

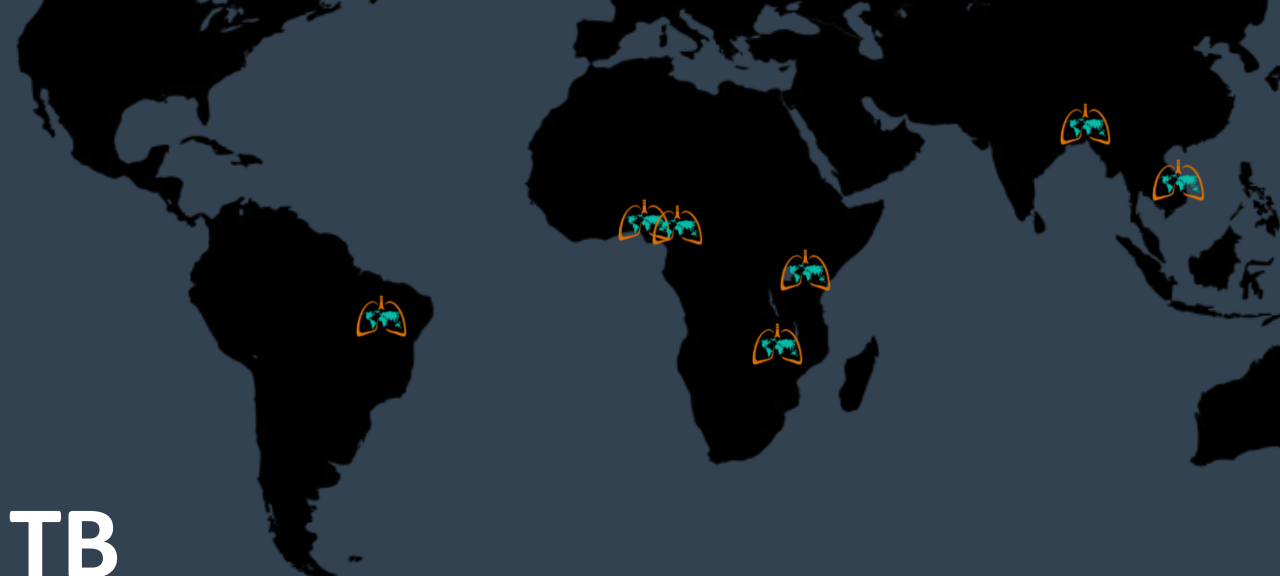
Diagnostic performance and efficiency of pooled sputum testing for TB

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Stop TB Partnership

ASLM LabCoP Webinar | 16 April 2026



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- **Design:** Prospective multicentre diagnostic accuracy study
- **Participants:** 14,040 individuals with valid pooled result
- **7 countries:** Bangladesh, Brazil, Cameroon, Kenya, Malawi, Nigeria, Viet Nam
- **Settings:** PHC, District Hospital, community-based case finding
 - children in Cameroon and Viet Nam
- **Index test:** Xpert MTB/RIF Ultra in pools of 2, 3, or 4 (Dorfman two-stage); positive pools deconvoluted individually
- **Comparator:** Individual Xpert MTB/RIF Ultra
- **Reference standard:** Mycobacterial culture (MGIT; LJ in Brazil)

Accuracy vs culture: pooled vs individual Xpert Ultra



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n=13,531 participants with complete data (pooled, individual Xpert Ultra, culture).

	Pooled testing	Individual Xpert Ultra	Difference
Sensitivity vs culture MRS	84.9% 95% CI 82.5–87.0	88.0% 95% CI 85.9–90.0	-3.2 % 95% CI -4.4 to -2.1 , p < 0.01
Specificity vs culture MRS	98.3% 95% CI 98.0–98.5	97.7% 95% CI 97.4–97.9	+0.6 % 95% CI 0.5 – 0.7, p<0.01

~3 percentage points of sensitivity traded for slightly better specificity against culture as reference.

Efficiency: ~51% fewer Xpert cartridges



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87% of the pools were of 4. Includes 2.3% inconclusive-repeat rate

Cartridge use

51.1%

reduction overall

7,028 cartridges used
vs 14,362 if tested individually

Savings = $f(\text{positivity, pool size})$
High positivity → No savings.
ACF → High savings.

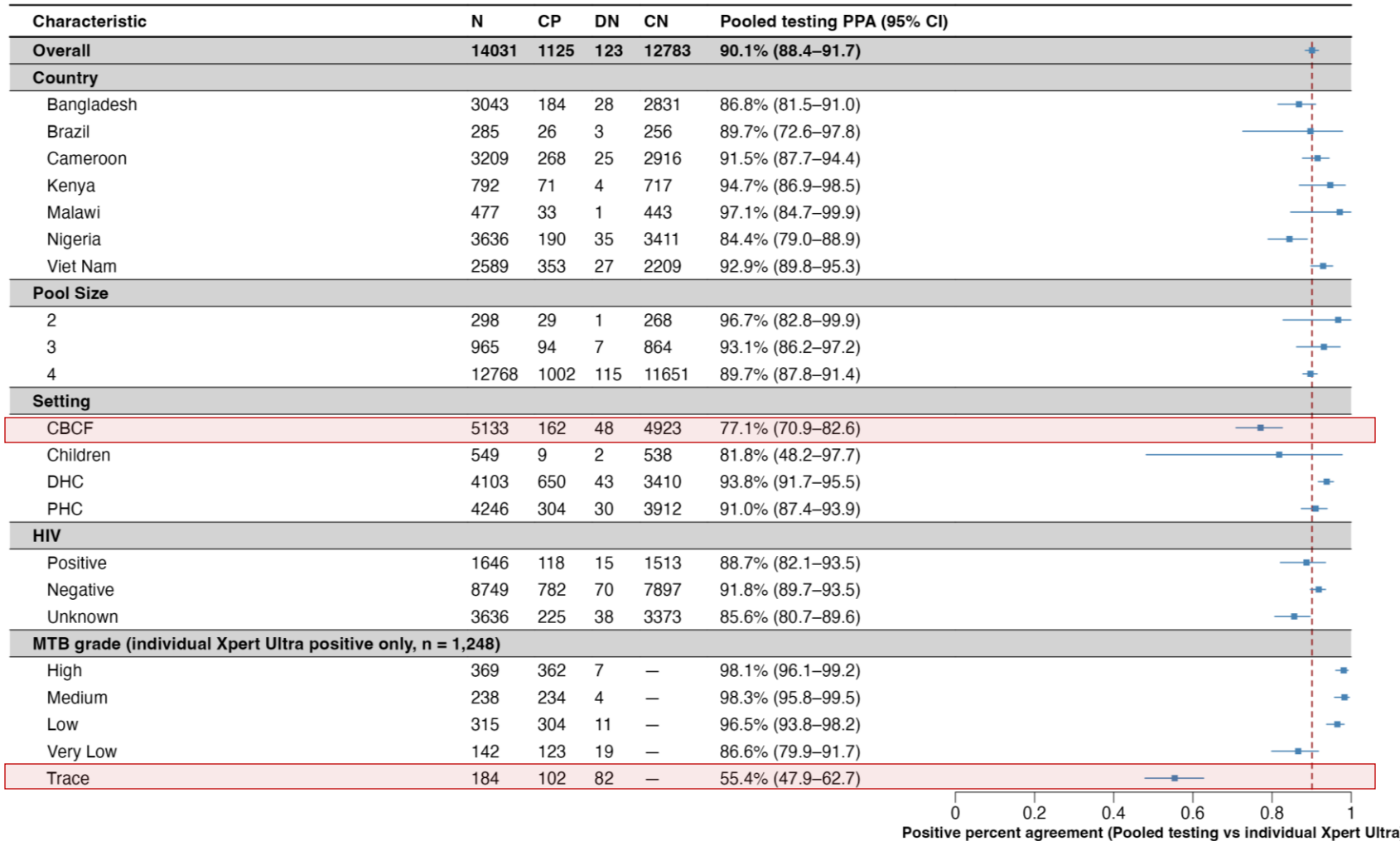
	Pool of 2	Pool of 3	Pool of 4
Pools	149	322	3,195
Cartridges for pooling	206	566	6,256
Cartridges if individual	305	989	13,069
Cartridges per result	0.69	0.59	0.49
Observed reduction	32.5%	42.8%	52.1%

Observed reduction tracks the Dorfman prediction.

Where does pooling work best — and worst?



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Bacillary load drives the gap

PPA: High 98.1% | Med 98.3% | Low 96.5% | Very Low 86.6% |

Trace 55.4%

Missed cases concentrate at the trace end.

Setting variation

PPA by recruitment:

PHC 91%, DH 93.8%, **CBCF 77%**

CBCF has more lower burden cases, so more trace misses.

PPA of pooled vs individual Xpert Ultra, by country, pool size, setting, HIV, and MTB grade.



1 Accuracy

84.9% sensitivity |
98.3% specificity
vs culture across 7 countries.

A ~3% sensitivity drop
compared to
individual Xpert Ultra,
concentrated at the trace
end

2 Efficiency

~51% fewer Xpert cartridges

Nearly doubles the number
of people testable on the
same budget.

Use *Dorfman formula* to
estimate savings based on
positivity and pool size

3 Policy

WHO endorsed sputum pooling

Impactful when expanding molecular
testing. Slashes per test cost.

At similar levels of TB dx budgets,
increased access to molecular
diagnostics.

Need to test more to find more
people with TB. Sensitivity tradeoff
can only be offset by testing more
people (CBCF)

The Start4All Partnership



Acknowledgements

The Start4All consortium expresses its thanks to all stakeholders, collaborators, and participants who supported our research efforts.

For more information, see our online Acknowledgements page:
www.lstmed.ac.uk/start4all/acknowledgements

Start4All consortium and its work is funded by Unitaid

Grant Ref: 2022-50-START-4-ALL

