

S3 Table. Standards for Reporting Diagnostic accuracy studies (STARD) checklist used in this study

The checklist obtained from <http://www.equator-network.org/reporting-guidelines/stard> (43).

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 2
ABSTRACT			
	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	Page 2
INTRODUCTION			
	3	Scientific and clinical background, including the intended use and clinical role of the index test	Page 3
	4	Study objectives and hypotheses	Page 4
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)	Page 4-5
<i>Participants</i>	6	Eligibility criteria	Page 4-5
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	Page 4-5
	8	Where and when potentially eligible participants were identified (setting, location and dates)	Page 4-5
	9	Whether participants formed a consecutive, random or convenience series	Page 4-5
<i>Test methods</i>	10a	Index test, in sufficient detail to allow replication	Page 6-8
	10b	Reference standard, in sufficient detail to allow replication	Page 9
	11	Rationale for choosing the reference standard (if alternatives exist)	Page 9
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	Page 6
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	Page 9
	13a	Whether clinical information and reference standard results were available to the performers/readers of the index test	Reference standard results were compared with ddPCR results in Table 2.
	13b	Whether clinical information and index test results were available to the assessors of the reference standard	Index test results were compared with reference standard results in Table 2.
<i>Analysis</i>	14	Methods for estimating or comparing measures of diagnostic accuracy	Page 9-11
	15	How indeterminate index test or reference standard results were handled	There is no indeterminate index test or reference standard results.
	16	How missing data on the index test and reference standard were handled	There is no missing data.
	17	Any analyses of variability in diagnostic accuracy, distinguishing pre-specified from exploratory	Page 13
	18	Intended sample size and how it was determined	Page 4
RESULTS			
<i>Participants</i>	19	Flow of participants, using a diagram	Figure 1
	20	Baseline demographic and clinical characteristics of participants	Page 4
	21a	Distribution of severity of disease in those with the target condition	No
	21b	Distribution of alternative diagnoses in those without the target condition	No
	22	Time interval and any clinical interventions between index test and reference standard	Page 14 There is no clinical intervention.
<i>Test results</i>	23	Cross tabulation of the index test results (or their distribution) by the results of the reference standard	Page 13 Table 2
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	Page 9-10
	25	Any adverse events from performing the index test or the reference standard	No
DISCUSSION			

	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalizability	Page 16
	27	Implications for practice, including the intended use and clinical role of the index test	Page 17
OTHER INFORMATION			
	28	Registration number and name of registry	No
	29	Where the full study protocol can be accessed	No
	30	Sources of funding and other support; role of funders	Page 17