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Comparison of Pluslife MiniDock MTB, an automated, near-point of care (nPOC) tuberculosis testing platform to a manual, laboratory ideal for use with tongue swabs

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Medicine and Health Sciences
EyeNzululwazi ngezoNyango neMpilo
Geneeskunde en Gesondheidswetenskappe



BACKGROUND & AIM

Non-sputum sample types have long been sought, with tongue swabs as a key contender for years. Our first work reported oral swabbing for TB in 2015.

- Tongue swabbing (TS) for detecting cases of pulmonary tuberculosis (TB) was recently endorsed by the WHO as a novel sample type for use with Near-Point-Of-Care Nucleic Acid Amplification Tests (nPOC NAATs).
- We compared the performance of one such nPOC NAAT, Pluslife MiniDock MTB (MiniDock), alongside a highly-sensitive, but labor-intensive manual laboratory method.



World Health Organization

The new guidelines on TB diagnosis recommend:

A new class of near-point-of-care nucleic acid amplification tests (NPOC-NAATs) for the initial detection of TB without rifampicin resistance at peripheral levels of the health system (i.e., peripheral laboratories, primary healthcare centers and communities) and at lower unit costs than other molecular test and instrument types;

Tongue swabs as new, readily available and easy-to-collect specimens for use with NPOC-NAATs and low-complexity automated NAATs (LC-aNAATs) for the initial detection of TB with and without rifampicin resistance among adults and adolescents that are unable to produce sputum; and

Pooling of sputa as a diagnostic strategy for the initial detection of TB and rifampicin resistance using LC-aNAATs with the potential to improve turnaround times and costs when resources are constrained.

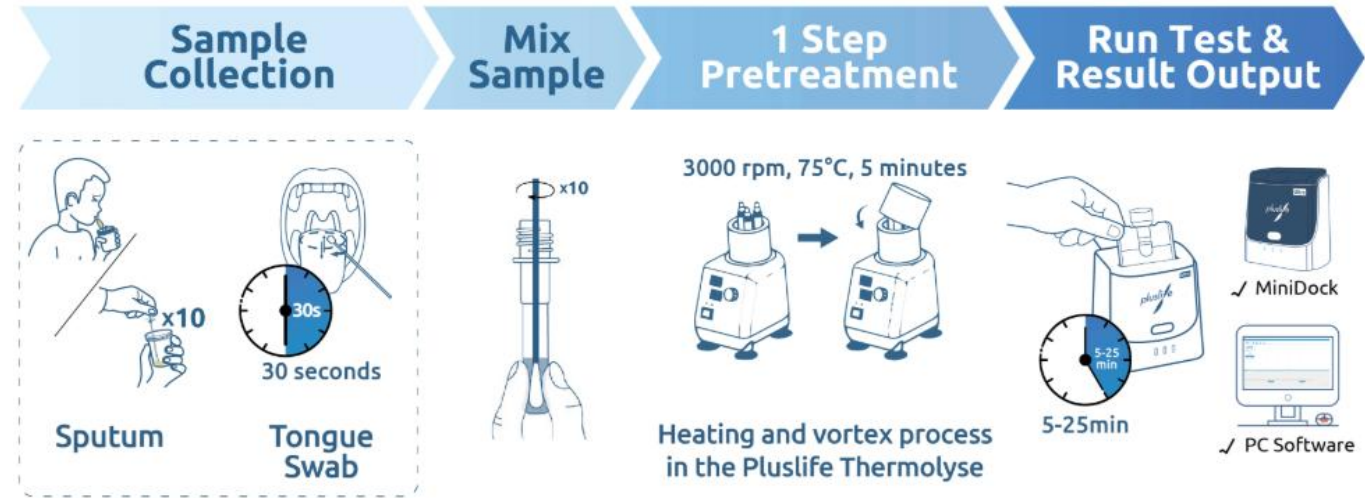


METHODS

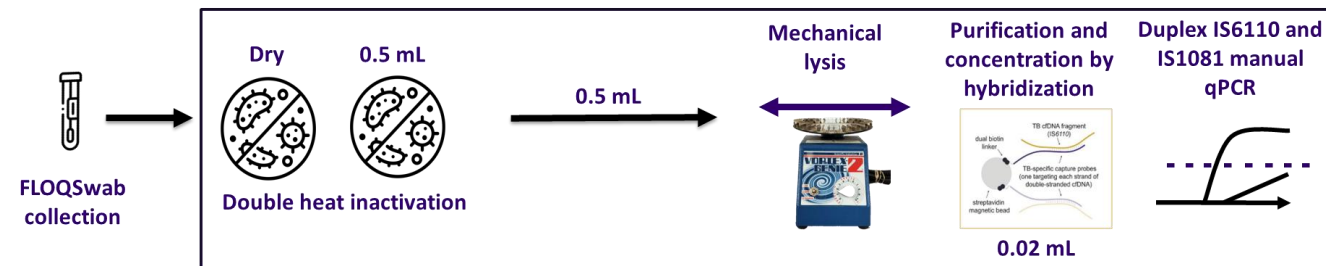
Paired Copan FLOQSwabs collected from tongue dorsa of symptomatic, TB care-seeking South Africans (N=197) were retrospectively tested for *Mtb* DNA using two protocols:



1. Pluslife MiniDock MTB (MiniDock), a WHO-endorsed, semi-automated nPOC platform requiring <30 minutes sample-to-result



2. Sequence-specific magnetic capture-qPCR (SSMaC), a manual laboratory method requiring ~5 hours sample-to-result that we recently showed to have high sensitivity for *Mtb* DNA in FLOQSwabs (Olson AM *et al.*, 2025)



An extended microbiological reference standard (eMRS) defined a TB case as sputum *Mtb*-positivity by culture or Xpert Ultra; and MRS as sputum *Mtb*-positivity by Xpert Ultra “very low” or stronger.

RESULTS

Similar performance was observed between the two methods.

- Total percent sensitivities are not statistically different by Z test ($p > 0.05$) for either e/MRS.
- MiniDock performs as well as the labor-intensive laboratory method with reduced cost, time, effort, training, and need for laboratory space/equipment.
- This study is limited by the small N in the lower categories and overall.

Sensitivity	Total TB-positive	SSMaC positive	MiniDock positive	SSMaC % sensitivity	95% CI	MiniDock % sensitivity	95% CI
Relative to eMRS	43	24	28	56%	40-71%	65%	49-79%
Relative to MRS	36	24	27	67%	59-81%	75%	58-88%
Sensitivity stratified by sputum semi-quantitative value							
High	17	15	16	88%	64-99%	94%	71-100%
Medium	6	5	6	83%	36-99%	100%	54-100%
Low	5	3	3	60%	15-95%	60%	15-95%
Very Low	3	1	1	33%	1-91%	33%	1-91%
Trace	5	0	1	0%	0-52%	20%	1-72%
Sputum Xpert negative (eMRS+)	7	0	1	0%	0-41%	14%	14-58%
Specificity							
Specificity	Total TB-negative	SSMaC negative	MiniDock negative	SSMaC % specificity	95% CI	MiniDock % specificity	95% CI
Relative to eMRS	117	115	117	98%	94-100%	100%	97-100%
Relative to MRS	124	122	124	98%	94-100%	99%	96-100%

SSMaC+qPCR does not “rescue” false negatives in duplicate or remnant TS:

- False negative samples tested by modified SSMaC+qPCR after processing for MiniDock.
- Paired TS tested by the unmodified SSMaC+qPCR method, typically a highly-sensitive lab-based test, did not perform with an observable difference.
- Possible that some participants do not have TB bacilli on the tongue surface and require alternate approaches.
- “On-label” MiniDock with suggestive identical performance, lower costs, reduced complexity and labor requirements is a clear choice for endorsement in presumptive testing.

Test result heat map of paired duplicate TS specimen and opportunistic-TS-remnant testing in N=20 participants.

Sputum Xpert Ultra	N	N	N	N	N	N	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
TS Pluslife	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	TP	TP	TP	TP	TP
TS SSMaC+qPCR	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	TP	TP	TP	TP	TP
TS Pluslife Remnant SSMaC+qPCR	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	TP	TP	TP	TP	TP
Participant	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	

Xpert Semiquant Result	High	Medium	Low	Very Low	Trace	False Neg	SSMaC Cq Result	<26	26-30	31-35	36-40	>40	False Neg	Pluslife Result	Unspecified positive	False Neg
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TS-MiniDock false negativity was associated with normal chest x-rays ($p=0.04$), and highly associated with sputum Xpert Ultra negativity ($p=0.001$).



SSMaC+qPCR does not “rescue” false negatives in duplicate or remnant TS:

	False negative (Yes) N = 15 n (%)	False negative (No) N = 28 n (%)	Z test, One-tailed p- value
Variables			
Smoked past 7 days	7 (47)	6 (21)	0.042949 *
CXR abnormal	12 (80)	27 (96)	0.038560 *
Sputum Xpert Neg, Culture positive only	6 (40)	1 (4)	0.001022 **

Test result heat map of paired duplicate TS specimen and opportunistic-TS-remnant testing in N=20 participants.

Sputum Xpert Ultra	N	N	N	N	N	N	P	P	P	P	P	P	P	P	P	P	P	P	P	P	
TS Pluslife	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	TP	TP	TP	TP	TP
TS SSMaC+qPCR	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	TP	TP	TP	TP	TP
TS Pluslife Remnant SSMaC+qPCR	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	FN	TP	TP	TP	TP	TP
Participant	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	

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CONCLUSIONS

TS is headed for prime time.

- In this paired evaluation, the accuracy of the fast, semi-automated, WHO-endorsed Pluslife Minidock MTB platform was not inferior to that of SSMaC, a labor-intensive lab-based method previously shown to be highly sensitive and specific.
- Future studies should evaluate performance among people with lower bacillary loads, including in screening settings.

Some of which is already happening!



Preprints are preliminary reports that have not undergone peer review.
They should not be considered conclusive, used to inform clinical practice,
or referenced by the media as validated information.

Diagnostic accuracy of Pluslife MiniDock MTB on tongue swabs in sputum scarce people with presumptive TB: a retrospective analysis

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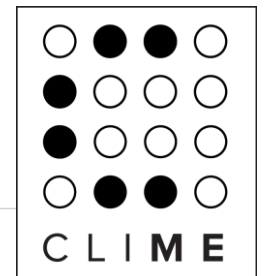
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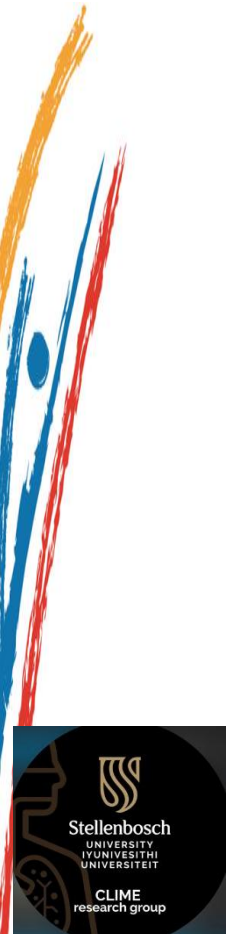
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Short Report



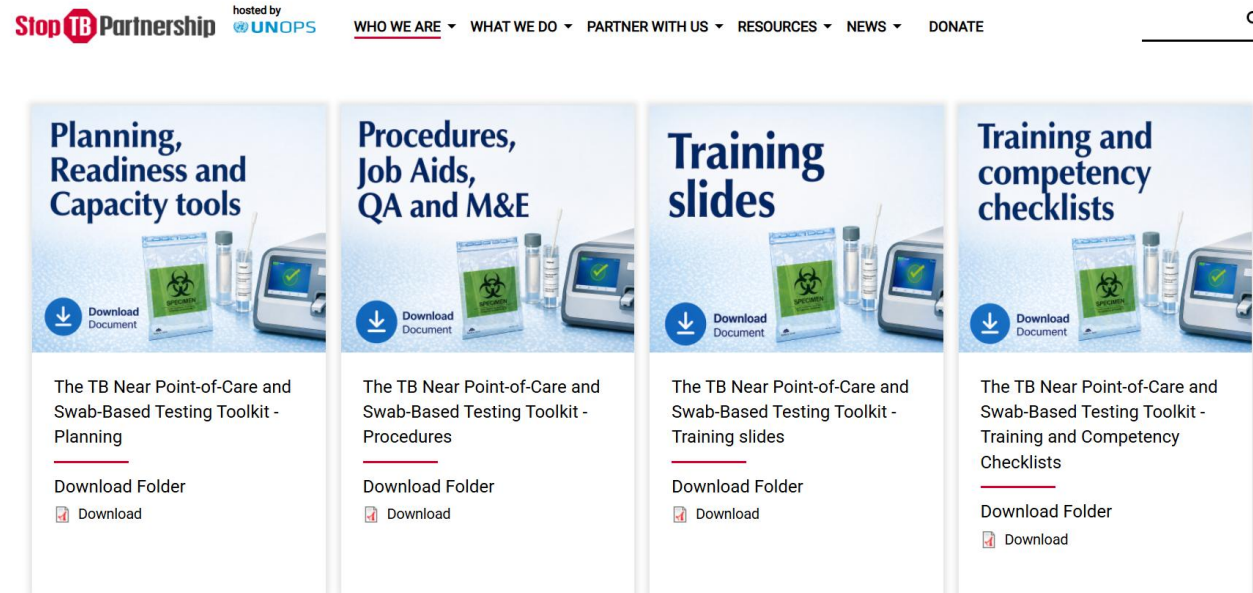
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- Future studies should evaluate performance among people with lower bacillary loads, including in screening settings.

Adding on or initiating swab testing work is easier than ever.



Stop TB Partnership



SCAN ME!



THANK YOU!

Study participants & study staff

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10 JUNE
16:00 - 17:30
BARCELONA VENUE

Dr Robinah Nakawunde

Hidden lung impairment at tuberculosis diagnosis: a comprehensive physiological and imaging assessment.



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