# Diagnostic accuracy of the Xpert® MTB/RIF cycle threshold level to predict smear positivity : a meta-analysis

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**Abstract:**

Setting: Xpert® MTB/RIF is the most widely used molecular assay for rapid diagnosis of tuberculosis (TB). The number of polymerase chain reaction cycles after which detectable product is generated (cycle threshold value, CT) correlates with the bacillary burden.OBJECTIVE To investigate the association between Xpert CT values and smear status through a systematic review and individual-level data meta-analysis.

Design: Studies on the association between CT values and smear status were included in a descriptive systematic review. Authors of studies including smear, culture and Xpert results were asked for individual-level data, and receiver operating characteristic curves were calculated.

Results: Of 918 citations, 10 were included in the descriptive systematic review. Fifteen data sets from studies potentially relevant for individual-level data meta-analysis provided individual-level data (7511 samples from 4447 patients); 1212 patients had positive Xpert results for at least one respiratory sample (1859 samples overall). ROC analysis revealed an area under the curve (AUC) of 0.85 (95%CI 0.82-0.87). Cut-off CT values of 27.7 and 31.8 yielded sensitivities of 85% (95%CI 83-87) and 95% (95%CI 94-96) and specificities of 67% (95%CI 66-77) and 35% (95%CI 30-41) for smear-positive samples.

Conclusion: Xpert CT values and smear status were strongly associated. However, diagnostic accuracy at set cut-off CT values of 27.7 or 31.8 would not replace smear microscopy. How CT values compare with smear microscopy in predicting infectiousness remains to be seen.

**Keywords:**
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