Note: This is Online Appendix for Mntonintshi M, Sossen B, Bookholane H, Lifson A, Africa L, René Goliath et al. Urine-based assays for inpatients with HIV-associated tuberculosis in rural South Africa. S Afr J HIV Med. 2025;26(1), a1705. https://doi.org/10.4102/sajhivmed.v26i1.1705

ONLINE APPENDIX 1

TABLE 1-A1: STARD checklist

Section & Topic	No.	Item	Reported on page #
Title or abstract	1	Identification as a study of diagnostic accuracy using at least one measure of accuracy (such as sensitivity, specificity, predictive values, or AUC)	1
Abstract	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	1
Introduction	3	Scientific and clinical background, including the intended use and clinical role of the index test	1-2
	4	Study objectives and hypotheses	2-3
Methods			
Study design	5	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	2-3
Participants	6	Eligibility criteria	2
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	2
	8	Where and when potentially eligible participants were identified (setting, location and dates)	2
	9	Whether participants formed a consecutive, random or convenience series	2
Test methods	10a	Index test, in sufficient detail to allow replication	3
	10b	Reference standard, in sufficient detail to allow replication	2-3
	11	Rationale for choosing the reference standard (if alternatives exist)	3
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	3
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	2-3
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test	3
	13b	Whether clinical information and index test results were available to the assessors of the reference standard	3
Analysis	14	Methods for estimating or comparing measures of diagnostic accuracy	3
	15	How indeterminate index test or reference standard results were handled	3
	16	How missing data on the index test and reference standard were handled	3
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	3
	18	Intended sample size and how it was determined	3
Results			
Participants	19	Flow of participants, using a diagram	4
	20	Baseline demographic and clinical characteristics of participants	4-5
	21a	Distribution of severity of disease in those with the target condition	4-5
	21b	Distribution of alternative diagnoses in those without the target condition	N/A
	22	Time interval and any clinical interventions between index test and reference standard	3
Test results	23	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	4
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	5-6
	25	Any adverse events from performing the index test or the reference standard	N/A
Discussion	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	8
	27	Implications for practice, including the intended use and clinical role of the index test	8-9
Other information	28	Registration number and name of registry	N/A
	29	Where the full study protocol can be accessed	9
	30	Sources of funding and other support; role of funders	9

TABLE 2-A1: Clinical details of patients deemed "false-positive" on Urine Xpert Ultra, against the composite reference standard

Age	Sex	CD4	ART status	Haemoglobin	Prior TB history	Urine Xpert Ultra category	AlereLAM result	Sputum tests	Other TB tests	Alternative diagnosis made	3-month follow up status
26	Male	157	Naïve	16.5	No	Trace positive	Negative	Not done	Negative	Young CVA	Alive; not on TB treatment
69	Male	362	On ART	13.4	Yes	Trace positive	Negative	Not done	Negative	Prostate adenocarcinoma	Alive; not on TB treatment
41	Female	206	Naïve	9.2	No	Trace positive	Negative	Negative	Negative	Newly diagnosed HIV and diabetes	Alive; not on TB treatment
22	Female	Unknown	On ART	Unknown	No	Trace positive	Negative	Negative	Negative	Anaemia of unknown origin	Alive; not known to be on TB treatment
49	Female	362	On ART	5.3	No	Trace positive	Not done	Negative	Negative	Gastroenteritis	Alive; not on TB treatment

TABLE 3-A1: Rifampicin probe results on Urine-XPU in comparison to Rifampicin resistance tests on all other available specimens

Variable	Urine-XPU Sensitive	Urine-XPU Resistant	Urine-XPU Indeterminate	Urine-XPU Negative	Urine-XPU Not done
Other tests Sensitive	16	3	7	16	0
Other tests Resistant	0	0	0	0	0
Other tests Indeterminate	0	1	0	3	0
Other tests all negative	3	0	6	149	2

TABLE 4-A1: Clinical and Laboratory details of participants with Rifampicin resistance detected on Urine Xpert Ultra

Demographics	ART status	TB history	AlereLAM result	Urine Xpert Ultra semi-quantitative result	Sputum Xpert Ultra	Sputum Culture	Urine Culture	Blood Culture	Other TB Tests
45 yr Male	Interrupted	No	Negative	Low	Trace MTB	Contaminated	Contaminated	Negative	None
47 yr Female	On ART	No	Positive	Low	Not done	Not done	Rifampicin sensitive MTB	Rifampicin sensitive MTB	None
39 yr Male	On ART	No	Negative	Medium	Rifampicin sensitive MTB	Rifampicin sensitive MTB	Contaminated	Negative	None
25 yr Female	On ART	No	Positive	Low	Not done	Not done	Rifampicin sensitive MTB	Rifampicin sensitive MTB	Lymph node aspirate: Rifampicin sensitive MTB

A

AlereLAM positive (n=28)

Started TB Treatment — n=23 (82.1%)

Did not start TB Treatment — n=3 (10.7%)

PID	Demographics	ART status	CD4	Hb	Sputum tests	FASH ultrasound	Other TB tests	10-week outcome	Alternative diagnosis made
RR013	18years, female	On ART	652	13.6	Not done	Negative	Urine, CSF neg	Alive	None; signed herself out of hospital without alternative diagnosis
RR090	57 years, female	On ART	137	11.1	Negative	Negative	Urine, Ascites neg	Alive	Unknown
RR117	47years, female	On ART	6	6	Not done	Not done	Rif Resistant MTB on Urine	Died before treatment initiated (day 1 of study)	None

B

FASH ultrasound suggestive (n=17)

Started TB Treatment — n=14 (82.4%)

Did not start TB Treatment — n=3 (17.6%)

PID	Demographics	ART status	CD4	Hb	Sputum tests	AlereLAM	Other TB tests	10-week outcome	Alternative diagnosis made
RR054	31years, female	On ART	22	3.7	Xpert negative	Negative	Urine and blood cultures negative	Alive	Chronic gastroenteritis
RR106	48years, female	ART interr.	Unk	Unk	Xpert negative	Negative	Urine and blood cultures negative	Lost to follow up	Ascites of unknown cause
RR213	28years, female	Naïve	Unk	7.8	Not done	Not done	Urine Xpert positive; Ascites ADA 50, Urine & Blood cultures positive MTB	Died day 5 of study, before treatment initiated	None

C

Urine-XPU positive (n=35)

Started TB Treatment — n=23 (65.7%)

Did not start TB Treatment — n=11 (31.4%)

PID	Demographics	ART status	CD4	Hb	Sputum tests	Bedside tests	Other TB tests	10-week outcome	Alternative diagnosis made
RR038	26years, male	Naïve	157	16.5	Not done	AlereLAM and FASH ultrasound neg	Urine & blood cultures neg	Alive	Young CVA
RR077	69years, male	On ART	362	13.4	Not done	AlereLAM and FASH ultrasound neg	Urine & blood cultures neg	Alive	Malignancy of bladder/prostate
RR101	41years, female	Naïve	206	9.2	Negative	AlereLAM and FASH ultrasound neg	Urine & blood cultures neg	Alive	Newly diagnosed HIV and Diabetes
RR117	47years, female	On ART	6	6.0	Not done	AlereLAM positive FASH ultrasound not done	Urine & blood cultures neg	Died before treatment initiated (day 1 of study)	None
RR120	27years, female	ART interr.	270	6.3	Positive MTB	AlereLAM and FASH ultrasound neg	Blood culture positive MTB	Died day 17 of study; results missed	COPD
RR124	35years, male	On ART	Unk	15.4	Not done	AlereLAM and FASH ultrasound neg	Urine & blood cultures neg	Alive; started TB treatment after study period	Epilepsy
RR130	43years, male	On ART	Unk	8.0	Not done	AlereLAM and FASH ultrasound neg	Blood & urine cultures positive MTB	Died day 8 of study; before treatment initiated	Pneumonia and Diarrhoea
RR133	22years, female	On ART	Unk	Unk	Negative	AlereLAM and FASH ultrasound neg	Urine & blood cultures neg	Alive	Anaemia
RR167	33years, male	On ART	128	10.6	Negative	AlereLAM and FASH ultrasound neg	Urine culture positive MTB	Died day 18 of study; results missed	Pneumonia
RR207	49years, female	On ART	362	5.3	Negative	AlereLAM not done FASH ultrasound neg	Urine & blood cultures neg	Alive	Acute gastroenteritis
RR213	28years, female	Naive	Unk	7.8	Not done	AlereLAM not done FASH ultrasound suggestive	Ascites ADA 50, Urine & Blood cultures positive MTB	Died day 5 of study, before treatment initiated	None

D

Sputum-XPU positive (n=31)

Started TB Treatment — n=22 (71.0%)

Did not start TB Treatment — n=7 (22.6%)

PID	Demographics	ART status	CD4	Hb	Sputum tests	Bedside tests	Other TB tests	10-week outcome	Alternative diagnosis made
RR093	33years, male	Naive	174	12.2	Trace positive Xpert; culture negative	AlereLAM negative FASH ultrasound negative	Urine Xpert, culture and blood culture negative	Alive	None
RR097	38years, male	ART interr.	241	13.7	Xpert and culture positive	AlereLAM negative FASH ultrasound negative	Urine Xpert, culture and blood culture negative	Alive	Pneumonia; discharged before result available and unable to trace patient to return
RR120	27years, female	ART interr.	270	6.3	Xpert and culture positive	AlereLAM negative FASH ultrasound negative	Urine Xpert and Blood culture positive MTB	Died day 17 of study; results missed	COPD
RR122	47years, female	ART interr.	248	11.7	Xpert and culture positive	AlereLAM negative FASH ultrasound negative	Urine Xpert, culture and blood culture negative	Lost to follow up	First presentation seizures; dysphagia to solids; TB diagnosis missed
RR129	46years, male	ART interr.	Unk	Unk	Xpert positive	AlereLAM negative FASH ultrasound not suggestive	Urine Xpert, CSF Xpert and blood culture negative	Died day 2 of study, before treatment initiated	Pneumonia and diarrhoea
RR131	65years, male	On ART	Unk	15.3	Trace positive Xpert; Culture AFBs but contam.	AlereLAM negative FASH ultrasound not suggestive	Urine Xpert and blood culture negative	Died day 3 of study, before treatment initiated	Structural lung disease with cor pulmonalae
RR194	39years, female	Unknown	Unk	Unk	Xpert positive	AlereLAM negative FASH ultrasound not suggestive	Urine Xpert and blood culture negative	Alive	Unknown

FIGURE 1-A1: TB treatment per rapid diagnostic test (A) for AlereLAM, (B) for FASH ultrasound, (C) for Urine Xpert Ultra and (D) for Sputum Xpert Ultra), with associated tables of clinical details in those with positive rapid diagnostic tests who were not initiated on TB treatment.