

Table S1. STARD (Standards for Reporting of Diagnostic Accuracy Studies) checklist.

Section & Topic	No	Item	Reported in section (§)
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)	Title (NA)
ABSTRACT	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	Abstract (NA)
INTRODUCTION			
	3	Scientific and clinical background, including the intended use and clinical role of the index test	1 (1–7)
	4	Study objectives and hypotheses	1 (7)
METHODS			
<i>Study design</i>	5	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	4.2 (2)
	6	Eligibility criteria	4.2 (3)
<i>Participants</i>	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	4.2 (3, 4)
	8	Where and when potentially eligible participants were identified (setting, location and dates)	4.2 (1)
	9	Whether participants formed a consecutive, random or convenience series	4.2 (2, 4)
	10a	Index test, in sufficient detail to allow replication	4.4 (1, 2)
	10b	Reference standard, in sufficient detail to allow replication	4.3 (1)
	11	Rationale for choosing the reference standard (if alternatives exist)	4.2 (2)
<i>Test methods</i>	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	4.4 (3)
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	4.3 (2) and 4.2 (4)
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test	4.2 (1, 2)
	13b	Whether clinical information and index test results were available to the assessors of the reference standard	4.2 (1, 2)
	14	Methods for estimating or comparing measures of diagnostic accuracy	4.5 (2)
<i>Analysis</i>	15	How indeterminate index test or reference standard results were handled	4.4 (3) and 4.3 (2)
	16	How missing data on the index test and reference standard were handled	4.5 (1)
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	4.5 (2)
	18	Intended sample size and how it was determined	4.2 (4)
RESULTS			
<i>Participants</i>	19	Flow of participants, using a diagram	Figure S1
	20	Baseline demographic and clinical characteristics of participants	2 (1)
	21a	Distribution of severity of disease in those with the target condition	4.2 (4)

	21b	Distribution of alternative diagnoses in those without the target condition	Figure S1
	22	Time interval and any clinical interventions between index test and reference standard	4.2 (1)
<i>Test results</i>	23	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	1 (Table 1)
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	1 (Tables 2 and 3)
	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	3 (6)
	27	Implications for practice, including the intended use and clinical role of the index test	3 (1,4,5)
OTHER INFORMATION	28	Registration number and name of registry	See the note below
	29	Where the full study protocol can be accessed	See the note below
	30	Sources of funding and other support; role of funders	Funding

Note: The study aim and design is described in the grant agreement No 101003713; NA, not applicable.