Reviewer’s report

Title: Performance of Loop-Mediated Isothermal Amplification assay in the diagnosis of pulmonary tuberculosis in a high prevalence TB/HIV rural setting in Uganda

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Reviewer: Paul Drain

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Review for BMC Infectious Diseases

Title: Performance of Loop-Mediated Isothermal Amplification assay in the diagnosis of pulmonary tuberculosis in a high prevalence TB/HIV rural setting in Uganda

October 21, 2017

The authors conducted a diagnostic accuracy study of TB-LAMP, a novel isothermal amplification assay of TB genomes, for accessible point-of-need testing for TB. Overall, among patients with TB symptoms, the diagnostic sensitivity and specificity of the test was limited, when compared to Tb culture. Overall, the test showed rather low sensitivity among those with smear-negative disease, which is often the majority of people who would benefit from Tb testing. The study is helpful by including a comparison to the GeneXpert, but is limited by not comparing TB-LAMP to the urine LAM assay.

The authors concluded that sample transportation reduced the sensitivity of the test. However, the sensitivity may be related to the bacillary burden of disease, which does not appear to have been measured in this study. I would suggest the authors remove this conclusion from their abstract.

The methodology was to use 'left-over expectorated sputum' which may have limited the sensitivity of the test. In addition, it appears that only 1 sputum samples was obtained. These limitations should be discussed in more detail in the Discussion.

Overall, this is a nice manuscript and I have no major suggested changes.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes
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