosis, especially for paucibacillary infections such as extra-pulmonary TB (EPTB) where the diagnosis depends on the quantity and quality of the sample. In recent years, the incidence of EPTB disease has consistently increased, accounting for up to 16% of the total disease burden [3], yet we still heavily depend on the invasive biopsy specimens with moderate clinical sensitivity for diagnosis.

The use of TB culture, often regarded as the gold standard in diagnosis, is hindered by time constraints and low efficacy due to the paucity of bacteria in samples [4]. The

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