Reviewers report

Title: Evaluation of Mycobacterium tuberculosis viability in OMNiGene-SPUTUM reagent upon multi-day transport at ambient temperature

Version: 0 Date: 20 Jul 2017

Reviewer: Max Salfinger

Reviewers report:

The authors study a very important aspect of the laboratory diagnosis of tuberculosis, the pre-analytical phase.

Title: Is the title indeed appropriate? multi-day transport at ambient temperature?

Line 77-time period/season of the study?

Line 78-first assessed by smear microscopy - direct or concentrated?

Line 81-processed for MGIT, reference 5 recommends MGIT and LJ - was a LJ inoculated as well?

Line 83-MGIT with PANTA?

Line 84-what is the CPC concentration in the OM-S reagent?

Line 87-shipped in ambient temperature… how long were the samples in transit? To which temperature exposed during transit? Overnight courier or regular mail?

Line 88-how were the samples stored and at which temperature (samples for Italy)?

Line 90-are there any studies published on the effect of CPC on MGIT?

Line 93-instead of 'DE' use Germany
According to Table 1, there are only 37 TB positive cultures and not 42 - please clarify.

Contamination rate is 13%; however, it should be <10% according to reference #5 - any explanations? This is concerning since these samples were collected in-house.

Among 48 AFB smear positive samples, 33 resp. 35 were culture positive - does this mean 15 resp. 13 samples were AFB positive and culture negative or AFB positive and culture positive for nontuberculous mycobacteria (NTM)? Please provide more details.

9 resp. 10 were AFB negative and culture positive for TB. With OM-S, there were a total of 42 TB culture positive and with conventional a total of 45. The proportion of AFB smear positive is 33/42 (79%) for OM-S and 35/45 (78%) for conventional. While the culture positivity of 13% resp. 14% is reasonable for samples from TB suspects, the AFB smear positivity of 79% resp. 78% is high. Any explanations?

Replace 'DE' with Germany

Out of 51 specimens tested… according to Line 94, only the samples from TB confirmed cases were processed for LPA [there are only 48 TB positive cultures], please clarify.

As far as this reviewer understands, the authors compared only samples at most 1 day at ambient temperature (in-house) versus several weeks at ambient (25C) temperature. The real challenge is the field experience with uncontrolled temperature exposure during shipping; however, this aspect has not been studied.

17.7%, please provide the numerator and denominator.

Discussion: Include Tazir M et al Tubercle 1979 60(1):31-36

References #6 and #8 are identical

Reference #11 not referenced in text
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

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.

Not relevant to this manuscript

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Please indicate the quality of language in the manuscript:

Acceptable

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