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## Rapid detection of *Mycobacterium tuberculosis* complex in sputum Samples using PURE TB-LAMP assay

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### ARTICLE INFO

#### Article history:

Received 19 September 2016

Accepted 23 September 2016

Available online xxxx

#### Keywords:

Diagnosis

TB-LAMP assay

Tuberculosis

Ziehl-Neelsen staining

### ABSTRACT

**Objective/background:** Lack of rapid and accurate diagnostic testing is a critical obstacle to global tuberculosis (TB) control. Sensitivity of sputum smear microscopy (SSM) is not optimal; however, it remains the most prevalent tool for TB confirmation in poor countries. As a part of passive case finding of TB detection, this study was conducted to determine the clinical performance of PURE TB-LAMP assay using liquid culture medium as the gold standard.

**Methods:** Centre Antituberculeux de Yopougon is one of the 17 intermediate Tuberculosis centers in Côte d'Ivoire. A standardized questionnaire was submitted to patients with signs and symptoms consistent with tuberculosis by a trained caregiver. After obtaining signed consent forms, sputum samples were collected according to National TB Control Programme guidelines (spot-morning). SSM after Ziehl-Neelsen staining and TB-LAMP assay were blindly performed on the first sample. Samples transported to Institut Pasteur de Côte d'Ivoire were decontaminated according to the N-acetyl-L-Cystein method. In Mycobacteria Growth Indicator Tube (MGIT), 500 mL of pellets were inoculated and incubated in the MGIT 960 system. MPT64 antigen was detected in positive cultures.

**Results:** Of the 500 patients enrolled, 469 (232 men and 239 women) patients were included. The mean ages of men and women were 36.9 (15–86) and 37.3 (15–37.3) years, respectively. There were 56 (12.2%) HIV-infected patients, including 14 women. Clinical isolates of *M. tuberculosis* complex were detected for 157 (33.5%) patients. Compared with culturing, the overall sensitivity and specificity of SSM were 86% (95% confidence interval [CI] = 81–91) and 96% (95% CI = 94–98), respectively. The overall sensitivity and specificity for TB-LAMP was 92% (95% CI = 0.88–0.96) and 94% (95% CI = 0.91–0.97), respectively. Positive likelihood ratios for TB-LAMP and SSM were 15.3 and 21.5, respectively, and negative likelihood ratios for TB-LAMP and SSM were 0.09 and 0.15, respectively.

Among the 469 patients, active tuberculosis was detected using TB-LAMP assay and SSM in 162 (34.5%) and 147 (31.3%) patients, respectively.

**Conclusion:** For accurate diagnostic of pulmonary TB, TB-LAMP could be used as a tool of the first intention.

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Peer review under responsibility of Asian African Society for Mycobacteriology.

<http://dx.doi.org/10.1016/j.ijmyco.2016.09.025>

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**Conflicts of interest**

None of the authors has a financial relationship with a commercial entity.