Truenat MTB Ultima Pilot Study Results



Study Population: Consecutive people ≥12 years with presumed TB presenting to outpatient clinics in Uganda, India and Vietnam from Feb-August 2024

Clinical Performance Against Microbiological Reference Standard (liquid culture x 2)				
MTB Ultima	Sensitivity: n/N (%, 95% CI)	Specificity: n/N (%, 95% CI)	Error Rate: n/N (%)	
Tongue swab	111/144 (<mark>77%</mark> , 69-84)	735/750 (<mark>98%</mark> , 97-99)	11/905 (<mark>1.2%</mark>)*	
Sputum swab	42/46 (<mark>91%</mark> , 79-98)	122/125 (<mark>97.6%</mark> , 93-100)	0/171 (0.0%)	
Comparator tests	Sensitivity: n/N (%, 95% CI)	Specificity: n/N (%, 95% CI)	Error Rate: n/N (%)	
Sputum Xpert	125/135 (<mark>93%</mark> , 87-97)	741/749 (<mark>99%</mark> , 98-100)	1/885 (<mark>0.1%</mark>)^	
Sputum Smear	85/145 (<mark>58%</mark> , 50-67)	760/763 (<mark>99%,</mark> 99-100)	N/A	

^{*}Includes 905 of 908 participants who had a tongue swab collected

[^]Excludes 23 participants with a trace result on Sputum Xpert Ultra



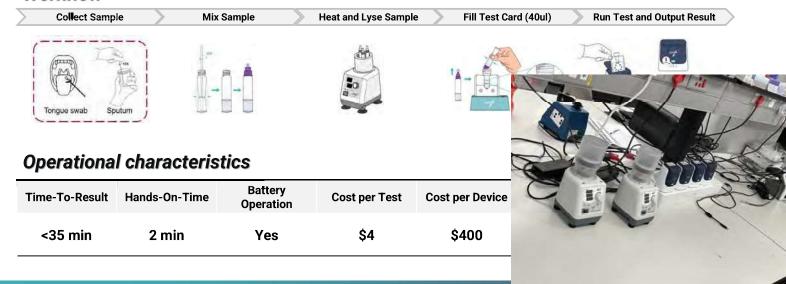
Novel Swab-based Molecular Diagnostic – Example 2

Platform: Integrated Nucleic Acid Testing Device (Pluslife Mini Dock & Pluslife Dock Pro 8) **Assay:** Mycobacterium tuberculosis Nucleic Acid Test Card (Pluslife MTB Assay)

Technology holder: Guangzhou Pluslife Biotech Co., Ltd., China



Workflow



Pluslife MTB Pilot Study Results



Study Population: Consecutive people ≥12 years with presumed TB presenting to outpatient clinics in Uganda and Vietnam from April-August 2024

Clinical Performance Against Microbiological Reference Standard (liquid culture x 2)				
Pluslife MTB	Sensitivity: n/N (%, 95% CI)	Specificity: n/N (%, 95% CI)	Error Rate: n/N (%)	
Tongue swab	46/52 (<mark>89%</mark> , 77-96)	170/170 (<mark>100%,</mark> 98-100)	0/222 (0%)	
Sputum swab	48/51 (<mark>94%</mark> , 84-99)	163/167 (<mark>98%</mark> , 94-99)	1/219 (<mark>0.4%</mark>)*	
Comparator tests	Sensitivity: n/N (%, 95% CI)	Specificity: n/N (%, 95% CI)	Error Rate: n/N (%)	
Sputum Xpert	49/50 (<mark>98%</mark> , 89-100)	165/166 (<mark>99%</mark> , 97-100)	1/217 (0.5%)^	
Sputum Smear	37/52 (<mark>71.2%</mark> , 57-83)	170/170 (<mark>100%</mark> , 98-100)	N/A	

^{*}Denominator excludes 3 participants who provided not provide sputum

Data package ~1400 PlusLife and Molbio Truelyse samples is prepared for WHO review in 2025

[^]Excludes 5 participants with a trace result on sputum Xpert Ultra

USTAR PORTNAT MTB ASSAY - EXAMPLE 3









Sample type: Tongue Swab
Time to result: 30 minutes
Claimed LOD: 400 CFU/mL

• Targets: IS6110 and IS1081

• Throughput: 1 sample

Electricity supply: main power or third-party batteryDigital connectivity: Mobile application or desktop

Read-out: On device (traffic light) or mobile/desktop app





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AN EXPANDING CLUSTER OF NEAR POINT OF CARE MDX PLATFORMS TARGETING TB FROM TONGUE SWABS







THE FINE PRINT - CALIBRATING OUR EXPECTATIONS

KEY CONSIDERATIONS FOR NEAR POC TOOLS

- · Not a 'one size fits all' test
- Countries will need to <u>consider its use case within the context of their own</u> <u>programmes</u> – consideration of diagnostic network optimization
- Trade-offs exist with performance but improves access
- Follow-up testing for <u>DST still required</u>
- Expected to enable better testing integration with other disease programmes
- Training and capacitation of healthcare workforce will be essential
- Referral and Linkage Systems will be crucial no value in a faster test result if health system is not strengthened for linkage to care
- Advocating for <u>funding models that support multi-disease diagnostics</u> and the healthcare infrastructure needed for integrated program delivery



WHAT DID WE PLAN? MIXED-METHOD STUDY







QUANTITATIVE Surveys



QUALITATIVE

Semi-structured interviews (SSI)



TB service recipients
(n=150 / country)



Health care workers (n=100 / country)



Civil Society stakeholders (n=20 / country)



Public health experts (n=20 / country)



Health care workers (n=10 / country)



Civil Society stakeholders (n=5 / country)



Public health experts (n=5 / country)



PREFERENCES AND ACCEPTABILITY OF NOVEL SAMPLE TYPES TB SERVICE RECIPIENTS



