

# Diagnostic performance of the novel FujiLAM assay to detect tuberculosis in HIV-positive clients in Uganda

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# Background

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- Tuberculosis is the leading cause of death in HIV-positive persons
- Under-diagnosis mainly due to reliance sputum for diagnosis  
Difficult to obtain among very ill HIV-positive patients
- The use of urine point-of-care tests to identify TB using AlereLAM has benefits  
Possibility to predict mortality  
Cost-effectiveness in a TB diagnostic algorithm
- The Fujifilm LAM (FujiLAM) can detect LAM antigens at low concentrations  
Higher sensitivity (28%), reduced specificity (4%) than AlereLAM  
CD4 $\geq$ 200 cells/ $\mu$ L; 44% with FujiLAM compared to 12% with AlereLAM
- However, FujiLAM assessed only in one study (retrospective and using frozen urine)

# Background

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## Fujifilm SILVAMP TB LAM (FujiLAM):

- Point-of-care assay
  - Test results in 1 hour
  - Urine sample
  - Detects lower LAM concentrations compared to Determine TB-LAM (Abbot TB-LAM)
  - More complex to perform (several steps and waiting time) than Abbott TB-LAM
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- FIND called for research partners to conduct prospective evaluations on FujiLAM

**Primary objective:** To assess the diagnostic performance of FujiLAM in ambulatory HIV-positive clients

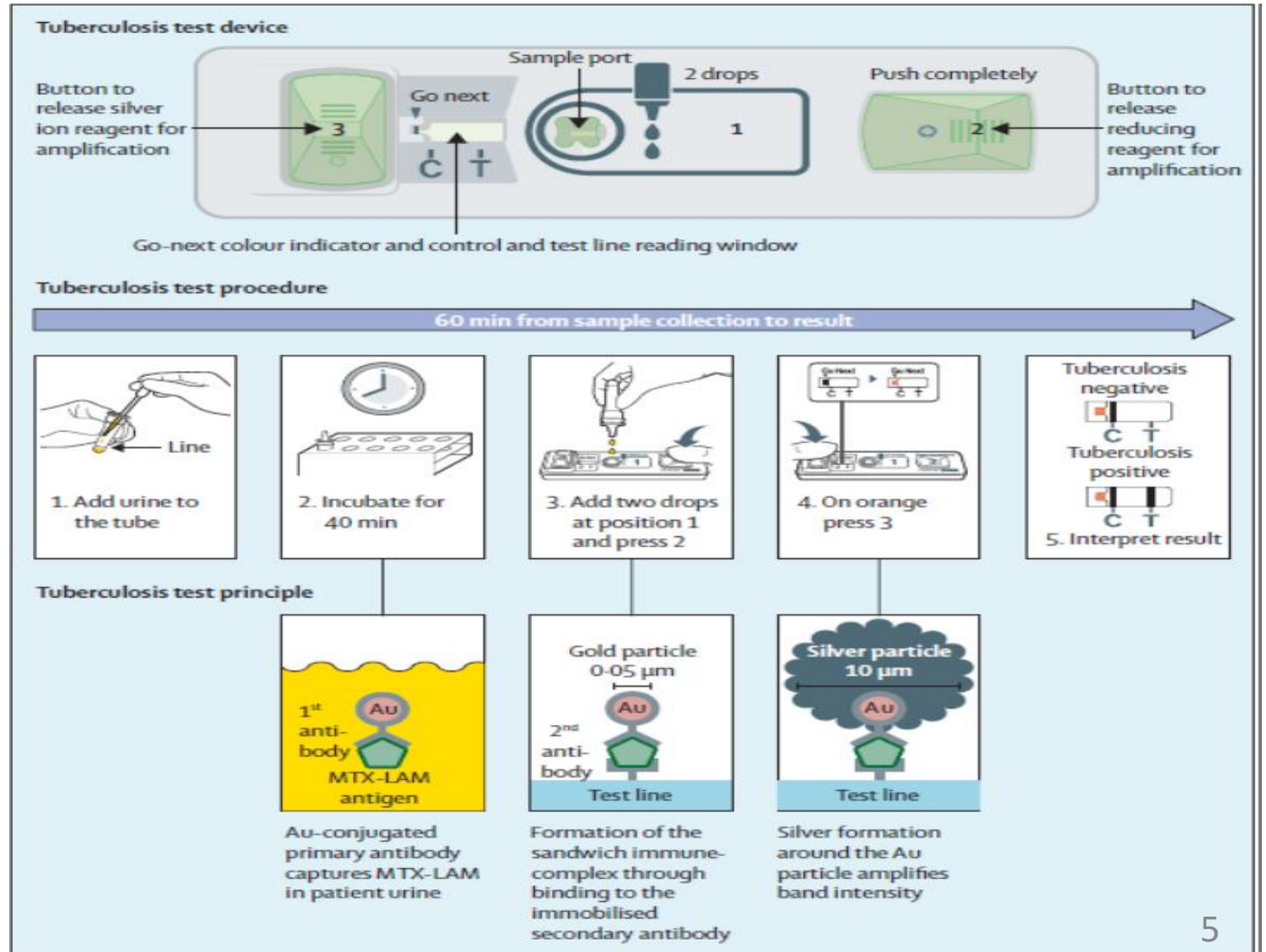
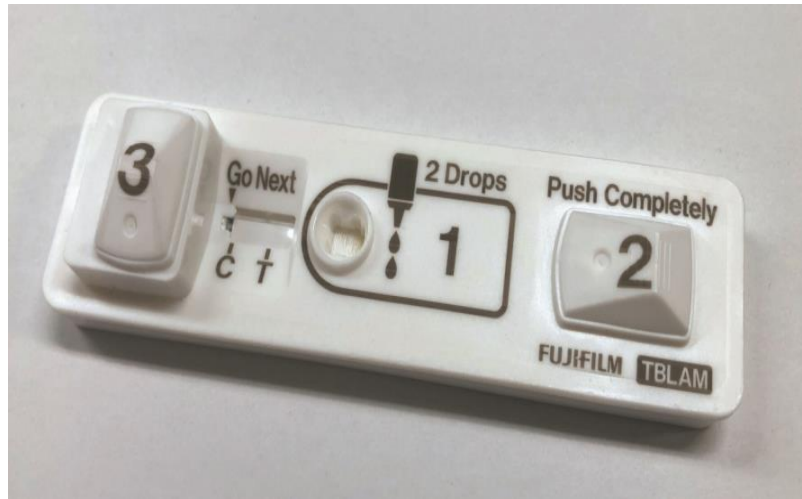
# Methods

- Multicentric prospective diagnostic study. For Mbarara site, ISS clinic at MRRH
- Ambulatory HIV-positive adults:
  - **Group 1:** with signs and **symptoms of TB**
  - **Group 2:** with advanced HIV disease and **no symptoms of TB**
- **Inclusion criteria:** 15 years of age or older HIV-positive
- **Exclusion criteria:** Intake of anti-tuberculosis drugs in the month prior to the consultation except preventive TB treatment
- **Procedures:**
  - Clinical examination
  - FujiLAM & Abbott TB-LAM on urine
  - Xpert MTB/RIF Ultra on sputum or urine & culture on sputum
  - Chest X-ray
- Microbiological reference based on Xpert MTB/RIF and culture



# Methods

## FujiLAM test demonstration



# Results

Inclusions: 795 clients (August 2020 to September 2021)

	Group 1	Group 2
	TB symptoms N=539, n (%)	No TB symptoms & advanced HIV N=256, n (%)
Women	290 (53.8%)	105 (41.0%)
Age, median [IQR]	43 [34 – 51]	36 [29 – 43]
CD4 count, median [IQR]	579 [307 – 815.5]	118 [65 – 159.5]
On ART	476 (88.3)	218 (85.2)
Seriously ill	12 (2.2)	1 (0.4)

# TB diagnostic tests

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	Group 1	Group 2
	TB symptoms % (n/N)	No TB symptoms & advanced HIV % (n/N)
Abbott TB-LAM positive	14.1 (76 / 539)	14.1 (36 / 256)
FujiLAM positive	19.4 (104 / 539)	18.8 (48 / 256)
Xpert or Culture positive (Confirmed TB)	9.1 (49 / 539)	4.3 (11 / 256)

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# Sensitivity and Specificity of FujiLAM and Abbott TB LAM

In **Group 1**, Xpert or culture results (*any sample*) were available for 100% patients and **49/539 (9.1%) patients** had an Xpert or culture positive result.

In **Group 2**, Xpert or culture results (*any sample*) were available for 100% patients and **11/256 (4.3%) patients** had an Xpert or culture positive result.

	FujiLAM		Abbott TB-LAM	
	%	95%CI	%	95%CI
Sensitivity				
- Group 1 (TB symptoms, all CD4)	58.3	43.2-72.4	39.6	25.8-54.7
- Group 2 (no TB symptoms, advanced HIV)	45.5	16.7-76.6	9.1	0.2-41.3
Specificity				
- Group 1 (TB symptoms, all CD4)	84.2	80.6-87.4	88.4	85.2-91.2
- Group 2 (no TB symptoms, advanced HIV)	83.5	78.0-88.1	85.3	79.9-89.6

# FujiLAM sensitivity among confirmed TB

	FujiLAM		Abbott TB-LAM	
	% (n/N)	(95%CI)	% (n/N)	(95%CI)
<b>Group 1 (TB symptoms regardless CD4) (N=49)</b>	<b>58.3</b>	<b>(43.2-72.4)</b>	<b>39.6</b>	<b>(25.8-54.7)</b>
- CD4 <200	61.2 (13/21)	(50.9-91.3)	57.1 (12/21)	(43.3-75.1)
- CD4 200-349	54.5 (6/11)	(23.4-83.3)	45.5 (5/11)	(20.3-66.5)
- CD4 ≥350	41.2 (7/17)	(18.4-67.1)	11.5 (2/17)	(2.4-30.2)
<b>Group 2 (no TB symptoms &amp; advanced HIV) (N=11)</b>				
- CD4 <200	45.5 (5/11)	(16.7-76.6)	9.1 (1/11)	(0.2-41.3)

# Conclusions

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- **FujiLAM sensitivity was high** in both symptomatic and asymptomatic HIV-positive ambulatory patients with confirmed TB and **CD4 count <350 cells/ $\mu$ L**.
- **FujLAM sensitivity was lower** in less immunosuppressed patients ( **$\geq 350$  cells/ $\mu$ L**).
- **FujiLAM sensitivity was higher than** that of the currently recommended **Abbott Determine TB-LAM** at all CD4 count cut-offs.
- The point-of-care urine-based FujiLAM tests enabled the detection of a considerable proportion of TB patients, and it represents a **step forward for TB diagnosis**.

# Acknowledgements

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