Diagnostic performance of the novel FujiLAM assay to detect tuberculosis in HIV-positive patients from four African countries

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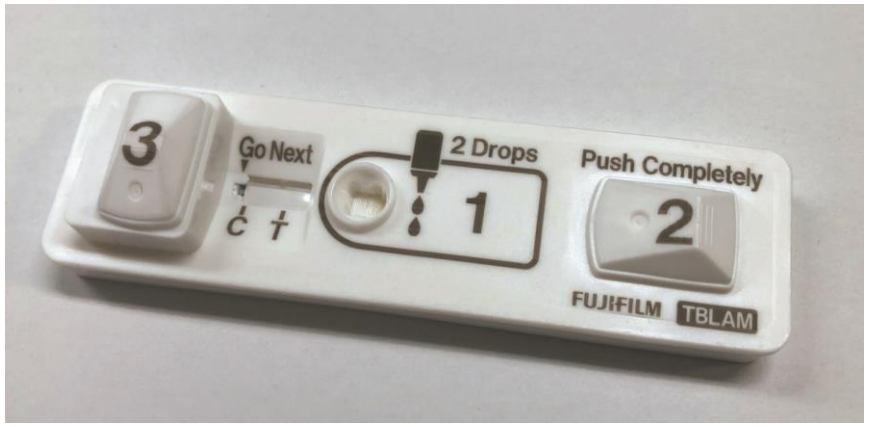
Background

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



Objective

Primary objective:

- To assess the diagnostic performance of FujiLAM in ambulatory HIV-positive patients

Secondary objectives:

- To assess feasibility of using FujiLAM and acceptability by test users (e-poster EP-27-361)
- To assess patients' perspectives on urine sampling for TB diagnosis (e-poster EP-27-366)
- To assess exposure and diagnosis of COVID-19 in HIV-positive patients investigated for TB (e-poster EP-11-202)

Methods

- Multicentric prospective diagnostic study
- Ambulatory HIV-positive adults:
  - **Group 1**: with signs and **symptoms of TB**
  - **Group 2**: with advanced HIV disease and **no symptoms of TB**
- 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

Results

Inclusions: 1 455 patients (August 2020 to August 2021)

	Group 1	Group 2
	TB symptoms N=927, n (%)	No TB symptoms & advanced HIV N=524, n (%)
Women	530 (57.2)	224 (42.7)
Age, median [IQR]	43 [35 – 53]	38 [30 – 45]
CD4 count, median [IQR]	539 [282 - 777]	133 [67 - 182]
On ART	796 (85.9)	448 (85.5)
Seriously ill	52 (5.6)	8 (1.5)

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TB diagnostic tests

	Group 1	Group 2
	TB symptoms % (n/N)	No TB symptoms & advanced HIV % (n/N)
Abbott TB-LAM positive	18.5 (171 / 926)	14.8 (77 / 521)
FujiLAM positive	17.1 (157 / 918)	15.5 (81 / 522)
Xpert or Culture positive (Confirmed TB)	10.1 (90 / 889)	3.7 (19 / 513)

FujiLAM vs Abbott TB-LAM results among confirmed TB

	FujiLAM			
	Negative		Positive	
	n	(%)	n	(%)
Group 1 (TB symptoms regardless CD4)				
- Abbott TB-LAM negative	28	(32.9)	25	(29.4)
- Abbott TB-LAM positive	6	(7.1)	26	(30.6)
Group 2 (no TB symptoms & advanced HIV)				
- Abbott TB-LAM negative	8	(42.1)	8	(42.1)
- Abbott TB-LAM positive	0	(0.0)	3	(15.8)

FujiLAM sensitivity among confirmed TB

	FujiLAM		Abbott TB-LAM	
	%	(95%CI)	%	(95%CI)
Group 1 (TB symptoms regardless CD4)	**60.0**	**(48.8-70.5)**	**40.0**	**(29.8-50.9)**
- CD4 <200	73.0	(55.9-86.2)	60.0	(43.3-75.1)
- CD4 200-349	72.2	(46.5-90.3)	42.1	(20.3-66.5)
- CD4 ≥350	32.0	(14.9-53.5)	11.5	(2.4-30.2)
Group 2 (no TB symptoms & advanced HIV)				
- CD4 <200	**61.1**	(35.7-82.7)	**16.7**	(3.6-41.4)

FujiLAM specificity among Xpert/Culture negative

	FujiLAM		Abbott TB-LAM	
	%	(95%CI)	%	(95%CI)
Group 1 (TB symptoms regardless CD4)	84.8	81.6-87.6	84.4	81.2-87.3
Group 2 (no TB symptoms & advanced HIV)	82.8	78.1-86.9	85.8	81.4-89.5

Conclusions

- **FujiLAM sensitivity was high** in both symptomatic and asymptomatic HIV-positive ambulatory patients with confirmed TB and **CD4 count <350 cells/µL**.
- **FujLAM sensitivity was lower** in less immunosuppressed patients (**≥ 350 cells/µL**).
- **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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