Appendix S2: 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)	Page # 1- 3 The title and abstract identify the manuscript as a study of diagnostic accuracy.
ABSTRACT	**2**	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	Page # 3 A structured abstract including objective, methods, results and conclusions are included.
INTRODUCTION	**3**	Scientific and clinical background, including the intended use and clinical role of the index test	Page # 4 and 5 The Introduction focuses on the manuscript in a wider context. It includes a brief review of the key references and the need for the development of the 'TB Concentration and Transport' and 'TB DNA Extraction' kits and evaluation for its compatibility with Who endorsed GenoType MTBDR*plus* and GenoType MTBDR*sl* tests.
	4	Study objectives and hypotheses	Page # 5 The 'TB Concentration and Transport' kit consisting of *Trans*-Filter device was developed to fulfil the need of sputum transport from lower-level laboratories to central laboratories in a bio-safe and a cost-effective manner. The 'TB DNA Extraction' kit was developed to extract DNA from *Trans*-Filter for rapid detection of TB and its associated drug resistance. In the present study, we evaluated the compatibility of above mentioned kits extracted DNA with WHO endorsed GenoType MTBDR*plus* and GenoType MTBDR*sl* tests.
METHODS			

Study design	**5**	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	Page # 5 and 6 Data collection was planned before the index test and reference standard were performed. The study was a prospective study performed in a double-blind manner.
Participants	**6**	Eligibility criteria	Page # 5 and 6 Patients belonging to the Presumptive MDR-TB/XDR-TB patient group were included in the study.
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	Page # 5 and 6 Patients belonging to the Presumptive MDR-TB/XDR-TB patient were included in the study.
	8	Where and when potentially eligible participants were identified (setting, location and dates)	Page # 5 and 6 All patients were enrolled after Institutional Ethical Clearance at the National Institute of Tuberculosis and Respiratory Diseases (NITRD, NITRD/EC/2017/0228) and Translational Health Science and Technology Institute [THSTI, THS 1.8.1/ (70)]. We obtained written informed consent from participants prior to sample collection.
	9	Whether participants formed a consecutive, random or convenience series	Page # 5 and 6 Patients belonging to the Presumptive MDR-TB/XDR-TB group were included consecutively in the study.
Test methods	**10a**	Index test, in sufficient detail to allow replication	Since our study involves validation of the kits, we have given details of the kit(s) protocol in page number 7 which can be sufficiently replicated while using the kit manual/protocol.
	10b	Reference standard, in sufficient detail to allow replication	Page #7 and 8 MGIT Culture and Culture DST were used as a reference standard wherever applicable, which is the conventional gold standard for TB diagnosis. Details are explained in referenced page numbers.
	11	Rationale for choosing the reference standard (if alternatives exist)	NA
	12a	Definition of and rationale for test positivity cut-offs or result	Page # 8 and 9

		categories of the index test, distinguishing pre-specified from exploratory	The TB Concentration and Transport' and 'TB DNA Extraction' kits was assessed for its compatibility with WHO endorsed GenoType MTBDR*plus* and GenoType MTBDR*sl* tests.
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	Page # 9 and 10 MGIT Culture was performed by standard NALC-NaOH method. The results were confirmed by using ZN smear and SD BIOLINE TB Ag MPT64 Rapid test (Standard Diagnostics). Then, MGIT-DST was performed from primary culture with standard drug MICs.
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test	Page # 6 and 7 The clinical information and reference standard results were not available to the performers/readers of the index test as the study was carried out in a double-blind manner.
	13b	Whether clinical information and index test results were available to the assessors of the reference standard	Page # 6 and 7 The clinical information and index test results were not available to the assessors of the reference standard as the study was carried out in a double-blind manner.
Analysis	**14**	Methods for estimating or comparing measures of diagnostic accuracy	Page # 9 and 10 Included in statistical analysis.
	15	How indeterminate index test or reference standard results were handled	Page # 9 and 10, Supplementary Fig S2-S5. Samples with indeterminate results were excluded from the study.
	16	How missing data on the index test and reference standard were handled	Page # 9 and 10, Supplementary Fig S2-S5. Samples with indeterminate results were excluded from the study.
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	Page # 9 and 10 Included in statistical analysis.
	18	Intended sample size and how it was determined	Page # 6. Sample size was estimated based on 85% power, alpha of 5% and positivity of 44% vs. 32% of kit extracted DNA based sequencing vs. MGIT-DST for determination of MDR-TB (unpublished data) using G*Power 3 software.

RESULTS			
Participants	**19**	Flow of participants, using a diagram	Page # 10 and Supplementary Fig S2-S5.
	20	Baseline demographic and clinical characteristics of participants	Page # 10
	21a	Distribution of severity of disease in those with the target condition	NA
	21b	Distribution of alternative diagnoses in those without the target condition	NA
	22	Time interval and any clinical interventions between index test and reference standard	NA
Test results	**23**	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	Page # 10 and 11 (Table 1 and Table 2).
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	Page # 10 and 11 (Table 1 and Table 2).
	25	Any adverse events from performing the index test or the reference standard	NA
DISCUSSION			
	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	Page # 14 and 15 Included under Discussion section.
	27	Implications for practice, including the intended use and clinical role of the index test	Page # 15 The 'TB Concentration & Transport' kit is suitable for use in lower-level laboratories such as DMCs and PHCs as it eliminates the requirement of centrifugation for sputum concentration which requires electricity and carries a potential risk of aerosol generation. It combines smoothly with the 'TB DNA Extraction' kit which provides highly

			pure DNA directly from sputum samples that integrates with molecular diagnostic approaches methods. In the future, the kit-integrated LPA will be evaluated for operational feasibility and performance in field settings under 'NTEP' for the detection of MDR-TB and XDR-TB. Details are included in Discussion section.
OTHER INFORMATION			
	28	Registration number and name of registry	NA
	29	Where the full study protocol can be accessed	NA
	30	Sources of funding and other support; role of funders	Details are given in 'Funding information' section.