

# Evaluation of a stabilising medium for the isolation and detection of *Mycobacterium tuberculosis* from oral swabs

*Sharon L. Olifant, Remco P.H. Peters  
and P. Bernard Fourie*

Make today matter



UNIVERSITEIT VAN PRETORIA  
UNIVERSITY OF PRETORIA  
YUNIBESITHI YA PRETORIA

Faculty of  
Health Sciences

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Lefapha la Disaense tša Maphelo

# Background

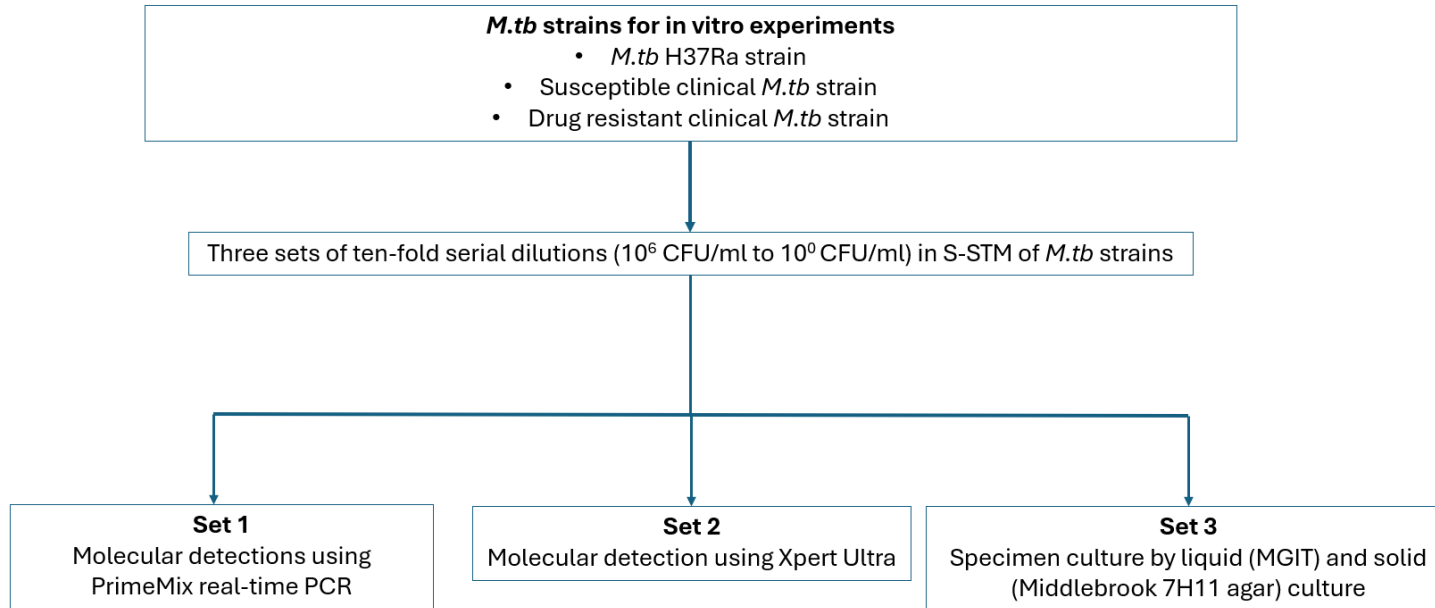
- There is a keen interest in developing a **nonsputum**, biomarker-based diagnostic test<sup>1</sup>
- Oral swab collections are a **nonsputum** sample that is **non-invasive**, **easy to perform**, **affordable** and **non-aerosol producing**<sup>2</sup>
- Effective specimen **storage** and **transport** are crucial for maintaining specimen integrity in TB testing
- Most specimen rely on cold chain and any change in temperature might affect specimen quality

# AIM

- Salorn stabilising Transport Medium (S-STM) is a newly developed transport medium that virucidal and bacteriostatic and can preserve whole bacterial cells<sup>3</sup>.
- Investigate the potential of a stabilizing transport medium to enable *M.tb* cells to be cultured and serving as a sample type for molecular assays
- Evaluate the value of using S-STM as a transport medium for oral swabs collected from presumptive TB patients

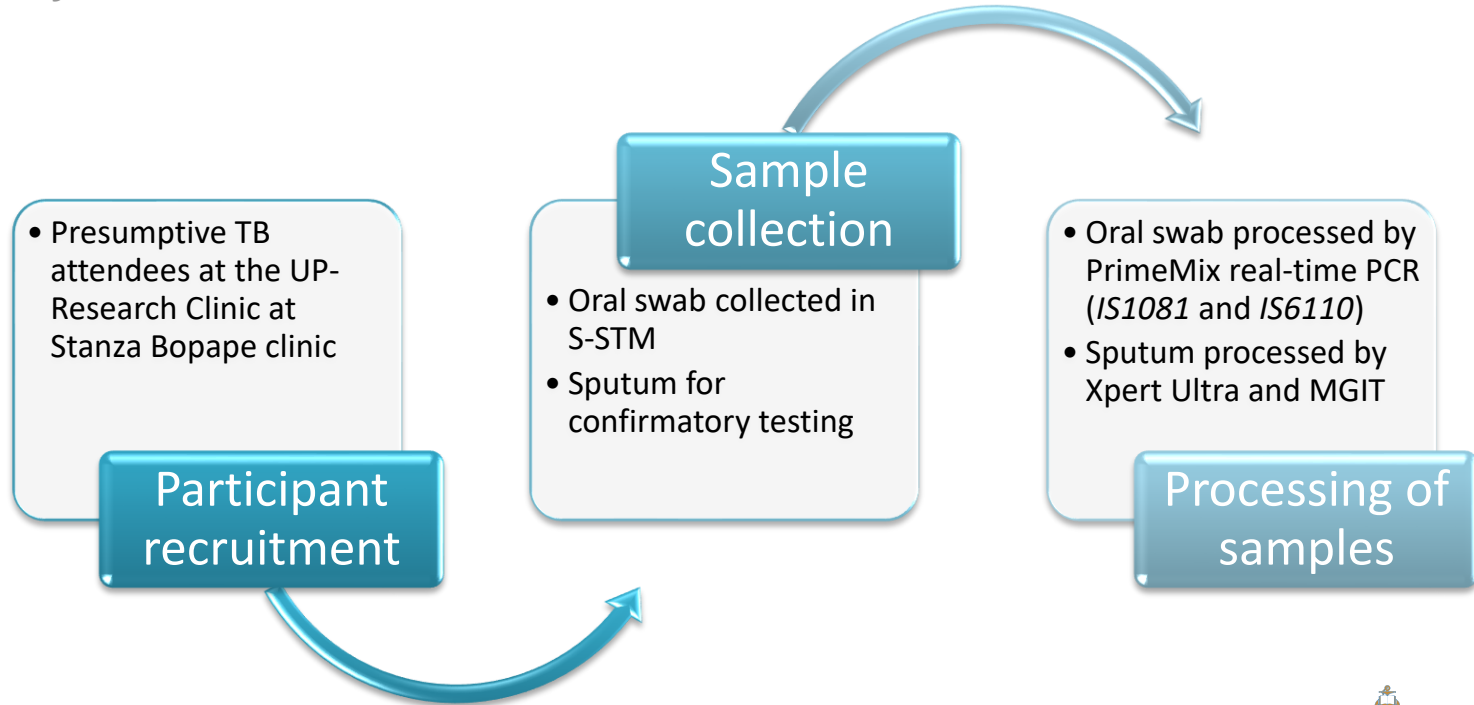
# Methods

## *In vitro*



# Methods

## Field study



# Methods

## Oral swab collection procedure



# Results

Mycobacterial culture on Middlebrook 7H11 agar

<b><i>M.tb</i> H37Ra STRAIN IN S-STM ON MIDDLEBROOK 7H11 AGAR</b>	
<b>S-STM DILUTION (CFU/ ml)</b>	<b>RESULT</b>
10 <sup>6</sup>	<i>M.tb</i> colonies observed in 42 days
10 <sup>5</sup>	<i>M.tb</i> colonies observed in 44 days
10 <sup>4</sup>	<i>M.tb</i> colonies observed in 52 days
10 <sup>3</sup>	<i>M.tb</i> colonies observed in 56 days
10 <sup>2</sup>	No visible growth by 56 days
10 <sup>1</sup>	No visible growth by 56 days
10 <sup>0</sup>	No visible growth by 56 days

# Results

## Molecular analysis

- Xpert Ultra
  - LoD for H37Ra –  **$10^2$  CFU/ ml**
  - LoD for susceptible clinical strain –  **$10^2$  CFU/ ml**
  - LoD for MDR clinical strain -  **$10^3$  CFU/ ml**
  
- Real-time PCR
  - LoD for H37Ra –  **$10^1$  CFU/ ml**
  - LoD for susceptible clinical strain –  **$10^2$  CFU/ ml**
  - LoD for MDR clinical strain –  **$10^1$  CFU/ ml**



# Results

## Field study

- 57 participants were enrolled
  - 68% male; 32% female
- TB confirmed in **60%** (34/57) of participants
  - 33 by Xpert Ultra; 32 by MGIT
- Oral swab positive in **50%**(17/34)
  - Sensitivity relative to MGIT: **53%**
  - Sensitivity relative to Xpert Ultra: **51%**
  - Specificity relative to MGIT: **68%**
  - Specificity relative to Xpert Ultra: **68%**

# Discussions

- *In vitro* studies demonstrated that *M.tb* can be cultured from a S-STM specimen
  - MGIT culture is not ideal for this specimen type
  - Growth on solid agar is comparable to sputum culture on LJ slants<sup>4</sup>
- This is the first study that used S-STM as a transport medium for oral swab collections
- The sensitivity and specificity of oral swabs was better in participants with high/medium Xpert Ultra results
  - High proportion of false negatives had a sputum Xpert result in the low/very low and trace categories
  - More false negatives in the HIV co-infected population

# Conclusion

- Demonstrated that *M.tb* can be cultured from a S-STM sample
- *M.tb* can be detected from oral swabs collected in S-STM and transported at ambient temperature

# References

- <sup>1</sup>Drain et al. (2019) Guidance for studies evaluating the accuracy of biomarker-based nonsputum tests to diagnose tuberculosis. *The Journal of Infectious Diseases*, 220:S108-15.
- <sup>2</sup>Nathavitharana et al. (2019) Guidance for studies evaluating the accuracy of tuberculosis triage tests. *The Journal of Infectious Diseases*, 220:S116-25.
- <sup>3</sup>Lonhgorn Vaccine & Diagnostics (2023). Salorn STM - Optimizing molecular testing through safer sample collection [web site]. ([lhnvd.com/salorn-stm](http://lhnvd.com/salorn-stm))
- <sup>4</sup>Sharp et al (2000) Lowenstein-Jensen Media: No longer necessary for Mycobacterial isolation. *American Journal of Clinical Pathology*, 113: 770-773.

# Acknowledgements



# Thank You

