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)	#3
ABSTRACT			
	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	#3
INTRODUCTION			
	3	Scientific and clinical background, including the intended use and clinical role of the index test	#4-5
	4	Study objectives and hypotheses	#6
METHODS			
Study design	**5**	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	#5
Participants	**6**	Eligibility criteria	#6, Supp. Data #5-6
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	#6
	8	Where and when potentially eligible participants were identified (setting, location and dates)	#6
	9	Whether participants formed a consecutive, random or convenience series	#6
Test methods	**10a**	Index test, in sufficient detail to allow replication	#6-7, Supp. Data #7
	10b	Reference standard, in sufficient detail to allow replication	#7-8
	11	Rationale for choosing the reference standard (if alternatives exist)	#1 and 7
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	#7, Supp. Data #7
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	#7
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test	#7
	13b	Whether clinical information and index test results were available to the assessors of the reference standard	#7
Analysis	**14**	Methods for estimating or comparing measures of diagnostic accuracy	#8
	15	How indeterminate index test or reference standard results were handled	#8
	16	How missing data on the index test and reference standard were handled	Not applicable
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	Not applicable
	18	Intended sample size and how it was determined	#6
RESULTS			
Participants	**19**	Flow of participants, using a diagram	#9, No diagram.
	20	Baseline demographic and clinical characteristics of participants	#20
	21a	Distribution of severity of disease in those with the target condition	#20
	21b	Distribution of alternative diagnoses in those without the target condition	#20
	22	Time interval and any clinical interventions between index test and reference standard	#9
Test results	**23**	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	Supp. Data #22-23
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	Not done, Phase 2
	25	Any adverse events from performing the index test or the reference standard	#11
DISCUSSION			
	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	#12-13
	27	Implications for practice, including the intended use and clinical role of the index test	#14
OTHER INFORMATION			
	28	Registration number and name of registry	#6
	29	Where the full study protocol can be accessed	#6
	30	Sources of funding and other support; role of funders	#14