

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)	2
INTRODUCTION			
	3	Scientific and clinical background, including the intended use and clinical role of the index test	3-5
	4	Study objectives and hypotheses	5-6
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)	6 prospective study
<i>Participants</i>	6	Eligibility criteria	6, Fig. 1
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	6, 7
	8	Where and when potentially eligible participants were identified (setting, location and dates)	6, 8
	9	Whether participants formed a consecutive, random or convenience series	6
<i>Test methods</i>	10a	Index test, in sufficient detail to allow replication	8-10
	10b	Reference standard, in sufficient detail to allow replication	8-10
	11	Rationale for choosing the reference standard (if alternatives exist)	N/A
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	N/A
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	N/A
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test	N/A
	13b	Whether clinical information and index test results were available to the assessors of the reference standard	N/A
<i>Analysis</i>	14	Methods for estimating or comparing measures of diagnostic accuracy	8
	15	How indeterminate index test or reference standard results were handled	N/A
	16	How missing data on the index test and reference standard were handled	N/A
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	N/A
	18	Intended sample size and how it was determined	8
RESULTS			
<i>Participants</i>	19	Flow of participants, using a diagram	Fig 1; 8
	20	Baseline demographic and clinical characteristics of participants	6, 7
	21a	Distribution of severity of disease in those with the target condition	N/A
	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	Fig 1; 8
<i>Test results</i>	23	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	8
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	11-15
	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	18-20
	27	Implications for practice, including the intended use and clinical role of the index test	19
OTHER INFORMATION			
	28	Registration number and name of registry	8, 9
	29	Where the full study protocol can be accessed	8, 21
	30	Sources of funding and other support; role of funders	N/A