Reviewer’s report

Title: A novel detection device for Mycobacterium tuberculosis antigen in breath

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Reviewer: Alamelu Raja

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Comments on the manuscript titled “A novel detection device for Mycobacterium tuberculosis in breath” by Ruth McNerney et al.

The manuscript evaluates the diagnostic potential of a novel device, TB breath analyzer, to detect M. tuberculosis Antigen 85 complex in the breath of TB patients and demonstrates its use under field conditions in an area of high TB incidence (Ethiopia). This is the first report of an easy, portable, “Point of care” test.

This is a preliminary report and no conclusive recommendations can be drawn based on the rather smaller numbers. Based on the results, it has been possible for the authors only to speculate that the device may be useful, along with smear results.

Major compulsory revisions:

1. It has been repeatedly stressed in various sections of the manuscript, quoting references that there is variability in the extent of bacilli shed at various times. That is why usually 3 sputa are collected for maximum positivity. When such is the situation, measuring at more than one time in this preliminary study, will throw some light on the real value of the test.

2. The breathalyzer results are obtained only once from each patient. Is any information available from the manufacturers about the reproducibility?

3. Is it known from the manufacturers as to the best time of the day for measurements using Breathalyser? Were all patients tested at similar time of the day?

4. Are there any cost calculations available for a single Breathalyser test, as compared to sputum test?

5. How were the haemoglobin, ESR and WBC counts made use of?

6. Is it known from the manufacturers, what is the minimum amount of antigen detected by the device?

7. 6 of the smear positive TB are negative for Breathalyser test (~30%). How do the positivity and negativity correlate with the smear 1+, 2+ and 3+ grading? 6 of the non-TB are positive for the test (~21%), restricting the specificity. It is well
known that Antigen 85 complex is not a M. tuberculosis specific antigen. How does it correlate with the prevalence of environmental mycobacteria? The discussion must be expanded to include these points.

8. The discussion must also elaborate on what the test measures in non-TB patients. If it is only Antigen 85, are the falsely positive patients close contacts of TB patients? If so, what is the role of this technique in a high endemic situation with a large number of latent TB?

9. Since the device alone in the absence of smear results, gives only ~75% sensitivity, to recommend the devise in cases like childhood TB, where it is difficult to obtain sputum, is not agreeable, with the present results.

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests