

# Performance of rapid rk39 tests for the diagnosis of Visceral Leishmaniasis in Ethiopia: A systematic Review and Meta-Analysis

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## Abstract

**Background:** Visceral Leishmaniasis (VL) is a severely neglected disease affecting millions of people with high mortality if left untreated. In Ethiopia, the primary laboratory diagnosis of VL is by using rK39-based rapid diagnostic tests (RDT). Different RDT brands are available with very variable performance and studies from Ethiopia showed a very wide range of sensitivity and specificity. Therefore, the objective of this systematic review and meta-analysis was to determine the pooled sensitivity and specificity of rk39 RDT in Ethiopia.

**Method:** PUBMED, EMBASE, and google scholar were searched using predefined search terms to systematically retrieve all relevant articles. Eligibility screening was independently performed by two members and disparities were solved by other reviewers in the team. Methodological quality was also checked using the quality assessment of diagnostic accuracy studies (QUADAS-2) checklists.

**Results:** A total of 664 articles were retrieved from the PUBMED, EMBASE and google scholar online database searches. After removal of duplicates and initial, and final selection steps, 12 articles were included in the study. The overall pooled sensitivity and specificity of all rk39-based RDTs reported to diagnose VL in Ethiopia were 88.0 % ( 95%CI: 86.0% to 89.0%) and 84.0 % ( 95% CI: 82.0% to 86.0%), respectively. The sensitivity and specificity of the two rk39-based commercial test kits were for DiaMed RDT: 86.9% (95% CI: 84.3% to 89.1%) and 82.2 % ( 95% CI: 79.3% to 85.0%), and for InBios RDT: 80.0% (95% CI: 77.0% to 82.8%) and 97.4% (95% CI: 95.0% to 98.8%), respectively.

**Conclusion:** The sensitivity and specificity of rk39-based RDTs for the diagnosis of VL in Ethiopia were found to be lower compared to other parts of the world. However, the sensitivity of rk39-based RDTs was higher than in other east African countries. On the other hand, the specificity was lower than the east Africa studies (91.1%). The sensitivity and specificity of the rk39-based RDTs were in northern Ethiopia notably lower than in the other parts of Ethiopia.

**Keywords:** VL, rk39, Sensitivity, Specificity, Ethiopia