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

Version: 0 Date: 29 Oct 2017

Reviewer: Vineel Reddy

Reviewer’s report:

1. Earlier clinical studies and meta analysis (Nagai et al 2016 sci Rep) shows that LAMP test has sensitivity close to 75-80%. Why this study has sensitivity close to 62% even though the sample collection and testing is done in Hospital (N=126) and the overall sensitivity has dropped to 55% (N=233). The low sensitivity of TB-LAMP results shown in this study is a bit concern. In addition sensitivity of LAMP in smear negative (N=190) is also very low (24.4%) compared to previous studies.

2. Does using TB-LAMP test have advantage over smear microscopy in diagnosing TB in patients who are already infected with HIV?. Does authors checked the comparison of LAMP with smear microscopy in HIV-TB patients also?. HIV TB co-infection seems to be major concern in the area.

3. Request authors to include significant "p" values wherever required in text as well as tables.

4. Line 50-51. Can rephrase the sentence for the sake of clarity. "TB-LAMP was performed by a technician after a week of training in the district hospital who had no prior experience in the technology".

5. Authors need to mention about TB-LAMP specificity and sensitivity at the end of abstract rather than smear microscopy data.

6. Methods section is written too elaborated. Especially TB-LAMP section. Authors can consider consizing. Authors did not mention about the primers used in TB-LAMP.

7. Authors need to mention about MGIT/LJ in the laboratory procedures.

8. Line 178. What does powder means? Authors can explain clearly.

9. Authors can move declaration (ethics approval and consent to participate) to the methods section.

10. Line 255. Could not find 49 (21%) in the tables. Need to check.
Lines 288-269. Smear positive (AFB) and smear negative numbers need to be added in table 1 for the sake of clarity. What was the reason for that low sputum smear positive for AFB in 18.5% (43/233) participants.

Line 289. Authors need to add TB-LAMP also in the line.

Lines 314-315. Is this data from reference.? If that is true then authors need to mention that Boehme's et al., showed that….

Line 333-335. Authors need to mention time factor in this sentence for the sake of clarity. Because single person has to setup the room and perform the tests which might cause delay in processing the samples within time.

Table 1. Authors can include females data, New TB treatment data numbers in table 1.

Table 2. Authors can include smear positive data in table 2.

1. Authors did not mentioned about HIV-infected data in text. Can be removed from table2.

2. LJ, MGIT can be elaborated in table legend.

Table 3. FM/ZN can be elaborated in table legend.

Previous clinical studies that used LAMP assay have not been cited in this study. References need to be up-to-date and formatted.

Affiliation no.7 is not assigned to author.

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

No

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

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

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