



Protocol for the Validation of a Rapid Diagnostic Test for Typhoid Fever Against Blood Culture in Febrile Paediatric Outpatients in Conakry, Guinea

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Published: 11 April 2012 | **Received:** 26 October 2011 | **Accepted:** 14 February 2012

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DOI: [10.5281/zenodo.18529769](https://doi.org/10.5281/zenodo.18529769)

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Abstract

Typhoid fever is a substantial public health burden in sub-Saharan Africa, disproportionately affecting children. In Guinea, diagnosis typically relies on clinical suspicion, contributing to antibiotic overuse and imprecise burden estimates. Blood culture, the reference standard, is seldom available in peripheral health facilities. Accessible and accurate point-of-care diagnostics are needed to guide appropriate clinical management. This protocol outlines a study to validate the diagnostic accuracy of a commercially available rapid diagnostic test (RDT) for typhoid fever in a primary care setting. The primary objective is to determine the sensitivity and specificity of the RDT against blood culture in febrile paediatric outpatients. A cross-sectional diagnostic accuracy study will be conducted at multiple outpatient departments in Conakry. We will consecutively enrol febrile children aged 6 months to 15 years. Each participant will provide a blood sample for the index RDT, performed immediately, and for blood culture as the reference standard. Laboratory personnel will be blinded to the results of the alternative test. The sample size is calculated to precisely estimate sensitivity and specificity. Data will be analysed to determine diagnostic accuracy metrics with 95% confidence intervals. This is a study protocol; no empirical findings are available. Anticipated results will include the calculated sensitivity and specificity of the RDT against the blood culture reference standard. The study will generate essential evidence on the field performance of a typhoid RDT in a typical West African outpatient setting. This evidence will inform considerations regarding its potential integration into fever management algorithms. If the RDT meets pre-defined accuracy thresholds, we will recommend its evaluation in a larger implementation study. Findings will be disseminated to the Guinean Ministry of Health and relevant stakeholders. typhoid fever, diagnostic accuracy, rapid diagnostic test, blood culture, paediatrics, Guinea, outpatient This protocol describes a study designed to produce locally relevant evidence to address a critical diagnostic gap in the management of febrile illness in Guinean children.

Keywords: *Typhoid fever, Diagnostic test validation, Blood culture, Paediatric, Sub-Saharan Africa, Febrile illness, Outpatient*

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