

# **Comparison of SpeedOligo test to Xpert MTB/Rif test for detection of Tuberculosis in smear-negative HIV-infected patients**

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# Background:



Laboratory diagnosis of PTB traditionally relies on smear microscopy and culture of the mycobacterium tuberculosis from clinical specimens.

# Background

- Since 2008, >7 commercial molecular tests for TB have been released.
  - Have greater diagnostic performance than microscopy (misses 50% cases)
  - Produce much faster results than conventional culture (21 days+)
  - useful in speciation of mycobacterium and screening for resistance to TB drugs.

## Xpert MTB/Rif test for simultaneous detection of TB and Rif resistance

Automated real-time nucleic acid amplification technology for rapid and simultaneous detection of tuberculosis and rifampicin resistance:

Xpert MTB/RIF assay for the diagnosis of pulmonary and extrapulmonary TB in adults and children

NEW DIAGNOSTIC TESTS  
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RIFAMPICIN  
TB  
DIAGNOSIS  
RESISTANCE  
ACCURACY  
RECOMMENDATIONS  
RAPID TB TEST  
PERFORMANCE  
ACCURACY  
MYCOBACTERIUM  
MOLECULAR DIAGNOSTICS



*The assay is largely automated-only 15 min of hands on (Addition of SR to raw sputum and transfer of inactivated/ liquefied sample to the Cartridge and in the instrument). Time to result 3 hours.*

# Evaluated molecular test (Speed-oligo<sup>®</sup> DIRECT *Mycobacterium tuberculosis*)



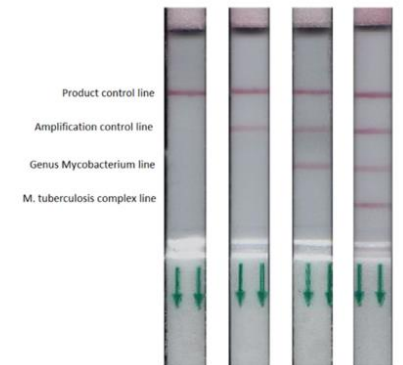
## Evaluation of the Speed-oligo Direct *Mycobacterium tuberculosis* Assay for Molecular Detection of Mycobacteria in Clinical Respiratory Specimens

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**A PCR-based method-probes attached to a dipstick, for the qualitative detection of *M. tuberculosis* complex (IS6110) or other Nontuberculous mycobacteria (16S rRNA)**

**-Sensitivity (93% SS+, 56% SS-), Specificity (99%), Ana Lara-Oya, 2013**





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## Evaluation of the Xpert<sup>®</sup> MTB/Rif test, microscopic observation drug susceptibility test and nitrate reductase assay, for rapid and accurate diagnosis of smear-negative tuberculosis in HIV patients

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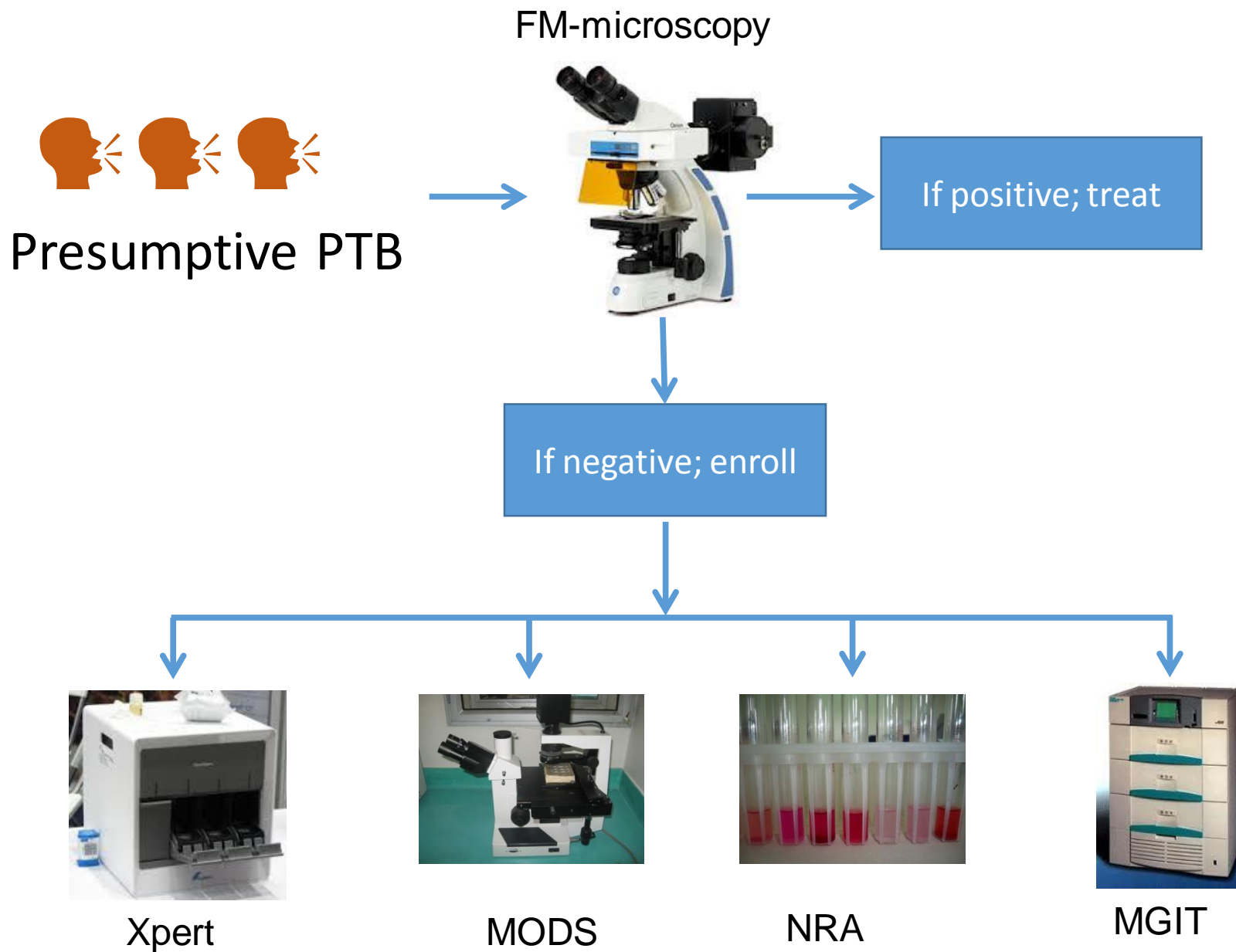
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### Context

Evaluation nested in a larger study to evaluate novel molecular (Xpert) and culture tests (MODS, NRA) for detection of PTB in SS- HIV patients in Uganda



Presumptive PTB

FM-microscopy

If positive; treat

If negative; enroll



Xpert



MODS



NRA



MGIT

# Study setting: Tertiary referral hospital, Kampala, Uganda



Mulago NRH, Kampala

- HIV OPD clinic 14,000 patients (MJAP)
- Routine TB screening
- TB/ART co-treatment



# Purpose

- To investigate if the SpeedOligo test could be a suitable alternative to the Xpert test for diagnosis of PTB in smear-negative HIV patients in our clinic

- Cost of cartridge, Annual calibration
- Logistical difficulties-stock outs



- Objective: To compare the sensitivity/specificity of Speed-oligo<sup>®</sup> DIRECT test for *Mycobacterium tuberculosis* in reference to X-pert<sup>®</sup>

# Methods

- One hundred and nine (109) stored sediments from previously processed (NALC/NAOH 2%) smear-negative sputum, were tested with SpeedOligo.
- The SpeedOligo test was performed as per the manufacturers' instructions (DNA extraction, amplification, detection-3 hours).
- The SpeedOligo results were compared to the Xpert results which were not available until the final results of SpeedOligo were reported.
- The test results of both SpeedOligo and Xpert were then compared to a combination of liquid (MGIT) and solid (L-J) culture results.

# Results

Test	Sensitivity (%)	Specificity (%)
SpeedOligo vs Xpert	64	83
SpeedOligo vs Culture	26	74
Xpert vs Culture	49	95

- Agreement between SpeedOligo and Xpert was **67%** for positive results and **95.4%** for negative results
- Invalid results 6/109 (SpeedOligo) compared to 0/109 (Xpert)
- Variability in band intensity of SpeedOligo resulting in difficulty in test interpretation (high false positive rate).

# Conclusion

- The diagnostic performance of SpeedOligo for TB in smear-negative HIV infected patients was only moderate compared to Xpert.
- Other challenges (difficulty in test interpretation, more invalid tests)
- SpeedOligo could not be implemented as an alternative to Xpert in our clinic.

# Acknowledgements

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- Clinicians at Mulago Hospital for providing medical care to the patients enrolled in this project