Author's response to reviews

Title: Performance evaluation of three commercial molecular assays for the detection of Mycobacterium tuberculosis from clinical specimens in a high TB-HIV-burden setting

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Version: 5 Date: 9 October 2015

Author's response to reviews: see over
Dear Editor

Re: Performance evaluation of three commercial molecular assays for the detection of *Mycobacterium tuberculosis* from clinical specimens in a high TB-HIV-burden setting

Thank you for considering our work for publication in the *BMC Infectious Diseases* journal. We provide below a point by point response to your concerns. In addition we submit a revised version of the manuscript.

We look forward to further feedback.

Kind regards

Dr F Ismail

**Editor’s concerns**

1. Thank you for addressing the question about informed consent from the patients in your manuscript. Could you however please expand that section and clarify if, when the samples were taken from the patients, they were aware that the samples would be stored and could potentially be used for medical research.

   - Patients with presumptive TB in the public health services in South Africa have specimens submitted by the attending health care worker to the laboratory for TB investigations which include smear and culture and more recently Xpert MTB/Rif. These specimens are processed for the requested test at the laboratory and reported. Remnant sediments are stored routinely for repeat TB testing should it be required as a standard practice. Patients are aware that their samples will be tested for TB but would not be aware of the specific TB tests performed routinely nor of the tests performed on the remnant stored sediments used in this study. This study was retrospective in nature and finding patients in the local context to gain informed context is often not possible as tracing information is inaccurate. Similar challenges are also experienced for routinely tested positive patients. However, we sought ethical
approval from the Faculty of Health Sciences Research Ethics Committee to waive informed consent to use these sediments for this laboratory based evaluation.

Could you also clarify in the manuscript if it was the ethical committee approving your study protocol that provided a waiver of the requirement for informed consent. If this is not the case, can you please add a reference for the regulations stating that this type of studies do not require informed consent in South Africa.

- This is clarified in the methods section: lines 134-138.
- The Faculty of Health Sciences Research Ethics Committee complies with the SA National Act 61 of 2003 as it pertains to health research and the United States Code of Federal Regulations Title 45 and 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

2. Section titles

Please change section title 'Introduction' to 'Background', and section title 'Materials and Methods' to 'Methods'.

- These changes have been implemented in the text.