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META-ANALYSIS



# The diagnostic accuracy of seven commercial molecular *in vitro* SARS-CoV-2 detection tests: a rapid meta-analysis

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**ABSTRACT**

**Objective**: To compare the accuracy parameters of seven commercial molecular *in vitro* diagnostic tests for detecting SARS-CoV-2.

**Methods**: Studies evaluating the accuracy of seven different commercial molecular diagnostic tests for detecting SARS-CoV-2 (Cepheid Xpert Xpress SARS-CoV-2 test, Simplexa COVID-19 Direct, Abbott ID NOW COVID-19, Cobas SARS-CoV-2, Allplex 2019-nCoV Assay, Panther Fusion SARS-CoV-2, and BioFire COVID-19 Test) were included. The quality of the included studies was assessed using the QUADAS-2 checklist. A bivariate random-effects regression model was implemented..

**Results**: Meta-analysis of 12 included studies showed that the performances of commercial COVID-19 molecular *in vitro* diagnostic tests were high, with a summary sensitivity of 95.9% (95% CI 93.9–97.2%, $I^2$ = 60.22%) and specificity of 97.2% (95% CI 95.5–98.3%, $I^2$ = 56.66%). Among seven evaluated tests, the Abbott ID NOW COVID-19 and Simplexa COVID-19 Direct displayed lower sensitivity (91.6%, 95% CI 80.5–96.6% and 92%, 95% CI 86.2–95.5, respectively).

**Conclusion**: All evaluated tests showed good accuracy. However, the slightly lower sensitivity observed in the Abbott ID Now COVID-19 and Simplexa COVID-19 Direct should be considered when deciding on a test platform. Moreover, the diagnostic accuracy of COVID-19 commercial diagnostic tests should be weighed against their ease of use and speed.

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SARS-CoV-2; COVID-19; diagnostic accuracy; diagnostic performance; molecular *in vitro* diagnostic tests

## 1. Introduction

To date, the coronavirus disease 2019 (COVID-19) pandemic remains a major burden worldwide [1–6]. Accurate diagnosis of COVID-19 still relies on reverse transcription-polymerase chain reaction (RT-PCR) of the SARS-CoV-2 viral RNA as the gold standard [7]. To contain and help stop the spread of the disease, rapid, precise, and large-scale detection of COVID-19 is crucial, and the need for a sensitive, user-friendly, and rapid diagnostic test becomes increasingly urgent.

Currently, many commercial molecular *in vitro* diagnostic tests for COVID-19 have become available to fulfill this demand. However, accurate and validated data on the diagnostic tests are still needed, as manufacturer-independent evaluation data are scarce. Several early reports have shown the higher rate of false-negative findings [8] as a flaw of currently available tests. This emphasizes the fact that many factors can influence the sensitivity and specificity of a test [9], such as the core amplification technology, variations in the performance of the tests, and sampling method. Hence, in this current study, we aimed to compare the performance of seven readily available COVID-19 molecular *in vitro* diagnostic tests from different manufacturers through a meta-analysis.

## 2. Methods

### 2.1. Search strategy and eligibility criteria

This study was performed according to Preferred Reporting Items for a Systematic Review and Meta-analysis of Diagnostic Test Accuracy Studies (PRISMA-DTA) statement [10]. First, a literature search was conducted in PubMed and Scopus without limits of time frame or language (dated up to December 2020), with the following terms used individually or in combination: 'diagnostic,' 'sensitivity,' 'specificity,' 'commercial,' 'molecular *in vitro* diagnostic tests,' 'nucleic acid amplification test (NAAT),' 'COVID-19,' and 'SARS-CoV-2.' An additional literature search approach was implemented using the brand name of US FDA-approved molecular *in vitro* diagnostic tests for SARS-CoV-2 detection as the descriptors.

Initially, studies were included if they meet the following criteria: (1) Evaluation of any FDA-approved, commercially available molecular *in vitro* diagnostic tests for COVID-19; (2) utilizing human clinical sample; (3) reporting accuracy data; and (4) using either composite standard reference, modified CDC SARS-CoV-2 assay, or consensus standard as the study reference standard. Any commercial kits reported in a single study were excluded, leaving only seven kits (Xpert Xpress SARS-CoV-2 test (Cepheid),

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Supplemental data for this article can be accessed here.

Table 1. Comparison of seven different commercial molecular *in vitro* diagnostic tests for the detection of SARS-CoV-2.

| Brand name | Method | Sample type | Assay run time (min) | Sample volume required (µl) | .Extraction required | Analytical sensitivity per claim | Target |
|---|---|---|---|---|---|---|---|
| Xpert Xpress SARS-CoV-2 test (Cepheid) | Real-time RT-PCR | Nasopharyngeal, oropharyngeal, nasal, or mid-turbinate swab and/or nasal wash/aspirate | ~45 | 300 | Yes (automated) | 250 copies/mL | N2 and E genes |
| Simplexa COVID-19 Direct (DiaSorin Molecular LLC) | Real-time RT-PCR | Bronchoalveolar lavage, nasal swab, nasal wash/ aspirate, nasopharyngeal swab, and saliva specimens | ~60 | 50 | No | 242 copies/mL | ORF1ab and S genes |
| Cobas SARS-CoV-2 (Roche Molecular Systems, Inc.) | Real-time RT-PCR | Nasal, nasopharyngeal, or oropharyngeal swabs | ~210 | 600 | Yes (automated) | 46 copies/mL | ORF1ab, a non-structural region that is unique to SARS-CoV-2, and E genes. |
| ID NOW COVID-19 (Abbott Diagnostics Scarborough, Inc.) | Isothermal nucleic acid amplification | Nasal, nasopharyngeal, or throat swabs | <15 | 200 | No | 100 copies/mL | RdRp gene |
| Allplex 2019-nCoV Assay (Seegene Inc.) | Real-time RT-PCR | Nasopharyngeal swab, oropharyngeal swab, anterior nasal swab, and midturbinate and sputum specimens | 75 | 300 | Yes (automated) | 100 copies/ml | E, RdRP, and N genes |
| Panther Fusion SARS-CoV-2 (Hologic, Inc.) | Real-time RT-PCR | Nasopharyngeal and oropharyngeal swabs | ~145 | 250–500 | Yes (automated) | 62.5 copies/ml | Two conserved regions of ORF1ab gene |
| BioFire COVID-19 Test (BioFire Defense, LLC) | Nested multiplexed RT-PCR test | Nasopharyngeal swab | ~50 | 300 | Yes (automated) | 165 copies/mL | ORF1ab and ORF8, N1, N2, and N3 genes |

N2: nucleocapsid gene; E: envelope gene; RdRp: RNA-dependent RNA polymerase; ORF: Open reading frame, S: spike glycoprotein gene.

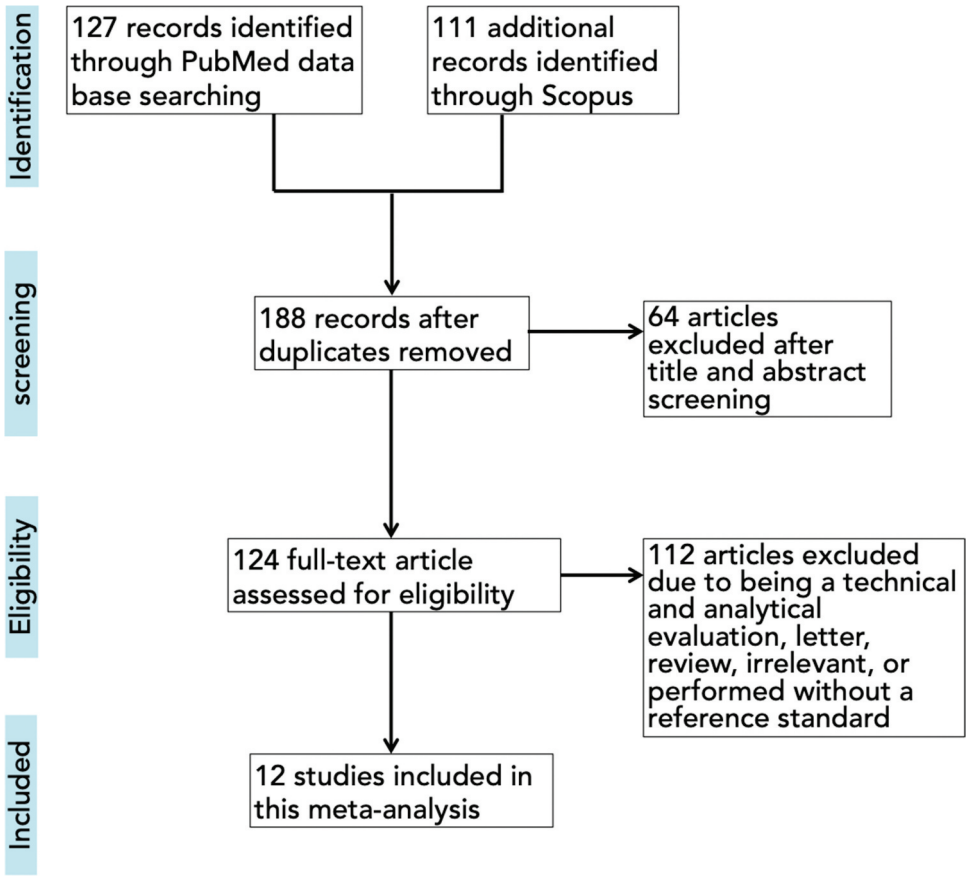


Figure 1. Flowchart of included studies.

Simplexa COVID-19 Direct (DiaSorin Molecular LLC), ID NOW COVID-19 (Abbott Diagnostics Scarborough, Inc.), Cobas SARS-CoV-2 (Roche Molecular Systems, Inc.), Allplex 2019-nCoV Assay (Seegene Inc.), Panther Fusion SARS-CoV-2 (Hologic, Inc.), and BioFire COVID-19 Test (BioFire Defense, LLC)) were then further analyzed. The manufacturer's specifications are summarized in Table 1.

### 2.2. Data extraction and statistical analysis

The following data were extracted: First author, year of publication, type of sample, type of reference standard, brand name, type of sample, sample size, and data of the diagnostic value for each test [number of true positive (TP), false positive (FP), true negative (TN), and false negative (FN)].

The risk bias in each study was evaluated using the Diagnostic Precision Study Quality Assessment Tool (QUADAS-2). The meta-analyses were performed according to the brand name and type of reference standard. The bivariate (random effect) model was implemented, with a minimum of two studies. Forest plots and summary receiver operating characteristic (SROC) curves were performed using Review Manager (RevMan) Version 5.3 and OpenMeta-Analyst [11–14].

## 3. Results

A total of 188 articles were identified after duplicate removal, of which 176 were excluded during the screening phase and further evaluation, leaving 12 records being fully examined (Figure 1) [15–26]. The main characteristics of the included study are summarized in Supplementary Table 1. The overall sensitivity and specificity of all included studies on commercial molecular *in vitro* diagnostic tests for COVID-19 were examined, reaching 95.9% (95% CI 93.9–97.2%, $I^2$ = 60.22%) and 97.2% (95% CI 95.5–98.3%, $I^2$ = 56.66%), respectively (Supplementary Figure 1(a,b)), with SROC curves are shown in Supplementary Figure 2.

We then further analyzed the parameters of accuracy (sensitivity and specificity) from seven commercially available molecular *in vitro* diagnostic tests for COVID-19, with results depicted in Figure 2 and Table 2. Regardless of the reference standard and sample types used in this study, sensitivity and specificity from five tests were comparable (sensitivity ranging from 95.6% to 99.4%; specificity ranging from 96.4% to 99.8%; Table 2). However, studies utilizing ID NOW COVID-19 and the Simplexa COVID-19 Direct exhibited lower sensitivity 91.6% (95% CI 80.5–96.6%, $I^2$ = 65.42) and 92% (95% CI 86.2–95.5, $I^2$ = 42.13%), respectively (Table 2). Although the specificity of ID NOW COVID-19 was slightly lower compared to other kits, it is notable that substantial heterogeneity existed ($I^2$ = 79.63%; Table 2), and thus, this should be interpreted with caution. The SROC plot and overview of seven molecular *in vitro* diagnostic tests for COVID-19 with their summary sensitivity and specificity are shown in Figure 3.

The quality assessment of the included studies is presented in Figure 4(a,b). None of the studies had a low risk of bias in all four domains of QUADAS-2. Of the total 12 included studies, 7 (58.3%) had unclear risk of bias due to the lack of information regarding selection and randomization of patients/samples,

**Simplexa COVID-19 Direct**

| Study | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|
| Cardic et al | 30 | 0 | 3 | 151 | 0.91 [0.76, 0.98] | 1.00 [0.98, 1.00] |
| Lephart et al | 12 | 0 | 3 | 63 | 0.80 [0.52, 0.96] | 1.00 [0.94, 1.00] |
| Lima et al | 22 | 0 | 0 | 21 | 1.00 [0.85, 1.00] | 1.00 [0.84, 1.00] |
| Liotti et al [a] | 48 | 7 | 0 | 70 | 1.00 [0.93, 1.00] | 0.91 [0.82, 0.96] |
| Procop et al | 148 | 20 | 1 | 70 | 0.99 [0.96, 1.00] | 0.78 [0.68, 0.86] |
| Rhoads et al | 92 | 4 | 0 | 0 | 1.00 [0.96, 1.00] | 0.00 [0.00, 0.60] |

**Xpert Xpress SARS-CoV-2 test**

| Study | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|
| Lephart et al | 25 | 2 | 0 | 60 | 1.00 [0.86, 1.00] | 0.97 [0.89, 1.00] |
| Procop et al | 163 | 4 | 5 | 66 | 0.97 [0.93, 0.99] | 0.94 [0.86, 0.98] |

**Cobas SARS-CoV-2**

| Study | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|
| Cardic et al | 33 | 0 | 0 | 151 | 1.00 [0.89, 1.00] | 1.00 [0.98, 1.00] |
| Ling Ho et al | 16 | 1 | 1 | 750 | 0.94 [0.71, 1.00] | 1.00 [0.99, 1.00] |

**Allplex™ 2019-nCoV Assay**

| Study | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|
| Garg et al | 40 | 0 | 0 | 10 | 1.00 [0.91, 1.00] | 1.00 [0.69, 1.00] |
| Liotti et al [a] | 54 | 1 | 0 | 70 | 1.00 [0.93, 1.00] | 0.99 [0.92, 1.00] |

**Panther Fusion SARS-CoV-2**

| Study | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|
| Smith et al | 74 | 0 | 1 | 74 | 0.99 [0.93, 1.00] | 1.00 [0.95, 1.00] |
| Wong et al | 79 | 0 | 2 | 77 | 0.98 [0.91, 1.00] | 1.00 [0.95, 1.00] |

**BioFire COVID-19 Test**

| Study | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|
| Liotti et al [b] | 80 | 6 | 0 | 34 | 1.00 [0.95, 1.00] | 0.85 [0.70, 0.94] |
| Smith et al | 74 | 0 | 1 | 75 | 0.99 [0.93, 1.00] | 1.00 [0.95, 1.00] |

**ID NOW COVID-19**

| Study | TP | FP | FN | TN | Sensitivity (95% CI) | Specificity (95% CI) |
|---|---|---|---|---|---|---|
| Cardic et al | 33 | 0 | 0 | 151 | 1.00 [0.89, 1.00] | 1.00 [0.98, 1.00] |
| Lephart et al | 12 | 0 | 13 | 63 | 0.48 [0.28, 0.69] | 1.00 [0.94, 1.00] |
| Procop et al | 140 | 28 | 0 | 69 | 1.00 [0.97, 1.00] | 0.71 [0.61, 0.80] |
| Rhoads et al | 90 | 4 | 0 | 0 | 1.00 [0.96, 1.00] | 0.00 [0.00, 0.60] |

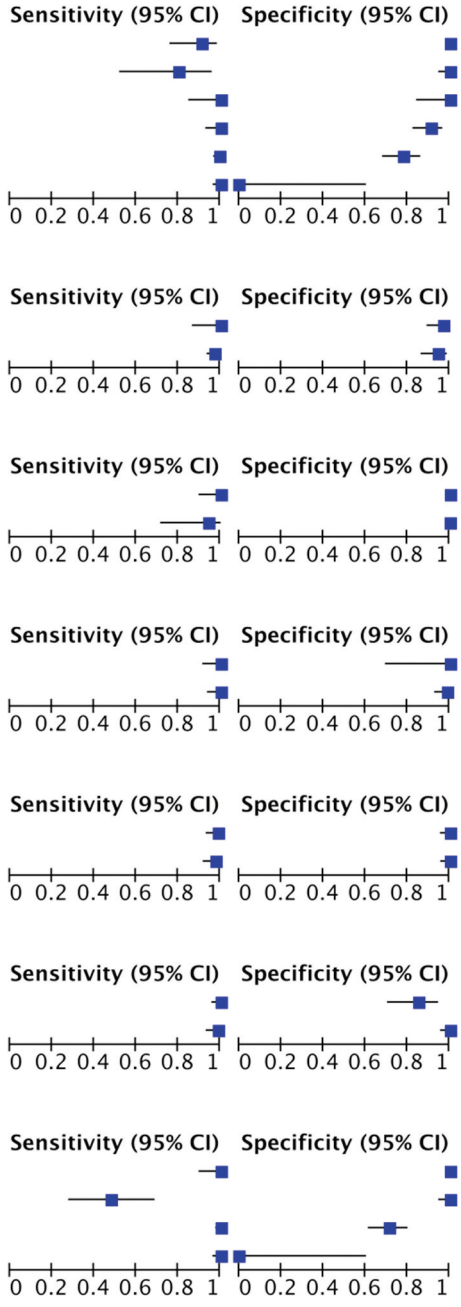


Figure 2. Forest plot of pairs of sensitivity and specificity in each study included stratified by brand name. TP: true positive; FP: false positive; FN: false negative; TN: true negative.

whereas one study (8.3%) exhibited high risk of bias due to the study utilizing convenience sampling method. All studies (100%) scored unclear risk of bias for the reference standard domain because gold standard (culture or sequencing) was not employed. Two studies (16.7%) had high risk of bias for the flow and timing domain, mainly because of the lack of information on the interval time between index test and reference standard.

## 4. Discussion

Accurate diagnostic confirmation of COVID-19 followed by subsequent isolation and tracing is the core approach for mitigating the current spread of SARS-CoV-2 infection. Because molecular diagnostic testing for SARS-CoV-2 is crucial and urgently needed during this challenging period, accelerated development of SARS-CoV-2 nucleic acid amplification test (NAAT) as well as Emergency Use Authorization (EUA) from FDA has been implemented [18,27]. However, recent studies have highlighted the potential problems of diagnostic accuracy from several platforms [15,19].

In this study, we performed a meta-analysis on the performance of seven FDA-approved and commercially available SARS-CoV-2 molecular diagnostic tests. We found that the overall performance of commercial COVID-19 molecular *in vitro* diagnostic tests was high, with a summary sensitivity

Table 2. Meta-analysis of the parameters of accuracy in different commercial molecular *in vitro* diagnostic tests for the detection of SARS-CoV-2 stratified by brand name.

| Brand name | Sample | No. of studies | Pooled sensitivity (95% CI) | Pooled specificity (95% CI) |
|---|---|---|---|---|
| Xpert Xpress SARS-CoV-2 test (Cepheid) | Nasopharyngeal and nasal swab | 2 | 0.956 (0.849–0.988) $I^2$ = 63.75% | 0.964 (0.779–0.995) $I^2$ = 54.54% |
| Simplexa COVID-19 Direct (DiaSorin Molecular LLC) | Nasopharyngeal, oropharyngeal, and nasal swab | 6 | 0.920 (0.862–0.955) $I^2$ = 42.13% | 0.970 (0.937–0.986) $I^2$ = 18.32% |
| Cobas SARS-CoV-2 (Roche Molecular Systems, Inc.) | Nasopharyngeal, throat, sputum, saliva, stool, aspiration, and serum | 2 | 0.963 (0.836–0.993) $I^2$ = 0% | 0.998 (0.991–1.000) $I^2$ = 0% |
| ID NOW COVID-19 (Abbott Diagnostics Scarborough, Inc.) | Nasopharyngeal and nasal swab | 4 | 0.916 (0.805–0.966) $I^2$ = 65.42% | 0.942 (0.708–0.991) $I^2$ = 79.63% |
| Allplex 2019-nCoV Assay (Seegene Inc.) | Nasopharyngeal, oropharyngeal, and nasal swab | 2 | 0.978 (0.916–0.995) $I^2$ = 0% | 0.982 (0.884–0.998) $I^2$ = 0% |
| Panther Fusion SARS-CoV-2 (Hologic, Inc.) | Nasopharyngeal swabs, deep throat saliva, and lower respiratory tract | 2 | 0.994 (0.956–0.999) $I^2$ = 0% | 0.982 (0.931–0.995) $I^2$ = 0% |
| BioFire COVID-19 Test (BioFire Defense, LLC) | Nasopharyngeal, oropharyngeal, and nasal swab | 2 | 0.967 (0.743–0.997) $I^2$ = 64.77% | 0.982 (0.931–0.995) $I^2$ = 0% |

of 95.9% (95% CI 93.9–97.2%, $I^2$ = 60.22%) and specificity of 97.2% (95% CI 95.5–98.3%, $I^2$ = 56.66%). However, our study revealed that the ID NOW COVID-19 (Abbott) and the Simplexa COVID-19 Direct exhibited lower sensitivity relative to other platforms, consistent with previously reported studies [8,15,18,19,28–30]. Previously, several studies have also shown reduced sensitivity of both ID NOW COVID-19 and the Simplexa COVID-19 Direct in samples with higher $C_T$ values (lower viral load) [8,19]. Since both platforms utilize extraction-free approaches for amplification, a plausible reason for the reduced sensitivity may be due to the potential presence of multiple inhibitory substances or contaminants in the raw

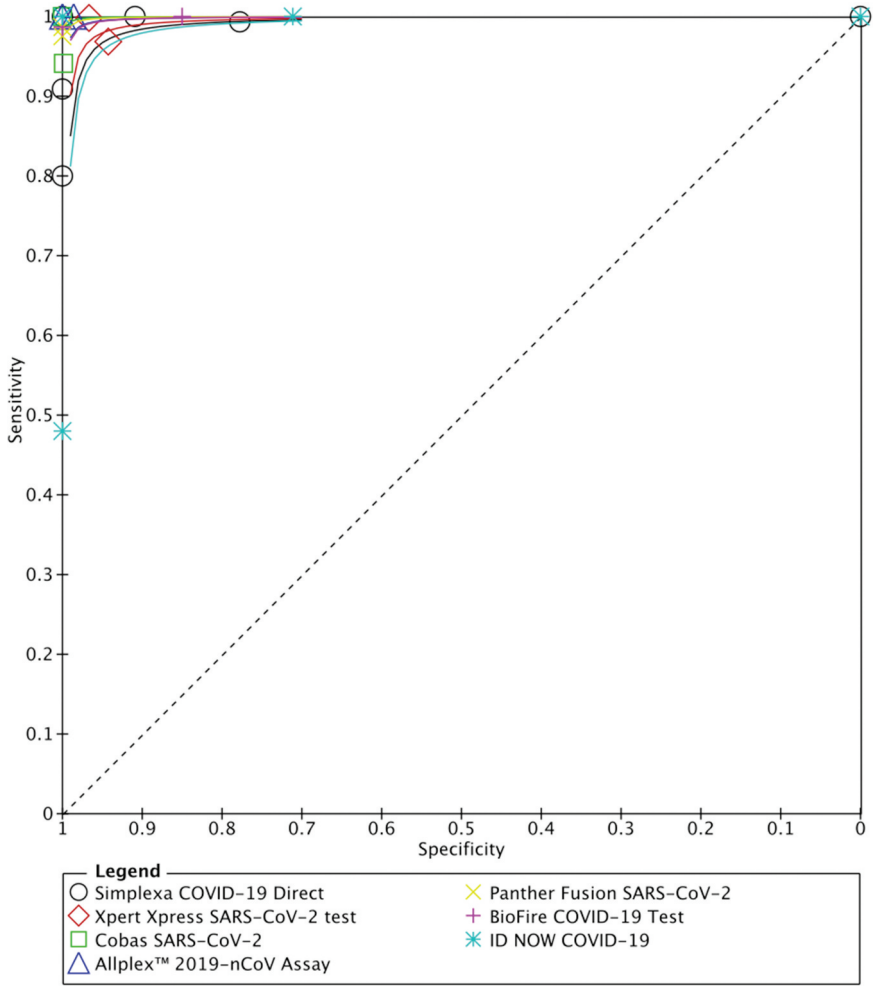


Figure 3. Summary of ROC curves from seven commercial molecular *in vitro* diagnostic tests for detecting SARS-CoV-2.

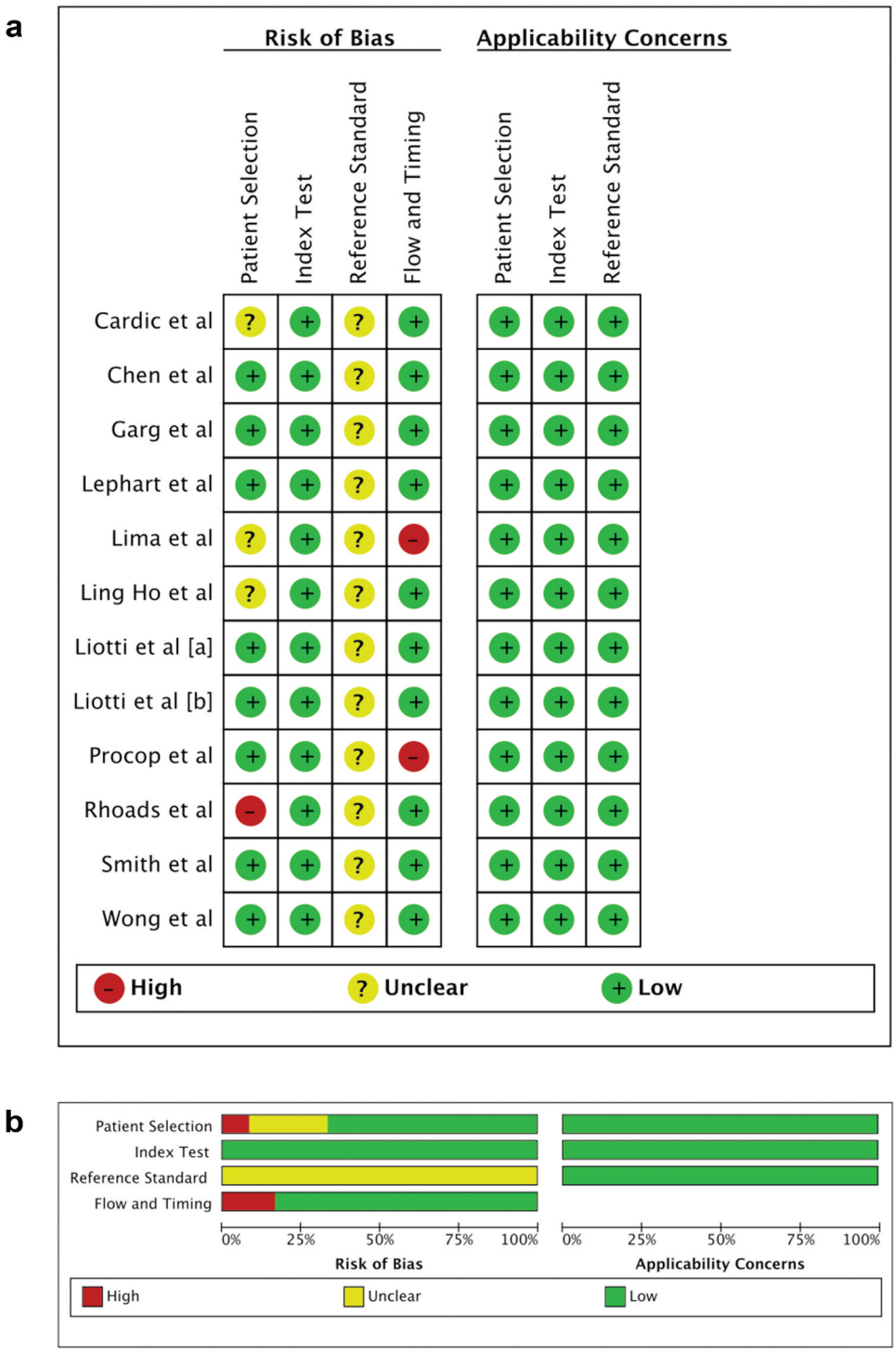


Figure 4. Methodological quality of the included studies. (a) Individual assessment and (b) summary.

sample matrix [31]. The inhibitory effect of the raw samples not only is observable in RT-PCR assays but has also been shown to occur in isothermal amplification assays such as loop-mediated isothermal amplification [32,33].

Other factors, such as LoD (limit of detection), also contribute to differences in comparative performance between kits. Despite ID NOW COVID-19 demonstrating comparable analytical LoD (Table 1), Zhan et al. [28] observed that ID NOW COVID-19 had much higher LoD (20,000 copies/mL) than that claimed (100 copies/mL). Therefore, caution should be considered when using ID NOW COVID-19 for patients with lower viral load, despite having shorter turnaround time.

Limitations of our analysis include variations in the reference standard used (due to lack of concrete gold standard diagnostics), patient characteristics, sampling method and medium, specimen variations, and small sample size of each test. Additionally, the low-quality score reported in some studies may also influence the accuracy of our analyses. Therefore, these findings should be interpreted with caution.

In summary, the lower sensitivity found in the ID NOW COVID-19 (Abbott) and the Simplexa COVID-19 Direct should be taken into consideration by decision makers when deciding on a testing platform, particularly in community setting. Appropriate sample specimens as well as confirmatory testing need to be comprehensively evaluated prior to clinical use. In the end, diagnostic accuracy of COVID-19 commercial diagnostic tests should be weighed against their ease of use and speed.

## 5. Expert opinion

Early detection of SARS-CoV-2 is crucial in mitigating the COVID-19 pandemic. Several commercial molecular in vitro SARS-CoV-2 detection tests have been introduced with the Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA). Since the rapid approval process was necessary as a quick response towards demands for diagnostic modalities during the pandemic, post-market surveillance of diagnostics performance becomes even more crucial to ensure optimal field implementation. Therefore, evaluations on the diagnostic performance of commercial molecular in vitro test for SARS-CoV-2 is urgently needed as a guide in choosing the right testing platform for clinical implementation.

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## Declaration of interest

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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