

Supplementary Table 2: Downloadable version of the STARD-AI checklist

Section and Topic	No.	STARD-AI Item	Reported on page
Title or abstract			
	1	Identification as a study reporting AI-centred diagnostic accuracy and reporting at least one measure of accuracy within title or abstract	1
Abstract			
	2	Structured summary of study design, methods, results and conclusions (for specific guidance, please see STARD for Abstracts)	3
Introduction			
	3	Scientific and clinical background, including the intended use of the index test, whether it is novel or an established index test, and its integration into an existing or new workflow, if applicable	5
	4	Study objectives and hypotheses	5
Methods			
Study design	5	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	6
Ethics	6	Formal approval from an ethics committee. If not required, justify why	7
Participants	7	Eligibility criteria: listing separate inclusion and exclusion criteria in the order that they are applied at both participant level and data level	Not applicable
	8	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	Not applicable
	9	Where and when potentially eligible participants were identified (setting, location, and dates)	Not applicable
	10	Whether participants formed a consecutive, random, or convenience series	Not applicable
Dataset	11	Source of the data and whether it has been routinely collected, specifically collected for the purpose of the study or acquired from an open-source repository	6
	12	Who undertook the annotations for the dataset (including experience levels and background) and how (within the same clinical context or in a post-hoc fashion), if applicable	Not applicable
	13	Devices (manufacturer, model) that were used to capture data; software (with version number) used to engineer the index test, highlighting the intended use	6
	14	Data acquisition protocols (e.g. contrast protocol or reconstruction method for medical images) and details of data pre-processing in sufficient detail to allow replication	6
Test methods	15a	Index test, in sufficient detail to allow replication	6
	15b	How the index test was developed, including any training, validation, testing and external evaluation, detailing sample sizes, when applicable	6
	15c	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	6
	15d	The specified end user of the index test and the level of expertise required of users	7
	16a	Reference standard, in sufficient detail to allow replication	6

	16b	Rationale for choosing the reference standard (if alternatives exist)	
	16c	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	6
	17a	Whether clinical information and reference standard results were available to the performers or readers of the index test	Not applicable
	17b	Whether clinical information and index test results were available to the assessors of the reference standard	Not applicable
Analysis	18	Methods for estimating or comparing measures of diagnostic accuracy	6
	X 19	How indeterminate index test or reference standard results were handled	
	X 20	How missing data on the index test and reference standard were handled	
	21	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	7
	X 22	Intended sample size and how it was determined	
	23	Details of any performance error analysis, and algorithmic bias and fairness assessments if undertaken	7
Results			
Participants and dataset	24	Flow of participants, using a diagram	Not applicable
	25	Baseline demographic, clinical and technical characteristics of training, validation and test set, if applicable	Not applicable
	26a	Distribution of severity of disease in those with the target condition	Not applicable
	26b	Distribution of alternative diagnoses in those without the target condition	Not applicable
	27	Time interval and any clinical interventions between index test and reference standard	Not applicable
	28	Whether the datasets represent the distribution of the target condition that one would expect from the intended use population	Not applicable
	29	For external evaluation on an independent dataset, an assessment of how this differs from the training, validation and test sets	Not applicable
Test results	30	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	8
	31	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	8
	32	Any adverse events from performing the index test or the reference standard	Not applicable
Discussion			
	33	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	12
	34	Implications for practice, including the intended use and clinical role of the index test	12
	35	Ethical considerations and adherence to ethical standards associated with the use of the index test and issues of fairness	13
Other information			
	36	Registration number and name of registry	Not applicable
	37	Where the full study protocol can be accessed	7
	38	Sources of funding and other support; role of funders	1
	39	Commercial interests, if applicable	1
	40a	Availability of datasets and code; detailing any restrictions on their reuse and repurposing	7
	40b	Whether outputs are stored, auditable and available for evaluation, if necessary	7