OPEN

Comparison of diagnostic accuracy of rapid antigen tests for COVID-19 compared to the viral genetic test in adults: a systematic review and meta-analysis

Ellyn Hirabayashi[1] • Guadalupe Mercado[1] • Brandi Hull[1] • Sabrina Soin[1] • Sherli Koshy-Chenthittayil[1] • Sarina Raman[1] • Timothy Huang[1] • Chathushya Keerthisinghe[1] • Shelby Feliciano[1] • Andrew Dongo[1] • James Kal[1] • Azliyati Azizan[1] • Karen Duus[1] • Terry Else[1] • Megan DeArmond[2,3] • Amy E.L. Stone[1]

[1]Touro University Nevada, College of Osteopathic Medicine, Department of Basic Sciences, Henderson, NV, USA, [2]Touro University Nevada, Jay Sexter Library, Henderson, NV, USA, and [3]Touro University Nevada: JBI Affiliated Group, Henderson, NV, USA

ABSTRACT

Objective: The objective of this review was to determine the diagnostic accuracy of the currently available and upcoming point-of-care rapid antigen tests (RATs) used in primary care settings relative to the viral genetic real-time reverse transcriptase polymerase chain reaction (RT-PCR) test as a reference for diagnosing COVID-19/SARS-CoV-2 in adults.

Introduction: Accurate COVID-19 point-of-care diagnostic tests are required for real-time identification of SARS-CoV-2 infection in individuals. Real-time RT-PCR is the accepted gold standard for diagnostic testing, requiring technical expertise and expensive equipment that are unavailable in most primary care locations. RATs are immunoassays that detect the presence of a specific viral protein, which implies a current infection with SARS-CoV-2. RATs are qualitative or semi-quantitative diagnostics that lack thresholds that provide a result within a short time frame, typically within the hour following sample collection. In this systematic review, we synthesized the current evidence regarding the accuracy of RATs for detecting SARS-CoV-2 compared with RT-PCR.

Inclusion criteria: Studies that included nonpregnant adults (18 years or older) with suspected SARS-CoV-2 infection, regardless of symptomology or disease severity, were included. The index test was any available SARS-CoV-2 point-of-care RAT. The reference test was any commercially distributed RT-PCR–based test that detects the RNA genome of SARS-CoV-2 and has been validated by an independent third party. Custom or in-house RT-PCR tests were also considered, with appropriate validation documentation. The diagnosis of interest was COVID-19 disease and SARS-CoV-2 infection. This review considered cross-sectional and cohort studies that examined the diagnostic accuracy of COVID-19/SARS-CoV-2 infection where the participants had both index and reference tests performed.

Methods: The keywords and index terms contained in relevant articles were used to develop a full search strategy for PubMed and adapted for Embase, Scopus, Qinsight, and the WHO COVID-19 databases. Studies published from November 2019 to July 12, 2022, were included, as SARS-CoV-2 emerged in late 2019 and is the cause of a continuing pandemic. Studies that met the inclusion criteria were critically appraised using QUADAS-2. Using a customized tool, data were extracted from included studies and were verified prior to analysis. The pooled sensitivity, specificity, positive predictive, and negative predictive values were calculated and presented with 95% CIs. When heterogeneity was observed, outlier analysis was conducted, and the results were generated by removing outliers.

Correspondence: Megan DeArmond, mde_armo@touro.edu

The authors declare no conflicts of interest.

Supplemental digital content is available for this article. Direct URL citations are provided in the HTML and PDF versions of this article on the journal's website, www.jbievidencesynthesis.com.

DOI: 10.11124/JBIES-23-00291

Results: Meta-analysis was performed on 91 studies of 581 full-text articles retrieved that provided true-positive, true-negative, false-positive, and false-negative values. RATs can identify individuals who have COVID-19 with high reliability (positive predictive value 97.7%; negative predictive value 95.2%) when considering overall performance. However, the lower level of sensitivity (67.1%) suggests that negative test results likely need to be retested through an additional method.

Conclusions: Most reported RAT brands had only a few studies comparing their performance with RT-PCR. Overall, a positive RAT result is an excellent predictor of a positive diagnosis of COVID-19. We recommend that Roche's SARS-CoV-2 Rapid Antigen Test and Abbott's BinaxNOW tests be used in primary care settings, with the understanding that negative results need to be confirmed through RT-PCR. We recommend adherence to the STARD guidelines when reporting on diagnostic data.

Review registration: PROSPERO CRD42020224250

Keywords: COVID19; point of care; rapid antigen tests; respiratory infection; SARS-CoV-2

JBI Evid Synth 2024; 22(10):1939–2002.

Summary of Findings

Test accuracy of STANDARD Q COVID-19 Antigen test from SD Biosensor for COVID-19 or SARS-CoV-2 infection in symptomatic adults

Sensitivity	0.782 (95% CI: 0.587 to 0.900)		
Specificity	0.984 (95% CI: 0.949 to 0.995)		
Prevalences	0.5%	5%	10%

Outcome	№ of studies (№ of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 1000 patients tested			Test accuracy certainty of evidence
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	Pre-test probability of 0.5% (95% CI)	Pre-test probability of 5% (95% CI)	Pre-test probability of 10% (95% CI)	
True positives	4 studies (3179 patients)	cross-sectional (cohort type accuracy study)	not serious	not serious	very serious[a]	not serious	none	4 (3 to 5)	39 (29 to 45)	78 (59 to 90)	⨁⨁◯◯ Low
False negatives								1 (0 to 2)	11 (5 to 21)	22 (10 to 41)	
True negatives	4 studies (3179 patients)	cross-sectional (cohort type accuracy study)	not serious	not serious	serious[a]	not serious	none	979 (944 to 990)	935 (902 to 945)	886 (854 to 896)	⨁⨁⨁◯ Moderate
False positives								16 (5 to 51)	15 (5 to 48)	14 (4 to 46)	

Explanations:
a. High heterogeneity across studies.

Test accuracy of PanBio by Abbott for COVID-19 or SARS-CoV-2 infection in symptomatic adults

Sensitivity	0.780 (95% CI: 0.610 to 0.889)		
Specificity	0.999 (95% CI: 0.993 to 1.000)		
Prevalences	0.5%	5%	10%

Outcome	№ of studies (№ of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 1000 patients tested			Test accuracy certainty of evidence
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	Pre-test probability of 0.5% (95% CI)	Pre-test probability of 5% (95% CI)	Pre-test probability of 10% (95% CI)	
True positives	2 studies (1324 patients)	cross-sectional (cohort type accuracy study)	not serious	not serious	very serious[a]	not serious	none	4 (3 to 4)	39 (31 to 44)	78 (61 to 89)	⨁⨁◯◯ Low
False negatives								1 (1 to 2)	11 (6 to 19)	22 (11 to 39)	
True negatives	2 studies (1324 patients)	cross-sectional (cohort type accuracy study)	not serious	not serious	not serious	not serious	none	994 (988 to 995)	949 (943 to 950)	899 (894 to 900)	⨁⨁⨁⨁ High
False positives								1 (0 to 7)	1 (0 to 7)	1 (0 to 6)	

Explanations:
a. High heterogeneity across studies.

Test accuracy of Roche SARS-CoV-2 Rapid Antigen Test for COVID-19 or SARS-CoV-2 infection in symptomatic adults

Sensitivity	0.812 (95% CI: 0.762 to 0.855)		
Specificity	0.996 (95% CI: 0.974 to 0.999)		
Prevalences	0.5%	5%	10%

Outcome	№ of studies (№ of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 1000 patients tested			Test accuracy certainty of evidence
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	Pre-test probability of 0.5% (95% CI)	Pre-test probability of 5% (95% CI)	Pre-test probability of 10% (95% CI)	
True positives	2 studies (874 patients)	cross-sectional (cohort type accuracy study)	not serious	not serious	not serious	not serious	none	4 (4 to 4)	41 (38 to 43)	81 (76 to 86)	⨁⨁⨁⨁ High
False negatives								1 (1 to 1)	9 (7 to 12)	19 (14 to 24)	
True negatives	2 studies (874 patients)	cross-sectional (cohort type accuracy study)	not serious	not serious	not serious	not serious	none	991 (969 to 994)	946 (925 to 949)	896 (877 to 899)	⨁⨁⨁⨁ High
False positives								4 (1 to 26)	4 (1 to 25)	4 (1 to 23)	

Test accuracy of BinaxNOW by Abbott for COVID-19 or SARS-CoV-2 infection in symptomatic adults

Sensitivity	0.867 (95% CI: 0.797 to 0.919)		
Specificity	0.988 (95% CI: 0.974 to 0.996)		
Prevalences	0.5%	5%	10%

Outcome	№ of studies (№ of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 1000 patients tested			Test accuracy certainty of evidence
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	Pre-test probability of 0.5% (95% CI)	Pre-test probability of 5% (95% CI)	Pre-test probability of 10% (95% CI)	
True positives	1 study 642 patients	cross-sectional (cohort type accuracy study)	not serious	not serious	not serious	not serious	none	4 (4 to 5)	43 (40 to 46)	87 (80 to 92)	⨁⨁⨁⨁ High
False negatives								1 (0 to 1)	7 (4 to 10)	13 (8 to 20)	
True negatives	1 study 642 patients	cross-sectional (cohort type accuracy study)	not serious	not serious	not serious	not serious	none	983 (969 to 991)	939 (925 to 946)	889 (877 to 896)	⨁⨁⨁⨁ High
False positives								12 (4 to 26)	11 (4 to 25)	11 (4 to 23)	

Introduction

According to the World Health Organization, as of August 2024, there were more than 775 million confirmed cases of COVID-19 caused by the virus SARS-CoV-2 and more than 7 million deaths.[1] In addition to recently updated vaccines, testing and accurate diagnosis of SARS-CoV-2 has been a key tool in fighting the pandemic.[2] Based on the current statistics of new cases[1] showing that the virus remains in circulation within human and animal populations,[3] accurate diagnostic testing is required to prevent future outbreaks that can lead to additional loss of life.

Accurate COVID-19 point-of-care (POC) diagnostic tests are required for real-time identification of SARS-CoV-2 infections in individuals. Early and accurate identification of potential cases leads to better control of virus transmission and early treatment interventions for individuals at high risk of severe disease. At this point, asymptomatic screening for SARS-CoV-2 infection has fallen out of fashion, with most public locations not requiring tests as part of day-to-day life. However, symptomatic individuals who present at primary care locations need to be diagnosed quickly and reliably. Real-time reverse transcriptase PCR (qRT-PCR or RT-PCR) is the accepted gold standard for diagnostic testing[4] and is available in many health care settings. However, RT-PCR requires technical expertise and expensive equipment that are not available in most primary care locations. Additionally, samples are required to be collected at the POC and sent to off-site laboratories for testing. The time delay between visiting the primary care provider and receiving results can increase transmission and delay appropriate treatment. For SARS-CoV-2 infections, RT-PCR detects viral RNA but is unable to discriminate between transmissible and replicating viruses and RNA remaining after the infection has been contained by the immune system.[5] Primary care providers should have access to reliable POC rapid antigen tests (RATs) for COVID-19, similar to those that are available for many other infectious diseases. Evaluation of the accuracy of POC diagnostic tests is needed to utilize these tests with confidence.[6]

Rapid antigen tests are immunoassays that detect the presence of a specific viral protein, glycan, or nucleic acid, which implies a current infection with SARS-CoV-2. RATs are useful for identifying infectious viruses as they detect viral proteins, which are cleared before the remaining viral RNA.[5] The accuracy of these tests compared with the gold standard RT-PCR appears to vary depending on the manufacturer. However, many studies have reported disparate

accuracy results compared with manufacturers' reported results.[7–12] In this systematic review, we synthesized the current evidence regarding RAT accuracy for the detection of SARS-CoV-2, and considered the overall performance of these techniques compared with the gold standard RT-PCR.

A search of PROSPERO, DARE (Database of Abstracts of Reviews of Effects), PubMed, the Cochrane Database of Systematic Reviews, JBI Registration of Systematic Review Titles, and *JBI Evidence Synthesis* was conducted in November 2020. We identified 1 review in PROSPERO[13] and 2 systematic reviews in the Cochrane Database of Systematic Reviews,[14,15] each of which became available after our title registration in PROSPERO and the JBI Registration of Systematic Review Titles in June 2020. The PROSPERO review examined peer-reviewed publications for tests commercially available before August 15, 2020.[13] Our systematic review included additional sources for tests, including gray literature available from the manufacturers, and included search results from tests not yet commercially available. The literature searches of the 2 Cochrane reviews ended in May 2020[14,15] and were updated in July 2022, with a search that ended in March 2021.[16] In the time since then, significant amounts of research and numbers of tests have become available, warranting an additional review. With the rapidly changing environment around COVID-19, our review adds to those published with a longer, more recent timeline. Additionally, our question is of a more general nature of POC diagnostic accuracy for primary care settings anywhere in the world. Our review has important implications for health care providers caring for patients in both resource-rich and resource-poor regions.

We framed our review question using the population index test reference test diagnosis (PIRD) mnemonic, which is commonly used for diagnostic reviews.[17] The objective of this systematic review was to synthesize the best available evidence related to the diagnostic accuracy of the available POC RATs (index test) relative to a certified medical laboratory viral genetic RT-PCR test (reference test) for the diagnosis of COVID-19/SARS-CoV-2 in adults 18 years and older. The rationale for combining both test types in this systematic review was to provide a comprehensive comparison of RT-PCR with the POC RATs. As the COVID-19 pandemic continues to rapidly evolve, the highest diagnostic accuracy, lowest cost, and quickest results are important considerations for monitoring and managing disease spread in a primary care setting. The aim of this study was to identify the rapid diagnostic tests that fit this requirement.

Review question

What is the diagnostic accuracy of the currently available and upcoming POC RATs used in primary care settings relative to the viral genetic RT-PCR test as a reference for the diagnosis of COVID-19/SARS-CoV-2 in adults?

Inclusion criteria

Participants

The review examined studies that included non-pregnant adults (18 years and older) with suspected SARS-CoV-2 infection, regardless of symptomology or disease severity. Persons of any ethnicity or race in any geographic location were considered. Studies that included data from pregnant women or children within the study population that could be separated from the overall study data were included in the review. We excluded studies that only contained tests that could not be used in primary care settings, such as those that required larger equipment or specialized expertise. The setting of the study was recorded but not used as an exclusion criterion. Any non-primary care setting was initially an exclusion criterion,[18] but upon further discussion, the criterion was adjusted to focus on the RAT used rather than the setting in which the RAT was used.

Index test

The index tests investigated in this review were any currently available or pre-market POC SARS-CoV-2 RATs. RATs are qualitative or semi-quantitative diagnostics that provide a result within a short time frame, typically within the hour following sample collection.[19] Tests could use any easily obtained bodily fluid or sample, including saliva, mucus, blood, urine, breath, or feces. Most of the studies considered used nasopharyngeal, nasal, or oropharyngeal swab specimens. RATs include a variety of techniques, such as chromogenic-based or fluorescence-based detection and lateral flow-based detection, but as a common denominator, all detect viral antigens from presently infected fluids and cells.[19] Tests that detect immunoglobulin against SARS-CoV-2 were excluded from this review, as antibodies develop upon resolution of

SARS-CoV-2 infection or from vaccination and, therefore, are not used in the POC setting for diagnosing acute infection.[6]

Reference test

The reference test was commercially distributed RT-PCR–based tests that detect the RNA genome of SARS-CoV-2 and have been validated by an independent third party. Additionally, custom or in-house RT-PCR tests were considered with appropriate validation documentation. For example, Japan's National Institute of Infectious Disease method was accepted as a validated RT-PCR test.[20] These tests must be performed in certified laboratories where personnel have been trained to perform RT-PCR assays.

Diagnosis of interest

The diagnoses of interest were COVID-19 disease and SARS-CoV-2 infection.

Types of studies

This review considered any English-language or English-translated cross-sectional or cohort study that examined the diagnostic accuracy (sensitivity and specificity, positive predictive value, negative predictive value) of COVID-19/SARS-CoV-2 infection where the participants had both index and reference tests performed. Case-control studies were excluded due to high risk of bias (see "Assessment of methodological quality"). Meta-analysis was performed on studies that provided true-positive (TP), true-negative (TN), false-positive (FP), and false-negative (FN) values. Studies published from November 2019 to July 12, 2022, were included, as SARS-CoV-2 emerged in late 2019 and is the cause of a continuing pandemic.

Methods

This systematic review was conducted in accordance with JBI methodology for systematic reviews of diagnostic test accuracy[17] and follows our published protocol,[18] with exceptions noted throughout.

Search strategy

The search strategies for all databases aimed to locate published and unpublished studies, including preprints. An initial limited search of several sources was undertaken to identify articles, review other search strategies, and search for published articles on the topic. These initial sources were PubMed, PROSPERO, *JBI Evidence Synthesis*, Cochrane Database of Systematic Reviews, DARE, and the Cochrane Central Register of Controlled Trials. The text words contained in the titles and abstracts of relevant articles and the articles' index terms were used to develop a full search strategy for PubMed. We adopted the Canadian Agency for Drugs and Technologies (CADTH) COVID-19 search string developed for PubMed.[21] Once a draft was fully developed, the PubMed search strategy was peer-reviewed by a medical librarian following the Peer Review of Electronic Search Strategy (PRESS) Guideline Statement.[22] After that initial pilot search, the search strategy was further edited and finalized for review. The search strategy, including all identified keywords and index terms, was adapted for each included information source.

The full search of MEDLINE (PubMed), Embase, Scopus, Qinsight (Quertle), and the World Health Organization (WHO) COVID-19 database was undertaken in July 2021 and updated on July 12, 2022 (with the exception of Qinsight, which was no longer available). See Appendix I for the full search strategy. Scopus, Qinsight, and WHO COVID-19 include gray literature.

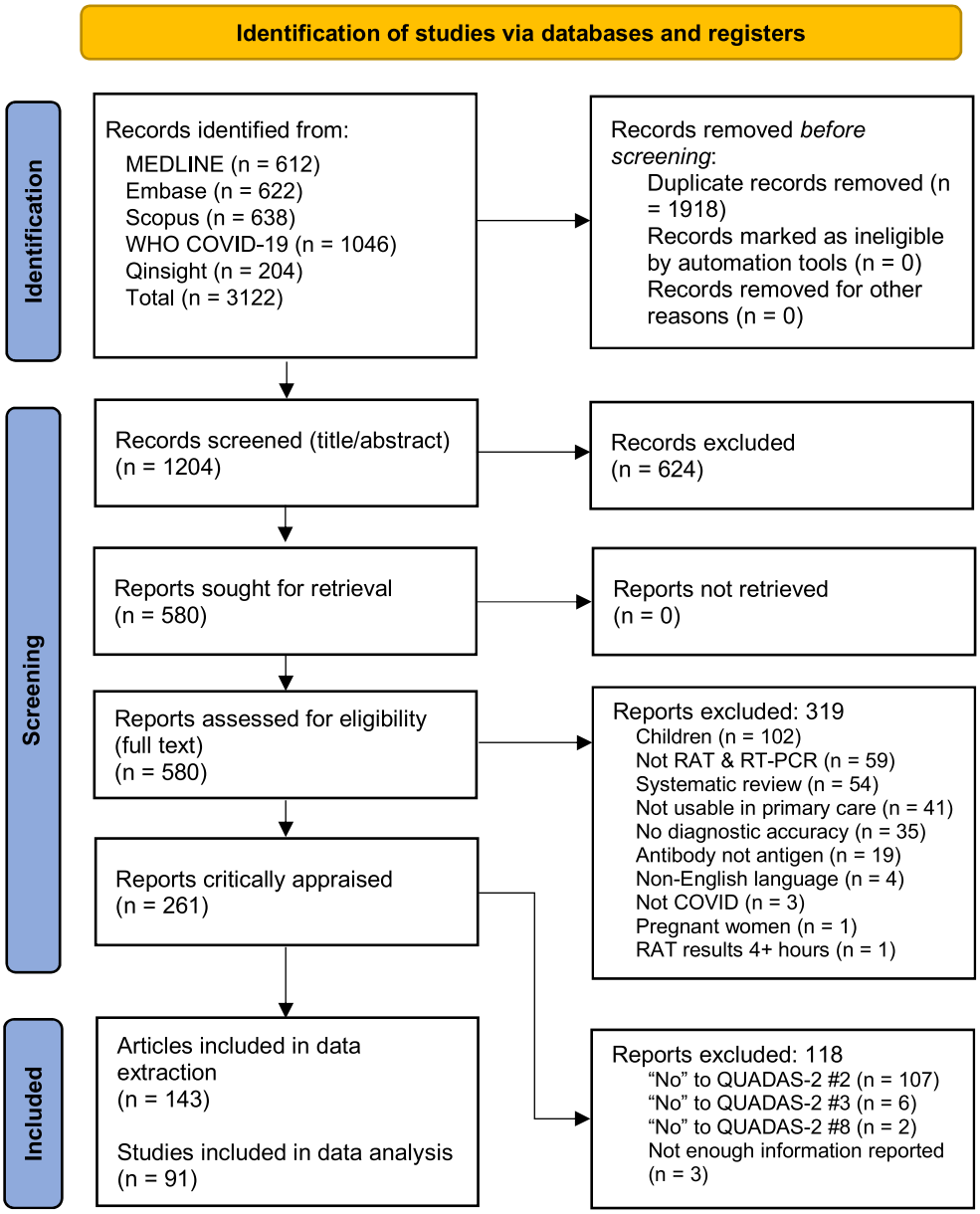
Study selection

Following the search, all identified citations were collated and uploaded into EndNote v.X9.3.3. The EndNote edition was later upgraded to EndNote 20.5 (Clarivate Analytics, PA, USA). All duplicates were removed using a method developed and detailed by Bramer *et al*.[23] Titles and abstracts were screened first by 2 independent reviewers of the research team (EH, GM, BH, SS, SR, TH, CK, SF, AD, JK, AA, KD, TE, MD, AS) against the inclusion criteria using Google Sheets. Potentially relevant studies were retrieved in full, and their citation details were imported into a Google Sheet. The full texts of selected citations were assessed in detail against the inclusion criteria by at least 2 reviewers from the team independently (EH, GM, BH, SS, SR, TH, CK, SF, AD, JK, AA, KD, TE, MD, AS). Conflicts were resolved at the completion of each stage by a third reviewer (AS, AA, KD, TE). Reasons for the exclusion of full-text studies that did not meet the inclusion criteria were recorded and are provided in Supplemental Digital Content 1, http://links.lww.com/SRX/A55. The results of the search and screening are presented in a Preferred Reporting

Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram[24] (Figure 1).

Assessment of methodological quality

Selected studies were critically appraised by at least 2 reviewers from the team independently (EH, GM, BH, SS, SR, TH, CK, SF, AD, JK, AA, KD, TE, MD, AS) for risk of bias using the standardized critical appraisal instrument from the QUADAS-2.[25] QUADAS-2 provides a series of yes/no questions to appraise studies. At a minimum, we required the following questions to be answered "yes" for a study



RAT, rapid antigen test; RT-PCR, reverse transcriptase polymerase chain reaction

Figure 1: Search results and study selection and inclusion process[24]

to be included in the systematic review: #2: Was a case-control design avoided? #3: Did the study avoid inappropriate exclusions? #6: Is the reference standard likely to correctly classify the target condition? #8: Was there an appropriate interval between the index test and reference standard?

Studies that answered "no" or "unclear" to any of these 4 QUADAS-2 questions were excluded. Disagreements were resolved through discussion or with an additional reviewer. The decision to exclude was based on the consensus of the 2 independent reviewers and, if needed, an additional reviewer (EH, GM, BH, SS, SR, TH, CK, SF, AD, JK, AA, KD, TE, MD, AS). Studies were excluded from data extraction if specificity and sensitivity were not presented or the data could not be used to calculate specificity and sensitivity. We did not exclude any studies due to low statistical power.

Data extraction

We performed a pilot data extraction of 52 studies to determine the effectiveness of our initial data extraction tool. Based on the challenges of combining the extracted data from the pilot data extraction, a new custom data extraction tool was developed, building on the initial tool. The custom data extraction tool was modified from the original protocol to better separate and standardize the data during extraction. See Appendix II for the updated data extraction tool. We identified specific portions of the data extraction tool to be standardized prior to data extraction, including the setting, sample, reference test, and index test. For these, we used drop downs for the data extractors to select from, including an "other" option that allowed the entering of data items not found in the initial pilot extraction. The extracted data were reviewed and verified prior to analysis. The final standardization of data was performed by 2 individuals (SK-C, AS) to ensure inter-extractor reliability.

For each study, we identified the primary (dominant) strain of SARS-CoV-2 circulating in the study country during the study time frame using CoVariants.org.[26] When specific dates or specific country-level data were not available, variants were estimated by the time frame of initial study submission and dominant strains in neighboring countries. Subgroup analyses were identified after pilot data extraction but prior to overall data extraction, and were used to refine the data extraction tool. The authors of studies missing key relevant information (such as TN, FN, TP, and FP) were contacted for additional information. If no reply was received on the first attempt, we attempted to contact the authors a second time. No additional information or data were retrieved from this effort.

Data synthesis

Papers that reported the TP, FP, TN, and FN were pooled in statistical meta-analysis using the R statistical software (R Foundation for Statistical Computing, Vienna, Austria) packages meta[27] and dmetar.[28] Due to our custom data extraction tool, we were unable to utilize the JBI System for the Unified Management, Assessment and Review of Information (JBI SUMARI; JBI, Adelaide, Australia) software as initially planned.[18] Studies that did not include these 4 values were excluded from meta-analysis. As we expected this information to be included in all published studies, these criteria were not stated in our inclusion/exclusion criteria in the original protocol.[18] However, without these data, the combined accuracy data could not be accurately calculated. As an *a priori* decision, we only included RATs that were reported in at least 5 studies for the meta-analysis due to the minimum number of groups needed to fully benefit from the random-effects model in dmetar.[28] The pooled sensitivity, specificity, positive predictive, and negative predictive values were calculated assuming a random-effects model and presented with 95% CIs. The positive predictive and negative predictive values were calculated using the formulas TP/(TP+FP) and TN/(FN +TN) when not presented in the papers. Forest plots for the sensitivity and specificity were generated using the R package meta.[27] Potential subgroups that were proposed in our protocol included index tests used, symptomatic vs asymptomatic, and cycle threshold (Ct) values. Where statistical pooling was not possible, the findings were presented in narrative format, including tables and figures.

Heterogeneity was assessed using the I^2 value. When heterogeneity above 90% was observed, outlier analysis was conducted to identify studies contributing to overall heterogeneity. The R package dmetar was used to identify outliers based on their contribution to heterogeneity and the pooled value of the measurement.[28] This package examines the 95% CI of each study compared with the pooled 95% CI. When a study was removed, the data set was

reanalyzed for heterogeneity. The results shown were generated by removing outliers. The code and the data used for data synthesis can be found at https://github.com/skoshyc/covid_systematic_review_2023.

Assessing certainty in the evidence

The Summary of Findings were created using GRADEPro GDT software (McMaster University, ON, Canada).[29] The GRADE approach for grading the certainty of evidence for diagnostic test accuracy was used.[30] The following outcomes are included in the Summary of Findings: the review question; the index test names and types; the reference tests used; the population; the estimates of true negatives, true positives, false negatives, and false positives; the absolute difference between the index and reference tests for these values per 1000 patients; the sample size; the number of studies contained within the sample set; the GRADE (Grading of Recommendations Assessment, Development and Evaluation) quality of evidence for each finding; and any comments associated with the finding.

Deviations from and clarifications to protocol

Title and abstract screening, full-text screening, critical appraisal, data extraction, and data synthesis were completed as described in our protocol[18] with the following exceptions.

Software and procedure flow

All steps were performed using Google Sheets set up specifically for our review. The full-text screening was adjusted to use a drop-down selection of prioritized reasons for exclusion. Reviewers selected the highest priority exclusion reason for excluded studies (Table 1). For critical appraisal, we used a drop-down setup for each question and the decision for inclusion or exclusion. The exclusions from the critical appraisal process were prioritized by question number from the JBI critical appraisal tool for diagnostic accuracy reviews.[25] We piloted and adjusted our data extraction tool using a subset of studies. This step was not specified in our published protocol.[18] We were not able to use JBI SUMARI due to our customized data extraction tool. We utilized R software with custom code instead. Rather than assessing heterogeneity visually as originally planned, we used the I^2 value. For the meta-analysis, we included only RATs reported in at least 5 studies.

Table 1: Prioritized exclusion criteria for studies, as selected by reviewers during full-text screening

1	Not RAT compared to RT-PCR
2	Results took more than 4 hours to determine after test was initiated
3	Diagnostic accuracy was not provided
4	Children were included in the analysis
5	Pregnant individuals were included in the analysis
6	Studies were dated prior to the emergence of COVID-19
7	Study examined antibodies against COVID-19, not COVID-19 antigens
8	Test is incompatible with a standard primary care setting
9	Study is a review without primary data
10	Study is in a foreign language and not available in English
11	Duplicate article

RAT, rapid antigen test; RT-PCR, reverse transcriptase polymerase chain reaction.

Inclusion and exclusion criteria

We adjusted our inclusion/exclusion criteria to clarify several points. First, our protocol stated that we would exclude studies performed in non-primary care settings.[18] We included studies from non-primary care settings if the RAT being used could also be easily used in primary care settings. Instead, RATs that could not be performed in a primary care setting were excluded. Next, our protocol stated that the reference test considered was commercially available RT-PCR tests and that any RT-PCR test would be considered.[18] We considered and included studies where the reference test was a validated custom or in-house RT-PCR test. Third, we clarified that cross-sectional and cohort studies would be considered, but case-control studies were excluded for poor methodological quality.

Results

Study inclusion

A total of 3122 citations were identified from searches of databases and gray literature. After duplicates were removed through EndNote, 1204 records were screened for inclusion by title and abstract using JBI SUMARI (pilot search only) and Google Sheets. We examined the full text of 580 studies for inclusion based on our described criteria and excluded 319 (see Supplemental Digital Content 1, http://links.lww.com/SRX/A55. The most common reason for study exclusion was the inclusion of individuals younger than 18 years within the data set (n = 102). After removing studies based on our exclusion criteria, we

critically appraised 261 studies. The primary reason for excluding studies after critical appraisal was the use of a case-control study design (n = 107 out of 118 excluded studies; see Supplemental Digital Content 2, http://links.lww.com/SRX/A56. After critical appraisal, we extracted data from 143 articles.[7,8,11,31–170] From these articles, data from 91 studies were used for overall and subgroup analyses based on the data synthesis methods. See the full search results and study selection and inclusion process in Figure 1.

Methodological quality

The extracted studies had high certainty of evidence based on the GRADE analysis.[30] Given that we restricted our review to cross-sectional and cohort designs, all of the included studies began at "high" quality.

The majority of the studies had a low risk of bias based on the QUADAS-2 tool (Figure 2 [summary of risk of bias assessment] and Supplemental Digital Content 3, http://links.lww.com/SRX/A57 [individual study analysis]). While most papers stated that the reference test was performed at a different site or through a central public health laboratory, a few papers (16.0%) did not clearly indicate whether the reference test was interpreted without knowledge of the index test result (Q#7). All studies used a validated RT-PCR as their reference test, but some papers (15.3%) used multiple RT-PCR kits (Q#9). About 1 in 5 papers (20.8%) did not include all participants in their analysis (Q#10). The reasons cited for these exclusions were a lost sample or inconclusive/invalid results on either the index or reference test.

The indirectness, publication bias, and imprecision of the included studies represented minor or no concerns regarding the quality of evidence. The largest driver of the quality of evidence decrease was the high heterogeneity found across studies. This is discussed further in the review findings section.

Characteristics of included studies

The studies included in our data extraction consisted of retrospective and prospective cohort studies and cross-sectional studies. In general, most studies collected a single subject sample that was used for the index and reference tests, or 2 samples were collected consecutively at the same encounter. On occasion, 2 samples were taken from different anatomical locations from the same subject (eg, a nasopharyngeal sample for RT-PCR and an anterior nares sample for RAT). Most studies used a design where the RAT was performed on-site with the participant, and the RT-PCR sample was stored cold and transferred to a central laboratory location. For some studies, the laboratory was on-site, such as a clinical laboratory associated with the hospital performing the study. However, many studies used central public health laboratories within their local health districts to perform the RT-PCR. A benefit of using a clinical laboratory instead of utilizing their own laboratory staff to run the RT-PCRs is that the clinical laboratory technicians are blinded to the RAT results because they are not involved in the study.

Where possible, we validated the reported sensitivity and specificity numbers in each study using the TP, FP, TN, and FN values. Not every study provided

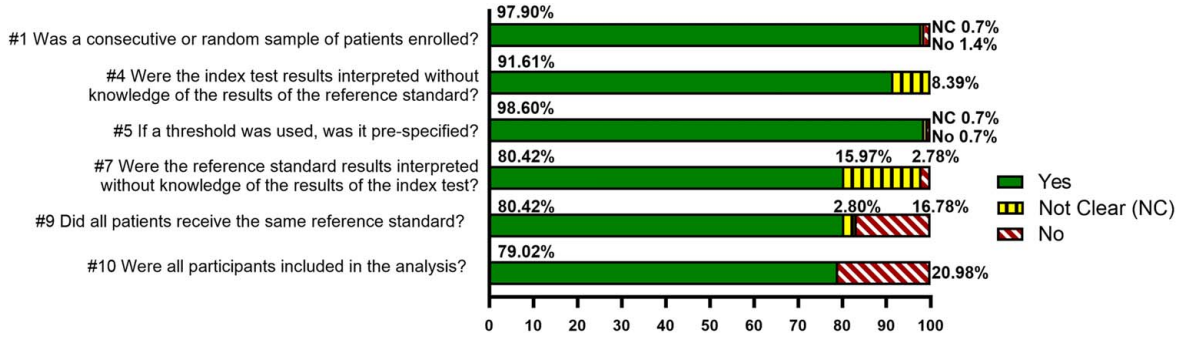


Figure 2: Summary of risk of bias assessment of included studies. The percentage of included studies where the answer to each question from the QUADAS-2 tool25 was "yes" (green, no stripes), "no" (red, diagonal stripes), or "not clear" (yellow, vertical stripes) are shown. Questions that required a "yes" answer for the study to be included in the data extraction are not shown (#2, #3, #6, and #8).

Table 2: Reported settings of included studies

Location	# of studies performed
COVID-19 testing site/screening location	52
Hospital - inpatient	38
Emergency department/room	26
College/university campus (medical center/ hospital)	25
Hospital - outpatient	15
Primary care location	15
Not described/unclear	8
Long-term care facility (nursing home, rehab centers)	5
Public area (not a designated screening location)	5
College/university campus (non-medical)	4
Urgent care location	1

these numbers, so some reported sensitivity and specificity calculations could not be verified. The key findings of each paper are summarized in Appendix III.

The studies included in our meta-analysis were performed in a variety of settings (Table 2). The breadth of study locations demonstrates the generalizability of RATs across different levels of health care and the ease of use of these POC tests. While we focused on determining best practices for primary care settings, these findings are applicable to a wide range of health care locations.

The studies were conducted in 44 countries across 6 continents starting in March 2020 through our search date in July 2022 (Figure 3A). We generated heatmaps showing the locations of dominant variants based on the countries of the studies (Figure 3B-D). Studies from the Beta and Gamma waves were less common (not shown). We had few studies completed

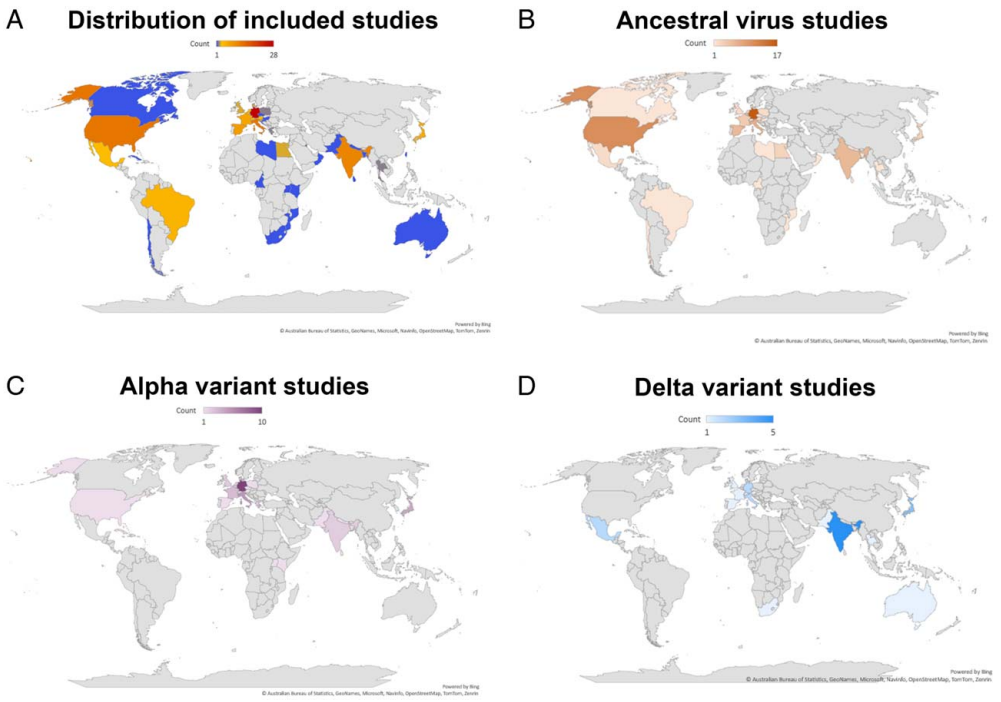


Figure 3: Maps of study locations. The heatmaps show the geography of the studies included in this review, illustrating the global nature of COVID-19 rapid antigen tests. (A) The number of included studies from each country is shown by heatmap. (B–D) The number of included studies from each country with data collected during the dominance of the Ancestral (B), Alpha (C), and Delta (D) strains of SARS-CoV-2 are shown by heatmap. Gray indicates that no included studies came from that country.

during the dominance of the Omicron variants due to the dates of our searches (not shown).

The included studies resulted in a total participant number of 212,874. There were 139 papers that either specified the number of participants, the number of samples, or both (Figure 4). The number of participants or samples ranged from 42 to 18,457, with a median of 635 participants. Overall, the studies included in the meta-analysis all shared the general design of testing subjects' samples collected at the same time with both RAT and RT-PCR.

The studies included in the analysis listed 50 commercially available RATs, whereas 3 studies described novel tests that were not yet commercially available (Appendix IV). Tests reported in fewer than 5 studies were excluded from the meta-analysis, as described in the methods.[28] The reported diagnostic accuracy data for all studies can be found in Appendix III. Most studies reported using nasopharyngeal swabs to acquire the test sample (Table 3). Many studies reported using multiple sample sites in their analysis. However, few studies compared the accuracy of the tests from multiple sample sites.

We did not restrict the use of reference tests to a specific manufacturer or target. The studies used a variety of RT-PCR tests as their reference test. All reference tests were either commercially available RT-PCRs or in-house primers based on national or international public health organization recommendations. Many studies used multiple reference tests due to the availability of the tests over the course of their studies. The most commonly reported reference test was the Roche cobas systems, with 30 studies reporting its use. Other common reference tests were Allplex assays by Seegene (23 studies), TaqPath assays by ThermoFisher (18 studies), and Xpert Xpress/GeneXpert assays by Cepheid (19 studies). Seventeen studies reported a custom or in-house PCR assay based on published primers, and 15 studies did not report a specific RT-PCR assay.

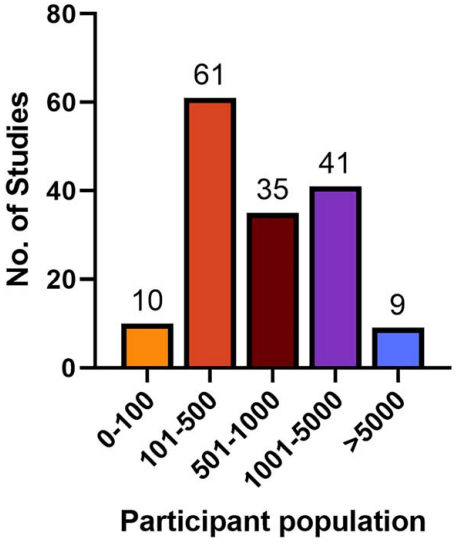


Figure 4: Numbers of participants/samples per included study. Studies were grouped by the number of participants. The number of studies for each group is shown.

Table 3: Sample types collected for COVID-19 testing, as reported in included studies

Sample type	# of studies
Nasopharyngeal swabs	128
Oropharyngeal swabs/throat swabs	41
Nasal swabs	37
Other	8
Saliva	7
Blood	2
Bronchoalveolar lavage/bronchial sample	1

Review findings

We compared the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) for each index test across the published studies. A total of 91 studies were used for synthesis, as those studies provided the TP, FP, TN, and FN values.[8,11,32–34,36–40,46–49,53–55,58–60,63,66,68,71,72,74,76–79,81–88,90,93–95,98–101,103,104,106–108,110,115,117,118,120,123,124,127–129,131–137,140,142,143,148,150–157,159–169] For the analysis of the index test, we considered the entries from the paper that specified the overall accuracy of the test across their entire study population.

We only included index tests examined in at least 5 studies for the pooled sensitivity, specificity, PPV, and NPV, which are shown in the forest plots. The tests meeting this criterion were STANDARD Q COVID-19 Ag Test (SD Biosensor; 27 studies), PanBio COVID-19 Ag Rapid Test Device (Abbott; 14 studies), SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics; 11), and BinaxNOW COVID-19 Antigen (Abbott; 10 studies). All tests that were considered are listed in Appendix IV.

Table 4: Pooled sensitivity of index tests (point-of-care SARS-CoV-2 rapid antigen tests), with outliers (as identified based on their contribution to heterogeneity)

Test name	# of studies	Pooled sensitivity	95% CI	I^2
STANDARD Q COVID-19 Ag (SD Biosensor)	27	66.0%	59.2-72.2%	95.3%
PanBio (Abbott)	13	70.2%	61.0-78.0%	92.7%
Roche SARS-CoV-2 Rapid Antigen Test (Roche)	11	69.3%	61.2-76.4%	83.1%
BinaxNOW (Abbott)	10	62.3%	49.4-73.6%	94.2%

We considered the studies that were outliers in the pooled analysis. An outlier was defined as described in the methods. On removing the outliers, we observed that overall heterogeneity reduced considerably.

Sensitivity

The maximum sensitivity reported was 100%, which included the Flowflex COVID-19 Antigen test (ACON Labs) and STANDARD Q COVID-19 Ag Test (SD Biosensor; Appendix IV). The heterogeneity of the data set was high when we considered the included studies,[11,32–34,36–39,46,48,49,55,58,59,63,66,71,76,77,79,83–87,93,98,99,101,103,107,108,118,123,124,127–129,131,132,134–136,142,150,151,154,155,160,161,165,166,168,169] as indicated by an I^2 value of 94.6% (95% CI 93.6–95.4%). The pooled sensitivity of these data was 67.0% (95% CI 62.6–71.1%). Each test's pooled sensitivity is shown in Table 4.

On removing the outliers, the pooled sensitivity was 66.7% (95% CI 63.4–69.8%), with an I^2 value of 70.4%.[11,32–34,36,39,46,48,49,55,58,66,71,76,79,84,87,107,108,118,127–129,131,132,134,136,142,154,169] The updated test subgroup results are shown in Table 5. The individual sensitivities reported for the 4 tests included in the pooled analysis are shown in Figure 5 (outliers removed). The high heterogeneity is still present in the large discrepancies in reported sensitivities and 95% CIs.

Specificity

The maximum specificity recorded was 100%, and there were 27 index tests that had this value (Appendix IV). As in the case of the sensitivity, the heterogeneity of the data set when we consider the included studies was high, as indicated by an I^2 value of 93.7% (95% CI 92.5–94.6%). The pooled specificity of these data was 99.6% (95% CI 99.3–99.8%).[11,32–34,36–39,46,48,49,55,58,59,63,66,71,76,77,79,83–87,93,98,99,101,103,107,108,118,123,124,127–129,131,132,134–136,142,150,151,154,155,160,161,165,166,168,169] Each test's pooled specificity is shown in Table 6.

On removing the outliers, the pooled specificity was 99.8% (95% CI 99.7–99.9%), with an I^2 value of 40.4%.[32–34,36,46,49,55,58,63,66,71,77,79,83,84,87,93,99,101,103,107,108,118,123,124,129,131,132,134–136,142,150,154,155,166,168,169] The updated test subgroup results are shown in Table 7. The individual specificities reported for the 4 tests included in the pooled analysis are shown in Figure 6 (outliers removed). The high heterogeneity is still present in the large discrepancies in reported specificities and 95% CIs.

Positive predictive value

The maximum recorded PPV was 100%, and there were 21 index tests that reported this value in at least 1 study (Appendix IV). To obtain the pooled PPV, we assumed the formula PPV = TP/(TP + FP), as most papers stated it this way. After removing outliers, as with sensitivity and specificity, we obtained a

Table 5: Pooled sensitivity of index tests (point-of-care SARS-CoV-2 rapid antigen tests), without outliers (as identified based on their contribution to heterogeneity)

Test name	# of studies	Pooled sensitivity	95% CI	I^2
STANDARD Q COVID-19 Ag (SD Biosensor)	15	65.4%	61.1-69.4%	70.0%
PanBio (Abbott)	6	71.0%	64.6-76.6%	73.8%
Roche SARS-CoV-2 Rapid Antigen Test (Roche)	7	68.5%	60.3-75.7%	73.3%
BinaxNOW (Abbott)	2	54.7%	46.0-63.1%	0.0%

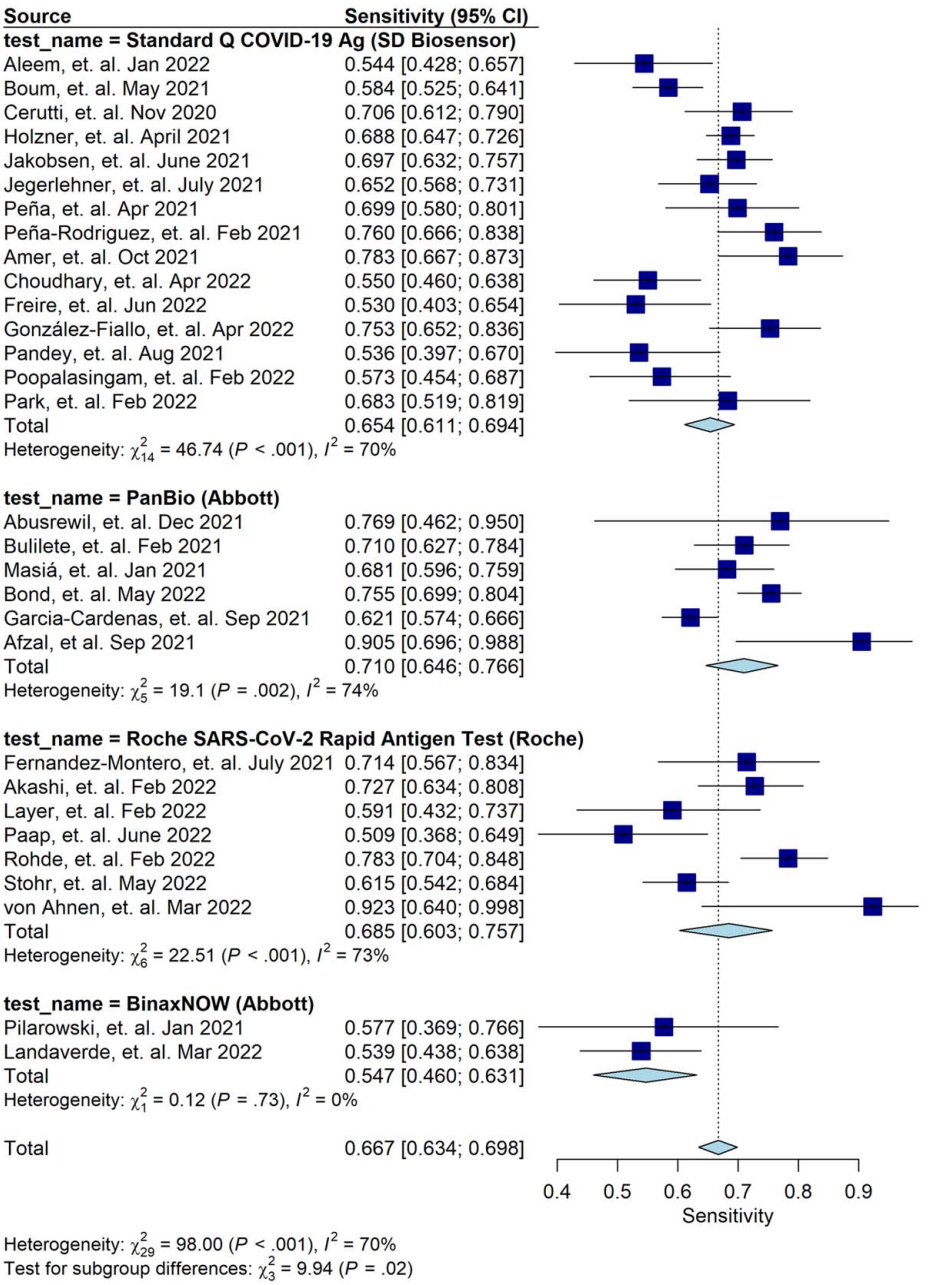


Figure 5: Diagnostic accuracy of COVID-19/SARS-CoV-2 infection—sensitivity forest plot for the overall cohort. The forest plot shows the sensitivities and 95% CIs reported for the STANARD Q COVID-19 Ag Test (SD Biosensor), PanBio (Abbott), Roche SARS-CoV-2 Rapid Antigen Test (Roche), and BinaxNOW (Abbott) index tests (point-of-care SARS-CoV-2 rapid antigen tests) after outlier studies were removed. Pooled sensitivity and heterogeneity value (I2) for each index test are shown at the bottom of each test section. The pooled sensitivity and 95% CI of all reported tests on the forest plot are shown at the bottom. The vertical line at 0.671 represents the pooled sensitivity value for all shown tests. Boxes represent the reported sensitivity, and solid horizontal lines represent the 95% CI reported by each study.

Table 6: Pooled specificity of index tests (point-of-care SARS-CoV-2 rapid antigen tests), with outliers (as identified based on their contribution to heterogeneity)

Test name	# of studies	Pooled specificity	95% CI	I^2
STANDARD Q COVID-19 Ag (SD Biosensor)	27	99.2%	98.4-99.6%	95.0%
PanBio (Abbott)	13	99.9%	99.6-100%	62.9%
Roche SARS-CoV-2 Rapid Antigen Test (Roche)	11	99.8%	98.9%-100%	93.8%
BinaxNOW (Abbott)	10	99.8%	99.5-99.9%	87.8%

pooled PPV value of 97.7% (95% CI 96.8–98.4%) and I^2 value of 0.0% (95% CI 0.0–34.8%).[11,32–34,36,39,46,49,55,58,63,71,77,79,83,85,87,93,99,101,103,107,108,118,123,124,129,131,132,134–136,142,150,151,154,155,160,161,168,169] The forest plot for the PPVs is shown in Figure 7. Each test's pooled PPV is shown in Table 8.

Negative predictive value

The maximum value was 100%, and included the Flowflex COVID-19 Antigen test (ACON Labs) and STANDARD Q COVID-19 Ag Test (SD Biosensor). To obtain the pooled NPV, we assumed the formula NPV = TN/(TN + FN), as most papers stated it this way. After removing outliers, as with sensitivity and specificity, we obtained a pooled NPV value of 95.2% (95% CI 94.3–95.9%) and I^2 value of 81.7% (95% CI 73.3–87.5%; see Table 9 and Figure 8).[34,36,37,46,49,58,63,76,77,83,87,98,99,118,127–129,131,132,136,154,168] The BinaxNOW (Abbott) subgroup of papers was excluded, as they all contributed substantially to the heterogeneity.

Symptomatic test subgroup

The protocols for testing and screening have changed over the course of the pandemic, and now widespread testing is uncommon. Symptom presentation has now replaced screening tests for most locations and businesses. Taking this into consideration, we performed an additional analysis of studies that reported subgroups of symptomatic and asymptomatic individuals. The symptomatic subgroup diagnostic accuracy may be the most relevant cohort for primary care settings, as most asymptomatic individuals will not present to their primary care providers to be screened for COVID-19.

We found differences in the accuracy of the index tests in subjects who were symptomatic or asymptomatic. There were 9 studies that examined symptomatic[34,99,103,118,128,150,160,165,166] and 11 studies that examined asymptomatic[34,84,99,103,118,128,135,149,150,165,166] subgroups, and provided the values used to calculate accuracy values (TP, FP, TN, and FN). If there was only 1 study in the group, I^2 was reported as "NA." As with the overall analysis of the studies, there was high heterogeneity between the studies. Due to fewer studies reporting these subgroups, we did not have enough studies to remove outliers from these analyses. The symptomatic subgroups showed higher overall levels of sensitivity compared to the overall group (Table 10 and Figure 9A). Specificity was slightly lower in the symptomatic subgroup than in the overall group (Table 10 and Figure 9B). The symptomatic subgroup also had a slightly lower PPV and NPV (Table 11) compared with the overall group (Figure 10).

Table 7: Pooled specificity of index tests (point-of-care SARS-CoV-2 rapid antigen tests), without outliers (as identified based on their contribution to heterogeneity)

Test name	# of studies	Pooled specificity	95% CI	I^2
STANDARD Q COVID-19 Ag (SD Biosensor)	16	99.6%	99.4-99.7%	46.7%
PanBio (Abbott)	10	99.9%	99.8-100.0%	0.0%
Roche SARS-CoV-2 Rapid Antigen Test (Roche)	7	99.9%	99.5-100.0%	0.0%
BinaxNOW (Abbott)	6	99.9%	99.7-100.0%	16.0%

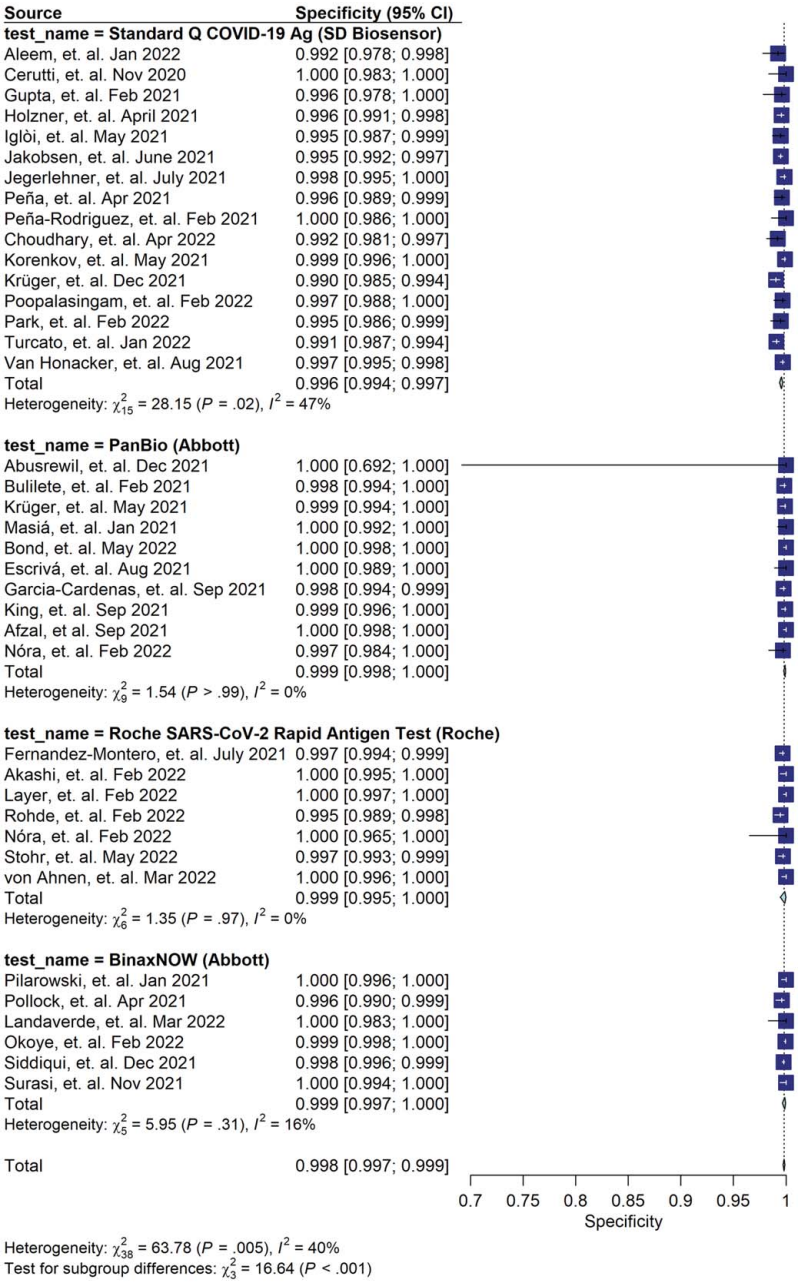


Figure 6: Diagnostic accuracy of COVID-19/SARS-CoV-2 infection—specificity forest plot for the overall cohort. The forest plot shows the specificities and 95% CIs reported for the STANARD Q COVID-19 Ag Test (SD Biosensor), PanBio (Abbott), Roche SARS-CoV-2 Rapid Antigen Test (Roche), and BinaxNOW (Abbott) index tests after outlier studies were removed. Pooled specificity and heterogeneity value (I2) for each index test are shown at the bottom of each test section. The pooled specificity and 95% CI of all reported tests on the forest plot are shown at the bottom. The vertical line at 0.996 represents the pooled specificity value for all shown tests. Boxes represent the reported specificity, and solid horizontal lines represent the 95% CI reported by each study.

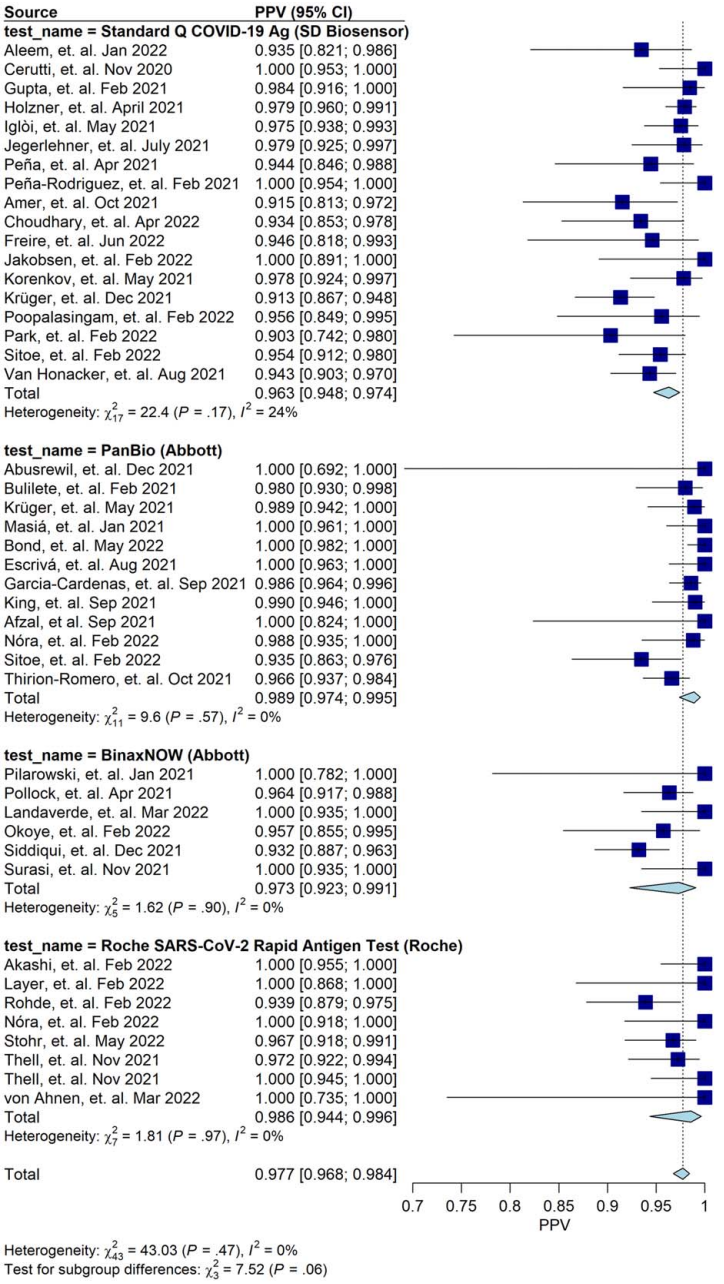


Figure 7: Diagnostic accuracy of COVID-19/SARS-CoV-2 infection—positive predictive values forest plot. The forest plot shows the positive predictive values (PPVs) and 95% CIs reported for the STANDARD Q (SD Biosensor), PanBio (Abbott), Roche SARS-CoV-2 Rapid Antigen Test (Roche), and BinaxNOW (Abbott) index tests after outlier studies were removed. Pooled PPV and heterogeneity value (I2) for each index test is shown at the bottom of each test section. The pooled PPV and 95% CI of all reported tests on the forest plot are shown at the bottom. The vertical line at 0.962 represents the pooled PPV for all shown tests. Boxes represent the reported PPV, and solid horizontal lines represent the 95% CI reported by each study. Some studies reported multiple sites and are included as an individual row for each site.

Table 8: Pooled positive predictive values of index tests (point-of-care SARS-CoV-2 rapid antigen tests), without outliers (as identified based on their contribution to heterogeneity)

Test name	# of studies	Pooled PPV	95% CI	I^2
STANDARD Q COVID-19 Ag (SD Biosensor)	18	96.3%	94.8-97.4%	24.1%
PanBio (Abbott)	12	98.9%	97.4-99.5%	0.0%
Roche SARS-CoV-2 Rapid Antigen Test (Roche)	8	98.6%	94.4-99.6%	0.0%
BinaxNOW (Abbott)	6	97.3%	92.3-99.1%	0.0%

PPV, positive predictive value.

Asymptomatic test subgroup

Asymptomatic test performance is relevant in any screening situation. The asymptomatic samples resulted in overall lower sensitivity in the RATs (Table 12 and Figure 11A), although specificity remained high (Table 12 and Figure 11B).[34,84,99,103,118,128,135,149,150,165,166] The PPV was lower in the asymptomatic group compared with the symptomatic and overall groups. However, the NPV remained similar between the 3 groups. Additional information about the PPV and NPV for this subgroup can be found in Table 13 and Figure 12.

Summary of Findings

Based on our meta-analysis, Roche's SARS-CoV-2 Rapid Antigen Test and Abbott's BinaxNOW tests meet the WHO's recommendation of minimum diagnostic accuracy for symptomatic individuals ($\geq$ 80% sensitivity and $\geq$ 97% specificity)[171] and can be reliably used in primary care settings (see the Summary of Findings). Other tests may also meet this standard, but we did not find sufficient studies for other tests. In the Summary of Findings, the effect per 1000 patients tested and certainty of evidence for test accuracy are shown for symptomatic adults using STANDARD Q, PanBio, Roche, and BinaxNOW.

Overall, RATs can identify individuals who have COVID-19 with high reliability when considering overall performance. However, the lower levels of sensitivity suggest that negative tests likely need to be retested through an additional method, such as RT-PCR or repeat testing over several days, when COVID-19 is suspected. Positive tests are highly likely to correctly diagnose SARS-CoV-2 infections, and based on our analyses, we recommend treating those patients as having a COVID-19 diagnosis. These results are likely driven by the symptomatic subject data, as subgroup analysis found higher reliability in symptomatic individuals than in asymptomatic individuals.

Considering only symptomatic individuals, RATs have a higher performance in correctly identifying negative cases, with similar reliability for detecting cases through a positive result. However, a sensitivity of 80% means that 1 in 5 people with a negative RAT have a false-negative result. Thus, negative COVID-19 RAT results in symptomatic patients should be interpreted with caution. As the symptomatic analysis of BinaxNOW included a single study and the same analysis of Roche's test had only 2 studies, more studies are needed to confirm these findings.

Discussion

Rapid antigen tests are an important tool in infectious disease control. RATs are less expensive, require less expertise, and are better indicators of

Table 9: Pooled negative predictive values of index tests (point-of-care SARS-CoV-2 rapid antigen tests), without outliers (as identified based on their contribution to heterogeneity)

Test name	# of studies	Pooled NPV	95% CI	I^2
STANDARD Q COVID-19 Ag (SD Biosensor)	15	95.3%	94.0-96.2%	84.1%
PanBio (Abbott)	4	95.1%	92.9-96.6%	87.2%
Roche SARS-CoV-2 Rapid Antigen Test (Roche)	3	94.9%	94.0-95.7%	39.3%

NPV, negative predictive value.

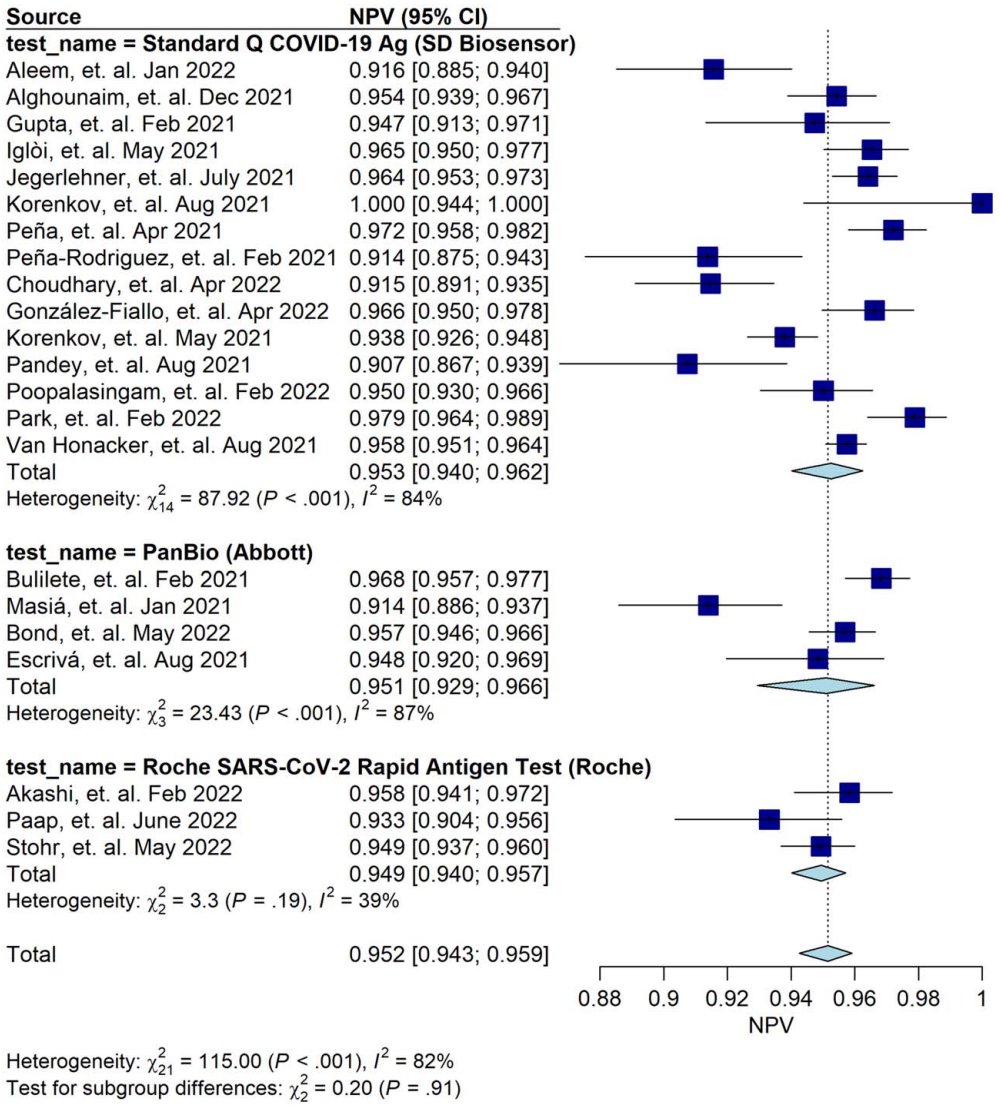


Figure 8: Diagnostic accuracy of COVID-19/SARS-CoV-2 infection—negative predictive value forest plot. The forest plot shows the negative predictive value (NPV) and 95% CIs reported for the STANDARD Q (SD Biosensor), PanBio (Abbott), Roche SARS-CoV-2 Rapid Antigen Test (Roche), and BinaxNOW (Abbott) index tests after outlier studies were removed. Pooled NPV and heterogeneity value (I2) for each index test is shown at the bottom of each test section. The pooled NPV and 95% CI of all reported tests on the forest plot are shown at the bottom. The vertical line at 0.949 represents the pooled NPV for all shown tests. Boxes represent the reported value, and solid horizontal lines represent the 95% CI reported by each study. Some studies reported multiple sites and are included as an individual row for each site.

infectious virus than the gold standard diagnostic of RT-PCR.[5] RATs have limitations in their performance, including large discrepancies in diagnostic accuracy depending on the situation in which they are used.

Discrepancies across studies and with manufacturer reported results

Of significant concern is the discrepancy between the manufacturer's listed diagnostic accuracy and the accuracy found in this analysis. Based on the

Table 10: Sensitivity and specificity of index tests (point-of-care SARS-CoV-2 rapid antigen tests) in the symptomatic subgroup

Test name	# of studies	Sensitivity (95% CI) I^2	Specificity (95% CI) I^2
STANDARD Q COVID-19 Ag (SD Biosensor)	4	78.2% (58.7–90.0%) 96.1%	98.4% (94.9–99.5%) 74.9%
PanBio (Abbott)	2	78.0% (61.0–88.9%) 90.7%	99.9% (99.3–100%) 0.0%
Roche SARS-CoV-2 Rapid Antigen Test (Roche)	2	81.2% (76.2–85.5%) 0.0%	99.6% (97.4–99.9%) 0.0%
BinaxNOW (Abbott)	1	86.7% (79.7–91.9%) NA	98.8% (97.4–99.6%) NA

NA, not applicable.

published accuracies on the manufacturers' websites, the manufacturers overestimate the accuracy of their tests.[172–175] Our meta-analysis found the pooled sensitivity of the SD Biosensor STANDARD Q test to be 66.1%, while the manufacturer's website lists the sensitivity as 85.0%.[175] For the Abbott tests, the pooled sensitivity from our analysis was 71.0% and 54.7% for PanBio and BinaxNOW tests, respectively. The product pages from the Abbott website list the sensitivities as 91.1% for PanBio and 84.6% for BinaxNOW.[172,173] Roche specifies that their listed sensitivity is for Ct values < 30 and reports a specificity of 95.5% [174] compared with our overall pooled sensitivity of

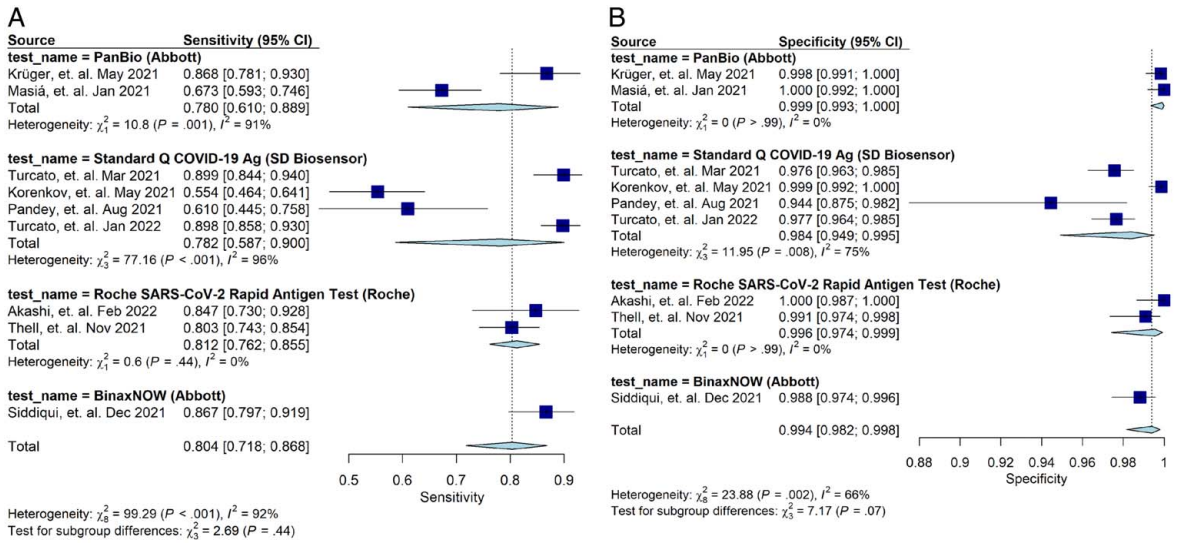


Figure 9: Diagnostic accuracy of COVID-19/SARS-CoV-2 infection—sensitivity and specificity forest plots for symptomatic subgroup. Forest plot shows the sensitivities (A) and specificities (B) and 95% CIs reported for the symptomatic subgroup for the STANDARD Q (SD Biosensor), PanBio (Abbott), Roche SARS-CoV-2 Rapid Antigen Test (Roche), and BinaxNOW (Abbott) index tests after outlier studies were removed. Pooled values and heterogeneity value (I2) for each index test are shown at the bottom of each test section. The pooled values and 95% CI of all reported tests on each forest plot are shown at the bottom. The vertical lines at 0.804 (sensitivity) and 0.994 (specificity) represent the pooled values for all shown tests. Boxes represent the reported sensitivity and specificity, and solid horizontal lines represent the 95% CI reported by each study.

Table 11: Positive and negative predictive values of index tests (point-of-care SARS-CoV-2 rapid antigen tests) in the symptomatic subgroup

Test name	# of studies	Pooled PPV (95% CI) I^2	Pooled NPV (95% CI) I^2
STANDARD Q COVID-19 Ag (SD Biosensor)	4	92.1% (85.9-95.6%) 63.2%	94.7% (89.0-97.5%) 93.8%
PanBio (Abbott)	2	99.5% (96.3-99.9%) 0.0%	95.5% (86.1-98.6%) 96.5%
Roche SARS-CoV-2 Rapid Antigen Test (Roche)	2	98.7% (95.9-99.6%) 0.0%	93.7% (85.0-97.5%) 92.4%
BinaxNOW (Abbott)	1	95.1% (89.7-98.2%) NA	96.5% (94.6-97.9%) NA

NA, not applicable; NPV, negative predictive value; PPV, positive predictive value.

68.5%. These discrepancies can increase the errors in medical practice by falsely increasing the confidence providers have in the various RATs. The differences in accuracy between the collected studies, our meta-analysis, and the manufacturer's reported values are likely driven by the same factors that may have contributed to the high heterogeneity in our results.

Potential sources of heterogeneity

We found high heterogeneity across the studies included in our data extraction and meta-analysis. Potential sources of heterogeneity could include the prevalence of the virus during each study's data collection phase, the access to various manufacturers' RATs, and the skill level at which the sample was taken.[176,177] Additionally, the level of infection within each subject will vary greatly depending on their previous immunity, the day post-exposure, or the day post-symptom compared to when the RAT was performed.

Gold standard is RT-PCR but the threshold for a positive result varies by manufacturer and kit. While all reference tests were performed by qualified individuals based on reporting in the studies, the conditions in which the tests were performed are not reflective of ideal conditions. The number of samples that needed processing at a single time, as well as the general increased sense of urgency felt by public health employees, may have resulted in heterogeneity across the reference samples, which would increase heterogeneity across the sensitivity and specificity.

Variants that alter the test epitope can change the accuracy of the RATs. The accuracy of the RATs decreased as the variants mutated further from the Ancestral strain.[178] A recent study of RATs intended for Delta and Omicron variant detection found no differences in sensitivity,[179] while other studies have

Table 12: Sensitivity and specificity of index tests (point-of-care SARS-CoV-2 rapid antigen tests) in the asymptomatic subgroup

Test name	# of studies	Sensitivity (95% CI) I^2	Specificity (95% CI) I^2
STANDARD Q COVID-19 Ag (SD Biosensor)	5	43.8% (30.4-58.2%) 86.3%	99.6% (99.4-99.7%) 0.0%
PanBio (Abbott)	3	57.7% (29.1-81.9%) 78.5%	100.0% (0.0-100.0%) 0.0%
Roche SARS-CoV-2 Rapid Antigen Test (Roche)	1	58.8% (44.2-72.4%) NA	100.0% (99.1-100.0%) NA
BinaxNOW (Abbott)	2	70.8% (62.9-77.7%) 0.0%	99.8% (99.5-99.9%) 72.8%

NA, not applicable.

Table 13: Positive and negative predictive values of index tests (point-of-care SARS-CoV-2 rapid antigen tests) in the asymptomatic subgroup

Test name	# of studies	PPV (95% CI) I^2	NPV (95% CI) I^2
STANDARD Q COVID-19 Ag (SD Biosensor)	5	80.4% (72.2-86.7%) 36.4%	97.7% (95.1-98.9%) 97.2%
PanBio (Abbott)	3	100.0% (0.0-100.0%) 0.0%	99.1% (93.0-99.9%) 97.4%
Roche SARS-CoV-2 Rapid Antigen Test (Roche)	1	100.0% (88.4-100.0%) NA	95.2% (92.7-97.0%) NA
BinaxNOW (Abbott)	2	90.3% (83.3-94.5%) 0.0%	99.1% (97.7-99.7%) 95.0%

NA, not applicable; NPV, negative predictive value; PPV, positive predictive value.

found a decrease in sensitivity between these 2 variants.[178] However, the tests in our review were developed and intended for use with the Ancestral strain. We examined the time frame and dominant variants of our studies to address this question. Further work is needed to have a better understanding of how changes in SARS-CoV-2 proteins affect RAT sensitivity. As novel variants emerge with distinct proteins (epitopes), the accuracy of the RATs will need to be reassessed.

Clinical significance of symptomatic and asymptomatic testing

The relevance of asymptomatic testing is lower than in symptomatic individuals because asymptomatic individuals are unlikely to present in a primary care

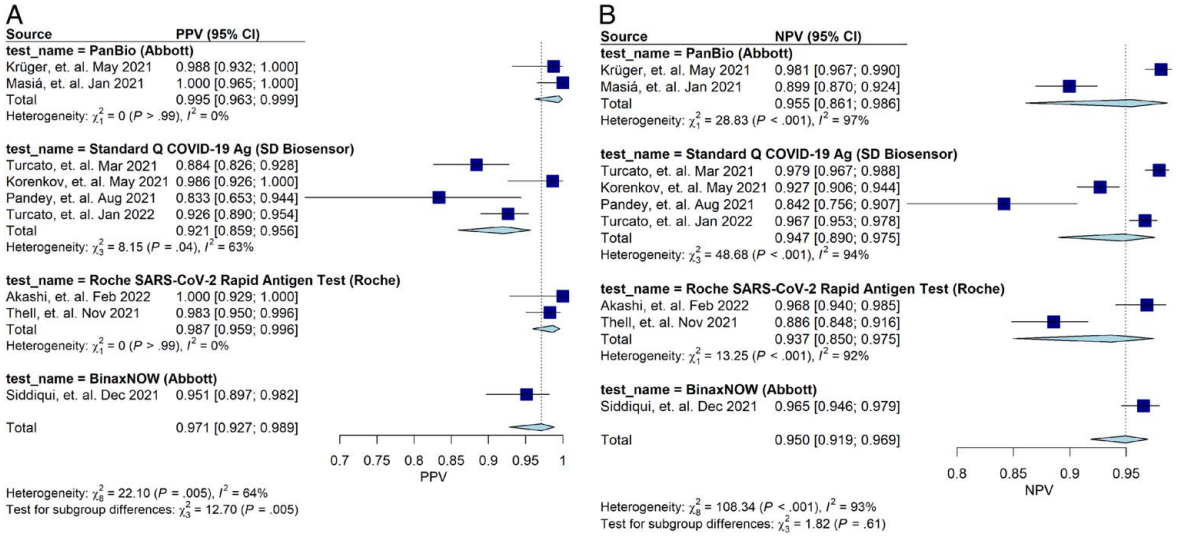


Figure 10: Diagnostic accuracy of COVID-19/SARS-CoV-2 infection–positive predictive value and negative predictive value forest plots for symptomatic subgroup. Forest plot shows the positive (A) and negative (B) predictive values (PPV/NPV) and 95% CIs reported for the symptomatic subgroups of the STANDARD Q (SD Biosensor), PanBio (Abbott), Roche SARS-CoV-2 Rapid Antigen Test (Roche), and BinaxNOW (Abbott) index tests after outlier studies were removed. Pooled values and heterogeneity values (I2) for each index test are shown at the bottom of each test section. The pooled values and 95% CI of all reported tests on the forest plot are shown at the bottom. The vertical lines at 0.971 (PPV) and 0.950 (NPV) represent the pooled values for all shown tests. Boxes represent the reported values, and solid horizontal lines represent the 95% CI reported by each study.

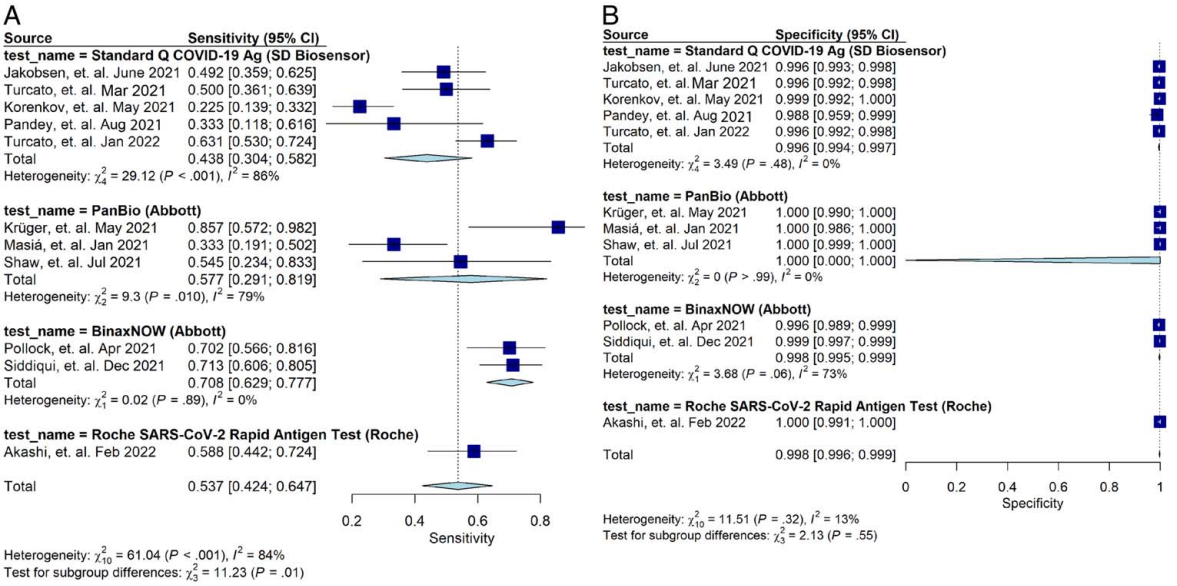


Figure 11: Diagnostic accuracy of COVID-19/SARS-CoV-2 infection—sensitivity and specificity forest plots for asymptomatic subgroup. Forest plot shows the sensitivities (A) and specificities (B) and 95% CIs reported for the asymptomatic subgroup for the STANDARD Q (SD Biosensor), PanBio (Abbott), Roche SARS-CoV-2 Rapid Antigen Test (Roche), and BinaxNOW (Abbott) index tests after outlier studies were removed. Pooled values and heterogeneity value (I2) for each index test are shown at the bottom of each test section. The pooled values and 95% CI of all reported tests on each forest plot are shown at the bottom. The vertical lines at 0.537 (sensitivity) and 0.998 (specificity) represent the pooled values for all shown tests. Boxes represent the reported sensitivity and specificity, and solid horizontal lines represent the 95% CI reported by each study.

setting. The individuals most likely to present in our target setting of primary care are those who are symptomatic. However, asymptomatic testing may continue in some contexts, such as during outbreaks, prior to certain elective procedures, or as part of ongoing surveillance and epidemiological efforts. The lower accuracy in the RATs in the asymptomatic context could lead to additional viral spread because of a false-negative result. Given the reduced accuracy, health care providers should interpret a negative result with caution and follow-up with RT-PCR testing for cases with a high suspicion of infection. The likelihood of a negative result from a RAT to be a true negative is dependent on disease prevalence in the patient's community. Health care practitioners in areas with high disease prevalence (10%) at the time of testing should assume that a negative result is positive 2.4% of the time. These situations make the overall test performance, and subgroup analyses of symptomatic and asymptomatic individuals, relevant across multiple health care settings.

Other systematic reviews of diagnostic accuracy have also noted similar sensitivity for symptomatic and asymptomatic cohorts.[180,181] These studies associated viral load as measured by RT-PCR Ct value with the positivity of the RATs.[180,181] The lower the Ct value, the more likely a RAT would detect the presence of viral protein.[180,181] Conflicting studies have reported similar and disparate Ct values in asymptomatic compared with symptomatic individuals (reviewed in Puhach *et al.*[5]). Asymptomatic individuals are considered to be major sources of transmission due to behavior changes when an individual develops symptoms.[182] Additional studies are needed to understand the connection between detectable viral protein via RATs, Ct values determined by RT-PCR, and transmission as measured by cell culture assays, because the clear difference in RAT performance between symptomatic and

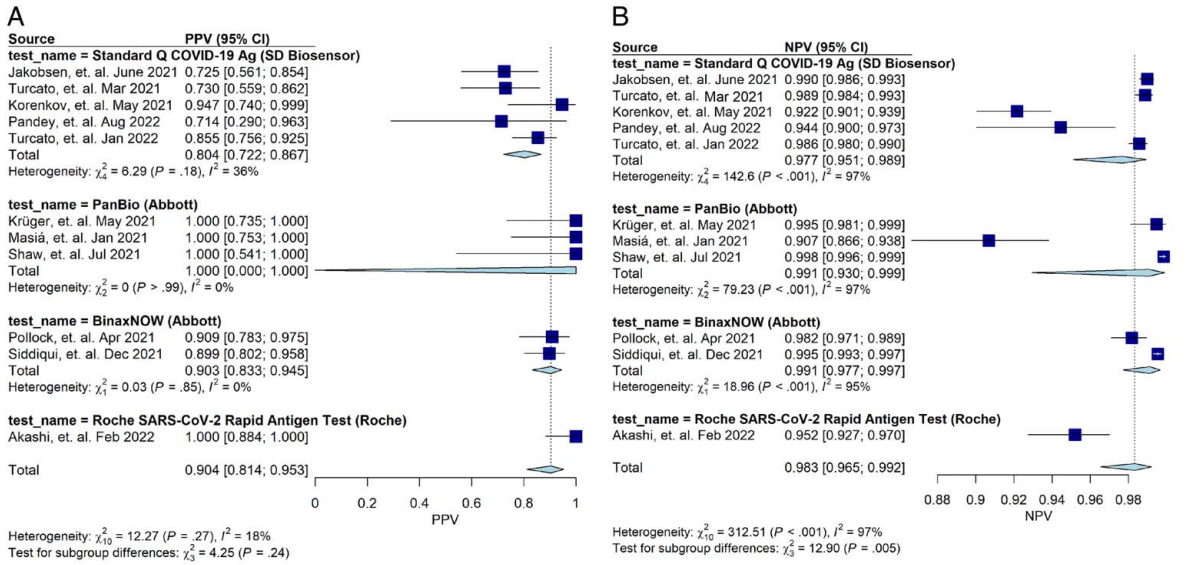


Figure 12: Diagnostic accuracy of COVID-19/SARS-CoV-2 infection–positive predictive value and negative predictive value forest plots for asymptomatic subgroup. Forest plot shows the positive (A) and negative (B) predictive values (PPV/NPV) and 95% CIs reported for the asymptomatic subgroups of the STANDARD Q (SD Biosensor), PanBio (Abbott), Roche SARS-CoV-2 Rapid Antigen Test (Roche), and BinaxNOW (Abbott) index tests after outlier studies were removed. Pooled values and heterogeneity values (I2) for each index test are shown at the bottom of each test section. The pooled values and 95% CI of all reported tests on the forest plot are shown at the bottom. The vertical lines at 0.904 (PPV) and 0.983 (NPV) represent the pooled values for all shown tests. Boxes represent the reported values, and solid horizontal lines represent the 95% CI reported by each study.

asymptomatic subjects does not align with the comparative Ct values[5] and cell culture positivity[182] previously reported.

Limitations of this review

One limitation of the review was that, due to author language proficiencies, the search strategies were limited to studies published in English. Records not available in English were not included in the review.

Heterogeneity can be studied and addressed in multiple ways, including outlier analysis and removal. The underlying source of heterogeneity is not immediately detectable in the data found within the studies and this could be investigated further. The high heterogeneity was an unexpected result. Revisions of this systematic review and meta-analysis could use a more stringent approach to reduce heterogeneity or better identify its sources through a different data extraction tool. Further, with additional collected data, more nuanced subgroup analyses could be performed.

Tied to symptom presentation, viral load has also been shown to impact RAT accuracy, with higher Ct values (lower viral loads) associated with decreased test accuracy.[180,181] Our review did not examine the subgroups of Ct values, which is a limitation of our review. A challenge with subdividing the collected data from the included studies is that the studies that reported values for various Ct values divided their data in different ways. The lack of consistent division makes grouping for meta-analysis challenging. Further, the Ct values across different reference tests may not be comparable. Each kit, primer set, and polymerase used to complete an RT-PCR reference test may vary in their specificity and sensitivity.[183] The Ct values that are reported are dependent on reference test reagent efficiency as well as the sample's viral RNA load.[183] Further work needs to be done to be able to accurately compare the Ct values to RAT performance or to viral load.

Sample type also has an impact on test accuracy. The most common sample types were nasopharyngeal swabs. These swabs are uncomfortable for patients and require a trained health care

professional for administration, limiting their use in wider settings. Nasal swabs and oropharyngeal swabs were present in about one-third of the studies each, and saliva samples were present in the selected studies. We did not analyze sample type within our meta-analysis due to a low number of studies identifying the sample location used specifically for the RAT compared with the RT-PCR tests. This is a limitation of our review. Other reviews have examined some of these sample types and found that anterior nares (nasal) swabs and nasopharyngeal swabs have similar sensitivities.[181] Saliva samples were noted to be of lower diagnostic accuracy than swabs.[181] Nasal swabs are a popular collection method and are found in many at-home and POC tests. These are easy to collect by anyone and have minimal associated discomfort, making them ideal for primary care settings. A potential future analysis on RAT accuracy could be performed to analyze the impact of nasal swab vs nasopharyngeal sample collection. These data may be more readily available as more studies are published regarding sample collections. The studies included in this analysis were primarily nasopharyngeal and most did not compare accuracy across sample types.

Given our experience with this systematic review and meta-analysis, it is clear that there are more parameters that would provide insight into the use of RATs in primary care settings that were not captured by our data extraction tool. These include potential sources of heterogeneity listed above, such as timing of RAT compared with symptom onset, and variations in sample collection methods.

Conclusions

We found high heterogeneity across studies examining the same RATs, leading to an overall decrease in the quality of evidence presented here. Many tests have only a few studies comparing their performance to RT-PCR. Future diagnostic accuracy studies need to adhere to the STARD guidelines[184] to provide the best evidence to build recommendations on. Studies without diagnostic accuracy numbers (2 × 2 tables) were excluded from the meta-analysis, resulting in a limitation to our review. Overall, RATs are excellent at predicting when a positive result means a positive diagnosis of COVID-19. However, these tests have reduced capacity to allow a negative result to rule out COVID-19 as a diagnosis. Misidentifying SARS-CoV-2 infection for other respiratory viral infections can lead to potential viral spread among vulnerable patients and health care workers. Further, it can delay appropriate treatment in cases with high risk of complications. In the primary care setting, false-negative results should be considered for further testing via RT-PCR or repeat RATs over several days[185] when there is high suspicion of COVID-19, such as loss of taste or smell as a presenting symptom. Overall negative likelihood ratio is dependent on local prevalence, and health care practitioners should take into account their current community status when determining the best course of action for a negative RAT result.

Recommendations for practice

Based on our findings, we recommend that Roche's SARS-CoV-2 Rapid Antigen Test and Abbott's BinaxNOW tests be used in primary care settings, with the understanding that negative results need to be confirmed through RT-PCR or repeated testing over several days when COVID-19 is highly suspected. These tests are widely available, relatively inexpensive, and have good reliability.

Recommendations for research

The primary recommendation for research is to adhere to the STARD guidelines when reporting on diagnostic data.[184] If all studies had adhered to these guidelines, that would have allowed significantly more information to be gleaned from the studies selected. The key components of these guidelines that would have greatly improved our meta-analysis are the inclusion of the STARD diagram or the cross-tabulation (also known as a contingency table or a 2 × 2 table).[184] We only included studies that reported the TP, FP, TN, and FN values (91/143 studies) in our meta-analysis. We further recommend that any subgroup analysis performed also include these components. Using the STARD guidelines improves generalizability of reported data,[184] whereas failing to adhere to these guidelines limits the usefulness of the published data in developing evidence-based practice recommendations.

As new variants emerge, new testing will be needed using high-quality, rigorous methods in populations of vulnerable subjects. As rapid testing will likely remain the first line diagnostic for primary and secondary care environments, and consecutive

testing using RATs or RT-PCR will be used as confirmation of a negative diagnosis, identifying the most sensitive and specific tests will remain critically important.

Author contributions

GM, BH and SS: These authors contributed equally to this work. SR and TH: These authors contributed equally to this work. AD and JK: These authors contributed equally to this work. KD and TE: These authors contributed equally to this work. MDeA and AE, LS: These authors contributed equally to this work.

Acknowledgments

Linsey Bui for assistance with screening steps and Cheryl Vanier for discussions and critique.

Funding

This work was supported by internal research support from Touro University Nevada and the Federal Work-Study program. The funder had no role in the content development.

References

1. World Health Organization. WHO coronavirus (COVID-19) dashboard [internet]. World Health Organization; 2023 [cited 2023 Nov 8]. Available from: https://covid19.who.int/.
2. Saleh FA, Sleem A. COVID-19: test, test and test. Med Sci 2021;9(1):1.
3. Madhusoodanan J. Animal reservoirs—where the next SARS-CoV-2 variant could arise. JAMA 2022;328(8):696–8.
4. Borillo GA, Kagan RM, Marlowe EM. Rapid and accurate identification of SARS-CoV-2 variants using real time PCR assays. Front Cell Infect Microbiol 2022;12:894613.
5. Puhach O, Meyer B, Eckerle I. SARS-CoV-2 viral load and shedding kinetics. Nat Rev Microbiol 2023;21(3):147–61.
6. Venter M, Richter K. Towards effective diagnostic assays for COVID-19: a review. J Clin Pathol 2020;73(7):370–7.
7. Bwogi J, Lutalo T, Tushabe P, Bukenya H, Eliku JP, Ssewanyana I, *et al*. Field evaluation of the performance of seven antigen rapid diagnostic tests for the diagnosis of SARs-CoV-2 virus infection in Uganda. PLoS One 2022;17(5):e0265334.
8. Cattelan AM, Sasset L, Zabeo F, Ferrari A, Rossi L, Mazzitelli M, *et al*. Rapid antigen test LumiraDx™ vs. real time polymerase chain reaction for the diagnosis of SARS-CoV-2 infection: a retrospective cohort study. Int J Environ Res Public Health 2022;19(7):3826.
9. Safiabadi Tali SH, LeBlanc JJ, Sadiq Z, Oyewunmi OD, Camargo C, Nikpour B, *et al*. Tools and techniques for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)/COVID-19 detection. Clin Bicrobiol Rev 2021;34(3):e00228–20.
10. Liu M, Lyu J, Zheng X, Liang Z, Lei B, Chen H, *et al*. Evolution of the newest diagnostic methods for COVID-19: a Chinese perspective. J Zhejiang Univ Sci B 2023;24(6):463–84.
11. Freire ML, Alves LL, de Souza CS, Saliba JW, Faria V, Pedras MJ, *et al*. Performance differences among commercially available antigen rapid tests for COVID-19 in Brazil. PLoS One 2022;17(6):e0269997.
12. Scheiblauer H, Filomena A, Nitsche A, Puyskens A, Corman VM, Drosten C, *et al*. Comparative sensitivity evaluation for 122 CE-marked rapid diagnostic tests for SARS-CoV-2 antigen, Germany, September 2020 to April 2021. Euro Surveill 2021;26(44):2100441.
13. Bayona HH, Cabaluna IT, Dans L, Dans A. Diagnostic accuracy of rapid antigen tests for COVID-19. PROSPERO 2020. CRD42020205693.
14. Dinnes J, Deeks JJ, Berhane S, Taylor M, Adriano A, Davenport C, *et al*. Rapid, point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection. Cochrane Database Syst Rev 2021;3(3):CD013705.
15. Stegeman I, Ochodo EA, Guleid F, Holtman GA, Yang B, Davenport C, *et al*. Routine laboratory testing to determine if a patient has COVID-19. Cochrane Database Syst Rev 2020;11(11):CD013787.
16. Dinnes J, Sharma P, Berhane S, van Wyk SS, Nyaaba N, Domen J, *et al*. Rapid, point-of-care antigen tests for diagnosis of SARS-CoV-2 infection. Cochrane Database Syst Rev 2022;7(7):CD013705.
17. Campbell JM, Kulgar M, Ding S, Carmody DP, Hakonsen SJ, Jadotte YT, *et al*. Chapter 9: Diagnostic test accuracy systematic reviews. In: Aromataris E, Munn Z, editors. JBI Manual for Evidence Synthesis [internet]. JBI; 2020 [cited 2023 Nov 8]. Available from: https://synthesismanual.jbi.global
18. DeArmond M, Feliciano S, Hirabayashi E, Duus KM, Else TA, Stone AEL. Diagnostic accuracy of rapid antigen tests for COVID-19 compared to the viral genetic test in adults: a systematic review protocol. JBI Evid Synth 2021;19(5):1148–56.
19. Verma N, Patel D, Pandya A. Emerging diagnostic tools for detection of COVID-19 and perspective. Biomed Microdevices 2020;22(4):83.
20. Shirato K, Tomita Y, Katoh H, Yamada S, Fukushi S, Matsuyama S, *et al*. Performance evaluation of real-time RT-PCR assays for the detection of severe acute respiratory syndrome coronavirus-2 developed by the National Institute of Infectious Diseases, Japan. Jpn J Infect Dis 2021;74(5):465–72.
21. Canadian Agency for Drugs and Technologies in Health. CADTH COVID-19 search strings [internet]. CADTH; 2020

[cited 2020 Oct 5]. Available from: https://covid.cadth.ca/literaturesearching-tools/cadth-covid-19-search-strings/.
22. McGowan J, Sampson M, Salzwedel DM, Cogo E, Foerster V, Lefebvre C. PRESS Peer Review of Electronic Search Strategies: 2015 Guideline Statement. J Clin Epidemiol 2016;75:40–6.
23. Bramer WM, Giustini D, de Jonge GB, Holland L, Bekhuis T. De-duplication of database search results for systematic reviews in EndNote. J Med Libr Assoc 2016;104(3):240–3.
24. Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, *et al*. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71.
25. Whiting PF, Rutjes AW, Westwood ME, Mallett S, Deeks JJ, Reitsma JB, *et al*. QUADAS-2: a revised tool for the quality assessment of diagnostic accuracy studies. Ann Intern Med 2011;155(8):529–36.
26. Hodcroft EB. CoVariants: SARS-CoV-2 mutations and variants of interest [internet]. CoVariants; 2021 [cited 2023 Nov 8]. Available from: https://covariants.org/.
27. Balduzzi S, Rucker G, Schwarzer G. How to perform a meta-analysis with R: a practical tutorial. Evid Based Ment Health 2019;22(4):153–60.
28. Harrer M, Cuijpers P, Furukawa T, Ebert DD. dmetar: companion R package for the guide 'Doing Meta-Analysis in R' [internet]. R package version 0.1.0. dmetar; 2019 [cited 2023 Nov 8]. Available from: http://dmetar.protectlab.org/.
29. McMaster University, Evidence Prime Inc. GRADEpro GDT: GRADEpro Guideline Development Tool. 2022.
30. Schünemann H, Brożüek J, Guyatt, Oxman A. GRADE handbook for grading quality of evidence and strength of recommendations. The GRADE Working Group; 2013 [cited 2023 Nov 8]. Available from: https://gdt.gradepro.org/app/handbook/handbook.html.
31. Abdelrazik AM, Elshafie SM, Abdelaziz HM. Potential use of antigen-based rapid test for SARS-CoV-2 in respiratory specimens in low-resource settings in Egypt for symptomatic patients and high-risk contacts. Lab Med 2021;52(2):e46–9.
32. Abusrewil Z, Alhudiri IM, Kaal HH, El Meshri SE, Ebrahim FO, Dalyoum T, *et al*. Time scale performance of rapid antigen testing for SARS-CoV-2: evaluation of 10 rapid antigen assays. J Med Virol 2021;93(12):6512–8.
33. Afzal RK, Ali S, Ahmad F, Nasir S, Younas M, Ahmad T. Diagnostic accuracy of PANBIO COVID-19 rapid antigen method for screening in emergency cases. Pak Armed Forces Med J 2021;71(5):1607–10.
34. Akashi Y, Horie M, Takeuchi Y, Togashi K, Adachi Y, Ueda A, *et al*. A prospective clinical evaluation of the diagnostic accuracy of the SARS-CoV-2 rapid antigen test using anterior nasal samples. J Infect Chemother 2022;28(6):780–5.
35. Al-Alawi S, Al-Hinai H, Al-Kindi N, Al-Rashidi M, Al-Kindi H, Al-Shukri I, *et al*. Evaluation of four rapid antigen tests for detection of SARS-CoV-2 virus. Oman Med J 2021;36(5):e297.
36. Aleem S, Zahoor N, Jeelani A, SalimKhan SM. Diagnostic accuracy of STANDARD QCOVID-19 antigen detection kit in comparison with RT-PCR assay using nasopharyngeal samples in India. J Clin Diagn Res 2022;16(1):DC01–5.
37. Alghounaim M, Bastaki H, Bin Essa F, Motlagh H, Al-Sabah S. The performance of two rapid antigen tests during population-level screening for SARS-CoV-2 infection. Front Med 2021;8:797109.
38. Allan-Blitz LT, Klausner JD. A real-world comparison of SARS-CoV-2 Rapid Antigen Testing versus PCR testing in Florida. J Clin Microbiol 2021;59(10):e0110721.
39. Amer RM, Samir M, Gaber OA, El-Deeb NA, Abdelmoaty AA, Ahmed AA, *et al*. Diagnostic performance of rapid antigen test for COVID-19 and the effect of viral load, sampling time, subject's clinical and laboratory parameters on test accuracy. J Infect Public Health 2021;14(10):1446–53.
40. Anastasiou OE, Holtkamp C, Schäfer M, Schön F, Eis-Hübinger AM, Krumbholz A. Fast detection of SARS-CoV-2 RNA directly from respiratory samples using a loop-mediated isothermal amplification (LAMP) test. Viruses 2021;13(5):801.
41. Avgoulea K, Beredaki MI, Vourli S, Siopi M, Siafakas N, Pournaras S. field evaluation of the new rapid NG-Test® SARS-CoV-2 Ag for diagnosis of COVID-19 in the emergency department of an academic referral hospital. Front Public Health 2022;10:840984.
42. Babu GR, Sundaresan R, Athreya S, Akhtar J, Pandey PK, Maroor PS, *et al*. The burden of active infection and anti-SARS-CoV-2 IgG antibodies in the general population: results from a statewide sentinel-based population survey in Karnataka, India. Int J Infect Dis 2021;108:27–36.
43. Bachman CM, Grant BD, Anderson CE, Alonzo LF, Garing S, Byrnes SA, *et al*. Clinical validation of an open-access SARS-COV-2 antigen detection lateral flow assay, compared to commercially available assays. PLoS One 2021;16(8):e0256352.
44. Basso D, Aita A, Padoan A, Cosma C, Navaglia F, Moz S, *et al*. Salivary SARS-CoV-2 antigen rapid detection: a prospective cohort study. Clin Chim Acta 2021;517:54–9.
45. Blairon L, Wilmet A, Beukinga I, Tré-Hardy M. Implementation of rapid SARS-CoV-2 antigenic testing in a laboratory without access to molecular methods: Experiences of a general hospital. J Clin Virol 2020;129:104472.
46. Bond KA, Smith B, Gardiner E, Liew KC, Williams E, Walsham N, *et al*. Utility of SARS-CoV-2 rapid antigen testing for patient triage in the emergency department: a clinical implementation study in Melbourne, Australia. Lancet Reg Health West Pac 2022;25:100486.
47. Borro M, Salerno G, Montori A, Petrucca A, Anibaldi P, Marcolongo A, *et al*. SARS-CoV-2 transmission control measures in the emergency department: the role of rapid

antigenic testing in asymptomatic subjects. Healthcare 2022;10(5):790.
48. Boum Y, Fai KN, Nicolay B, Mboringong AB, Bebell LM, Ndifon M, *et al*. Performance and operational feasibility of antigen and antibody rapid diagnostic tests for COVID-19 in symptomatic and asymptomatic patients in Cameroon: a clinical, prospective, diagnostic accuracy study. Lancet Infect Dis 2021;21(8):1089–96.
49. Bulilete O, Lorente P, Leiva A, Carandell E, Oliver A, Rojo E, *et al*. Panbio™ rapid antigen test for SARS-CoV-2 has acceptable accuracy in symptomatic patients in primary health care. J Infect 2021;82(3):391–8.
50. Burdino E, Cerutti F, Panero F, Allice T, Gregori G, Milia MG, *et al*. SARS-CoV-2 microfluidic antigen point-of-care testing in emergency room patients during COVID-19 pandemic. J Virol Methods 2022;299:114337.
51. Caruana G, Croxatto A, Kampouri E, Kritikos A, Opota O, Foerster M, *et al*. Implementing SARS-CoV-2 rapid antigen testing in the emergency ward of a Swiss university hospital: the INCREASE Study. Microorganisms 2021;9 (4):798.
52. Caruana G, Lebrun LL, Aebischer O, Opota O, Urbano L, de Rham M, *et al*. The dark side of SARS-CoV-2 rapid antigen testing: screening asymptomatic patients. New Microbes New Infect 2021;42:100899.
53. Cassuto NG, Gravier A, Colin M, Theillay A, Pires-Roteira D, Pallay S, *et al*. Evaluation of a SARS-CoV-2 antigen-detecting rapid diagnostic test as a self-test: diagnostic performance and usability. J Med Virol 2021;93(12): 6686–92.
54. Cento V, Renica S, Matarazzo E, Antonello M, Colagrossi L, Di Ruscio F, *et al*. Frontline screening for SARS-CoV-2 infection at emergency department admission by third generation rapid antigen test: can we spare RT-qPCR? Viruses 2021;13(5):818.
55. Cerutti F, Burdino E, Milia MG, Allice T, Gregori G, Bruzzone B, *et al*. Urgent need of rapid tests for SARS CoV-2 antigen detection: evaluation of the SD-Biosensor antigen test for SARS-CoV-2. J Clin Virol 2020;132:104654.
56. Chaimayo C, Kaewnaphan B, Tanlieng N, Athipanyasilp N, Sirijatuphat R, Chayakulkeeree M, *et al*. Rapid SARS-CoV-2 antigen detection assay in comparison with real-time RT-PCR assay for laboratory diagnosis of COVID-19 in Thailand. Virol J 2020;17(1):177.
57. Cheng CC, Liu CC, Chiu TF, Shiou-Sheng Chen S. Evaluation of a rapid antigen test for the diagnosis of SARS-CoV-2 during the COVID-19 pandemic. Inquiry 2022; 59:469580221105354.
58. Choudhary SIA. Validation of rapid SARS-COV-2 antigen detection test as a screening tool for detection of Covid-19 infection at district hospital in northern India. Asian J Med Sci 2022;13(4):7–10.
59. Cottone E, Van Hoecke F, Martens GA, De Laere E, De Smedt R, Vervaeke S, *et al*. Pitfalls of SARS-CoV-2 antigen testing at emergency department. Infect Dis (Lond) 2022; 54(10):731–7.
60. Cubas-Atienzar AI, Bell F, Byrne RL, Buist K, Clark DJ, Cocozza M, *et al*. Accuracy of the Mologic COVID-19 rapid antigen test: a prospective multi-centre analytical and clinical evaluation [version 1; peer review 1: 1 approved with reservations]. Wellcome Open Res 2021;6:132.
61. Dierks S, Bader O, Schwanbeck J, Groß U, Weig MS, Mese K, *et al*. Diagnosing SARS-CoV-2 with antigen testing, transcription-mediated amplification and real-time PCR. J Clin Med 2021;10(11):2404.
62. Escribano P, Sánchez-Pulido AE, González-Leiva J, Valero-López I, Catalán P, Muñoz P, *et al*. Different performance of three point-of-care SARS-CoV-2 antigen detection devices in symptomatic patients and close asymptomatic contacts: a real-life study. Clin Microbiol Infect 2022;28(6):865–70.
63. Escrivá BF, Mochón MDO, González RM, García CS, Pla AT, Ricart AS, *et al*. The effectiveness of rapid antigen test-based for SARS-CoV-2 detection in nursing homes in Valencia, Spain. J Clin Virol 2021;143:1104941.
64. Faíco-Filho KS, Júnior FEF, Moreira LVL, Lins PRG, Justo AFO, Bellei N. Evaluation of the Panbio™ COVID-19 ag rapid test at an emergency room in a hospital in São Paulo, Brazil. Braz J Infect Dis 2022;26(2):102349.
65. Farfour E, Amiel C, Jolly E, Zia-Chahabi S, Mazaux L, Simonin P, *et al*. The Panbio COVID-19 Ag Rapid Test: which performances are for COVID-19 diagnosis? Clin Lab 2021;67(11):2525–32.
66. Fernandez-Montero A, Argemi J, Rodríguez JA, Ariño AH, Moreno-Galarraga L. Validation of a rapid antigen test as a screening tool for SARS-CoV-2 infection in asymptomatic populations. Sensitivity, specificity and predictive values. EClinicalMedicine 2021;37:100954.
67. Ferté T, Ramel V, Cazanave C, Lafon ME, Bébéar C, Malvy D, *et al*. Accuracy of COVID-19 rapid antigenic tests compared to RT-PCR in a student population: the StudyCov study. J Clin Virol 2021;141:104878.
68. Fitoussi F, Tonen-Wolyec S, Awaida N, Dupont R, Bélec L. Analytical performance of the point-of-care BIOSYNEX COVID-19 Ag BSS for the detection of SARS-CoV-2 nucleocapsid protein in nasopharyngeal swabs: a prospective field evaluation during the COVID-19 third wave in France. Infection 2021. [epub ahead of print].
69. Ford L, Whaley MJ, Shah MM, Salvatore PP, Segaloff HE, Delaney A, *et al*. Antigen test performance among children and adults at a SARS-CoV-2 community testing site. J Pediatric Infect Dis Soc 2021;10(12):1052–61.
70. Galliez RM, Bomfim L, Mariani D, Leitão IC, Castiñeiras ACP, Gonçalves CCA, *et al*. Evaluation of the Panbio COVID-19 antigen rapid diagnostic test in subjects infected with omicron using different specimens. Microbiol Spectr 2022;10(3):e0125022.
71. Garcia-Cardenas F, Franco A, Cortés R, Bertin J, Valdéz R, Peñaloza F, *et al*. Analytical performances of the COVISTIX™

and Panbio™ antigen rapid tests for SARS-CoV-2 detection in an unselected population (all comers). medRxiv 2021.
72. Garcia-Cardenas F, Peñaloza F, Bertin-Montoya J, Valdéz-Vázquez R, Franco A, Cortés R, *et al*. Analytical performances of the COVISTIX™ antigen rapid test for SARS-CoV-2 detection in an unselected population (all-comers). Pathogens 2022;11(6):628.
73. García-Fernández S, Pablo-Marcos D, de la Fuente SV, Rodríguez MJR, Gozalo M, Rodríguez-Lozano J, *et al*. Evaluation of the rapid antigen detection test STANDARD F COVID-19 Ag FIA for diagnosing SARS-CoV-2: experience from an emergency department. Diagn Microbiol Infect Dis 2022;103(2):115683.
74. García-Fiñana M, Hughes DM, Cheyne CP, Burnside G, Stockbridge M, Fowler TA, *et al*. Performance of the Innova SARS-CoV-2 antigen rapid lateral flow test in the Liverpool asymptomatic testing pilot: population based cohort study. BMJ 2021;374:n1637.
75. Goga A, Mayne ES, Woeber K, Takuva S, Nsibande D, Lekalakala M, *et al*. Point-of-care antibody tests for COVID-19: field-based performance, South Africa [CROI Abstract 824]. In special issue: Abstracts from the 2022 Conference on Retroviruses and Opportunistic Infections. Top Antiv Med 2022;30(1s):137.
76. Gonzalez-Fiallo S, Mena-Rodriguez I, Castro-Batista P, Doeste-Hernandez VM, Louit-Laborit V. Evaluation of SARS-CoV-2 rapid antigen tests in use on the Isle of Youth. Cuba MEDICC Rev 2022;24(2):15–9.
77. Gupta A, Khurana S, Das R, Srigyan D, Singh A, Mittal A, *et al*. Rapid chromatographic immunoassay-based evaluation of COVID-19: a cross-sectional, diagnostic test accuracy study & its implications for COVID-19 management in India. Indian J Med Res 2021;153(1 & 2):126–31.
78. Harris DT, Badowski M, Jernigan B, Sprissler R, Edwards T, Cohen R, *et al*. SARS-CoV-2 rapid antigen testing of symptomatic and asymptomatic individuals on the University of Arizona Campus. Biomedicines 2021;9(5):539.
79. Holzner C, Pabst D, Anastasiou OE, Dittmer U, Manegold RK, Risse J, *et al*. SARS-CoV-2 rapid antigen test: fast-safe or dangerous? An analysis in the emergency department of an university hospital. J Med Virol 2021;93(9):5323–7.
80. Homza M, Zelena H, Janosek J, Tomaskova H, Jezo E, Kloudova A, *et al*. Five antigen tests for SARS-CoV-2: virus viability matters. Viruses 2021;13(4):684.
81. Hörber S, Drees C, Ganzenmueller T, Schmauder K, Peter S, Biskup D, *et al*. Evaluation of a laboratory-based high-throughput SARS-CoV-2 antigen assay. Clin Chem Lab Med 2022;60(9):1478–85.
82. Ifko M, Tkalčić Švabek Ž, Friščić I, Kardum Paro MM, Prkačin I, Đerek L, *et al*. Diagnostic validation of two SARS-CoV-2 immunochromatographic tests in Slovenian and Croatian hospitals. Croat Med J 2021;62(5):513–7.
83. Igloi Z, Velzing J, van Beek J, van de Vijver D, Aron G, Ensing R, *et al*. Clinical evaluation of Roche SD Biosensor Rapid Antigen Test for SARS-CoV-2 in Municipal Health Service Testing Site, the Netherlands. Emerg Infect Dis 2021;27(5):1323–9.
84. Jakobsen KK, Jensen JS, Todsen T, Tolsaard MG, Kirkby N, Lippert F, *et al*. Accuracy and cost description of rapid antigen test compared with reverse transcriptase-polymerase chain reaction for SARS-CoV-2 detection. Dan Med J 2021;68(7):A03210217.
85. Jakobsen KK, Jensen JS, Todsen T, Kirkby N, Lippert F, Vangsted AM, *et al*. Accuracy of anterior nasal swab rapid antigen tests compared with RT-PCR for massive SARS-CoV-2 screening in low prevalence population. APMIS 2022;130(2):95–100.
86. Jeewandara C, Guruge D, Pushpakumara PD, Madhusanka D, Jayadas TT, Chaturanga IP, *et al*. Sensitivity and specificity of two WHO approved SARS-CoV2 antigen assays in detecting patients with SARS-CoV2 infection. BMC Infect Dis 2022;22(1):276.
87. Jegerlehner S, Suter-Riniker F, Jent P, Bittel P, Nagler M. Diagnostic accuracy of a SARS-CoV-2 rapid antigen test in real-life clinical settings. Int J Infect Dis 2021;109:118–22.
88. Jegerlehner S, Suter-Riniker F, Jent P, Bittel P, Nagler M. Diagnostic accuracy of SARS-CoV-2 saliva antigen testing in a real-life clinical setting. Int J Infect Dis 2022;119:38–40.
89. Jirungda S, Khamphrom P, Klaprajun K, Prachakul T, Kraisin J. Clinical performance of the standard F COVID-19 AG FIA for the detection of SARS-COV-2 infection. Clinica Chimica Acta 2022;530:S291.
90. Kahn M, Schuierer L, Bartenschlager C, Zellmer S, Frey R, Freitag M, *et al*. Performance of antigen testing for diagnosis of COVID-19: a direct comparison of a lateral flow device to nucleic acid amplification based tests. BMC Infect Dis 2021;21(1):798.
91. Kessler HH, Prüller F, Hardt M, Stelzl E, Föderl-Höbenreich E, Pailer S, *et al*. Identification of contagious SARS-CoV-2 infected individuals by Roche's Rapid Antigen Test. Clin Chem Lab Med 2022;60(5):778–85.
92. Kim D, Lee J, Bal J, Seo SK, Chong CK, Lee JH, *et al*. Development and clinical evaluation of an immunochromatography-based rapid antigen test (GenBody™ COVAG025) for COVID-19 diagnosis. Viruses 2021;13(5):796.
93. King C, Lista-de Weever E, Henry M, Steingrover R, Fleming C, Panneflek R, *et al*. Validation of the Panbio™ COVID-19 Antigen Rapid Test (Abbott) to screen for SARS-CoV-2 infection in Sint Maarten: a diagnostic accuracy study. medRxiv 2021.
94. Kiyasu Y, Takeuchi Y, Akashi Y, Kato D, Kuwahara M, Muramatsu S, *et al*. Prospective analytical performance evaluation of the QuickNavi™-COVID19 Ag for asymptomatic individuals. J Infect Chemother 2021;27(10):1489–92.
95. Klajmon A, Olechowska-Jarząb A, Salamon D, Sroka-Oleksiak A, Brzychczy-Włoch M, Gosiewski T. Comparison of antigen tests and qPCR in rapid diagnostics of infections caused by SARS-CoV-2 virus. Viruses 2021;14(1):17.

96. Klein JAF, Krüger LJ, Tobian F, Gaeddert M, Lainati F, Schnitzler P, *et al*. Head-to-head performance comparison of self-collected nasal versus professional-collected nasopharyngeal swab for a WHO-listed SARS-CoV-2 antigen-detecting rapid diagnostic test. Med Microbiol Immunol 2021;210(4):181–6.
97. Kohmer N, Toptan T, Pallas C, Karaca O, Pfeiffer A, Westhaus S, *et al*. Article the comparative clinical performance of four SARS-CoV-2 rapid antigen tests and their correlation to infectivity in vitro. J Clin Med 2021;10(2):1–11.
98. Korenkov M, Poopalasingam N, Madler M, Vanshylla K, Eggeling R, Wirtz M, *et al*. Evaluation of a rapid antigen test to detect SARS-CoV-2 infection and identify potentially infectious individuals. J Clin Microbiol 2021;59(9): e0089621.
99. Korenkov M, Poopalasingam N, Madler M, Vanshylla K, Eggeling R, Wirtz M, *et al*. Assessment of SARS-CoV-2 infectivity by a rapid antigen detection test. medRxiv 2021.
100. Krüger LJ, Klein JAF, Tobian F, Gaeddert M, Lainati F, Klemm S, *et al*. Evaluation of accuracy, exclusivity, limit-of-detection and ease-of-use of LumiraDx™: an antigen-detecting point-of-care device for SARS-CoV-2. Infection 2021. [epub ahead of print].
101. Krüger LJ, Tanuri A, Lindner AK, Gaeddert M, Köppel L, Tobian F, *et al*. Accuracy and ease-of-use of seven point-of-care SARS-CoV-2 antigen-detecting tests: a multi-centre clinical evaluation. EBioMedicine 2021;75:103774.
102. Krüger LJ, Lindner AK, Gaeddert M, Tobian F, Klein J, Steinke S, *et al*. A multicenter clinical diagnostic accuracy study of SureStatus, an affordable, WHO emergency use-listed, rapid, point-of-care antigen-detecting diagnostic test for SARS-CoV-2. Microbiol Spectr 2022;10 (5):e01229–22.
103. Krüger LJ, Gaeddert M, Tobian F, Lainati F, Gottschalk C, Klein JAF, *et al*. The Abbott PanBio WHO emergency use listed, rapid, antigen-detecting point-of-care diagnostic test for SARS-CoV-2-Evaluation of the accuracy and ease-of-use. PLoS One 2021;16(5):e0247918.
104. Kurihara Y, Kiyasu Y, Akashi Y, Takeuchi Y, Narahara K, Mori S, *et al*. The evaluation of a novel digital immunochromatographic assay with silver amplification to detect SARS-CoV-2. J Infect Chemother 2021;27(10):1493–7.
105. Kweon OJ, Lee JH, Choi YS, Kim BS, Lim YK, Lee MK, *et al*. Positivity of rapid antigen testing for SARS-CoV-2 with serial followed-up nasopharyngeal swabs in hospitalized patients due to COVID-19. J Korean Med Sci 2022;37(21): e168.
106. Kyritsi M, Vontas A, Voulgaridi I, Matziri A, Komnos A, Babalis D, *et al*. Rapid test ag 2019-nCoV (PROGNOSIS, BIOTECH, Larissa, Greece); performance evaluation in hospital setting with real time RT-PCR. Int J Environ Res Public Health 2021;18(17):9151.
107. Landaverde L, Turcinovic J, Doucette-Stamm L, Gonzales K, Platt J, Connor JH, *et al*. Comparison of BinaxNOW TM and SARS-CoV-2 qRT-PCR detection of the omicron variant from matched anterior nares swabs2022;10(6):e0130722.
108. Layer E, Hoehl S, Widera M, Bojkova D, Westphal T, Gottschalk R, *et al*. SARS-CoV-2 screening strategies for returning international travellers: evaluation of a rapid antigen test approach. Int J Infect Dis 2022;118: 126–31.
109. LeGoff J, Kernéis S, Elie C, Mercier-Delarue S, Gastli N, Choupeaux L, *et al*. Evaluation of a saliva molecular point of care for the detection of SARS-CoV-2 in ambulatory care. Sci Rep 2021;11(1):21126.
110. Leixner G, Voill-Glaninger A, Bonner E, Kreil A, Zadnikar R, Viveiros A. Evaluation of the AMP SARS-CoV-2 rapid antigen test in a hospital setting. Int J Infect Dis 2021; 108:353–6.
111. Linares M, Pérez-Tanoira R, Carrero A, Romanyk J, Pérez-García F, Gómez-Herruz P, *et al*. Panbio antigen rapid test is reliable to diagnose SARS-CoV-2 infection in the first 7 days after the onset of symptoms. J Clin Virol 2020; 133:104659.
112. Lindner AK, Nikolai O, Kausch F, Wintel M, Hommes F, Gertler M, *et al*. Head-to-head comparison of SARS-CoV-2 antigen-detecting rapid test with self-collected nasal swab versus professional-collected nasopharyngeal swab. Eur Respir J 2021;57(4):2003961.
113. Lindner AK, Nikolai O, Rohardt C, Burock S, Hülso C, Bölke A, *et al*. Head-to-head comparison of SARS-CoV-2 antigen-detecting rapid test with professional-collected nasal versus nasopharyngeal swab. Eur Respir J 2021;57(5): 2004430.
114. Lindner AK, Nikolai O, Rohardt C, Kausch F, Wintel M, Gertler M, *et al*. Diagnostic accuracy and feasibility of patient self-testing with a SARS-CoV-2 antigen-detecting rapid test. J Clin Virol 2021;141:104874.
115. Mandal DK, Bhattarai BR, Pokhrel S, Chhusyabaga M, Bhandari P, Bhatt MP, *et al*. Diagnostic performance of SARS-CoV-2 rapid antigen test in relation to RT-PCR CqValue. Adv Virol 2022;2022:9245248.
116. Mane A, Jain S, Jain A, Pereira M, Sirsat A, Pathak G, *et al*. Diagnostic performance of oral swab specimen for SARS-CoV-2 detection with rapid point-of-care lateral flow antigen test. Sci Rep 2022;12(1):7355.
117. Maniscalco M, Ambrosino P, Ciullo A, Fuschillo S, Valente V, Gaudiosi C, *et al*. A rapid antigen detection test to diagnose SARS-CoV-2 infection using exhaled breath condensate by a modified Inflammacheck® device. Sensors 2021;21(17):5710.
118. Masiá M, Fernández-González M, Sánchez M, Carvajal M, García JA, Gonzalo-Jiménez N, *et al*. Nasopharyngeal Panbio COVID-19 Antigen performed at point-of-care has a high sensitivity in symptomatic and asymptomatic

patients with higher risk for transmission and older age. Open Forum Infect Dis 2021;8(3):ofab059.
119. Mizrahi A, Nguyen Van JC, El Helali N, Lourtet-Hascoet J, Jabnoune I, Pacreau ML, *et al*. The Coris BioConcept COVID 19 Ag Respi-Strip, a field experience feedback. J Virol Methods 2022;300:114366.
120. Møller IJB, Utke AR, Rysgaard UK, Østergaard LJ, Jespersen S. Diagnostic performance, user acceptability, and safety of unsupervised SARS-CoV-2 rapid antigen-detecting tests performed at home. Int J Infect Dis 2022; 116:358–64.
121. Nagura-Ikeda M, Imai K, Tabata S, Miyoshi K, Murahara N, Mizuno T, *et al*. clinical evaluation of self-collected saliva by quantitative reverse transcription-PCR (RT-qPCR), direct RT-qPCR, reverse transcription-loop-mediated isothermal amplification, and a rapid antigen test to diagnose COVID-19. J Clin Microbiol 2020;58(9).
122. Nikolai O, Rohardt C, Tobian F, Junge A, Corman VM, Jones TC, *et al*. Anterior nasal versus nasal mid-turbinate sampling for a SARS-CoV-2 antigen-detecting rapid test: does localisation or professional collection matter? Infect Dis 2021;53(12):947–52.
123. Nóra M, Déri D, Veres DS, Kis Z, Barcsay E, Pályi B. Evaluating the field performance of multiple SARS-Cov-2 antigen rapid tests using nasopharyngeal swab samples. PLoS One 2022;17(2):e0262399.
124. Okoye GA, Kamara HI, Strobeck M, Mellman TA, Kwagyan J, Sullivan A, *et al*. Diagnostic accuracy of a rapid diagnostic test for the early detection of COVID-19. J Clin Virol 2022; 147:105023.
125. Onsongo SN, Otieno K, van Duijn S, Adams E, Omollo M, Odero IA, *et al*. Performance of a rapid antigen test for SARS-CoV-2 in Kenya. Diagn Microbiol Infect Dis 2022;102 (2):115591.
126. Osmanodja B, Budde K, Zickler D, Naik MG, Hofmann J, Gertler M, *et al*. Accuracy of a novel sars-cov-2 antigen-detecting rapid diagnostic test from standardized self-collected anterior nasal swabs. J Clin Med 2021;10 (10):2099.
127. Paap KC, van Loon AM, Koene FM, van Buul LW, Jurriaans S, Smalbrugge M, *et al*. Clinical evaluation of single-swab sampling for rapid COVID-19 detection in outbreak settings in Dutch nursing homes. Eur Geriatr Med 2022;13 (3):711–8.
128. Pandey AK, Mohanty A, Hada V, Rath RS, Kumar S, Kishore S, *et al*. Comparison of the rapid antigen testing method with RT-qPCR for the diagnosis of COVID-19. Cureus 2021;13(8): e17405.
129. Park JY, Lee JH, Cha BK, Kim B-S, Lee H-J, Kim GH, *et al*. Analysis of the efficacy of universal screening of coronavirus disease with antigen-detecting rapid diagnostic tests at point-or-care settings and sharing the experience of admission protocol-a pilot study 2022;12(2):319.
130. Peacock WF, Soto-Ruiz KM, House SL, Cannon CM, Headden G, Tiffany B, *et al*. Utility of COVID-19 antigen testing in the emergency department. J Am Coll Emerg Physicians Open 2022;3(1):e12605.
131. Peña M, Ampuero M, Garcés C, Gaggero A, García P, Velasquez MS, *et al*. Performance of SARS-CoV-2 rapid antigen test compared with real-time RT-PCR in asymptomatic individuals. Int J Infect Dis 2021; 107:201–4.
132. Peña-Rodríguez M, Viera-Segura O, García-Chagollán M, Zepeda-Nuño JS, Muñoz-Valle JF, Mora-Mora J, *et al*. Performance evaluation of a lateral flow assay for nasopharyngeal antigen detection for SARS-CoV-2 diagnosis. J Clin Lab Anal 2021;35(5):e23745.
133. Peronace C, Tallerico R, Colosimo M, Sacco V, Talarico R, De Fazio M, *et al*. Validation of GeneFinder COVID-19 Ag Plus Rapid Test and its potential utility to slowing infection waves: a single-center laboratory evaluation study. Diagnostics 2022;12(5):1126.
134. Pilarowski G, Lebel P, Sunshine S, Liu J, Crawford E, Marquez C, *et al*. Performance characteristics of a rapid severe acute respiratory syndrome coronavirus 2 antigen detection assay at a public plaza testing site in San Francisco. J Infect Dis 2021;223(7):1139–44.
135. Pollock NR, Jacobs JR, Tran K, Cranston AE, Smith S, O'Kane CY, *et al*. Performance and implementation evaluation of the Abbott BinaxNOW Rapid Antigen Test in a high-throughput drive-through community testing site in Massachusetts. J Clin Microbiol 2021;59(5): e00083–21.
136. Poopalasingam N, Korenkov M, Ashurov A, Strobel J, Fish I, Hellmich M, *et al*. Determining the reliability of rapid SARS-CoV-2 antigen detection in fully vaccinated individuals. J Clin Virol 2022;148:105119.
137. Prost M. Evaluation of a rapid in vitro diagnostic test device for detection of SARS-CoV-2 antigen in nasal swabs. Health Sci J 2021;15(11):1–3.
138. Rahman MM, Hoque AF, Karim Y, Kawser Z, Siddik AB, Sumiya MK, *et al*. Clinical evaluation of SARS-CoV-2 antigen-based rapid diagnostic test kit for detection of COVID-19 cases in Bangladesh. Heliyon 2021;7(11):e08455.
139. Rana N, Thakur P, Saxena S, Manchanda V, Arora R. Evaluation of the currently used antigen-based rapid diagnostic test for the detection of SARS CoV-2 virus in respiratory specimens. Indian J Med Microbiol 2021;39:S68.
140. Rastawicki W, Gierczyński R, Juszczyk G, Mitura K, Henry BM. Evaluation of PCL rapid point of care antigen test for detection of SARS-CoV-2 in nasopharyngeal swabs. J Med Virol 2021;93(4):1920–2.
141. Soleimani R, Deckers C, Huang TD, Bogaerts P, Evrard S, Wallemme I, *et al*. Rapid COVID-19 antigenic tests: usefulness of a modified method for diagnosis. J Med Virol 2021; 93(9):5655–9.

142. Rohde J, Himmel W, Hofinger C, Lâm TT, Schrader H, Wallstabe J, *et al*. Diagnostic accuracy and feasibility of a rapid SARS-CoV-2 antigen test in general practice - a prospective multicenter validation and implementation study. BMC Prim Care 2022;23(1):149.
143. Salcedo N, Sena BF, Qu X, Herrera BB. Comparative evaluation of rapid isothermal amplification and antigen assays for screening testing of SARS-CoV-2. Viruses 2022; 14(3):468.
144. Salvagno GL, Gianfilippi G, Bragantini D, Henry BM, Lippi G. Clinical assessment of the Roche SARS-CoV-2 rapid antigen test. Diagnosis 2021;8(3):322–6.
145. Salvagno GL, Gianfilippi G, Pighi L, De Nitto S, Henry BM, Lippi G. Real-world assessment of Fluorecare SARS-CoV-2 Spike Protein Test Kit. Adv Lab Med 2021;2(3):409–12.
146. Savage HR, Finch L, Body R, Watkins RL, Hayward G, Cook E, *et al*. A prospective diagnostic evaluation of accuracy of self-taken and healthcare worker-taken swabs for rapid COVID-19 testing. PLoS One 2022;17(6):e0270715.
147. Schildgen V, Demuth S, Lüsebrink J, Schildgen O. Limits and opportunities of sars-cov-2 antigen rapid tests: an experienced-based perspective. Pathogens 2021;10(1):1–7.
148. Selvabai RAP, Koshy LV, Shanmugam P. Diagnostic efficacy of COVID-19 rapid antigen detection card in diagnosis of SARS-CoV-2. J Lab Physicians 2022;14 (03):324–8.
149. Shaw JLV, Deslandes V, Smith J, Desjardins M. Evaluation of the Abbott PanbioTM COVID-19 Ag rapid antigen test for the detection of SARS-CoV-2 in asymptomatic Canadians. Diagn Microbiol Infect Dis 2021;101 (4):115514.
150. Siddiqui ZK, Chaudhary M, Robinson ML, McCall AB, Peralta R, Esteve R, *et al*. Implementation and accuracy of BinaxNOW Rapid Antigen COVID-19 test in asymptomatic and symptomatic populations in a high-volume self-referred testing site. Microbiol Spectr 2021;9(3): e0100821.
151. Sitoe N, Sambo J, Nguenha N, Chilaule J, Chelene I, Loquiha O, *et al*. Performance evaluation of the STANDARD™ Q COVID-19 and Panbio™ COVID-19 antigen tests in detecting SARS-CoV-2 during high transmission period in Mozambique. Diagnostics 2022;12(2):475.
152. Skvarč M. Clinical validation of two immunochromatographic SARS-CoV-2 antigen tests in near hospital facilities. J Infect Dev Ctries 2022;16(3):418–21.
153. Smith RD, Johnson JK, Clay C, Girio-Herrera L, Stevens D, Abraham M, *et al*. Clinical evaluation of Sofia Rapid Antigen Assay for detection of severe acute respiratory syndrome coronavirus 2 among emergency department to hospital admissions. Infect Control Hosp Epidemiol 2022; 43(8):968–73.
154. Stohr JJJM, Zwart VF, Goderski G, Meijer A, Nagel-Imming CRS, Kluytmans-van den Bergh MFQ, *et al*. Self-testing for the detection of SARS-CoV-2 infection with rapid antigen tests for people with suspected COVID-19 in the community. Clin Microbiol Infect 2022;28(5):695–700.
155. Surasi K, Cummings KJ, Hanson C, Kate Morris M, Salas M, Seftel D, *et al*. Eff ectiveness of abbott binaxnow rapid antigen test for detection of sars-cov-2 infections in outbreak among horse racetrack workers, california, usa. Emerg Infect Dis 2021;27(11):2761–7.
156. Suzuki H, Akashi Y, Kato D, Takeuchi Y, Kiyasu Y, Terada N, *et al*. Analytical performance of rapid antigen tests for the detection of SARS-CoV-2 during widespread circulation of the omicron variant. medRxiv 2022.
157. Suzuki H, Akashi Y, Ueda A, Kiyasu Y, Takeuchi Y, Maehara Y, *et al*. Diagnostic performance of a novel digital immunoassay (RapidTesta SARS-CoV-2): a prospective observational study with nasopharyngeal samples. J Infect Chemother 2022;28(1):78–81.
158. Terpos E, Ntanasis-Stathopoulos I, Skvarč M. Clinical application of a new SARS-CoV-2 antigen detection kit (Colloidal Gold) in the detection of COVID-19. Diagnostics 2021; 11(6):995.
159. Thakur P, Saxena S, Manchanda V, Rana N, Goel R, Arora R. Utility of antigen-based rapid diagnostic test for detection of SARS-CoV-2 virus in routine hospital settings. Lab Med 2021;52(6):e154–8.
160. Thell R, Kallab V, Weinhappel W, Mueckstein W, Heschl L, Heschl M, *et al*. Evaluation of a novel, rapid antigen detection test for the diagnosis of SARS-CoV-2. PLoS One 2021;16(11):e0259527.
161. Thirion-Romero I, Guerrero-Zúñiga DS, Arias-Mendoza DA, Cornejo-Juárez DDP, Meza-Meneses DP, Torres-Erazo DDS, *et al*. Evaluation of Panbio rapid antigen test for SARS-CoV-2 in symptomatic patients and their contacts: a multicenter study. Int J Infect Dis 2021;113:218–24.
162. Tonelotto V, Davini A, Cardarelli L, Calderone M, Marin P. Efficacy of Fluorecare SARS-CoV-2 Spike Protein Test Kit for SARS-CoV-2 detection in nasopharyngeal samples of 121 individuals working in a manufacturing company. PLoS One 2022;17(1):e0262174.
163. Toptan T, Eckermann L, Pfeiffer AE, Hoehl S, Ciesek S, Drosten C, *et al*. Evaluation of a SARS-CoV-2 rapid antigen test: potential to help reduce community spread? J Clin Virol 2021;135:104713.
164. Trobajo-Sanmartín C, Navascués A, Miqueleiz A, Ezpeleta C. Evaluation of the rapid antigen test CerTest SARS-CoV-2 as an alternative COVID-19 diagnosis technique. Infect Dis 2021;53(9):730–2.
165. Turcato G, Zaboli A, Pfeifer N, Ciccariello L, Sibilio S, Tezza G, *et al*. Clinical application of a rapid antigen test for the detection of SARS-CoV-2 infection in symptomatic and asymptomatic patients evaluated in the emergency department: a preliminary report. J Infect 2021;82(3):e14–6.
166. Turcato G, Zaboli A, Pfeifer N, Sibilio S, Tezza G, Bonora A, *et al*. Rapid antigen test to identify COVID-19 infected patients with and without symptoms admitted

to the emergency department. Am J Emerg Med 2022; 51:92–7.
167. Van der Moeren N, Zwart VF, Lodder EB, Van den Bijllaardt W, Van Esch H, Stohr J, *et al*. Evaluation of the test accuracy of a SARS-CoV-2 rapid antigen test in symptomatic community dwelling individuals in the Netherlands. PLoS One 2021;16(5):e0250886.
168. Van Honacker E, Van Vaerenbergh K, Boel A, De Beenhouwer H, Leroux-Roels I, Cattoir L. Comparison of five SARS-COV-2 rapid antigen tests in a hospital setting and performance of one antigen assay in routine practice: a useful tool to guide isolation precautions? J Hosp Infect 2021;114:144–52.
169. von Ahnen T, von Ahnen M, Wirth U, Schardey HM, Herdtle S. Evaluation of a rapid-antigen test for COVID-19 in an asymptomatic collective: a prospective study. Wien Med Wochenschr 2022;172(3-4):70–3.
170. Wertenauer C, Brenner Michael G, Dressel A, Pfeifer C, Hauser U, Wieland E, *et al*. Diagnostic performance of rapid antigen testing for SARS-CoV-2: the COVid-19 AntiGen (COVAG) study. Front Med 2022;9:774550.
171. World Health Organization. Use of SARS-CoV-2 antigen-detection rapid diagnostic tests for COVID-19 self-testing [internet]. WHO; 2022 [cited 2023 Nov 8]. Available from: https://www.who.int/publications/i/item/WHO-2019-nCoV-Ag-RDTs-Self_testing-2022.1.
172. Abbott. PanBio COVID-19 Ag Rapid Test device product page [internet]. Abbott; 2023 [cited 2023 Nov 8]. Available from: https://www.globalpointofcare.abbott/en/product-details/panbio-covid-19-ag-antigen-test.html.
173. Abbott. BinaxNOW COVID-19 Ag Card product page [internet]. Abbott; 2023 [cited 2023 Nov 8]. Available from: https://www.globalpointofcare.abbott/us/en/product-details/binaxnow-covid-19.html.
174. Roche Diagnostics. SARS-CoV-2 Rapid Antigen Test product page [internet]. Roche Diagnostics; 2023 [cited 2023 Nov 8]. Available from: https://diagnostics.roche.com/global/en/products/params/sars-cov-2-rapid-antigen-test.html.
175. SD Biosensor. Standard Q COVID-19 Ag product page [internet]. SD Biosensor; 2023 [cited 2023 Jul 2]. Available from: https://www.sdbiosensor.com/product/product_view?product_no=241.
176. Würstle S, Spinner CD, Voit F, Hoffmann D, Hering S, Weidlich S, *et al*. Self-sampling versus health care professional-guided swab collection for SARS-CoV-2 testing. Infection 2021;49(5):927–34.
177. Therchilsen JH, von Buchwald C, Koch A, Dam Nielsen S, Rasmussen DB, Thudium RF, *et al*. Self-collected versus healthcare worker-collected swabs in the diagnosis of severe acute respiratory syndrome coronavirus 2. Diagnostics 2020;10(9):678.
178. Cocherie T, Bastide M, Sakhi S, Zafilaza K, Flandre P, Leducq V, *et al*. decreased sensitivity of rapid antigen test is associated with a lower viral load of omicron than delta SARS-CoV-2 variant. Microbiol Spectr 2022;10(5): e01922.
179. Sakai-Tagawa Y, Yamayoshi S, Halfmann PJ, Wilson N, Bobholz M, Vuyk WC, *et al*. Sensitivity of rapid antigen tests for omicron subvariants of SARS-CoV-2. J Med Virol 2023;95(5):e28788.
180. Parvu V, Gary DS, Mann J, Lin YC, Mills D, Cooper L, *et al*. Factors that influence the reported sensitivity of rapid antigen testing for SARS-CoV-2. Front Microbiol 2021; 12:714242.
181. Brümmer LE, Katzenschlager S, McGrath S, Schmitz S, Gaeddert M, Erdmann C, *et al*. Accuracy of rapid point-of-care antigen-based diagnostics for SARS-CoV-2: An updated systematic review and meta-analysis with meta-regression analyzing influencing factors. PLoS Med 2022;19(5):e1004011.
182. Glenet M, Lebreil AL, Heng L, N'Guyen Y, Meyer I, Andreoletti L. Asymptomatic COVID-19 adult outpatients identified as significant viable SARS-CoV-2 shedders. Sci Rep 2021;11(1):20615.
183. Bustin SA, Mueller R. Real-time reverse transcription PCR (qRT-PCR) and its potential use in clinical diagnosis. Clin Sci 2005;109(4):365–79.
184. Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig L, *et al*. STARD 2015: an updated list of essential items for reporting diagnostic accuracy studies. BMJ 2015; 351:h5527.
185. Soni A, Herbert C, Lin H, Yan Y, Pretz C, Stamegna P, *et al*. Performance of rapid antigen tests to detect symptomatic and asymptomatic SARS-CoV-2 infection: a prospective cohort study. Ann Intern Med 2023;176(7):975–82.

Appendix I: Search strategy

The search strategy identified key terms in the question and searched terms related to COVID-19, rapid antigens, and sensitivity and specificity. The COVID-19 searches for PubMed, Embase, and Scopus were modified versions from CADTH COVID-19 literature searching strings (documented on https://covid.cadth.ca/literature-searching-tools/cadth-covid-19-search-strings/#covid-19-medline). The search was initially run on July 11, 2021, and rerun on July 12, 2022. All databases were rerun, with the exception of Qinsight, which was no longer available from Quertle as of April 2022.

MEDLINE (PubMed)
Search conducted July 11, 2021
Search reran July 12, 2022
Filters: English language; publication date October 31, 2019 to present

Search number	Query	Results retrieved
#1	(((“antigen s”[All Fields] OR “antigene”[All Fields] OR “antigenes”[All Fields] OR “antigenic”[All Fields] OR “antigenically”[All Fields] OR “antigenicities”[All Fields] OR “antigenicity”[All Fields] OR “antigenized”[All Fields] OR “antigens”[MeSH Terms] OR “antigens”[All Fields] OR “antigen”[All Fields]) AND (“based”[All Fields] OR “basing”[All Fields]) AND (“Rapid”[All Fields] OR “rapidities”[All Fields] OR “rapidity”[All Fields] OR “rapidness”[All Fields]) AND (“detect”[All Fields] OR “detectabilities”[All Fields] OR “detectability”[All Fields] OR “detectable”[All Fields] OR “detectables”[All Fields] OR “detectably”[All Fields] OR “detected”[All Fields] OR “detectible”[All Fields] OR “detecting”[All Fields] OR “detection”[All Fields] OR “detections”[All Fields] OR “detects”[All Fields]) AND (“research design”[MeSH Terms] OR (“research”[All Fields] AND “design”[All Fields]) OR “research design”[All Fields] OR “test*“[All Fields])) OR ((“antigens”[MeSH Terms] OR “antigen”[Text Word]) AND “test”[Title/Abstract]) OR “RAD”[Title/Abstract] OR “rapid antigen detection”[Title/Abstract] OR “Rapid antigen assay”[Title/Abstract] OR “Rapid antigen detection test”[Title/Abstract] OR “RADT”[Title/Abstract] OR “RAgT”[Title/Abstract] OR “VAT”[All Fields] OR “viral antigen test*“[Title/Abstract] OR ((“antigens/analysis”[MeSH Terms] OR “antigens/genetics”[MeSH Terms] OR “antigens/immunology”[MeSH Terms] OR “antigens/isolation and purification”[MeSH Terms] OR “antigens/ultrastructure”[MeSH Terms] OR “antigens/virology”[MeSH Terms] OR (“antigens”[MeSH Terms] OR “antigen”[Text Word])) AND “test”[Title/Abstract]) OR (“Rapid”[All Fields] AND “point of care”[All Fields] AND (“antigen s”[All Fields] OR “antigene”[All Fields] OR “antigenes”[All Fields] OR “antigenic”[All Fields] OR “antigenically”[All Fields] OR “antigenicities”[All Fields] OR “antigenicity”[All Fields] OR “antigenized”[All Fields] OR “antigens”[MeSH Terms] OR “antigens”[All Fields] OR “antigen”[All Fields]))) AND 2019/10/31:2021/12/31[Date - Publication]	
#2	(((“coronavirus”[MeSH Terms:noexp] OR “betacoronavirus”[MeSH Terms:noexp] OR “Coronavirus Infections”[MeSH Terms:noexp]) AND (“Disease Outbreaks”[MeSH Terms:noexp] OR “epidemics”[MeSH Terms:noexp] OR “pandemics”[MeSH Terms])) OR “COVID-19 testing”[MeSH Terms] OR “COVID-19 drug treatment”[Supplementary Concept] OR “COVID-19 serotherapy”[Supplementary Concept] OR “COVID-19 vaccines”[MeSH Terms] OR “spike protein sars cov 2”[Supplementary Concept] OR “COVID-19”[Supplementary Concept] OR “SARS-CoV-2”[MeSH Terms] OR “nCoV”[Title/Abstract] OR “nCoV”[Transliterated Title] OR “2019nCoV”[Title/Abstract] OR “2019nCoV”[Transliterated Title] OR “covid19*“[Title/Abstract] OR “covid19*“[Transliterated Title] OR “COVID”[Title/Abstract] OR “COVID”[Transliterated Title] OR “SARS-CoV-2”[Title/Abstract] OR “SARS-CoV-2”[Transliterated Title] OR “SARSCOV-2”[Title/Abstract] OR “SARSCOV2”[Title/Abstract] OR “SARSCOV2”[Transliterated Title] OR “Severe Acute Respiratory Syndrome Coronavirus 2”[Title/Abstract] OR ((“severe acute respiratory syndrome”[Title/Abstract] OR “severe acute respiratory syndrome”[Transliterated Title]) AND “corona virus 2”[Title/Abstract]) OR “new coronavirus”[Title/Abstract] OR (“new”[Transliterated Title] AND “coronavirus”[Transliterated Title]) OR “novel coronavirus”[Title/Abstract] OR “novel coronavirus”[Transliterated Title] OR “novel corona virus”[Title/Abstract] OR (“novel”[Transliterated Title] AND “corona virus”[Transliterated Title]) OR “novel CoV”[Title/Abstract] OR (“novel”[Transliterated Title] AND “CoV”[Transliterated Title]) OR “novel HCoV”[Title/Abstract] OR (“novel”[Transliterated Title] AND “HCoV”[Transliterated Title]) OR ((“19”[Title/Abstract] OR “19”[Transliterated Title] OR “2019”[Title/Abstract] OR “2019”[Transliterated Title] OR “Wuhan”[Title/Abstract] OR “Wuhan”[Transliterated Title] OR “Hubei”[Title/Abstract] OR “Hubei”[Transliterated Title]) AND (“coronavirus*“[Title/Abstract] OR “coronavirus*“[Transliterated Title] OR “corona virus*“[Title/Abstract] OR “corona virus*“[Transliterated Title] OR “CoV”[Title/Abstract] OR “CoV”[Transliterated Title] OR “HCoV”[Title/Abstract] OR “HCoV”[Transliterated Title])) OR ((“coronavirus*“[Title/Abstract] OR “coronavirus*“[Transliterated Title] OR “corona virus*“[Title/Abstract] OR “corona virus*“[Transliterated Title] OR “betacoronavirus*“[Title/Abstract]) AND (“outbreak*“[Title/Abstract] OR “outbreak*“[Transliterated Title] OR “epidemic*“[Title/Abstract] OR “epidemic*“[Transliterated Title] OR “pandemic*“[Title/Abstract] OR “pandemic*“[Transliterated Title] OR “crisis”[Title/Abstract] OR “crisis”[Transliterated Title])) OR ((“Wuhan”[Title/Abstract] OR “Wuhan”[Transliterated Title] OR “Hubei”[Title/Abstract] OR “Hubei”[Transliterated Title]) AND (“pneumonia”[Title/Abstract] OR “pneumonia”[Transliterated Title]))) AND 2019/10/31:2021/12/31[Date - Publication]	

(*Continued*)

MEDLINE (PubMed)
Search conducted July 11, 2021
Search reran July 12, 2022
Filters: English language; publication date October 31, 2019 to present

Search number	Query	Results retrieved
#3	"predictive value of tests"[MeSH Terms] OR "predictive value of tests"[All Fields] OR "Sensitivity and Specificity"[MeSH Terms] OR "Sensitivity and Specificity"[All Fields]	
#4	#1 AND #2 AND #3	239
Reran search July 12, 2022		373

Qinsight (Quertle)
Search conducted July 11, 2021

Search number	Query	Results retrieved
#1	covid	
#2	rapid antigen test	
#3	sensitivity and specificity	
#4	#1 AND #2 AND #3	204

Embase
Search conducted on July 11, 2021
Search reran on July 12, 2022
Filters: English language; publication date October 31, 2019 to present

Search number	Query	Results retrieved
#1	(('sars-related coronavirus'/exp OR 'coronavirinae'/exp OR 'betacoronavirus'/exp OR 'coronavirus infection'/exp) AND ('epidemic'/exp OR 'pandemic'/exp)) OR ('severe acute respiratory syndrome coronavirus 2'/exp OR 'sars coronavirus 2 test kit'/exp OR 'sars-cov-2 OR (clinical isolate wuhan/wiv04/2019)'/exp OR 'coronavirus disease 2019'/exp) OR ((ncov* OR 2019ncov OR 19ncov OR covid19* OR covid OR 'sars cov 2' OR 'sarscov 2' OR 'sars cov2' OR sarscov2 OR severe) AND (acute AND respiratory AND syndrome AND coronavirus AND 2 OR severe) OR (acute AND respiratory AND syndrome AND corona AND virus AND 2)) OR (new OR novel OR '19' OR '2019' OR wuhan OR hubei OR china OR chinese) AND (coronavirus* OR corona) AND (virus* OR betacoronavirus* OR cov OR hcov) OR (coronavirus* OR corona) AND (virus* OR betacoronavirus*) AND (pandemic* OR epidemic* OR outbreak* OR crisis) OR (wuhan OR hubei) NEAR/5 pneumonia	
#2	rapid antigen test'/exp OR 'rapid antigen detection test'/exp OR (rapid AND antigen AND test)	
#3	('predictive value'/exp OR 'sensitivity and specificity'/exp) OR ('predictive value' OR 'sensitivity and specificity')	
#4	#1 AND #2 AND #3	212
Reran search July 12, 2022		410

WHO Covid-19 Database https://search.bvsalud.org/global-literature-on-novel-coronavirus-2019-ncov/ Search conducted July 11, 2021 Search reran on July 12, 2022		
Search number	**Query**	**Results retrieved**
#1	tw:(rapid antigen test)	
#2	tw:(predictive value)	
#3	tw:(sensitivity and specificity)	
#4	la:("en")	
#5	#1 AND (#2 OR #3) AND #4	627
Reran search July 12, 2022		702

Scopus Search conducted July 11, 2021 Search reran on July 12, 2022 Filters English Language; Publication year greater than 2018		
Search number	**Query**	**Results retrieved**
#1	(TITLE-ABS-KEY ({coronavirus} OR {betacoronavirus} OR {coronavirus infections}) AND TITLE-ABS-KEY ({disease outbreaks} OR {epidemics} OR {pandemics}) OR TITLE-ABS-KEY ((ncov*) OR {2019nvoc} OR {19ncov} OR {covid19*} OR[15] OR {sars-cov-2} OR {severe acute respiratory syndrome coronavirus 2} OR {severe Acute Respiratory Syndrome Corona Virus 2}) OR TITLE-ABS-KEY ((new 2/3 coronavirus*) OR (new W/3 betacoronavirus*) OR (new W/3 cov) OR (new W/3 hcov) OR (novel W/3 coronavirus*)) OR TITLE-ABS-KEY ((corona AND virus* W/3 epidemic*) OR (corona AND virus* W/3 outbreak*) OR (corona AND virus* W/3 crisis) OR (betacoronavirus* W/3 pandemic*)) OR TITLE-ABS-KEY ((corona AND virus* W/3 epidemic*) OR (corona AND virus* W/3 outbreak*) OR (corona AND virus* W/3 crisis) OR (betacoronavirus* W/3 pandemic*) OR (betacoronavirus* W/3 epidemic*) OR (betacoronavirus* W/3 outbreak*) OR (betacoronavirus* W/3 crisis))) AND PUBYEAR > 2018	
#2	(TITLE-ABS-KEY ({rapid antigen test} OR "rapid antigen test*") OR TITLE-ABS-KEY ("rapid" AND "antigen" AND "test")) AND PUBYEAR > 2018	
#3	(TITLE-ABS-KEY ({predictive value} OR {sensitivity and specificity}) AND TITLE-ABS-KEY ("predictive value" OR "sensitivity and specificity")) AND PUBYEAR > 2018	
#4	#1 AND #2 AND #3	176
Reran search July 12, 2022		462

Appendix II: Data extraction instrument

Field name	Entry type
Data extractor	Free-text
Data validated by	Free-text
Article #	Free-text
Article first author	Free-text
Article title	Free-text
Month, year	Free-text
DOI/PMID/other identifier	Free-text
Country	Free-text
Setting/context	Drop-down
Primary care location	
Hospital – inpatient	
COVID-19 testing site/screening location	
Urgent care location	
Emergency dept/room	
Public area (not a designated screening location)	
College/university campus (non-medical)	
Long-term care facility (nursing home, rehab centers)	
Not described/unclear	
Hospital – outpatient	
College/university campus (medical center/hospital)	
Year/time frame for data collection	Free-text
Participant characteristics (age range, gender breakdown, rural/urban, etc)	Free-text
Number of participants	Free-text
Sample type	Drop-down
Nasopharyngeal swabs (NP)	
Blood (Bld)	
Bronchoalveolar lavage (BAL)/bronchial sample	
Nasal swabs (NS)	
Oropharyngeal swabs (OP)	
Other	
Saliva (Sal)	
Throat swabs (TS)	

Sample type if other	Free-text
Reference test description	Drop-down
Abbott RealTime SARS-CoV-2 (Abbott)	
Alinity m SARS-CoV-2 AMP (Abbott)	
Allplex assays (Seegene)	
ARGENE SARS-CoV-2 R-Gene (Biomerieux)	
BD Max (Becton-Dickinson)	
BGI 2019-nCoV Real-time Fluorescent RT-PCR kit (BGI Genomics)	
Biofire	
CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	
Cobas Kits/Systems (Roche)	
COVID-19 Multiplex RT-PCR kit (DIANA Biotech)	
COVID-19 Real-time PCR kit (HBRT-COVID-19) (Chaozhou Hybribio Biochemistry Ltd., China)	
Covidsure Multiplex RT-PCR kit (Trivitron Healthcare Labsystems Diagnostics)	
CRSP SARS-CoV-2 (Clinical Research Sequencing Platform, Harvard/MIT)	
Custom/In-house SARS-2 primers	
DAAN Gene RT-PCR COVID-19 (DaAnGene)	
FTD SARS-CoV-2 Assay (Fast Track Diagnostics, Luxembourg)	
GENECUBE (Toyobo Co., Ltd.)	
GeneFinder COVID-19 Plus RealAmp Kit (Osang Healthcare Co., Ltd)	
Genesig Real-time PCR Coronavirus assay/Z-Path-COVID-19-CE (Primerdesign)	
GenomeCoV19 Detection kit (ABM)	
IDT SARS-CoV-2 (2019-nCoV) multiplex CDC qPCR probe Assay (Integrated DNA Technologies)	
Japanese National Institute of Infectious Diseases (NIID)	
LabTurbo AIO COVID-19 RNA Testing Kit	
LightMix SarbecoV (TIB Microbiol)	
Luna Universal Probe One-Step RT-PCR for Detection of COVID-19 (SignaGen Labs)	
Meril COVID-19 One-Step RT-PCR Kit	
MutaPLEX Coronavirus Real-time-RT-PCR kit (Immundiagnostik AG)	
NeuMoDx SARS-CoV-2 Assay (Qiagen)	
Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR kit (Liferiver)	
Panther Fusion or Aptima SARS-CoV-2 assay (Hologic)	

PCR Biosystems	
PerkinElmer SARS-CoV-2 Real-time RT-PCR Assay	
Real-Q 2019-nCoV Detection Kit (Biosewoom)	
REALQUALITY RQ-SARS-CoV-2 kit (AB Analitica)	
RealStar SARS-CoV-2 RT-PCR kit (Altona)	
RIDAGENE SARS-CoV-2 (R-Bio-pharm)	
Sansure Biotech COVID-19 Nucleic Acid Test kit	
Shimadzu Ampdirect 2019 novel coronavirus detection kit	
Simplexa (DiaSorin)	
Specific Test Not Described	
Standard M nCoV Real-Time Detection Kit (SD Biosenor)	
Takara Bio SARS-CoV-2 direct detection RT-qPCR kit	
TaqPath COVID-19 Combo kit (Applied Biosystems/ThermoFisher)	
VIASURE (CerTest)	
Vitassay (Vitassay)	
Xpert Xpress SARS-CoV-2/GeneXpert (Cepheid)	
Reference test if other	Free-text
Reference test comments (if any)	Free-text
Index test description	Drop-down
STANDARD Q COVID-19 Ag Test	
PanBio COVID-19 Ag Rapid Test Device	
SARS-CoV-2 Rapid Antigen Test	
BinaxNOW COVID-19 Antigen	
Rapid Test Ag 2019-nCov	
SARS-CoV-2 Ag	
Custom/Novel/In-house	
COVISTIX (COVIDMARK) Covid 19 Antigen Rapid Test Device	
AMP Rapid Test SARS-CoV-2 Ag	
BD Veritor COVID-19 Rapid Antigen Test	
CerTest SARS-CoV-2	
Espline SARS-CoV-2	
SARS-CoV-2 Antigen Rapid Test	
HUMASIS COVID-19 Ag Test	
Mologic Covid-19 Rapid Antigen Test	
BIOCREDIT COVID-19 Ag	

Rida Quick SARS-CoV-2 Antigen Test	
STANDARD F COVID-19 Ag FIA	
RapidTesta SARS-CoV-2	
Fluorecare SARS-CoV-2 Spike Protein Test kit (Colloidal Gold)	
CLINITEST Rapid COVID-19 Antigen Test	
Immupass VivaDiag	
COVID-VIRO COVID-19 Ag Rapid Test	
Flowflex COVID-19 Antigen test	
COVID-19 Antigen Rapid Test	
Alltest COVID-19 ART Antigen Rapid Test	
COVID-19 Antigen Rapid Test	
COVID-19 RAT kit	
NowCheck COVID-19 Ag test	
Novel Corona Virus (SARS-CoV-2) Ag Rapid Test kit	
Covid-19 AG BSS	
Helix i-SARS-CoV-2 Ag Rapid Test	
COVID-19 Ag K-SeT	
Liaison SARS-CoV-2 Ag	
COVID-19 Antigen Detection	
COVID-19 Ag ECO Teste	
Inflammacheck CoronaCheck	
GenBody COVAG025	
GENEDIA W COVID-19 Ag Test	
Rapid COVID-19 Antigen Test	
Innova SARS-CoV-2 Antigen Rapid test	
Accucare PathoCatch Covid-19 Ag Detection Kit	
Orient Gene Rapid Covid-19 (Antigen) Self-Test	
GeneFinder COVID-19 Ag Plus Rapid Test	
Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	
Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)	
2019-nCoV Antigen Test	
Index test if other	Free-text
Index test comments (if any)	Free-text
Subgroups (if any; include overall)	Free-text

True positive (TP)	Free-text
False positive (FP)	Free-text
True negative (TN)	Free-text
False negative (FN)	Free-text
Sensitivity (TP/[TP+FN])	Free-text
Sensitivity 95% CI (low, high)	Free-text
Specificity (TN/[TN+FP])	Free-text
Specificity 95% CI (low, high)	Free-text
Positive predictive value PPV (TP/[TP+FP])	Free-text
Negative predictive values NPV (TN/[FN+TN])	Free-text
Description of main results (include adverse events from tests)	Free-text
Exclusion reasons (if any)	Free-text
Notes	Free-text
Need to contact authors? Put contact info here	Free-text

Appendix III: Characteristics of included studies

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Abdelrazik, *et al.*[31] Mar 2021	Potential use of antigen-based rapid test for SARS-CoV-2 in respiratory specimens in low-resource settings in Egypt for symptomatic patients and high-risk contacts	RapiGen (BioCredit)	43.1			
Abusrewil, *et al.*[32] Dec 2021	Time scale performance of rapid antigen testing for SARS-CoV-2: evaluation of ten rapid antigen assays	PanBio (Abbott)	76.92	46.19, 94.96	100	
		Flowflex COVID-19 Antigen test (ACON Labs)	100	78.20, 100	100	
		AMP Rapid Test SARS-CoV-2 Ag (AMP Diagnostics)	85.71	42.13, 99.64	100	
		COVID-19 Antigen Rapid Test (Assut Europe)	71.43	29.04, 96.33	100	
		Novel Corona Virus (SARS-CoV-2) Ag Rapid Test kit (Bioperfectus)	80	44.39, 94.78	100	
		CerTest SARS-CoV-2 (Certest Biotech)	62.5	24.49, 91.48	100	
		Espline SARS-CoV-2 (Fujirebio)	80	44.39, 97.48	100	
		Fluorecare (Colloidal Gold/Fluorescent) SARS-CoV-2 Spike Protein Test kit (Shenzen Microprofit)	91.67	61.52, 99.79	100	
		Orient Gene Rapid Covid-19 (Antigen) Self-Test (Orient Gene)	50	18.71, 81.29	100	
		RapiGen (BioCredit)	62.5	35.4, 84.80	100	
Afzal, *et al.*[33] Sep 2021	Diagnostic accuracy of PANBIO COVID-19 rapid antigen method for screening in emergency cases	PanBio (Abbott)	90.47		100	
Akashi, *et al.*[34] Feb 2022	A prospective clinical evaluation of the diagnostic accuracy of the SARS-CoV-2 rapid antigen test using anterior nasal samples	Roche SARS-CoV-2 Rapid Antigen Test (Roche)	72.7	63.4, 80.8	100	99.5, 100
Al-Alawi, *et al.*[35] Jan 2021	Evaluation of four rapid antigen tests for detection of SARS-CoV-2 virus	STANDARD Q COVID-19 Ag (SD Biosensor)	65.8	48.65, 80.37	100	87.66, 100
		PCL COVID19 Ag Rapid FIA Antigen Test (PCL)	69.8	55.66, 81.66	94.1	80.32, 99.28
		RapiGen (BioCredit)	64	49.19, 77.08	100	86.28, 100
		Sofia SARS Rapid Antigen FIA/Sofia 2 (Quidel)	64.3	50.36, 76.64	100	84.56, 100

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Aleem, *et al.*[36] Jan 2022	Diagnostic accuracy of STANDARD Q COVID-19 antigen detection kit in comparison with RT-PCR assay using naso-pharyngeal samples in India	STANDARD Q COVID-19 Ag (SD Biosensor)	54.43	42.83, 65.69	99.24	97.79, 99.84
Alghounaim, *et al.*[37] Dec 2021	The performance of two rapid antigen tests during population-level screening for SARS-CoV-2 infection	Liaison	43.3	30.6, 56.8	99.9	99.3, 100
		STANDARD Q COVID-19 Ag (SD Biosensor)	30.6	19.6, 43.7	98.8	97.8, 99.4
Allan-Blitz, *et al.*[38] Sep 2021	A real-world comparison of SARS-CoV-2 rapid antigen testing versus PCR testing in Florida	BinaxNOW (Abbott) - all sample types PCR	49.2	47.4, 50.9	98.8	98.6, 98.9
		BinaxNOW (Abbott) - Anterior Nares PCR	47.5	39.1, 56.1	100	99.3, 100
		BinaxNOW (Abbott) - Nasopharyngeal Fluid PCR	46.1	37.3, 55.1	99.7	98.9, 100
		BinaxNOW (Abbott) - Oral Fluid PCR	49.37	47.5, 51.2	98.7	98.5, 98.8
Amer, *et al.*[39] Oct 2021	Diagnostic performance of rapid antigen test for COVID-19 and the effect of viral load, sampling time, subject's clinical and laboratory parameters on test accuracy (preprint)	STANDARD Q COVID-19 Ag (SD Biosensor)	78.2	67, 86	64.2	38, 83
Anastasiou, *et al.*[40] Apr 2021	Fast detection of SARS-CoV-2 RNA directly from respiratory samples using a loop-mediated isothermal amplification (LAMP) test	Custom/Novel/In-house	68.8	57.3, 78.4	100	90.6, 100
Avgoulea, *et al.*[41] Apr 2022	Field evaluation of the new rapid NG-Test(®) SARS-CoV-2 Ag for diagnosis of COVID-19 in the emergency department of an academic referral hospital	Custom/Novel/In-house - NP sample	81	73, 87	99	95, 100
		Custom/Novel/In-house - OP sample	51	42, 59	100	96, 100
Babu, *et al.*[42] Jul 2021	The burden of active infection and anti-SARS-CoV-2 IgG antibodies in the general population: Results from a statewide sentinel-based population survey in Karnataka, India	STANDARD Q COVID-19 Ag (SD Biosensor)	Not reported			

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Bachman, *et al.*[43] Aug 2021	Clinical validation of an open-access SARS-CoV-2 antigen detection lateral flow assay, compared to commercially available assays	Custom/Novel/In-house - PCR collected by NP	69	60, 78	97	88, 100
		BinaxNOW (Abbott) - PCR collected by NP	82	73, 88	100	94, 100
		Sofia SARS Rapid Antigen FIA/Sofia 2 (Quidel) - PCR collected by NP	74	64, 82	98	91, 100
		Custom/Novel/In-house - PCR collected by NS	83	74, 90	97	91, 100
		BinaxNOW (Abbott) - PCR collected by NS	91	84, 96	94	85, 98
		Sofia SARS Rapid Antigen FIA/Sofia 2 (Quidel) - PCR collected by NS	86	77, 92	96	89, 99
Basso, *et al.*[44] Feb 2021	Salivary SARS-CoV-2 antigen rapid detection: a prospective cohort study	Espline SARS-CoV-2 (Fujirebio)	48		100	
Blairon, *et al.*[45] Aug 2020	Implementation of rapid SARS-CoV-2 antigenic testing in a laboratory without access to molecular methods: experiences of a general hospital	Respi-Strip (Coris BioConcept)	30	16.7, 47.9	100	
Bond, *et al.*[46] May 2022	Utility of SARS-CoV-2 rapid antigen testing for patient triage in the emergency department: a clinical implementation study in Melbourne, Australia	PanBio (Abbott)	75.5	69.9, 80.4	100	99.8, 100
Borro, *et al.*[47] Apr 2022	SARS-CoV-2 transmission control measures in the emergency department: the role of rapid antigenic testing in asymptomatic subjects	Green Spring "SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)" - standard protocol	79.8		100	
		Green Spring "SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)" - UTM modified protocol	70.7		100	
		Green Spring "SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)" - UTM modified protocol	43.9		100	
Boum, *et al.*[48] May 2021	Performance and operational feasibility of antigen and antibody rapid diagnostic tests for COVID-19 in symptomatic and asymptomatic patients in Cameroon: a clinical, prospective, diagnostic accuracy study	STANDARD Q COVID-19 Ag (SD Biosensor)	58.4	53.0, 64.8	93.2	88.0, 97.0

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Bulilete, *et al.*[49] Feb 2021	Panbio™ rapid antigen test for SARS-CoV-2 has acceptable accuracy in symptomatic patients in primary health care	PanBio (Abbott)	71.4	63.1, 78.7	99.8	99.4, 99.9
Burdino, *et al.*[50] Oct 2021	SARS-CoV-2 microfluidic antigen point-of-care testing in emergency room patients during COVID-19 pandemic	SARS-CoV-2 Ag (LumiraDx)	90.1	86.2, 93.1	99.4	98.6, 99.8
Bwogi, *et al.*[7] May 2022	Field evaluation of the performance of seven antigen rapid diagnostic tests for the diagnosis of SARs-CoV-2 virus infection in Uganda	Immupass VivaDiag (VivaChek Biotech)	30.2	18.0, 46.1	94.1	90.1, 96.6
		MEDsan SARS-CoV-2 Antigne Rapid Test	13	8.1, 20.3	100	96.9, 100
		Novegent COVID-19 Antigen Rapid Test Kit (Colloidal gold)	46	36.3, 56.0	89.9	83.3, 94.1
		PanBio (Abbott)	49.4	38.7, 60.1	100	96.4, 100
		PCL COVID19 Ag Rapid FIA Antigen Test (PCL)	37.6	28.2, 48.1	89.9	80.8, 94.9
		RapiGen (BioCredit)	27.4	20.5, 35.6	98.2	93.1, 99.6
		Respi-Strip (Coris BioConcept)	19.4	11.5, 30.9	99.2	94.5, 99.9
Caruana, *et al.*[51] Apr 2021	Implementing SARS-CoV-2 rapid antigen testing in the emergency ward of a Swiss university hospital: the INCREASE Study	PanBio (Abbott)	41.2		99.5	
		BD Veritor COVID-19 Rapid Antigen Test (Becton-Dickinson)	41.2		99.7	
		Exdia (Precision Biosensor)	48.3		99.5	
		STANDARD Q COVID-19 Ag (SD Biosensor)	41.2		99.7	
Caruana, *et al.*[52] May 2021	The dark side of SARS-CoV-2 rapid antigen testing: screening asymptomatic patients	STANDARD Q COVID-19 Ag (SD Biosensor)	28.6		98.2	
Cassuto, *et al.*[53] Jul 2021	Evaluation of a SARS-CoV-2 antigen-detecting rapid diagnostic test as a self-test: diagnostic performance and usability	COVID-VIRO nasal swab test	96.88	83.78, 99.92	100	98.19, 100.00
Cattelan, *et al.*[8] Mar 2022	Rapid antigen test LumiraDx(TM) vs real time polymerase chain reaction for the diagnosis of SARS-CoV-2 infection: a retrospective cohort study	SARS-CoV-2 Ag (LumiraDx)	76.3	70.8, 81.8	94.4	88.3, 100

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Cento, *et al.*[54] May 2021	Frontline screening for SARS-CoV-2 infection at emergency department admission by third generation rapid antigen test: can we spare RT-qPCR?	SARS-CoV-2 Ag (LumiraDx)	85.6	82, 89	97.05	96, 98
Cerutti, *et al.*[55] Nov 2020	Urgent need of rapid tests for SARS CoV-2 antigen detection: evaluation of the SD-Biosensor antigen test for SARS-CoV-2	STANDARD Q COVID-19 Ag (SD Biosensor)	70.6		100	
Chaimayo, *et al.*[56] Nov 2020	Rapid SARS-CoV-2 antigen detection assay in comparison with real-time RT-PCR assay for laboratory diagnosis of COVID-19 in Thailand	STANDARD Q COVID-19 Ag (SD Biosensor)	98.33	91.06, 99.6	98.73	97.06, 99.59
Cheng, *et al.*[57] May 2022	Evaluation of a rapid antigen test for the diagnosis of SARS-CoV-2 during the COVID-19 pandemic	Enimmune Speedy COVID-19 AG Rapid Test - Heping	69.1	68.8, 69.5	99.1	99.1, 99.1
		PanBio (Abbott) - RenAi	62	61.6, 62.3	99.9	99.9, 99.9
		VTRUST COVID-19 Antigen Rapid Test (Taidoc Technology Corporation) - YangMing	78.6	78.2, 78.9	98.2	98.2, 98.3
		VTRUST COVID-19 Antigen Rapid Test (Taidoc Technology Corporation) - Zhongxiao	60.5	60.1, 60.8	99.1	99.0, 99.1
		Enimmune Speedy COVID-19 AG Rapid Test - Zhongxing	64.6	64.3, 64.8	98.3	98.3, 98.3
Choudhary, *et al.*[58] Apr 2022	Validation of rapid SARS-CoV-2 antigen detection test as a screening tool for detection of Covid-19 infection at district hospital in northern India	Standard Q COVID-19 Ag (SD Biosensor)	55.04	46.43, 63.35	99.2	98.15, 99.66
Cottone, *et al.*[59] May 2022	Pitfalls of SARS-CoV-2 antigen testing at emergency department	Roche SARS-CoV-2 Rapid Antigen Test (Roche)	45.5	35.6, 55.8	98.1	96.1, 99.2
Cubas-Atienzar, *et al.*[60] May 2021	Accuracy of the Mologic COVID-19 rapid antigen test: a prospective multi-centre analytical and clinical evaluation	Mologic Covid-19 Rapid Antigen Test (Mologic Ltd. United Kingdom) - Northumberland	86	76.9, 92.6	97.5	93.8, 99.3
		Mologic Covid-19 Rapid Antigen Test (Mologic Ltd. United Kingdom) - Yorkshire	84.6	54.6, 98.1	100	91.2, 100
Dierks, *et al.*[61] May 2021	Diagnosing SARS-CoV-2 with antigen testing, transcription-mediated amplification and real-time PCR	SARS-CoV-2 Ag (LumiraDx)	45.45	20.22, 73.26	99.54	98.17, 99.88
		NADAL COVID-19 Antigen Rapid Test (New Art Laboratories/nal von minden)	14.29	1.94, 58.35	76.44	70.16, 81.74

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Escribano, *et al.*[62] Feb 2022	Different performance of three point-of-care SARS-CoV-2 antigen detection devices in symptomatic patients and close asymptomatic contacts: a real-life study	PanBio (Abbott) - Close Asymptomatic Contacts	33.3	11.8, 61.6		
		SGTI-Flex - Close Asymptomatic Contacts	84.6	54.5, 98.1		
		NovaGen - Close Asymptomatic Contacts	55.5	30.7, 78.4		
		PanBio (Abbott)-COVID-19 Suspected Cases	71.1	55.6, 83.6		
		SGTI-Flex - COVID-19 Suspected Cases	68.8	55.7, 80		
		NovaGen - COVID-19 Suspected Cases	84.6	72.0, 93.1		
Escrivá, *et al.*[63] Aug 2021	The effectiveness of rapid antigen test-based for SARS-CoV-2 detection in nursing homes in Valencia, Spain	PanBio (Abbott)	85	90, 99	100	100, 100
Faíco-Filho, *et al.*[64] Mar 2022	Evaluation of the Panbio™ COVID-19 Ag rapid test at an emergency room in a hospital in São Paulo, Brazil	PanBio (Abbott)	Not reported			
Farfour, *et al.*[65] Mar 2021	The Panbio COVID-19 Ag rapid test: which performances are for COVID-19 diagnosis?	PanBio (Abbott)	Not reported			
Fernandez-Montero, *et al.*[66] Jul 2021	Validation of a rapid antigen test as a screening tool for SARS-CoV-2 infection in asymptomatic populations. Sensitivity, specificity and predictive values	Roche SARS-CoV-2 Rapid Antigen Test (Roche)	71.43	56.74, 83.42	99.68	99.37, 99.86
Ferté, *et al.*[67] Jun 2021	Accuracy of COVID-19 rapid antigenic tests compared to RT-PCR in a student population: the StudyCov study	PanBio (Abbott)	63.5	49.0, 76.4	100	99.4, 100
Fitoussi, *et al.*[68] Oct 2021	Analytical performance of the point-of-care BIOSYNEX COVID-19 Ag BSS for the detection of SARS-CoV-2 nucleocapsid protein in nasopharyngeal swabs: a prospective field evaluation during the COVID-19 third wave in France	BIOSYNEX Ag-RDT	81.80	79.2, 84.1	99.60	98.9, 99.8

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Ford, *et al.*[69] Sep 2021	Antigen test performance among children and adults at a SARS-CoV-2 community testing site	BinaxNOW (Abbott) - Exposed	79.80		99.70	
		BinaxNOW (Abbott)	80.80		99.90	
Freire, *et al.*[11] Jun 2022	Performance differences among commercially available antigen rapid tests for COVID-19 in Brazil	PanBio (Abbott) - NP Swab	60.00	45.9, 73.0	100	69.2, 100
		PanBio (Abbott) - NS Swab	58.20	44.1, 71.4	100	69.2, 100%
		COVID-19 Ag ECO Teste (Eco Diagnostica)	42.90	30.5, 56.0	83.30	58.6, 96.4
		STANDARD Q COVID-19 Ag (SD Biosensor)	53.00	40.3, 65.4	86.70	59.5, 98.3
		CORIS Bioconcept1 Ag-RDT (Nanosens)	9.80	3.7, 20.2	100	78.2, 100
		CELLER WONDFO SARSCOV2 Ag-RDT	47.20	33.3, 61.4	100	69.2, 100
		NowCheck COVID-19 Ag test (Bionote)	60	45.9, 73.0	100	66.4, 100
		Ag-RDT COVID-19 (Acro Biotech)	81.10	68.0, 90.6	84.60	54.5, 98.1
Galliez, *et al.*[70] Jun 2022	Evaluation of the Panbio COVID-19 antigen rapid diagnostic test in subjects infected with omicron using different specimens	PanBio (Abbott) - NS Swab	89	82.4, 93.3	100	94.4, 100
		PanBio (Abbott) - Oral Specimen	12.6	7.9, 19.5	100	94.4, 100
Garcia-Cardenas, *et al.*[71] Sep 2021	Analytical performances of the COVISTIX and Panbio antigen rapid tests for SARS-CoV-2 detection in an unselected population (all comers)	PanBio (Abbott)	62%	58, 64	99	99, 100
		COVISTIX Covid 19 Antigen Rapid Test Device	81	76, 85	96	94, 98
Garcia-Cardenas, *et al.*[72] May 2022	Analytical performances of the COVISTIX™ antigen rapid test for SARS-CoV-2 detection in an unselected population (all-comers)	COVISTIX Covid 19 Antigen Rapid Test Device	81	75.0, 85.0	96	94.0, 98.0
		COVISTIX Covid 19 Antigen Rapid Test Device	93	88, 98	98	97, 99
García-Fernández, *et al.*[73] Mar 2022	Evaluation of the rapid antigen detection test STANDARD F COVID-19 Ag FIA for diagnosing SARS-CoV-2: experience from an emergency department	STANDARD F COVID-19 Ag FIA (SD Biosensor Inc.)	84	76.1, 89.7	99.6	98.5, 99.9
García-Fiñana, *et al.*[74] Jul 2021	Performance of the Innova SARS-CoV-2 antigen rapid lateral flow test in the Liverpool asymptomatic testing pilot: population based cohort study	Innova (recalled 06/2021)	40	28.5, 52.4	99.9	99.8, 99.99

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Goga, *et al.*[75] Mar 2022	Utility of COVID-19 point-of-care antigen tests in low-middle income settings	RapiGen (BioCredit)	34.8	26.1, 44.2	97.6	93.9, 99.3
		STANDARD Q COVID-19 Ag (SD Biosensor)	49.1	43.3, 55.0	95.7	93.5, 97.3
		SARS-CoV-2 Ag (LumiraDx)	63.8	55.9, 71.2	97	95.5, 98.3
González-Fiallo, *et al.*[76] Apr 2022	Evaluation of SARS-CoV-2 rapid antigen tests in use on the Isle of Youth, Cuba	STANDARD Q COVID-19 Ag (SD Biosensor)	75.30%	66.0, 84.6	96.10	94.5, 97.6
Gupta, *et al.*[77] Feb 2021	Rapid chromatographic immunoassay-based evaluation of COVID-19: a cross-sectional, diagnostic test accuracy study & its implications for COVID-19 management in India	STANDARD Q COVID-19 Ag (SD Biosensor)	81.8	71.3, 89.6	99.6	97.8, 99.9
Harris, *et al.*[78] May 2021	SARS-CoV-2 rapid antigen testing of symptomatic and asymptomatic individuals on the University of Arizona campus	Sofia SARS Rapid Antigen FIA/Sofia 2 (Quidel)	91.4		100	
Holzner, *et al.*[79] Apr 2021	SARS-CoV-2 rapid antigen test: fast-safe or dangerous? An analysis in the emergency department of an university hospital	STANDARD Q COVID-19 Ag (SD Biosensor)	68.8	66.84, 70.73	99.56	99.3, 99.82
Homza, *et al.*[80] Apr 2021	Five antigen tests for SARS-CoV-2: virus viability matters	Ecotest (Assure Tech)	75.7	66.5, 83.5	96.7	93.3, 98.7
		Immupass VivaDiag (VivaChek Biotech)	41.8	31.5, 52.6	96	92.0, 98.4
		ND Covid (NDFOS)	70.1	58.6, 80	56.1	46.5, 65.4
		SARS-CoV-2 Antigen Rapid Test (JoysBio)	57.8	46.9, 68.1	98.5	94.8, 99.8
		STANDARD Q COVID-19 Ag (SD Biosensor)	61.9	45.6, 76.4	99	94.4, 100
Hörber, *et al.*[81] Jun 2022	Evaluation of a laboratory-based high-throughput SARS-CoV-2 antigen assay	CoV2Ag assay (Siemens Healthineers, Eschborn, Germany)	88.50	83.7, 91.9	99.50	97.4, 99.9
Ifko, *et al.*[82] Jul 2021	Diagnostic validation of two SARS-CoV-2 immunochromatographic tests in Slovenian and Croatian hospitals	NADAL COVID-19 Antigen Rapid Test (New Art Laboratories/nal von minden)	84.61	54.55, 98.08	100	90.75, 100
		NADAL COVID-19 Antigen Rapid Test (New Art Laboratories/nal von minden)	86.96	66.41, 97.23	88.24	80.35, 93.77
Igloi, *et al.*[83] May 2021	Clinical evaluation of Roche SD Biosensor rapid antigen test for SARS-CoV-2 in municipal health service testing site, the Netherlands	STANDARD Q COVID-19 Ag (SD Biosensor)	84.9	79.1, 89.4	99.5	98.7, 99.8

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Jakobsen, *et al.*[84] Jun 2021	Accuracy and cost description of rapid antigen test compared with reverse transcriptase-polymerase chain reaction for SARS-CoV-2 detection	STANDARD Q COVID-19 Ag (SD Biosensor)	69.7		99.5	
Jakobsen, *et al.*[85] Feb 2022	Accuracy of anterior nasal swab rapid antigen tests compared with RT-PCR for massive SARS-CoV-2 screening in low prevalence population	STANDARD Q COVID-19 Ag (SD Biosensor)	48.5		100	
Jeewandara, *et al.*[86] Mar 2022	Sensitivity and specificity of two WHO approved SARS-CoV2 antigen assays in detecting patients with SARS-CoV2 infection	STANDARD Q COVID-19 Ag (SD Biosensor)	36.24	33.1, 39.5	97.6	97, 98
		PanBio (Abbott)	52.6	46.7, 58.5	99.6	99.2, 99.8
Jegerlehner, *et al.*[87] Jul 2021	Diagnostic accuracy of a SARS-CoV-2 rapid antigen test in real-life clinical settings	STANDARD Q COVID-19 Ag (SD Biosensor)	65.3	56.8, 73.1	99.9	99.5, 100
		PCL COVID19 Ag Rapid FIA Antigen Test (PCL)	30.2	18.3, 44.3	98.1	96.0, 99.3
Jegerlehner, *et al.*[88] Jun 2022	Diagnostic accuracy of SARS-CoV-2 saliva antigen testing in a real-life clinical setting	PCL COVID19 Ag Rapid FIA Antigen Test (PCL)	30.2	18.3, 44.3	98.1	96.0, 99.3
Jirungda, *et al.*[89] May 2022	Clinical performance of the STANDARD F COVID-19 AG FIA for the detection of SARS-COV-2 infection	STANDARD F COVID-19 Ag FIA (SD Biosensor Inc.)	98.8		89.7	
Kahn, *et al.*[90] Aug 2021	Performance of antigen testing for diagnosis of COVID-19: a direct comparison of a lateral flow device to nucleic acid amplification based tests	STANDARD F COVID-19 Ag FIA (SD Biosensor Inc.)	59.4		99	
Kessler, *et al.*[91] Mar 2022	Identification of contagious SARS-CoV-2 infected individuals by Roche's Rapid Antigen Test	Roche SARS-CoV-2 Rapid Antigen Test (Roche)- Central Lab				
Kim, *et al.*[92] Apr 2021	Development and clinical evaluation of an immunochromatography-based rapid antigen test (GenBody™ COVAG025) for COVID-19 diagnosis	GenBody COVAG025 (GenBody)	Not reported			
		GenBody COVAG025 (GenBody) - Prospective	94	87.4, 97.77	100	96.38, 100
		GenBody COVAG025 (GenBody) - Retrospective	90	73.47, 97.89	98	92.96, 99.76

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
King, *et al.*[93] Sep 2021	Validation of the Panbio™ COVID-19 Antigen Rapid Test (Abbott) to screen for SARS-CoV-2 infection in Sint Maarten: a diagnostic accuracy study	PanBio (Abbott)	84	76.2, 90.1	99.9	99.6, 100
Kiyasu, *et al.*[94] Jul 2021	Prospective analytical performance evaluation of the QuickNavi™-COVID19 Ag for asymptomatic individuals	QuickNavi-COVID19 Ag	80.3	73.9, 85.7	100	99.7, 100
Klajmon, *et al.*[95] Dec 2021	Comparison of antigen tests and qPCR in rapid diagnostics of infections caused by SARS-CoV-2 virus	Humasis COVID-19 Ag Test kit (Humasis Co., Ltd.)	91.49	79.62, 97.63	97.9	93.99, 99.57
Klein, *et al.*[96] May 2021	Head-to-head performance comparison of self-collected nasal versus professional-collected nasopharyngeal swab for a WHO-listed SARS-CoV-2 antigen-detecting rapid diagnostic test	PanBio (Abbott) - NMT	84.4	71.2, 92.3	99.2	97.1, 99.8
		PanBio (Abbott) - NP Swab	88.9	76.5, 95.5	99.2	97.1, 99.8
Kohmer, *et al.*[97] Jan 2021	The comparative clinical performance of four SARS-CoV-2 rapid antigen tests and their correlation to infectivity in vitro	SARS-CoV-2 Ag (LumiraDx)	50	38.1, 61.9	100	86.8, 100
		NADAL COVID-19 Antigen Rapid Test (New Art Laboratories/nal von minden)	24.3	15.1, 35.7	100	86.8, 100
		Rida Quick SARS-CoV-2 (R-Biopharm)	39.2	28, 51.2	96.2	80.4, 99.9
		Roche SARS-CoV-2 Rapid Antigen Test (Roche)	43.2	37.8, 55.3	100	86.8, 100
Korenkov, *et al.*[98] Aug 2021	Evaluation of a rapid antigen test to detect SARS-CoV-2 infection and identify potentially infectious individuals	STANDARD Q COVID-19 Ag (SD Biosensor)	100	88.3, 100	71.91	61.82, 80.20
Korenkov, *et al.*[99] May 2021	Assessment of SARS-CoV-2 infectivity by a rapid antigen detection test	STANDARD Q COVID-19 Ag (SD Biosensor)	42.86			99.89
Krüger, *et al.*[100] Aug 2021	Evaluation of accuracy, exclusivity, limit-of-detection and ease-of-use of LumiraDx™: an antigen-detecting point-of-care device for SARS-CoV-2	SARS-CoV-2 Ag (LumiraDx) - Berlin	80.2	70.3, 87.5	99.5	97.1, 100
		SARS-CoV-2 Ag (LumiraDx) - Heidelberg	84.6	7.9, 91.4	99.3	97.9, 99.7
		SARS-CoV-2 Ag (LumiraDx)	82.2	75.2, 87.5	99.3	97.9, 99.7

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Krüger, *et al.*[101] Dec 2021	Accuracy and ease-of-use of seven point-of-care SARS-CoV-2 antigen-detecting tests: A multi-centre clinical evaluation	Fluorecare (Colloidal Gold/Fluorescent) SARS-CoV-2 Spike Protein Test kit (Shenzen Microprofit) - Germany	66.7	41.7, 84.8	93.1	91.0, 94.8
		RapiGen (BioCredit) - Brazil	74.4	65.8, 81.4	98.9	97.2, 99.6
		STANDARD F COVID-19 Ag FIA (SD Biosensor Inc.) - Brazil	77.5	69.2, 84.1	97.9	95.7, 99
		NowCheck COVID-19 Ag test (Bionote) - Brazil	89.2	81.7, 93.9	97.3	94.8, 98.6
		RapiGen (BioCredit) - Germany	52	33.5, 70	100	99.7, 100
		STANDARD Q COVID-19 Ag (SD Biosensor) - Germany	76.2	68.0, 82.8	99.3	98.8, 99.6
		Espline SARS-CoV-2 (Fujirebio) - Germany	79.5	71.1, 85.9	100	99.4, 100
		Mologic Covid-19 Rapid Antigen Test (Mologic Ltd. United Kingdom) - Germany	90.1	85.1, 93.6	100	99.2, 100
		STANDARD F COVID-19 Ag FIA (SD Biosensor Inc.)	75.5	68.2, 81.5	97.2	96.0, 98.1
		STANDARD Q COVID-19 Ag (SD Biosensor)	81.9	76.4, 86.3	99	98.5, 99.4
		RapiGen (BioCredit)	70.4	62.4, 77.3	99.7	99.3, 99.9
Krüger, *et al.*[102] Dec 2022	A multi-center clinical diagnostic accuracy study of Surestatus - an affordable, WHO emergency-use-listed, rapid, point-of-care, antigen-detecting diagnostic test for SARS-CoV-2 (preprint)	SureStatus	82.4	76.6, 87.1	98.5	97.4, 99.1
Krüger, *et al.*[103] May 2021	The Abbott PanBio WHO emergency use listed, rapid, antigen-detecting point-of-care diagnostic test for SARS-CoV-2-Evaluation of the accuracy and ease-of-use	PanBio (Abbott)	86.8	79.0, 92.0	99.9	99.4, 100
Kurihara, *et al.*[104] Jul 2021	The evaluation of a novel digital immunochromato-graphic assay with silver amplification to detect SARS-CoV-2	Custom/Novel/In-house	74.7	64.0, 83.6	99.8	99.5, 100
		PanBio (Abbott)	Not reported			
		Roche SARS-CoV-2 Rapid Antigen Test (Roche)	Not reported			
		Espline SARS-CoV-2 (Fujirebio)	Not reported			

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Kweon, *et al.*[105] May 2022	Positivity of rapid antigen testing for SARS-CoV-2 with serial followed-up nasopharyngeal swabs in hospitalized patients due to COVID-19	STANDARD Q COVID-19 Ag (SD Biosensor) - E gene	43.9	37.7, 50.3		
		QuickNavi-COVID19 Ag	Not reported			
		STANDARD Q COVID-19 Ag (SD Biosensor) RdRp gene	43.9	37.7, 50.3		
Kyritsi, *et al.*[106] Aug 2021	Rapid Test Ag 2019-nCoV (PROGNOSIS, BIOTECH, Larissa, Greece); performance evaluation in hospital setting with real time RT-PCR	Rapid Test Ag 2019-nCov (PROGNOSIS, BIOTECH, Greece)	85.5	79.1, 90.5	99.8	98.8, 100
	Rapid Test Ag 2019-nCoV (PROGNOSIS, BIOTECH, Larissa, Greece); performance evaluation in hospital setting with real time RT-PCR	Rapid Test Ag 2019-nCov (PROGNOSIS, BIOTECH, Greece): 1 part/thousand prevalence	85.5	79.1, 90.5	99.8	98.8, 100
	Rapid Test Ag 2019-nCoV (PROGNOSIS, BIOTECH, Larissa, Greece); performance evaluation in hospital setting with real time RT-PCR	Rapid Test Ag 2019-nCov (PROGNOSIS, BIOTECH, Greece): 1 percent prevalence	85.5	79.1, 90.5	99.8	98.8, 100
	Rapid Test Ag 2019-nCoV (PROGNOSIS, BIOTECH, Larissa, Greece); performance evaluation in hospital setting with real time RT-PCR	Rapid Test Ag 2019-nCov (PROGNOSIS, BIOTECH, Greece): 5 percent prevalence	85.5	79.1, 90.5	99.8	98.8, 100
Landaverde, *et al.*[107] Mar 2022	Comparison of BinaxNOW TM and SARS-CoV-2 qRT-PCR detection of the omicron variant from matched anterior nares swabs (preprint)	BinaxNOW (Abbott)	53.9		100	
Layer, *et al.*[108] Feb 2022	SARS-CoV-2 screening strategies for returning international travellers: evaluation of a rapid antigen test approach	Roche SARS-CoV-2 Rapid Antigen Test (Roche)	59		100	
LeGoff, *et al.*[109] Oct 2021	Evaluation of a saliva molecular point of care for the detection of SARS-CoV-2 in ambulatory care	EasyCov (SkillCell-Alcen, France)	34	26, 44	97	96, 98
		STANDARD Q COVID-19 Ag (SD Biosensor)	85	77, 91	99	98, 99
Leixner, *et al.*[110] Jul 2021	Evaluation of the AMP SARS-CoV-2 rapid antigen test in a hospital setting	AMP Rapid Test SARS-CoV-2 Ag (AMP Diagnostics)	69.15	58.8, 78.3	99.66	98.1, 100

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Linares, *et al.*[111] Oct 2020	Panbio antigen rapid test is reliable to diagnose SARS-CoV-2 infection in the first 7 days after the onset of symptoms	PanBio (Abbott)	73.3	62.2, 83.8	100	
Lindner, *et al.*[112] Apr 2021a	Head-to-head comparison of SARS-CoV-2 antigen-detecting rapid test with self-collected nasal swab versus professional-collected nasopharyngeal swab	STANDARD Q COVID-19 Ag (SD Biosensor)-NMT	74.4	58.9, 85.4	99.2	97.1, 99.8
		STANDARD Q COVID-19 Ag (SD Biosensor)-NP	79.5	64.5, 89.2	99.6	97.8, 100
Lindner, *et al.*[113] Apr 2021b	Head-to-head comparison of SARS-CoV-2 antigen-detecting rapid test with professional-collected nasal versus nasopharyngeal swab	STANDARD Q COVID-19 Ag (SD Biosensor)-NMT	80.5	66.0, 89.8	98.6	94.9, 99.6
		STANDARD Q COVID-19 Ag (SD Biosensor)-NP	73.2	58.1, 84.3	99.3	96.0, 100
Lindner, *et al.*[114] May 2021	Diagnostic accuracy and feasibility of patient self-testing with a SARS-CoV-2 antigen-detecting rapid test	STANDARD Q COVID-19 Ag (SD Biosensor)-Professional	85	70.9, 92.9	99.1	94.8, 99.5
		STANDARD Q COVID-19 Ag (SD Biosensor)-Self testing	82.5	68.1, 91.3	100	96.5, 100
Mandal, *et al.*[115] May 2022	Diagnostic performance of SARS-CoV-2 rapid antigen test in relation to RT-PCR CqValue	Espline SARS-CoV-2 (Fujirebio)	63.60%	54.7, 71.9	97.90	93.6, 99.6
Mane, *et al.*[116] May 2022	Diagnostic performance of oral swab specimen for SARS-CoV-2 detection with rapid point-of-care lateral flow antigen test	PathoCatch (Accucare)	Not reported			
		PathoCatch (Accucare) - oral swabs	Not reported			
Maniscalco, *et al.*[117] Aug 2021	A rapid antigen detection test to diagnose SARS-CoV-2 infection using exhaled breath condensate by a modified Inflammacheck(®) device	Inflammacheck (Exhalation Technology LTD)	92.3	64.0, 99.8	98.9	94.1, 100.0
Masiá, *et al.*[118] Jan 2021	Nasopharyngeal Panbio COVID-19 antigen performed at point-of-care has a high sensitivity in symptomatic and asymptomatic patients with higher risk for transmission and older age	PanBio (Abbott)	68.1		100	

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Mizrahi, *et al.*[119] Nov 2021	The Coris BioConcept COVID 19 Ag Respi-Strip, a field experience feedback	Respi-Strip (Coris BioConcept) - Coris-Ag: 30-min reading (n = 294)	45.2		100	
		Respi-Strip (Coris BioConcept) - Period 1 (n = 158)	59.3		100	
		Respi-Strip (Coris BioConcept) - Period 2 (n = 136)	20		100	
Møller, *et al.*[120] Jan 2022	Diagnostic performance, user acceptability, and safety of unsupervised SARS-CoV-2 rapid antigen-detecting tests performed at home	SARS-CoV-2 Antigen Rapid Test (Hangzhou Immuno Biotech Co Ltd, China).	62.1	50.1, 72.9	100	98.9, 100
		COVID-19 Antigen Detection Kit (DNA Diagnostic A/S, Denmark)	65.7	49.2, 79.2	100	99, 100
		PanBio (Abbott)	Not estimable		100	95.6, 100
Nagura-Ikeda, *et al.*[121] Aug 2020	Clinical evaluation of self-collected saliva by quantitative reverse transcription-PCR (RT-qPCR), direct RT-qPCR, reverse transcription–loop-mediated isothermal amplification, and a rapid antigen test to diagnose COVID-19	Espline SARS-CoV-2 (Fujirebio)	11.7			
Nikolai, *et al.*[122] Aug 2021	Anterior nasal versus nasal mid-turbinate sampling for a SARS-CoV-2 antigen-detecting rapid test: does localisation or professional collection matter?	STANDARD Q COVID-19 Ag (SD Biosensor) - Prof.-sampling: All (N =36), Prof AN	86.1	71.3, 93.9	100	95.7, 100
		STANDARD Q COVID-19 Ag (SD Biosensor) - Self-sampling: All (N=34), Prof. NP	91.2	77, 97	100	94.2, 100
		STANDARD Q COVID-19 Ag (SD Biosensor) - Self-sampling: All (N=34), Self NMT	91.2	77.0, 97	98.4	91.4, 99.9
Nóra, *et al.*[123] Feb 2022	Evaluating the field performance of multiple SARS-Cov-2 antigen rapid tests using nasopharyngeal swab samples	PanBio (Abbott)	Not reported			
		CoV2Ag assay (Siemens Healthineers, Eschborn, Germany)	Not reported			
		GenBody COVAG025 (GenBody)	Not reported			
		GENEDIA W COVID-19 Ag Test (Green Cross Medical Science Corp.)	Not reported			
		Humasis COVID-19 Ag Test kit (Humasis Co., Ltd.)	Not reported			
		Immupass VivaDiag (VivaChek Biotech)	Not reported			
		Helix i-SARS-CoV-2 Ag Rapid Test (Cellex Biotech Co.)	Not reported			
		Roche SARS-CoV-2 Rapid Antigen Test (Roche)	Not reported			
		Rapid COVID-19 Antigen Test (Healgen Scientific)	Not reported			

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
		Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based) Nanjing Vazyme Medical Technology Co	Not reported			
Okoye, *et al.*[124] Feb 2022	Diagnostic accuracy of a rapid diagnostic test for the early detection of COVID-19	BinaxNOW (Abbott)	91.84	80.40, 97.73	99.95	99.81, 99.99
Onsongo, *et al.*[125] Feb 2022	Performance of a rapid antigen test for SARS-CoV-2 in Kenya	NowCheck COVID-19 Ag test (Bionote)	Not reported			
Osmanodja, *et al.*[126] May 2021	Accuracy of a novel sars-cov-2 antigen-detecting rapid diagnostic test from standardized self-collected anterior nasal swabs	Custom/Novel/In-house	88.6	78.7, 94.9	99.7	98.2, 100
Paap, *et al.*[127] Jun 2022	Clinical evaluation of single-swab sampling for rapid COVID-19 detection in outbreak settings in Dutch nursing homes	Roche SARS-CoV-2 Rapid Antigen Test (Roche)	50.9		89	
Pandey, *et al.*[128] Aug 2021	Comparison of the rapid antigen testing method with RT-qPCR for the diagnosis of COVID-19	STANDARD Q COVID-19 Ag (SD Biosensor)	53.6	39.7, 67.0	97.3	94.6, 98.9
Park, *et al.*[129] Feb 2022	Analysis of the efficacy of universal screening of coronavirus disease with antigen-detecting rapid diagnostic tests at point-or-care settings and sharing the experience of admission protocol—a pilot study	STANDARD Q COVID-19 Ag (SD Biosensor)	68.3		99.5	
Peacock, *et al.*[130] Jan 2022	Utility of COVID-19 antigen testing in the emergency department	BinaxNOW (Abbott)	76.9	69.9, 82.9	98.6	97.2, 99.4
Peña, *et al.*[131] Apr 2021	Performance of SARS-CoV-2 rapid antigen test compared with real-time RT-PCR in asymptomatic individuals	STANDARD Q COVID-19 Ag (SD Biosensor)	69.86	58.56, 9.18 *[typo in paper]*	99.61	98.86, 99.87
Peña-Rodriguez, *et al.*[132] Feb 2021	Performance evaluation of a lateral flow assay for nasopharyngeal antigen detection for SARS-CoV-2 diagnosis	STANDARD Q COVID-19 Ag (SD Biosensor)	75.9	66.5, 83.8	100	98.6, 100

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Peronace, *et al.*[133] May 2022	Validation of GeneFinder COVID-19 Ag plus rapid test and its potential utility to slowing infection waves: a single-center laboratory evaluation study	GeneFinder COVID-19 Ag Plus Rapid Test	96.03	91.55, 98.53	99.78	98.77, 99.99
Pilarowski, *et al.*[134] Jan 2021	Performance characteristics of a rapid SARS-CoV-2 antigen detection assay at a public plaza testing site in San Francisco	BinaxNOW (Abbott)	57.7	36.9, 76.6	100	99.6, 100
Pollock, *et al.*[135] Apr 2021	Performance and implementation evaluation of the Abbott BinaxNOW Rapid Antigen Test in a high-throughput drive-through community testing site in Massachusetts	BinaxNOW (Abbott)	84.1	77.4, 89.4	99.6	99.1, 99.9
Poopalasingam, *et al.*[136] Feb 2022	Determining the reliability of rapid SARS-CoV-2 antigen detection in fully vaccinated individuals	STANDARD Q COVID-19 Ag (SD Biosensor)	57.3	46.1, 67.9	99.7	98.8, 99.9
Prost, *et al.*[137] Dec 2021	Evaluation of a rapid in vitro diagnostic test device for detection of SARS-CoV-2 antigen in nasal swabs	SARS-CoV-2 Antigen Rapid Test (Hangzhou Immuno Biotech Co Ltd, China).	97.3	94.2, 99.0	99.5	97.3, 100
Rahman, *et al.*[138] Nov 2021	Clinical evaluation of SARS-CoV-2 antigen-based rapid diagnostic test kit for detection of COVID-19 cases in Bangladesh	STANDARD Q COVID-19 Ag (SD Biosensor)- Adults	85.76	81.25, 89.54		
Rana, *et al.*[139] Sept 2021	Evaluation of the currently used antigen-based rapid diagnostic test for the detection of SARS CoV-2 virus in respiratory specimens	STANDARD Q COVID-19 Ag (SD Biosensor)	37.5		99.79	
Rastawicki, *et al.*[140] Jan 2021	Evaluation of PCL rapid point of care antigen test for detection of SARS-CoV-2 in nasopharyngeal swabs	PCL COVID19 Ag Rapid FIA Antigen Test (PCL)	38.9		83.3	

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Rohde, *et al.*[142] Feb 2022	Diagnostic accuracy and feasibility of a rapid SARS-CoV-2 antigen test in general practice - a prospective multicenter validation and implementation study	Roche SARS-CoV-2 Rapid Antigen Test (Roche)	78.3	70.9, 84.6	99.5	99, 99.8
Salcedo, *et al.*[143] Feb 2022	Comparative Evaluation of Rapid Isothermal Amplification and Antigen Assays for Screening Testing of SARS-CoV-2	Custom/Novel/In-house	Not reported			
Salvagno, *et al.*[144] Jan 2021	Clinical assessment of the Roche SARS-CoV-2 rapid antigen test	STANDARD Q COVID-19 Ag (SD Biosensor)	72.5	64.6, 79.5	99.4	96.8, 100
Salvagno, *et al.*[145] May 2021	Real-world assessment of Fluorecare SARS-CoV-2 Spike Protein Test Kit	Fluorecare (Colloidal Gold/Fluorescent) SARS-CoV-2 Spike Protein Test kit (Shenzen Microprofit)	27.5	21.8, 33.7	99.2	95.5, 100
Savage, *et al.*[146] Jun 2022	A prospective diagnostic evaluation of accuracy of self-taken and healthcare worker-taken swabs for rapid COVID-19 testing	Covios COVID-19 Antigen Rapid Dianostic test-Health-care worker taken swab	78.4	69.0, 87.8	98.9	97.3, 100.0
		Covios COVID-19 Antigen Rapid Dianostic test-Self-taken swab	90.5	83.9, 97.2	99.4	98.3, 100.0
Schildgen, *et al.*[147] Jan 2021	Limits and opportunities of SARS-CoV-2 antigen rapid tests: an experienced-based perspective	PanBio (Abbott)	50	35, 64	77.4	60, 89
		RapiGen (BioCredit)	33.3	21, 48	87.1	71, 95
		Roche SARS-CoV-2 Rapid Antigen Test (Roche)	88.1	75, 95	19.4	9, 36
Selvabai, *et al.*[148] Apr 2022	Diagnostic Efficacy of COVID-19 Rapid Antigen Detection Card in Diagnosis of SARS-CoV-2	Athenese-DX COVID-19 RAT kit	74.19		100	
Shaw, *et al.*[149] Jul 2021	Evaluation of the Abbott Panbio(TM) COVID-19 Ag rapid antigen test for the detection of SARS-CoV-2 in asymptomatic Canadians	PanBio (Abbott)	Not reported			
Siddiqui, *et al.*[150] Dec 2021	Implementation and Accuracy of BinaxNOW Rapid Antigen COVID-19 Test in Asymptomatic and Symptomatic Populations in a High-Volume Self-Referred Testing Site	BinaxNOW (Abbott)	81	75, 86	99.8	100.0, 100.0

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Sitoe, *et al.*[151] Feb 2022	Performance Evaluation of the STANDARD(TM) Q COVID-19 and Panbio (TM) COVID-19 Antigen Tests in Detecting SARS-CoV-2 during High Transmission Period in Mozambique	PanBio (Abbott)	41.3	34.6, 48.4	98.2	96.2, 99.3
		STANDARD Q COVID-19 Ag (SD Biosensor)	45	39.9, 50.2	97.6	95.3, 99.0
Skvarč[152] Apr 2022	Clinical validation of two immunochromatographic SARS-CoV-2 antigen tests in near hospital facilities	Immupass VivaDiag (VivaChek Biotech)	90.6	84.94, 94.36	100	99.41, 100.0
		Alltest Covid19 Ag test	94.37	89.20, 97.54	100	98.83, 100.0
Smith, *et al.*[153] Jun 2021	Clinical Evaluation of Sofia Rapid Antigen Assay for Detection of Severe Acute Respiratory Syndrome Coronavirus 2 among Emergency Department to Hospital Admissions	Sofia SARS Rapid Antigen FIA/Sofia 2 (Quidel)	76.6	71, 82	99.7	99.0, 100
Soleimani, *et al.*[141] May 2021	Rapid COVID-19 antigenic tests: usefulness of a modified method for diagnosis	PanBio (Abbott)	75	68.9, 80.4		
		COVID19-Speed/Biospeedia COVID19 Antigen test (Biospeedia)	65.5	59.0, 71.6	100	
Stohr, *et al.*[154] May 2022	Self-testing for the detection of SARS-CoV-2 infection with rapid antigen tests for people with suspected COVID-19 in the community	BD Veritor COVID-19 Rapid Antigen Test (Becton-Dickinson)	49.1	41.7, 56.5	99.9	99.7, 100.0
		Roche SARS-CoV-2 Rapid Antigen Test (Roche)	61.5	54.6, 68.3	99.7	99.4, 99.9
Surasi, *et al.*[155] Nov 2021	Effectiveness of Abbott BinaxNOW rapid antigen test for detection of SARS-CoV-2 infections in outbreak among horse racetrack workers, California, USA	BinaxNOW (Abbott)	43.3	34.6, 52.4	100	99.4, 100.0
Suzuki, *et al.*[156] May 2022	Analytical performance of rapid antigen tests for the detection of SARS-CoV-2 during widespread circulation of the Omicron variant	QuickNavi-COVID19 Ag	94.2	91.6, 96.3	99.5	98.7, 99.9
Suzuki, *et al.*[157] Jan 2022	Diagnostic performance of a novel digital immunoassay (RapidTesta SARS-CoV-2): A prospective observational study with nasopharyngeal samples	RapidTesta SARS-CoV-2	71.6	59.9, 81.5	99.2	98.5, 99.7
		RapidTesta SARS-CoV-2	78.4	67.3, 87.1	97.6	96.5, 98.5

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Terpos, *et al.*[158] May 2021	Clinical Application of a New SARS-CoV-2 Antigen Detection Kit (Colloidal Gold) in the Detection of COVID-19	Custom/Novel/In-house	Not reported			
Thakur, *et al.*[159] Nov 2021	Utility of Antigen-Based Rapid Diagnostic Test for Detection of SARS-CoV-2 Virus in Routine Hospital Settings	PathoCatch (Accucare)	34.5	24.5, 45.6	99.8	99.1, 100
Thell, *et al.*[160] Nov 2021	Evaluation of a novel, rapid antigen detection test for the diagnosis of SARS-CoV-2	Roche SARS-CoV-2 Rapid Antigen Test (Roche)-Emergency Dept	77.9	70.0, 84.6	98.1	94.6, 99.6
		Roche SARS-CoV-2 Rapid Antigen Test (Roche)-Primary Health Care	84.4	74.4, 91.7	100	97.8, 100.0
Thirion-Romero, *et al.*[161] Oct 2021	Evaluation of Panbio rapid antigen test for SARS-CoV-2 in symptomatic patients and their contacts: a multicenter study	PanBio (Abbott)	54.2	51.2, 57.2	98.5	97.7, 99.2
Tonelotto, *et al.*[162] Jan 2022	Efficacy of Fluorecare SARS-CoV-2 Spike Protein Test Kit for SARS-CoV-2 detection in nasopharyngeal samples of 121 individuals working in a manufacturing company	Fluorecare (Colloidal Gold/Fluorescent) SARS-CoV-2 Spike Protein Test kit (Shenzen Microprofit)	84.6	54.6, 98.1	100	98.6, 100.0
Toptan, *et al.*[163] Feb 2021	Evaluation of a SARS-CoV-2 rapid antigen test: potential to help reduce community spread?	Rida Quick SARS-CoV-2 (R-Biopharm)-Berlin	77.6		100	
		Rida Quick SARS-CoV-2 (R-Biopharm)-Frankfurt	50		100	
Trobajo-Sanmartín, *et al.*[164] Mar 2021	Evaluation of the rapid antigen test CerTest SARS-CoV-2 as an alternative COVID-19 diagnosis technique	CerTest SARS-CoV-2 (Certest Biotech)	78.75	67.89, 86.79	100	97.08, 99.94
Turcato, *et al.*[165] Mar 2021	Clinical application of a rapid antigen test for the detection of SARS-CoV-2 infection in symptomatic and asymptomatic patients evaluated in the emergency department: a preliminary report	Standard Q COVID-19 Ag (SD Biosensor)	80.3	74.9, 85.4	99.1	98.6, 99.3
Turcato, *et al.*[166] Jan 2022	Rapid antigen test to identify COVID-19 infected patients with and without symptoms admitted to the emergency department	Standard Q COVID-19 Ag (SD Biosensor)	82.9	81.0, 84.8	99.1	98.8, 99.3

(*Continued*)

Author, year	Article title	Index test description	Sensitivity (TP/[TP+FN])	Sensitivity 95% CI (low, high)	Specificity (TN/[TN +FP])	Specificity 95% CI (low, high)
Van der Moeren, *et al.*[167] May 2021	Evaluation of the test accuracy of a SARS-CoV-2 rapid antigen test in symptomatic community dwelling individuals in the Netherlands	BD Veritor COVID-19 Rapid Antigen Test (Becton-Dickinson)	94.1	71.1, 100	100	98.9, 100
		BD Veritor COVID-19 Rapid Antigen Test (Becton-Dickinson)-Visual	94.1	71.1, 100	100	98.9, 100
Van Honacker, *et al.*[168] Aug 2021	Comparison of five SARS-CoV-2 rapid antigen tests in a hospital setting and performance of one antigen assay in routine practice. A useful tool to guide isolation precautions?	Standard Q COVID-19 Ag (SD Biosensor)	54.2		99.7	
von Ahnen, *et al.*[169] Mar 2022	Evaluation of a rapid-antigen test for COVID-19 in an asymptomatic collective: a prospective study	Roche SARS-CoV-2 Rapid Antigen Test (Roche)	92.3	78.0, 100	100	100.0, 100.0
Wertenauer, *et al.*[170] Mar 2022	Diagnostic performance of rapid antigen testing for SARS-CoV-2: the COVid-19 AntiGen (COVAG) study	PanBio (Abbott)	56.8		99.9	
		Roche SARS-CoV-2 Rapid Antigen Test (Roche)	60.4		99.7	

Appendix IV: Rapid antigen tests from included studies

	Name	Company	Study count	Reported 100% sensitivity in at least 1 study	Reported 100% specificity in at least 1 study	Reported 100% positive predictive value in at least 1 study	Reported 100% negative predictive value in at least 1 study
1	STANDARD Q COVID-19 Ag Test	SD Biosensor Inc.	28	X	X	X	X
2	PanBio COVID-19 Ag Rapid Test Device	Abbott	14		X	X	
3	SARS-CoV-2 Rapid Antigen Test	Roche Diagnostics	11		X	X	
4	BinaxNOW COVID-19 Antigen	Abbott	10		X	X	
5	Rapid Test Ag 2019-nCov	ProGnosis Biotech	4				
6	SARS-CoV-2 Ag	LumiraDx	3		X		
7	Custom/Novel/In-house	N/A	3				
8	COVISTIX (COVIDMARK) Covid 19 Antigen Rapid Test Device	Sorrento Therapeutics	3				
9	AMP Rapid Test SARS-CoV-2 Ag	AMP Diagnostics	2		X	X	
10	BD Veritor COVID-19 Rapid Antigen Test	Becton-Dickinson	2		X	X	
11	CerTest SARS-CoV-2	Certest Biotec	2		X	X	
12	Espline SARS-CoV-2	Fujirebio	2		X	X	
13	SARS-CoV-2 Antigen Rapid Test	Hangzhou Immuno Biotech Co Ltd	2		X		
14	HUMASIS COVID-19 Ag Test	Humasis Co., Ltd	2				
15	Mologic Covid-19 Rapid Antigen Test	Mologic Ltd. United Kingdom	2		X	X	
16	NADAL COVID-19 Ag Rapid Test	New Art Laboratories/nal von minden	2		X	X	
17	Quick Navi-COVID 19 Ag	Otsuka Pharmaceutical Co., Ltd.	2		X		
18	PCL COVID19 Ag Rapid FIA Antigen Test	PCL, Inc.	2				
19	Sofia SARS Rapid Antigen FIA/ Sofia 2	Quidel	2		X	X	
20	BIOCREDIT COVID-19 Ag	RapiGen, Inc.	2		X	X	
21	Rida Quick SARS-CoV-2 Antigen Test	R-Biopharm AG	2		X	X	
22	STANDARD F COVID-19 Ag FIA	SD Biosensor Inc	2				

(*Continued*)

	Name	Company	Study count	Reported 100% sensitivity in at least 1 study	Reported 100% specificity in at least 1 study	Reported 100% positive predictive value in at least 1 study	Reported 100% negative predictive value in at least 1 study
23	RapidTesta SARS-CoV-2	Sekisui Medical Co., Ltd	2				
24	Fluorecare SARS-CoV-2 Spike Protein Test kit (Colloidal Gold)	Shenzen Microprofit Biotech Co., Ltd.	2		X	X	
25	CLINITEST Rapid COVID-19 Antigen Test	Siemens Healthineers	2				
26	Immupass VivaDiag	VivaChek Biotech	2		X		
27	COVID-VIRO COVID-19 Ag Rapid Test	AAZ	1		X	X	
28	Flowflex COVID-19 Antigen test	ACON Labs	1	X	X	X	X
29	COVID-19 Antigen Rapid Test	Acro Biotech, Inc.	1				
30	Alltest COVID-19 ART Antigen Rapid Test	ALLTEST	1		X		
31	COVID-19 Antigen Rapid Test	Assut Europe	1		X	X	
32	COVID-19 RAT kit	Athenese-DX	1		X	X	
33	NowCheck COVID-19 Ag test	Bionote	1				
34	Novel Corona Virus (SARS-CoV-2) Ag Rapid Test kit	Bioperfectus	1		X	X	
35	Covid-19 AG BSS	BIOSYNEX	1				
36	Helix i-SARS-CoV-2 Ag Rapid Test	Cellex Biotech Co	1				
37	COVID-19 Ag K-SeT	Coris Bioconcept	1				
38	Liaison SARS-CoV-2 Ag	DiaSorin	1				
39	COVID-19 Antigen Detection	DNA Diagnostic A/S	1		X		
40	COVID-19 Ag ECO Teste	Eco Diagnostica	1				
41	Inflammacheck CoronaCheck	Exhalation Technology LTD	1				
42	GenBody COVAG025	GenBody	1				
43	GENEDIA W COVID-19 Ag Test	Green Cross Medical Science Corp	1				
44	Rapid COVID-19 Antigen Test	Healgen Scientific	1				
45	Innova SARS-CoV-2 Antigen Rapid test	Innova Medical Group	1				

(*Continued*)

	Name	Company	Study count	Reported 100% sensitivity in at least 1 study	Reported 100% specificity in at least 1 study	Reported 100% positive predictive value in at least 1 study	Reported 100% negative predictive value in at least 1 study
46	Accucare PathoCatch Covid-19 Ag Detection Kit	Mylab	1				
47	Orient Gene Rapid Covid-19 (Antigen) Self-Test	Orient Gene	1		X	X	
48	GeneFinder COVID-19 Ag Plus Rapid Test	OSANG Healthcare	1				
49	Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Shenzhen Lvshiyuan Biotechnology	1		X	X	
50	Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Antigen Detection Kit (Colloidal Gold-Based)	Vazyme Medical Technology Co	1				
51	2019-nCoV Antigen Test	Wondfo	1				

