STARD checklist (2015); essential items for reporting diagnostic accuracy studies

Section and topic	No	Item	Inclusion in manuscript
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)	Defined in objectives section in structured abstract
Abstract			
	2	Structured summary of study design, methods, results, and conclusions (for specific guidance, see STARD for Abstracts)	Structured abstract provided, including required sub-sections
Introduction			
	3	Scientific and clinical background, including the intended use and clinical role of the index test	Described in introduction, paragraph 3
	4	Study objectives and hypotheses	Described in final paragraph of introduction
Methods			
Study design	5	Whether data collection was planned before the index test and reference standard were performed (prospective study) or after (retrospective study)	Samples stratified based on timing of collection, and retrospectively based on RT-PCR diagnosis; described in ‘samples’ section of methods
Participants	6	Eligibility criteria	Sample selection described in ‘samples’ section of methods
	7	On what basis potentially eligible participants were identified (such as symptoms, results from previous tests, inclusion in registry)	Description of RT-PCR in paragraph 2 of results

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	8	Where and when potentially eligible participants were identified (setting, location, and dates)	Provided in methods
	9	Whether participants formed a consecutive, random, or convenience series	Provided in methods
Test methods	10a	Index test, in sufficient detail to allow replication	Provided in Supplementary Materials
	10b	Reference standard, in sufficient detail to allow replication	Provided in Supplementary Materials
	11	Rationale for choosing the reference standard (if alternatives exist)	RT-PCR is widespread reference standard with no relevant alterantives
	12a	Definition of and rationale for test positivity cut-offs or result categories of the index test, distinguishing pre-specified from exploratory	Provided in methods and results (including Figure 2)
	12b	Definition of and rationale for test positivity cut-offs or result categories of the reference standard, distinguishing pre-specified from exploratory	Provided in Supplementary Materials
	13a	Whether clinical information and reference standard results were available to the performers or readers of the index test	Clinical information not available to performers or readers of ELISA or lateral flow assays
	13b	Whether clinical information and index test results were available to the assessors of the reference standard	Clinical information not available to performers or readers or RT-PCR
Analysis	14	Methods for estimating or comparing measures of diagnostic accuracy	Sensitivity, specificity, positive and negative predictive value, and other statistical tests included in methods and in Fig 1D,E)
	15	How indeterminate index test or reference	Described in methods for LFIA devices (and

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		standard results were handled	Figure 1C)
	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	Confidence intervals around point estimates provided in figure S1
	18	Intended sample size and how it was determined	Pragmatic sample size based on availability of LFIA devices stated. Estimate of numbers needed to increase power stated in discussion section.
Results			
Participants	19	Flow of participants, using a diagram	142 pre-pandemic samples + 40 COVID-positive samples described in methods section entitled ‘samples’. Flow diagram not required to support description.
	20	Baseline demographic and clinical characteristics of participants	Provided in Suppl table S1
	21a	Distribution of severity of disease in those with the target condition	Provided in Suppl table S1
	21b	Distribution of alternative diagnoses in those without the target condition	Not applicable
	22	Time interval and any clinical interventions between index test and reference standard	Time intervals for symptoms provided in Suppl Table S1. No clinical interventions in this study.
Test results	23	Cross tabulation of the index test results (or their distribution) by the results of the reference	Subjects selected according to index test results; presented in Suppl Table S1.

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		standard	
	24	Estimates of diagnostic accuracy and their precision (such as 95% confidence intervals)	Provided in results; Table 1
	25	Any adverse events from performing the index test or the reference standard	Not applicable – laboratory work undertaken retrospectively on banked samples.
Discussion			
	26	Study limitations, including sources of potential bias, statistical uncertainty, and generalisability	Addressed in discussion.
	27	Implications for practice, including the intended use and clinical role of the index test	Addressed in dicussion.
Other information			
	28	Registration number and name of registry	Not applicable
	29	Where the full study protocol can be accessed	Fully study protocol provided within methods and supporting materials
	30	Sources of funding and other support; role of funders	Sources of funding and role of funders included in manuscript