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TB
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Retrospective evaluation of Pluslife MiniDock MTB on tongue and sputum-dipped swabs in sputum scarce people

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Background



- The reliance on sputum remains a significant bottleneck in the TB diagnostic process
- Individuals with early TB disease often struggle to produce adequate sputum
- More data on non-sputum-based diagnostic tools in this population are urgently needed to inform global policy
- Oral samples such as tongue swabs are alternative non-sputum specimen types
- Tongue swabs are promising but most data are from people who can already make sputum
- Most studies on oral samples for TB diagnosis have not recruited people with sputum scarcity
- OR offered induction without first confirming people are truly sputum scarce

Clinical Infectious Diseases

MAJOR ARTICLE



OXFORD

Oral Washes and Tongue Swabs for Xpert MTB/RIF Ultra–Based Tuberculosis Diagnosis in People With and Without the Ability to Make Sputum

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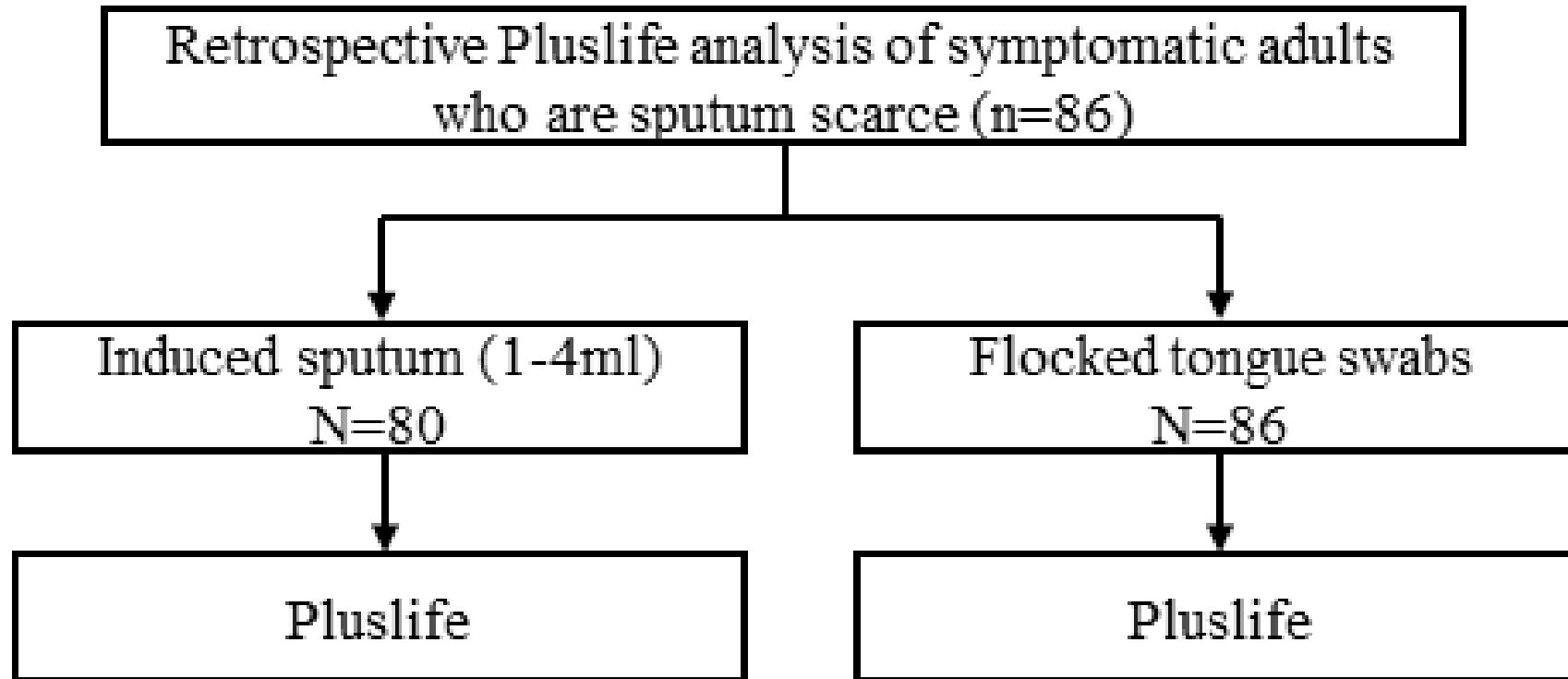
- The use of oral sampling in sputum scarce people could double the number of people with a positive Xpert Ultra result

Knowledge gaps



- Performance data are specifically needed from people with sputum scarcity where it could have the greatest impact
- Tongue swabs are easy to collect and non-invasive procedures are required
- A rapid, point-of-care, non-sputum-based test is needed to diagnose pulmonary tuberculosis
- We evaluated retrospective testing of the Pluslife MiniDock MTB Test on tongue and sputum-dipped swabs from people with presumptive TB
- This was done to generate data to inform WHO policy decisions

Cohort



Pluslife MiniDock MTB

Specimen Collection

Mix Sample

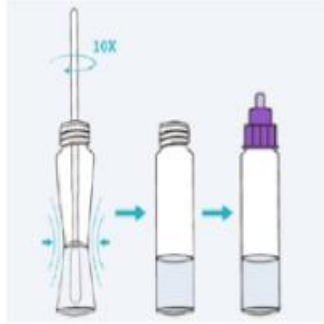
Lyse Sample

Fill Test Card

Run Test & Result Output



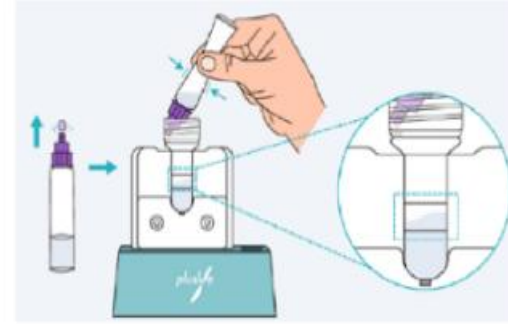
Tongue swab Sputum swab



Swirl swab 10X in buffer



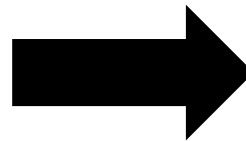
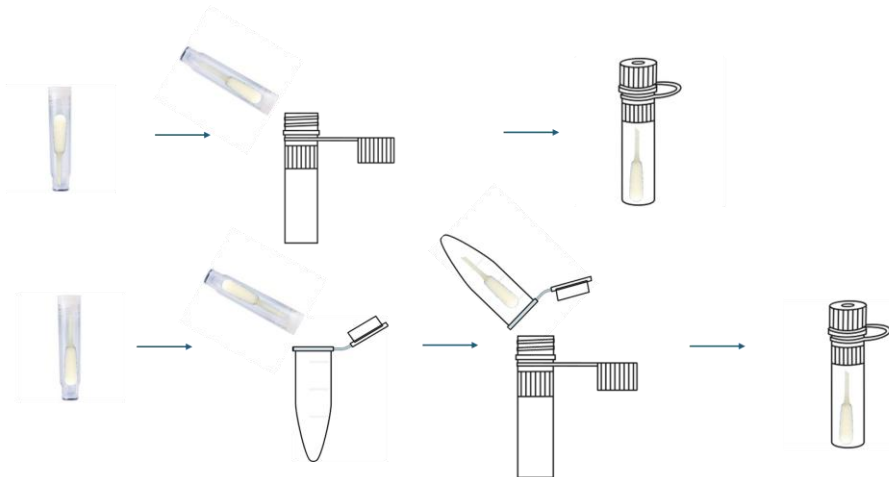
Lyse for 5 minutes



Use dropper cap to fill test card



Run test and record results



3. Treat Sample

Place the tube in the thermostatic vortex mixer, set it to 75°C, and mix at 3000 rpm for 5 minutes



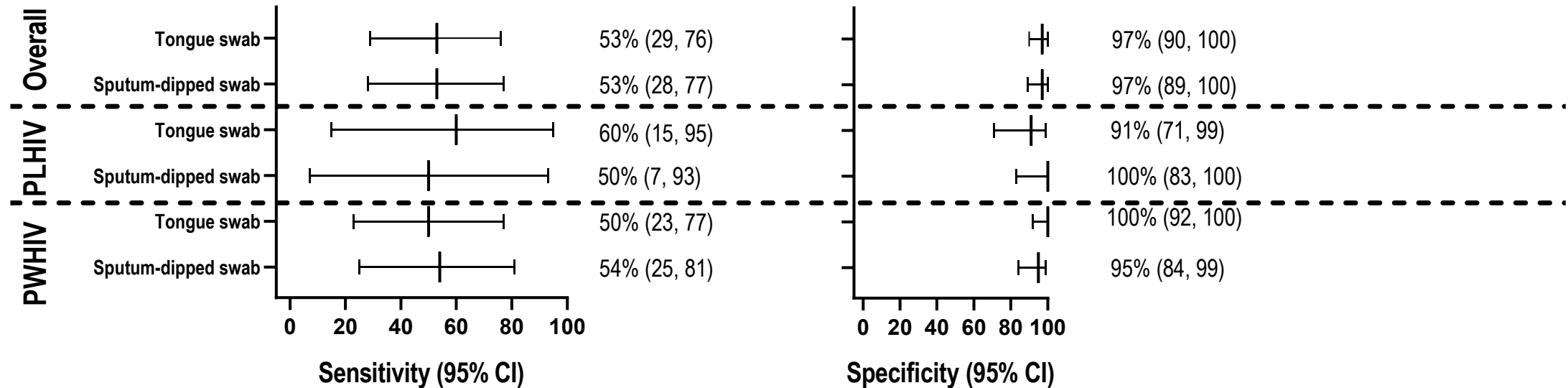
4. Run Test

Transfer the sample to the reaction card and insert it into device to start the test

Population

- Participants were recruited between August 2022 and March 2025 from clinics in Cape Town
- Microbiological reference standard: (induced sputum culture AND / OR Ultra)
 - 11/86 had no induced sputum culture done
 - Everyone had an induced sputum Ultra result
- 31% (27/86) were PLHIV
- 22% (19/86) had TB following the MRS
- 20% (17/86) had a previous TB episode

Diagnostic Accuracy



- Tongue and induced sputum-dipped swab demonstrated similar sensitivity and specificity
- Sensitivity and specificity across the two sample types did not differ by HIV status
 - In tongue swabs, reduced specificity was seen in PLHIV compared to those without HIV
- No significant difference when induced sputum culture and induced sputum Ultra individually used as reference standard

Tongue and sputum swab positivity by Ultra semi-quantitation



Induced sputum semi-quantitation	Tongue swab positivity	
	Negative (n=74)	Positive (n=12)
High (n=3)	1	2 (67%)
Medium (n=3)	0	3 (100%)
Low (n=4)	1	3 (75%)
Very Low (n=4)	3	1 (25%)
Trace (n=1)	1	0 (0%)
Negative (n=71)	68	3 (4%)

Induced sputum semi-quantitation	Induced sputum-dipped swab positivity	
	Negative (n=69)	Positive (n=11)
High (n=3)	1	2 (67%)
Medium (n=3)	0	3 (100%)
Low (n=3)	1	2 (67%)
Very Low (n=4)	3	1 (25%)
Trace (n=1)	1	0 (0%)
Negative (n=66)	63	3 (5%)

Concluding Remarks

- The consistent performance of MiniDock MTB across tongue and induced sputum-dipped swabs suggests that tongue swabs represent the more practical non-sputum alternative for diagnosing TB in sputum-scarce individuals
- Among PLHIV, sensitivity was unchanged, but specificity was significantly lower
- The proportion of people with sputum scarce TB that would ordinarily be missed by sputum-based tests and that would be diagnosed using MiniDock MTB on tongue swabs would more approximately halve

Limitations



- Despite the limitations associated with these data, the rest of the protocol was the same as per IFU
- The assay is designed for use on fresh samples, and the use of frozen samples could have contributed to poorer sensitivity
- Sputum scarcity could only be confirmed for participants recruited towards the end of the presumptive TB cohort

Acknowledgements

