Background

- Developing countries
  - Most patients are living in areas with access to direct smear microscopy only to confirm TB
  - Culture available only in national/regional TB laboratory

- High prevalence of TB and HIV co-infected patients
  - Lower sensitivity of direct smear microscopy (50%)
  - Risk of under and late TB diagnosis
  - Urgent need for better diagnostic test for smear-negative patients

Rationale

Reasons for selecting FASTPlaqueTB™ test for evaluation

- 2 days test
- According to literature, detects 50 to 87% smear-negative culture-positive cases
- Presented by the Manufacturer as potentially suitable for district laboratory
- No multiplication of Mycobacterium tuberculosis bacilli
- To evaluate the feasibility of FASTPlaqueTB™ test in a laboratory performing in routine only direct smear-microscopy

Methods

- Laboratory procedure
  - Collection of 1 spot sputum specimen
  - Decontamination: NALC/NaOH followed by Voluntary Counselling HIV Test
  - Working with a Laminar Flow Cabinet (LFC)
  - Move of LFC to a separate room with restricted access
  - Maintenance of LFC by technician from South Africa

- Outcomes
  - Sensitivity, specificity and predictive values
  - Inter reader reliability
  - Very good agreement if Kappa test >0.80
  - Feasibility criteria

- Time between specimen collection and result
  - 2 to 9 days because tests were performed only once a week to prevent wasting of tests and reagents (kits of 10 tests)

- Cost within the study context
  - The test costs 167€/patient, 60% being extra-cost to the cost of the FASTPlaqueTB™ test

Results of pilot study

- High contamination rate
  - FASTPlaqueTB™ 99.6% (44/44)
  - Culture 21.7% (10/46)

- Modifications before starting inclusions
  - Retraining of laboratory technologists in:
    - Aseptic techniques
    - Autoclave use
  - Increase in autoclave time to compensate for local altitude and volumes of liquid autoclaved
  - Move of LFC to a separate room with restricted access
  - Maintenance of LFC by technician from South Africa (expertise not available locally) and change of the HEPA filter after 3 months of use

Results of pilot study

- 201 patients included
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- FASTPlaqueTB™ results
  - 108 (5.0%) positive
  - 98 (48.8%) negative
  - 95 (46.3%) unreadable

- Preliminary culture results
  - Contaminated: 10/198 (5.1%)
  - Positive: 32/168 (16.5%)

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- FASTPlaqueTB™ remains still a potentially interesting test considering the 2 days results but requires culture level laboratory

- Upgrading of peripheral laboratory to perform culture level test might only be feasible in very few settings

- More R&D on new tests suitable for peripheral setting is a top priority