

LF-LAM diagnostics: *Development pipeline, Clinical adoption in field settings, Strategies for quality assessment*

ASLM ECHO session 4th May 2023

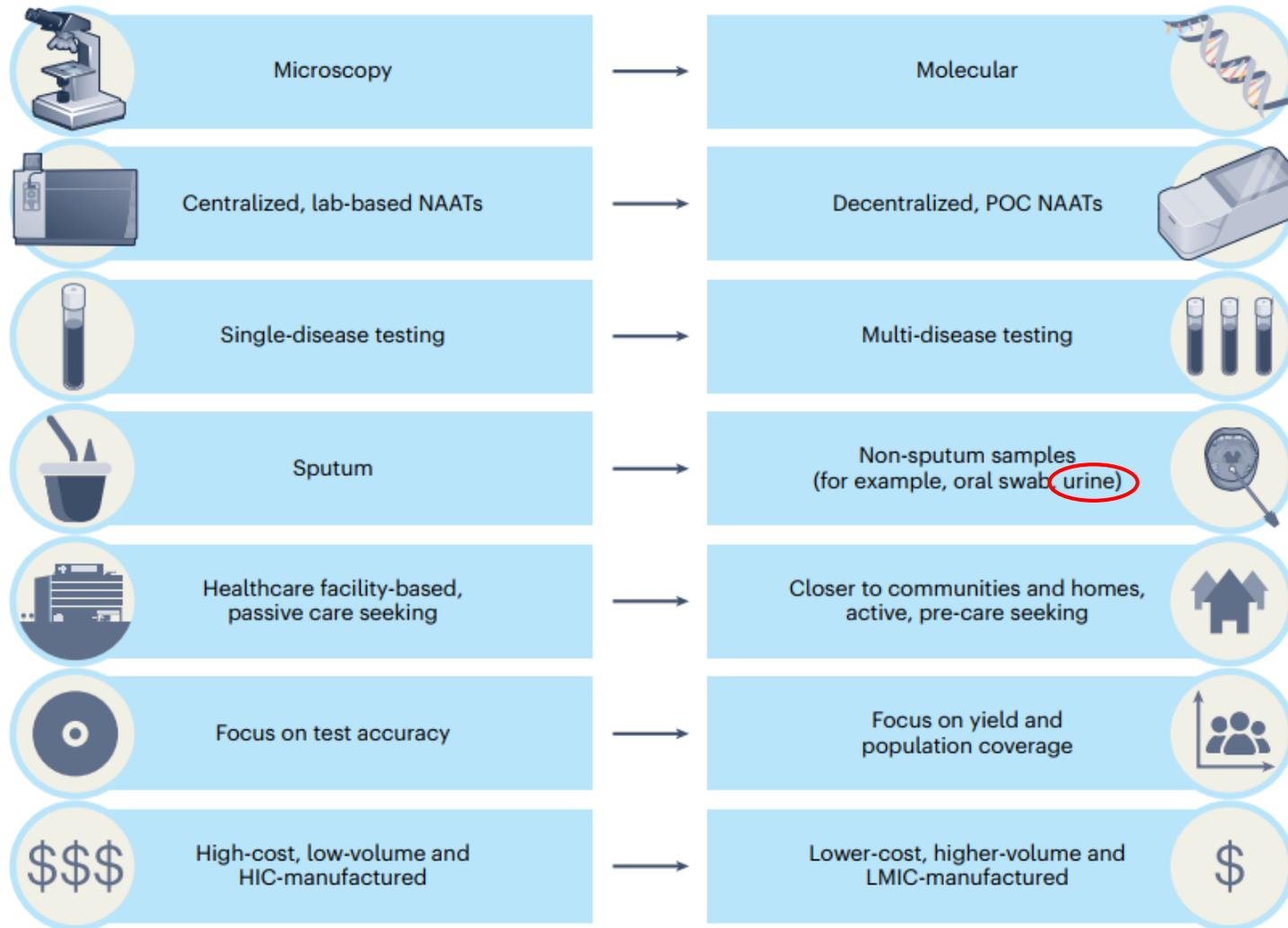


14 leading organizations from 8 countries

Series of clinical trials in Tanzania, Mozambique, and South Africa to evaluate the impact of diagnostic interventions on outcomes (including the effects of expanding TB testing strategies to PLHIV)

- TB LAM diagnostic overview (*Prof Lesley Scott, Head Research and Development, Wits Diagnostic Innovation Hub, University of the Witwatersrand, Johannesburg, South Africa*)
- TB LAM technology development pipeline (*Dr Morton Ruhwald, TB programme, FIND, Geneva*)
- Operationalising TB LAM testing: A use case for standardised implementation in the field (*Prof Jeremy Nel, Division of Infectious Diseases, Department of Internal Medicine, University of the Witwatersrand, Johannesburg, South Africa*)
- Approaches to developing a robust TB LAM quality assessment programme (*Anura David, Senior Medical Scientist, Wits Diagnostic Innovation Hub, University of the Witwatersrand, Johannesburg, South Africa*)
- QA

Massive gaps remain but our focus is clear



nature microbiology

Comment

<https://doi.org/10.1038/s41564-023-01365-3>

Transforming tuberculosis diagnosis

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Diagnosis is the weakest aspect of tuberculosis (TB) care and control. We describe seven critical transitions that can close the massive TB diagnostic gap and enable TB programmes worldwide to recover from the pandemic setbacks.

- *Quality diagnostics is critical across all*

LF-LAM for TB – what we know



- Inpatient settings: Strong recommendation for use to assist in the diagnosis of active TB in HIV infected adults, adolescents and children
 - signs and symptoms of pTB, EPTB, advanced HIV disease, those seriously ill, CD4 count < 200 cells/ul
- Outpatient settings: Conditional recommendation for use to assist in the diagnosis of active TB in HIV infected adults, adolescents and children
 - Signs and symptoms of pTB and EPTB, seriously ill, CD4 < 100 cells/ul

Review of the literature (155 publications on PubMed)

- **2001 – ELISA based – diagnostic evaluation in Ethiopia**
- **2020 – 2023** 62 published manuscripts:
 - Modeling and diagnostic value including uptake, impact studies and use in EPTB
 - Meta-analysis in children
 - Cross-sectional studies (4 African countries)
 - Alternative specimen types and multi-pathogen detection
 - Multi-assay use: LAM and Xpert
 - FujiLAM accuracy: systematic review
 - New LAM structure (other biomarkers) and antibodies to improve assay performance
 - User perspective and field feasibility
- Quality assessment for LF-LAM seldom featured
- QMS beyond laboratories not well translated
- LF-LAM quality framework requires scaling to field settings