

# **DIAGNOSTIC ACCURACY OF IN-HOUSE PCR FOR SMEAR-POSITIVE PULMONARY TUBERCULOSIS: META-ANALYSIS AND META-REGRESSION.**

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In-house PCR (hPCR) could speed the differential diagnosis between tuberculosis (TB) and non-tuberculous mycobacterial (NTM) disease in patients with positive smear and pulmonary infiltrates, but its reported accuracy fluctuates across studies. We conducted a systematic review and meta-analysis of hPCR sensitivity and specificity for smear-positive TB diagnosis, using culture as the reference standard. After searching English language studies in MEDLINE and EMBASE, we estimated cumulative accuracy by means of summary receiver operating characteristic analysis. The possible influence of hPCR procedures and study methodological features on accuracy was explored by univariate meta-regression, followed by multivariate adjustment of items selected as significant. Thirty-five articles (1991-2006) met the inclusion criteria. The pooled estimates of diagnostic odds ratio, sensitivity and specificity (random effect model) were, respectively, 60 (confidence interval [CI] 29-123), 0.96 (CI 0.95-0.97) and 0.81 (CI 0.78-0.84), but significant variations (mainly in specificity) limit their clinical applicability. Quality of reference test, detection method and real-time PCR use explained some of the observed heterogeneity. Probably due to the limited study power of our meta-analysis and to the wide differences in both laboratory techniques and methodological quality, only real-time PCR displayed a positive impact on accuracy also in the multivariate model. Currently, hPCR can be confidently used to exclude TB in smear-positive patients, but its low specificity could lead to erroneous initiation of therapy, isolation and contact investigation. As the inclusion of samples from treated patients could have artificially reduced specificity, future studies should report mycobacterial culture results for each TB and non-TB sample analyzed.

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