Performance of Antigen Detection Tests for SARS-CoV-2: A Systematic Review and Meta-Analysis

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Abstract: Coronavirus disease 2019 (COVID-19) initiated global health care challenges such as the necessity for new diagnostic tests. Diagnosis by real-time PCR remains the gold-standard method, yet economical and technical issues prohibit its use in points of care (POC) or for repetitive tests in populations. A lot of effort has been exerted in developing, using, and validating antigen-based tests (ATs). Since individual studies focus on few methodological aspects of ATs, a comparison of different tests is needed. Herein, we perform a systematic review and meta-analysis of data from articles in PubMed, medRxiv and bioRxiv. The bivariate method for meta-analysis of diagnostic tests pooling sensitivities and specificities was used. Most of the AT types for SARS-CoV-2 were lateral flow immunoassays (LFIA), fluorescence immunoassays (FIA), and chemiluminescence enzyme immunoassays (CLEIA). We identified 235 articles containing data from 220,049 individuals. All ATs using nasopharyngeal samples show better performance than those with throat saliva (72% compared to 40%). Moreover, the rapid methods LFIA and FIA show about 10% lower sensitivity compared to the laboratory-based CLEIA method (72% compared to 82%). In addition, rapid ATs show higher sensitivity in symptomatic patients compared to asymptomatic patients, suggesting that viral load is a crucial parameter for ATs performed in POCs. Finally, all methods perform with very high specificity, reaching around 99%. LFIA tests, though with moderate sensitivity, appear as the most attractive method for use in POCs and for performing seroprevalence studies.

Keywords: COVID-19; SARS-CoV-2; antigen test; meta-analysis; diagnostic performance; sensitivity; specificity

1. Introduction

COVID-19, caused by SARS-CoV-2, remains a global public health threat that has already claimed more than six million lives (https://covid19.who.int, accessed on 15 May 2022), with modeling estimates suggesting that this figure is probably much higher [1,2]. Vaccines, however, seem to perform well, especially after the administration of booster doses, providing moderate but short-lived protection from SARS-CoV-2 infection but significantly reducing COVID-19-related morbidity and mortality [3–9]. Non-pharmaceutical interventions (test-trace-isolate, hand washing, physical distancing, travel restrictions, school closures, closures of businesses, and stay-at-home orders) have also proved their effectiveness in containing the spread of the pandemic virus before the advent of vaccines [10–12]. Some of these measures will still be needed in our gradual efforts to return to normalcy. Testing in particular is essential to diagnosis, but also to developing and sustaining a reliable surveillance system for the years to come [13,14].

Real-time reverse transcription polymerase-chain-reaction (rt-PCR) test is the benchmark method for the clinical diagnosis of COVID-19 [15–17]. As such, it is designed for use...
with symptomatic people and has high analytical sensitivity. However, rt-PCR can detect viral genetic material even when the virus does not grow in a cell culture, suggesting that the presence of viral nucleic acid may not always reflect contagiousness. Moreover, it requires advanced laboratory equipment, specialist human resources, and significant infrastructure, often in a centralized setting, which increase costs, though these are less relevant for a single patient who needs a definite answer when he/she is tested. In summary, molecular diagnostic testing (nucleic acid amplification tests) becomes a less appealing method for frequent population screening to detect asymptomatic people with SARS-CoV-2 infection and as a tool to rapidly identify, contact-trace, and isolate highly infectious individuals. Antigen detection tests (AT) are immunoassays performed on pharyngeal, nasopharyngeal, nasal or throat swab specimens that detect the presence of a specific viral protein, which indicates viral activity [18,19]. The currently authorized AT include laboratory-based but also point-of-care (POC tests) and self-tests. AT are less expensive than rt-PCR, and most of them give results in approximately 15–30 min. In terms of weaknesses, AT are generally less sensitive than nucleic acid amplification tests. There are three main categories of AT used for the detection of SARS-CoV-2 infection. Lateral flow immunoassays (LFIA) are small, chromatography-based platforms used in POC. The sample is placed on the slot of the test plastic vector and an optical result (color) is obtained within 5–15 min [20]. Fluorescent immunoassays (FIA) are also small, handy, immunochromatography-based tests. The result is read by a fluorescence immunoassay analyzer within 5–20 min and can be performed in POC [21]. The chemiluminescence enzyme immunoassay (CLEIA) is a quick (about 30 min) and sensitive method to detect SARS-CoV-2 antigens. When the sample antigen reacts with the chemiluminescence substrate (antibody), the reaction product emits a photon of light instead of color development, which is read by an automated chemiluminescence analyzer [20].

Healthcare professionals, laboratory staff, and public health experts should comprehend the performance characteristics of AT, identify determinants of the accuracy of AT, and understand the differences among the three approaches to COVID-19-related testing (diagnostic, screening, and surveillance testing). In this respect, the aim of this meta-analysis is to comprehensively search the literature, to identify all relevant studies, to synthesize individual study estimates, and to determine the overall sensitivity and specificity of antigen-based methods for the detection of SARS-CoV-2, in comparison to quantitative rt-PCR (qPCR), for different types of clinical samples, and among both asymptomatic and symptomatic individuals.

2. Material and Methods

2.1. Literature Search Strategy

We conducted this systematic review and meta-analysis following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [22] along with the advice for best practices [23]. We performed the literature search in Pubmed (https://pubmed.ncbi.nlm.nih.gov accessed on 15 May 2022), medRxiv (https://www.medrxiv.org accessed on 15 May 2022) and BioRxiv (https://www.biorxiv.org, accessed on 15 May 2022) up until 4 July 2021. The search terms were “(SARS-CoV-2 OR “Coronavirus disease 2019” OR COVID-19) AND antigen”. References from the selected studies were also scrutinized. Four independent researchers (AT, MP, HM, GB) evaluated search results; potential disagreements were resolved by discussion with GB and PB and consensus. Articles of all languages were considered to avoid gray literature publication bias [24].

2.2. Study Selection Criteria

Eligible criteria for inclusion in the meta-analysis were: (a) diagnosis of SARS-CoV-2 infection based on detection/quantitation of the viral genome by qPCR, according to World Health Organization (WHO)-, Centers for Disease Control (CDC)-, and European Centre for Disease Prevention and Control (ECDC)-approved methods [16,25–27]; (b) detection
or measurement of nucleocapsid (N) or spike (S) proteins of SARS-CoV-2 (qualitatively or quantitatively depending on the method used); and (c) providing the necessary data that allow the calculation of sensitivity and specificity. We included studies that reported data on cases (positive samples) and healthy controls (negative samples) as well as studies with data available only for cases (see also Section 2.5).

2.3. Data Extraction

Data extraction was performed in a predetermined Microsoft Excel® sheet. From each study we extracted the following information: first author’s last name, type of antigen used, type of sample, method of detection used, and the qPCR cycle threshold (Ct) values used for the detection of SARS-CoV-2 RNA. Additionally, the method of antigen testing used was recorded along with the brand name and the name of the manufacturer and the existence of data from the virus culture. Symptomatic and asymptomatic cases as well as male/female ratios were also recorded, if given. To obtain sensitivity and specificity measures, a $2 \times 2$ contingency table was constructed; thus, true positive (TP), false negative (FN), true negative (TN), and false positive (FP) results were recorded. In cases where no controls were used, we used TP and FN values only.

2.4. Study Outcomes

The primary outcome of this meta-analysis was the sensitivity and specificity of AT in relation to qPCR. Secondary outcomes included the performance of AT on different sample types (namely, nasopharyngeal, saliva, and throat samples) and by symptoms (asymptomatic versus symptomatic SARS-CoV-2 infected persons). We also explored the performance of AT across the number of qPCR Ct values (a higher Ct indicated lower viral load).

2.5. Data Analysis

The Quality Assessment of Diagnostic Accuracy Studies 2 (QUADAS-2 tool) was used to assess the quality of the included studies in terms of diagnostic accuracy [28]. The four domains assessed were patient selection, index test, reference standard, and flow and timing. Each domain was evaluated following classifications according to judgment, i.e., low risk, high risk, and unclear risk.

The bivariate meta-analytic method modified for the meta-analysis of diagnostic tests was used [29]. This method has been reported to be equivalent to the so-called hsROC method [30]. It uses logit-transforms of true positive rate (TPR) and false positive rate (FPR) in order to model sensitivity and specificity; it can also be used for the evaluation of between-studies variability (heterogeneity). Studies that include information only for logit (TPR)—that is, only for sensitivity—were included in the bivariate model under the missing at random (MAR) assumption in order to maximize statistical power and allow the modeling of between-studies variability and correlation [31]. Begg’s rank correlation test [32] and Egger’s regression test [33] were used on logit (TPR) to evaluate the presence of publication bias. Stata13 [34] was used to perform the analysis and run the command “mvmeta” with the method of moments for multivariate meta-analyses and meta-regression [35]. Statistical significance was set at $p < 0.05$; meta-analysis was performed when two or more studies were available, whereas tests for publication bias and meta-regression were performed when five or more studies were available.

3. Results

3.1. Characteristics of Studies

Following the literature search in Pubmed, MedRxiv, and BioRxiv by 4 July 2021, we retrieved 4700 unique articles (Figure 1). After scrutinizing abstracts and full papers and testing for eligibility criteria, we ended up with 235 articles, which included 31,387 SARS-CoV-2 infected individuals and 188,636 individuals without SARS-CoV-2 infection (total: 220,049 individuals). Two hundred and sixteen studies provided data on
both cases and controls, while 19 studies reported results only for people with SARS-CoV-2 infection (Figure 1). Table 1 shows the characteristics of the included studies. All studies reported that SARS-CoV-2 infection was confirmed with qPCR of envelope (E), S or N protein according to WHO, CDC and ECDC guidelines. Various methods were used to identify or measure an antigen of SARS-CoV-2. The N antigen was investigated in 225 studies, the S antigen was investigated in eight studies, and in two studies, cumulative estimates were given for N + S or S + E + M (membrane) antigens. Four articles evaluated both N- and S-based assays. Most studies focused on rapid POC tests such as LFIA (181 studies), or FIA (38 studies). Chemiluminescence was used in 21 studies. In total, 83 different kits from 74 manufacturers and 18 in-house tests (LFIA, FIA, CLEIA) from the respective laboratories were used. Thirty-six studies used the same samples to compare different tests from different companies. Twelve studies used twelve unique techniques that are under development (LC-mass spectrometry [36,37], field-effect transistor (FET) based biosensing devices [38], organic electrochemical transistors-OECT [39], voltammetric-based immunosensor [40], optical waveguide-based biosensor technology [41], deep learning-based surface-enhanced Raman spectroscopy [42], paper-based impedance sensor [43], high-field asymmetric waveform ion mobility spectrometry (FAIMS)–parallel reaction monitoring (PRM) [44], a colorimetric biosensor [45], an electrochemical glucose sensor [46], and a urine foaming test [47]). Finally, two studies were performed with urine samples [36,47]. Most studies used nasopharyngeal, nasal, pharyngeal, throat, oropharyngeal or saliva samples. We classified the samples into two groups, named “NSP”, containing the first three sample types, and “TS”, containing the last three types. The type of sample was clearly mentioned in 207 studies, while all types of samples were used without distinction in 31 studies. The results from different types of samples were compared with the same method in 11 studies. Finally, data from 60 studies on asymptomatic persons and 73 on symptomatic patients were also used to explore differences in diagnostic accuracy between these two patients’ groups. The results of the quality assessment of the research using the QUADAS tool are provided in Supplementary Table S1 and in Supplementary File S1.

3.2. Analysis of Diagnostic Performance

A great amount of the available data, for all methods, concerned samples detected with qPCR Ct values of 20, and mostly of 30 and 40. As shown in Table 2, the sensitivity of LFIA tests (using the N antigen) based on NSP samples that were qPCR-positive for Ct < 20 was 0.945 (95% CI: 0.930, 0.961). It declined, however, considerably to 0.329 (95% CI: 0.265, 0.393) for 30 < Ct < 40. LFIA tests using TS samples performed worse in terms of sensitivity, with a highest estimate of 0.805 (95% CI: 0.599, 1.000) in samples positive for Ct < 20 and a lowest of 0.085 (0.000, 0.176) for Ct > 30 (Table 2). The specificity of LFIA on NSP and TS samples (using the N antigen) was very high across all Ct intervals, ranging from 0.959 (95% CI: 0.923, 0.995) to 0.996 (95% CI: 0.993, 0.998). The sensitivity of FIA (using the N antigen) on NSP samples also showed a declining pattern from 0.935 (95% CI: 0.880, 0.990) for Ct < 20 to 0.435 (95% CI: 0.190, 0.680) for 30 < Ct < 40. Specificity was also very high using NSP qPCR positive samples for Ct < 30 (0.992, 95%: 0.979, 1.000). CLEIA (using the N antigen) had high sensitivity based on NSP samples that were PCR-positive for Ct < 30 (0.980, 95% CI: 0.960, 0.999); this estimate, however, was based on a smaller number of studies and dropped considerably at higher Ct (30–40) values (0.515; 95% CI: 0.220, 0.810). The specificity of CLEIA was very high in all comparisons. The evaluation of the performance of other methods (using the N antigen) on NSP and TS samples for the above studied Ct values intervals (0–20, 21–30, and 31–40) was based on a few studies but showed similar patterns. Data on methods using other antigens (i.e., based on S, E or M protein) were too scarce to allow reliable estimations (Table 2).
Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram.
Table 1. Characteristics of the 235 studies included in the meta-analysis.

| Author               | Country of Study | Ag    | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                          | Kit Company                                      | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|----------------------|------------------|-------|----------------|----------------------------------------|-----------------------------------|-----------------------------------------------|------------------|-----------------------------------------------|--------------------|-------|----------|
| Mak et al. [48]      | China            | N     | 1. nsp, 2. ts  | 1. LFIA, 2. LFIA, 3. LFIA/virus culture data | 1. COVID-19 Ag Respi-Strip, 2. NADAL COVID-19 Ag Test, 3. Standard Q COVID-19 Ag | 1. Coris Bioconcept, Belgium, 2. NaVon Minden GmbH, Germany, 3. SD Biosensor, Korea | up to 20/up to 30 | Rapid/optional detector | 35       | 35    | NA       |
| Linares et al. [49]  | Spain            | N     | nsp            | LFIA                                   | Panbio COVID-19 Ag Rapid Test Device | Abbott Rapid Diagnostic Jena GmbH, Jena, Germany | Up to 40         | Rapid                                         | 255                | 60    | NA       |
| Gupta et al. [50]    | India            | N     | nsp            | LFIA                                   | Standard Q rapid antigen detection test | SD Biosensor, Inc., Gurugram                | Up to 40         | Rapid                                         | 330                | 77    | 253      |
| Fenollar et al. [51] | France           | N     | nsp            | LFIA                                   | PANBIO COVID-19 Ag rapid test device | Abbott, USA                                 | Up to 40         | Rapid                                         | 341                | 204   | 137      |
| Nalumansi et al. [52]| Uganda           | N     | nsp            | LFIA                                   | STANDARD Q COVID-19 Ag Test         | SD-Biosensor, Republic of Korea              | Up to 30/30–40   | Rapid                                         | 262                | 90    | 172      |
| Parada-Ricart et al. [53] | Spain        | N     | nsp            | FIA                                    | 2019-nCoV Antigen Rapid Test Kit (FIA) | Shenzhen Bioeasy Biotechnology CO LTD, China | Up to 40         | Rapid/detector                                | 172                | 26    | 146      |
| Lee et al. [54]      | Korea            | S     | nsp            | LFIA/virus culture data                | In-house test                      | Up to 40                                     | Rapid/detector   | 8                               | 3      | 5      |
| Cerutti et al. [55]  | Italy            | N     | nsp            | LFIA                                   | STANDARD Q COVID19 Ag               | SD-Biosensor, RELAB, I                      | Up to 40         | Rapid                                         | 330                | 109   | 221      |
| Diao et al. [56]     | China            | N     | nsp            | FIA                                    | In-house test                      | Up to 40                                     | Rapid/detector   | 502                | 356    | 146    |
| Young et al. [57]    | USA              | N     | nsp            | 1. LFIA, 2. FIA                        | 1. BD Veritor™ System, 2. Sofia 2 SARS Antigen FIA | 1. Becton-Dickinson and Company, USA 2. 2. Quidel, San Diego, CA | Up to 40         | Rapid/optional detector, Rapid/detector      | 612                | 81    | 531      |
| Liotti et al. [58]   | Italy            | N     | nsp            | FIA                                    | STANDARD F COVID19 Ag (FIA)         | SD Biosensor, Suwon, Korea                   | Up to 20/up to 30 | Rapid/detector                                | 359                | 104   | 255      |
| Ogawa et al. [59]    | Japan            | N     | Nsp            | CLEIA                                  | Lumipulse SARS-CoV-2 Ag            | Fujirebio, Tokyo, Japan                      | Up to 40         | Detector                                      | 325                | 24    | 301      |
| Author                  | Country of Study | Ag Type | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                             | Kit Company                              | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|------------------------|------------------|---------|----------------|----------------------------------------|---------------------------------------|------------------------------------------|------------------|-----------------------------------------------|-------------------|-------|----------|
| Hirotsu et al. [60]    | Japan            | N       | nsp            |                                        | LUMIPULSE SARS-CoV-2 Ag kit           | Fujirebio, Inc. (Tokyo, Japan)           | Up to 40         | Detector                                     | 313               | 58    | 255      |
| Nagura-Ikeda et al.    | Japan            | N       | ts             |                                        | LFIA Espline SARS-CoV-2               | Fuji Rebio Inc.                          | Up to 40         | Rapid                                        | 103               | 84    | 19       |
| Mak et al. [62]        | Hong Kong        | N       | 1. nsp/2. ts   |                                        | BIOCREDIT COVID-19 Ag kit             | RapiGEN Inc.                             | Up to 20/30/40/0–20/20–30 | Rapid optional detector | 160               | 51    | 109      |
| Mertens et al. [63]    | Belgium          | N       | nsp            |                                        | LFIA COVID-19 Ag RespiStrip           | Coris BioConcept                         | Up to 30/40       | Rapid                                        | 328               | 132   | 196      |
| Blairon et al. [64]    | Belgium          | N       | nsp            |                                        | LFIA COVID-19 Ag Respi-Strip          | Coris Bioconcept, Gembloux, Belgium      | Up to 40         | Rapid                                        | 774               | 159   | 615      |
| Porte et al. [21]      | Chile            | N       | nsp/ts         |                                        | FIA 2019-nCoV Antigen Rapid Test Kit  | Bioeasy Biotechnology Co., Shenzhen, China | Up to 30         | Rapid/detector                               | 127               | 82    | 45       |
| Scohy et al. [65]      | Belgium          | N       | nsp            |                                        | LFIA COVID-19 Ag Respi-Strip          | Coris BioConcept, Gembloux, Belgium      | Up to 40         | Rapid                                        | 148               | 106   | 62       |
| Lambert-Nicot et al.   | France           | N       | nsp            |                                        | LFIA COVID-19 Ag Respi-Strip          | Coris BioConcept, Gembloux, Belgium      | Up to 40         | Rapid                                        | 138               | 94    | 44       |
| Diao et al. [66]       | China            | N       | nsp            |                                        | In-house test                         |                                         | Up to 30/40–40    | Rapid                                        | 239               | 208   | 31       |
| Beck et al. [67]       | Milwaukee        | N       | nsp            |                                        | Sofia SARS FIA test (SOFIA)           | Quidel, San Diego, CA                    | Up to 40         | Rapid/detector                               | 346               | 61    | 285      |
| Krüttgen et al. [68]   | Germany          | N       | nsp            |                                        | LFIA SARS-CoV-2 Rapid Antigen Test    | Roche, Switzerland                       | Up to 20/30/40    | Rapid                                        | 150               | 75    | 75       |
| Albert et al. [70]     | Spain            | N       | nsp            |                                        | LFIA SARS FIA test (SOFIA)            | Quidel, San Diego, CA                    | Up to 40         | Rapid                                        | 412               | 54    | 358      |
| Chaimayo et al. [71]   | Thailand         | N       | nsp/ts         |                                        | LFIA Standard Q COVID-19 Ag test      | SD Biosensor®, Chuncheongbuk-do, Republic of Korea | Up to 40         | Rapid                                        | 454               | 60    | 394      |
| Author          | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                                   | Kit Company                          | Ct Values Tested           | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|----------------|------------------|----|----------------|----------------------------------------|--------------------------------------------|----------------------------------------|---------------------------|-----------------------------------------------|---------------------|-------|----------|
| Lanser et al.  | Austria          | N  | nsp            | LFIA                                    | Panbio™ COVID-19 Ag Rapid test            | Abbott, Chicago, Illinois             | Up to 30/up to 40/30–40 Rapid                           | 53                 | 51    | 2        |
| Gremmels et al.| The Netherlands/Aruba | N  | nsp            | LFIA                                    | Panbio COVID-19 Ag rapid test device      | Abbott, Lake Country, IL, USA         | Up to 40 Rapid                                      | 2948               | 202   | 2746     |
| Drevinek et al.| Czech Republic   | N  | nsp            | 1. LFIA 2. FIA 1. Panbio COVID-19 Ag Rapid Test 2. Standard F COVID-19 Ag FIA | 1. Abbott, Germany 2. SD Biosensor, Republic of Korea | Up to 20/up to 30/0–20/20–30/30–40 1. Rapid 2. Rapid/detector | 591                  | 223   | 368      |
| Schwob et al.  | Switzerland      | N  | nsp            | 1. LFIA 2. LFIA 3. LFIA 1. STANDARD Q COVID-19 Ag Test 2. Panbio COVID-19 Ag Test 3. COVID-VIRO | 1. SD - Biosensor, Republik of Korea 2. Abbott, Germany 3. AAZ-LMB | Up to 40 Rapid                                      | 928                  | 372   | 556      |
| Corman et al.  | Germany          | N  | nsp            | 1. LFIA 2. LFIA 3. LFIA 1. Panbio COVID-19 Ag Test 2. BIOCREDIT COVID-19 Ag kit 3. Coronavirus Ag Rapid Test Cassette (swab) 4. COVID-19 Ag Respi-Strip 5. RIDA®QUICK SARS-CoV-2 antigen 6. NADAL COVID19-Ag Test 7. SARS-CoV-2 Rapid Antigen Test | 1. Abbott, Germany 2. RapiGEN Inc. 3. Healgen 4. Coris Bioconcept, Gembloux, Belgium 5. R-Biopharm 6. NAL von minden 7. Roche | Up to 40 Rapid                                      | 150                 | 115   | 35       |
| Abdulrahman et al.| Bahrain         | N  | nsp            | LFIA                                    | Panbio COVID-19 antigen rapid test device | Abbott Rapid Diagnostic Jena GmbH, Jena, Germany | Up to 30 Rapid                                      | 4183               | 733   | 3450     |
| Yokota et al.  | Japan            | N  | Nsp, ts        | 1. LFIA 2. CLEIA 1. Espline SARS-CoV-2 2. Lumipulse SARS-CoV-2 Ag kit | 1. Fujirebio, Tokyo, Japan 2. Fujirebio, Tokyo, Japan | Up to 30/up to 40/20–30 1. Rapid 2. Quick/detector | 34                    | 34    | NA       |
| Author                     | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                  | Kit Company                          | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases  | Controls |
|----------------------------|------------------|----|----------------|----------------------------------------|---------------------------|--------------------------------------|------------------|-----------------------------------------------|-------------------|--------|----------|
| Nash et al. [79]           | USA/Brazil       | 1. N 2. S | nsp            | LFIA                                   | In-house                  |                                      | Up to 20/up to 30/40/0–20/20–30/30–40 | Rapid             | 311    | 172      | 139      |
| Van der Moeren et al. [80] | The Netherlands  | N  | nsp            | LFIA                                   | BD Veritor™ System        | Becton-Dickinson and Company, USA   | Up to 20/up to 30/40/0–20/20–30 | Rapid/optional detector | 351    | 17      | 334      |
| Porte et al. [81]          | Chile            | N  | nsp/ts         | 1. FIA 2. FIA                           | 1. SOFIA SARS Antigen FIA 2. STANDARD® F COVID-19 Ag FIA | 1. Quidel Corporation, San Diego, CA, USA 2. SD Biosensor Inc., Gyeonggi-do, Republic of Korea | Up to 30/up to 40 | Rapid/detector | 91      | 59      | 32       |
| Krüger et al. [82]         | Germany/UK       | N  | nsp/ts         | 1. FIA 2. LFIA 3. LFIA/virus culture data | 1. 2019-nCoV Ag Fluorescence Rapid Test Kit 2. COVID-19 Ag Respi-Strip 3. STANDARD Q COVID-19 Ag Test | 1. Shenzhen Bioeasy Biotechnology Co. Ltd., Guangdong Province, China 2. Coris Bioconcept, Gembloux, Belgium 3. SD Biosensor, Inc., Gyeonggi-do, Korea | Up to 30/up to 40 | 1. Rapid/detector 2. Rapid 3. Rapid | 2407   | 72      | 2335     |
| Singh et al. [46]          | San Diego        | S  | nsp            | ECGluS                                 | In-house                  |                                      | Up to 40          | Quick *                                      | 24      | 16      | 8        |
| Ventura et al. [83]        | Italy            | S + E + M | Nsp/ts        | CBS                                    | In-house                  |                                      | Up to 40          | Detector                                     | 94      | 45      | 49       |
| Herrera et al. [84]        | Florida          | N  | nsp            | LFIA                                   | NR/AdventHealth Centra Care |                                      | Up to 40          | Rapid                                        | 1669   | 486     | 1183     |
| Renuse et al. [44]         | USA              | N  | nsp            | FAIMS-PRM                              | In-house                  |                                      | Up to 40          | Detector                                     | 176    | 88      | 88       |
Table 1. Cont.

| Author               | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                                             | Kit Company                                      | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|----------------------|------------------|----|----------------|---------------------------------------|-----------------------------------------------------|--------------------------------------------------|------------------|-----------------------------------------------|-------------------|-------|----------|
| Pickering et al. [85] | UK               | N  | nsp-ts         | LFIA/virus culture data                | 1. Innova Rapid SARS-CoV-2 Antigen Test               | 1. Xiamen Biotime Biotechnology, Fujian, China     | 20–30 Rapid      | Rapid                                         | 200               | 100   | 100      |
|                      |                  |    |                |                                       | 2. Spring Healthcare SARS-CoV-2 Antigen Rapid Test Cassette | 2. Shanghai ZJ Bio-Tech, Shanghai, China           |                  |                                               |                   |       |          |
|                      |                  |    |                |                                       | 3. E25Bio Rapid Diagnostic Test                      | 3. E25Bio, Cambridge, MA, USA                      |                  |                                               |                   |       |          |
|                      |                  |    |                |                                       | 4. Encode SARS-CoV-2 Antigen Rapid Test Device       | 4. Zhuhai Encode Medical Engineering, Zhuhai, China |                  |                                               |                   |       |          |
|                      |                  |    |                |                                       | 5. SureScreen COVID-19 Rapid Antigen Test Cassette   | 5. SureScreen Diagnostics, Derby, UK               |                  |                                               |                   |       |          |
| Harmon et al. [86]   | Washington       | N  | nsp            | FIA                                   | Sofia-2 SARS-CoV-2 Antigen Tests                    | Quidel, San Diego, CA                              | Up to 40 Rapid   | Rapid/detector                                | 23,462            | 83    | 23,379   |
| Korenkov et al. [87] | Germany          | N  | nsp-ts         | LFIA/virus culture data                | STANDARD Q COVID-19 Ag Test                         | SD Biosensor, Inc., Gyeonggi-do, Korea            | Up to 20/up to 30/ up to 40/ (0–20/ 20–30/ 30–40) Rapid | 2028             | 210   | 1818     |
| Ehsan et al. [43]    | Saudi Arabia     | S  | nsp            | Paper-based impedance sensor          | In-house                                            |                                                  | Up to 40 Detector |                                               | 5                 | 3     | 2        |
| Seynaeve et al. [88] | Belgium          | N  | nsp            | LFIA                                  | 1. COVID-19 Ag Respi-Strip                          | 1. Coris Bioconcept, Belgium                       | Up to 30/ Up to 40/ 30–40 Rapid                | 163               | 98    | 65       |
|                      |                  |    |                |                                       | 2. coronavirus antigen rapid test cassette          | 2. Healgen Scientific, LLC, USA                    |                  |                                               |                   |       |          |
| Di Domenico et al. [89] | Italy          | 1. N 2. S | 1. nsp 2. ts   | 1. ELISA based 2. LFIA/virus culture data | 1. Portable COVID-19 Antigen Lab Test               | 1. Stark                                          | Up to 40 Rapid  |                                               | 433               | 36    | 397      |
|                      |                  |    |                |                                       | 2. Panbio17 COVID-19 Ag Rapid Test Device           | 2. Abbott Diagnostic GmbH, Jena, Germany          |                  |                                               |                   |       |          |
| Kiro et al. [90]     | India            | N  | nsp            | FIA                                   | STANDARD F COVID-19 Ag FIA                          | SD Biosensor Inc., Gyeonggi-do, Republic of Korea | Up to 40 Rapid/detector                          | 354               | 136   | 218      |
Table 1. Cont.

| Author            | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                  | Kit Company                          | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|-------------------|------------------|----|----------------|----------------------------------------|---------------------------|--------------------------------------|------------------|-----------------------------------------------|-------------------|-------|----------|
| Smith et al.      | Illinois         | N  | 1. nsp-ts 2. nsp | FIA/virus culture data                  | SOFINA SARS Antigen FIA   | Quidel Corporation, San Diego, CA, USA | Up to 40         | Rapid/detector                               | 43                | 43    | NA       |
| L’Huillier et al. | Switzerland      | N  | nsp           | LFIA                                   | Panbio™ COVID-19 Ag Rapid Test Device | Abbott Diagnostic GmbH, Jena, Germany | Up to 40         | Rapid                                        | 822               | 119   | 703      |
| Gupta et al.      | India            | S  | nsp           | ELISA                                  | In-house                 |                                       | Up to 40         | Quick                                        | 232               | 44    | 188      |
| Wagenhäuser et al.| Germany          | N  | ts            | LFIA                                   | 1. NADAL COVID-19 Ag Test 2. Panbio COVID-19 Ag rapid test device 3. MEDsan SARS-CoV-2 Antigen Rapid Test | 1. Nal Von Minden GmbH, Germany 2. Abbott Laboratories, Abbott Park IL, USA 3. MEDsan GmbH, Hamburg, Germany | Up to 40         | Rapid                                        | 5056              | 101   | 4955     |
| Fernandez et al.  | Spain            | N  | nsp           | FIA                                    | LumiraDx™                 | LumiraDx™ Limited, Londres, Reino Unido | Up to 40         | Rapid/detector                               | 46                | 24    | 22       |
| Amer et al.       | Egypt            | N  | nsp-ts        | LFIA                                   | STANDARD Q COVID-19 Ag Test | SD Biosensor, Inc., Gyeonggi-do, Korea | Up to 40         | Rapid                                        | 47                | 45    | 2        |
| Baccani et al.    | Italy            | N  | nsp           | 1. CLEIA 2. FIA 3. FIA                 | 1. Lumipulse G SARS-CoV-2 Ag 2. STANDARD® F COVID-19 Ag FIA 3. AFIAS COVID-19 Ag | 1. Fujirebio, Tokyo, Japan 2. SD Biosensor, Suwon-si, Korea 3. Menarini, Florence, Italy | Up to 30/Up to 40/Up to 30-40 | 1. Quick/detector 2. Rapid/detector 3. Rapid/detector | 375               | 85    | 290      |
| Matsuzaki et al.  | Japan            | N  | nsp           | CLEIA                                  | 1. VITROS® SARS-CoV-2 Antigen Test 2. LUMIPULSE® SARS-CoV-2 Ag Test | 2. Ortho Clinical Diagnostics, Rochester, NY, USA 3. Fujirebio, Tokyo, Japan | Up to 40         | 1. Quick/detector 2. Quick/detector          | 128               | 49    | 79       |
| Jakobsen et al.   | Denmark          | N  | nsp           | LFIA                                   | STANDARD Q COVID-19 Ag Test | SD Biosensor, Inc., Gyeonggi-do, Korea | Up to 40         | Rapid                                        | 4811              | 221   | 4590     |
| Ngo Nsoga et al.  | Switzerland      | N  | nsp-ts        | LFIA/virus culture data                | Panbio™ COVID-19 Ag Rapid Test Device | Abbott Diagnostic GmbH, Jena, Germany | Up to 40         | Rapid                                        | 402               | 168   | 234      |
| Author                  | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                      | Kit Company                          | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases Controls |
|-------------------------|------------------|----|----------------|----------------------------------------|------------------------------|--------------------------------------|------------------|-----------------------------------------------|------------------|---------------|
| Funabashi et al. [41]   | Japan            | N  | nsp            | Optical waveguide-based biosensor technology | In-house                     |                                      | Up to 40        | Detector                                      | 64               | 34            |
| Smith et al. [101]      | Maryland         | N  | nsp            | FIA                                    | SOFIA SARS Antigen FIA        | Quidel Corporation, San Diego, CA, USA | Up to 40        | Rapid/detector                                | 2887             | 235           | 2652          |
| Eleftheriou et al. [102]| Greece           | N  | nsp            | LFIA                                   | Panbio™ COVID-19 Ag Rapid Test Device | Abbott Diagnostic GmbH, Jena, German | Up to 40        | Rapid                                         | 744              | 51            | 693           |
| Huang et al. [42]       | China            | S  | ts             | Deep learning-based surface-enhanced Raman spectroscopy | In-house                     |                                      | Up to 40        | NA/detector                                    | 57               | 30            | 27            |
| Lindner et al. [103]    | Germany          | N  | nsp-ts         | LFIA                                   | STANDARD Q COVID-19 Ag Test   | SD Biosensor, Inc., Gyeonggi-do, Korea | Up to 20/Up to 30/Up to 40/0–20/20–30/30–40 | Rapid             | 146             | 40            | 106           |
| Ferte et al. [104]      | France           | N  | nsp            | LFIA                                   | Panbio™ COVID-19 Ag Rapid Test Device | Abbott Diagnostic GmbH, Jena, German | Up to 40        | Rapid                                         | 688              | 52            | 636           |
| Fernandez-Montero et al. [105] | Spain        | N  | nsp-ts        | LFIA                                   | SARS-CoV-2 Rapid Antigen Test | Roche                              | Up to 20/Up to 30/Up to 40/0–20/20–30/30–40 | Rapid             | 2543             | 49            | 2494          |
| Hoehl et al. [106]      | Germany          | N  | nsp            | LFIA                                   | RIDA®QUICK SARS-CoV-2 Antigen | R-Biopharm AG                      | Up to 30        | Rapid                                         | 9                | 9             | NA            |
| Author          | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                          | Kit Company                                 | Ct Values Tested                          | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|-----------------|------------------|----|----------------|---------------------------------------|-----------------------------------|-------------------------------------------|-------------------------------------------|---------------------------------------------|-------------------|-------|----------|
| Lee et al.      | Korea            | N  | nsp            | LFIA                                  | STANDARD Q COVID-19 Ag Test        | SD Biosensor, Inc., Gyeonggi-do, Korea   | Up to 20/Up to 30/Up to 40/0–20/20–30/30–40 | Rapid                                                      | 680               | 380   | 300      |
| Mayanskiy et al.| Russia           | N  | nsp            | ELISA                                 | CoviNAg ELISA                      | XEMA, Russia                             | Up to 20/Up to 30/Up to 40/0–20/20–30/30–40 | Detector                                                    | 277               | 182   | 95       |
| Leixner et al.  | Austria          | N  | nsp            | LFIA                                  | AMP Rapid Test SARS-CoV-2 Ag       | AMP Diagnostics, AMEDA Labordiagnostik GmbH, Graz, Austria | Up to 30/Up to 40/30–40                   | Rapid                                                       | 392               | 94    | 298      |
| Hirotsu et al.  | Japan            | N  | nsp            | 1. CLEIA 2. CLEIA                     | 1. LUMIPULSE® SARS-CoV-2 Ag Test 2. Elecsys® SARS-CoV-2 Antigen Assay | Fujirebio, Tokio, Japan 2. Roche, Basel, Switzerland | Up to 40                                      | Detector                                                   | 637               | 487   | 150      |
| Chavan et al.   | USA              | N  | urine          | mass spectrometry                    | In-house                           |                                           | Up to 40                                      | Detector                                                   | 50                | 39    | 11       |
| Fiedler et al.  | Germany          | N  | nsp            | CLEIA/virus culture data              | LIASON® SARS-CoV-2 Ag              | DiaSorin                                  | Up to 40                                      | Detector                                                   | 182               | 110   | 72       |
| Dierks et al.   | Germany          | N  | nsp            | 1. FIA 2. LFIA                        | 1. LumiraDx™ 2. NADAL COVID-19 Ag Test | 1. LumiraDx™ Limited, London, United Kingdom 2. NaL Von Minden GmbH, Germany | Up to 40                                      | 1. Rapid/detector 2. Rapid                           | 444               | 11    | 433      |
| Terpos et al.   | Slovenia          | N  | nsp            | LFIA                                  | COVID-19 Antigen Detection Kit (Colloidal Gold) | Zhuhai Lituo Biotechnology Co., Ltd.   | Up to 30/Up to 40/30–40                     | Rapid                                                       | 358               | 114   | 244      |
| Osmanodja et al.| Germany          | N  | nsp-ts         | LFIA                                  | Dräger Antigen Test SARS-CoV-2     | Dräger Safety AG and Co. KGaA Lübeck, Germany | Up to 20/Up to 30/Up to 40/0–20/20–30/30–40 | Rapid                                                       | 379               | 70    | 309      |
| Author              | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                        | Kit Company                      | Ct Values Tested | Signal Detection [Rapid (w/o Detector)/Quick] | Total Individuals | Cases | Controls |
|---------------------|------------------|----|----------------|----------------------------------------|---------------------------------|----------------------------------|------------------|-----------------------------------------------|-------------------|-------|----------|
| Harris et al. [115] | USA              | N  | nsp            | FIA                                    | SOFIA SARS Antigen FIA          | Quidel Corporation, San Diego, CA, USA | Up to 30/Up to 40/30–40 Rapid/detector | 2429              | 324               | 2105      |
| Cento et al. [116]  | Italy            | N  | nsp            | FIA                                    | LumiraDx™                      | LumiraDx™ Limited, Londres, Reino Unido | Up to 30/Up to 40/30–40 Rapid/detector | 960               | 347               | 613       |
| Kumar et al. [117]  | India            | N  | nsp            | LFIA                                   | STANDARD Q COVID-19 Ag Test     | SD Biosensor, Inc., Gyeonggi-do, Korea | Up to 40 Rapid   | 6                 | 6                  | NA      |
| Orsi et al. [118]   | Italy            | N  | nsp            | FIA                                    | 1. FREND™ COVID-19 Ag          | 1. NanoEntek, Korea 2. SD Biosensor; Suwon-si, Korea | Up to 30/Up to 40/30–40 Rapid/detector | 110              | 60                | 50        |
| Blairon et al. [119]| Belgium          | N  | nsp            | LFIA/virus culture data                | 1. Coronavirus Ag Rapid Test Cassette 2. GSD NovaGen SARS-CoV-2 (COVID-19) Antigen Rapid Test 3. Aegle Coronavirus Ag Rapid Test Cassette | 1. BioRad 2. NovaTec Immunodiagnostica GmbH 3. LumiraDx | Up to 20/Up to 30/Up to 40/20–30/30–40 Rapid | 199              | 97                | 102      |
| Bornemann et al. [120] | Germany          | N  | nsp            | FIA                                    | SOFIA SARS Antigen FIA          | Quidel Corporation, San Diego, CA, USA | Up to 30/Up to 40/30–40 Rapid/detector | 1391             | 91                | 1300     |
| Kruger et al. [121] | Germany          | N  | 1, nsp 2, ts 3, nsp-ts | LFIA                                  | Panbio™ COVID-19 Ag Rapid Test Device | Abbott Diagnostic GmbH, Jena, German | Up to 30/Up to 40/30–40 Rapid | 1108             | 106               | 1002     |
| Eissa et al. [40]   | Saudi Arabia     | N  | nsp            | Voltammetric-based immunosensor        | In-house                       |                                   | Up to 30/Up to 40/30–40 Detector | 6                | 5                 | 1        |
| Shaikh et al. [122] | USA              | N  | nsp            | LFIA                                   | BinaxNOWTM COVID-19 Ag Card     | Abbott Diagnostics Scarborough, Inc., USA | Up to 40 Rapid   | 199              | 39                | 160      |
| Diez Flecha et al. [123] | Spain            | N  | nsp            | LFIA                                   | Panbio™ COVID-19 Ag Rapid Test Device | Abbott Diagnostic GmbH, Jena, German | Up to 30/Up to 40/30–40 Rapid | 55               | 49                | 6        |
| Author                  | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name          | Kit Company                                      | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|------------------------|------------------|----|---------------|----------------------------------------|-------------------|-------------------------------------------------|-----------------|-----------------------------------------------|------------------|-------|----------|
| Yokota et al. [124]    | Japan            | N  | ts            | CLEIA                                  | In-house          | Up to 40                                        | detector        | 2056                                         | 89               | 1967  |
| Guo et al. [39]        | Saudi Arabia     | N  | 1. nsp 2. ts 3. nsp-ts | OECT                                  | In-house          | Up to 40                                        | detector        | 24                                           | 11               | 13    |
| Klein et al. [125]     | Germany          | N  | nsp           | LFIA                                   | Panbio™ Ag-RDT    | Up to 20/Up to 30/Up to 40/0–20/20–30/30–40 | Rapid           | 290                                         | 39               | 251   |
| Caramello et al. [126] | Italy            | N  | nsp           | LFIA                                   | Panbio™ Ag-RDT    | Up to 40                                        | 1. Rapid 2. Rapid/detector | 324                                         | 210             | 114   |
| Koeleman et al. [127]  | Netherlands      | N  | nsp-ts        | LFIA                                   | Panbio™ Ag-RDT    | Up to 40                                        | Rapid           | 980                                         | 340             | 640   |
| Šterbenc et al. [128]  | Slovenia         | N  | nsp           | LFIA                                   | Panbio™ Ag-RDT    | Up to 40                                        | Rapid           | 191                                         | 2               | 189   |
| Kumar et al. [129]     | India            | N  | nsp-ts        | FIA                                    | STANDARD™ Q COVID-19 Ag test kit | Up to 40                                        | Rapid/detector  | 204                                         | 12              | 192   |
| Author               | Country of Study | Ag  | Type of Sample | Ag Detection Method/Virus Culture Data                                                                 | Kit Name                      | Kit Company                          | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|---------------------|------------------|-----|----------------|--------------------------------------------------------------------------------------------------------|-------------------------------|--------------------------------------|------------------|-----------------------------------------------|-------------------|-------|----------|
| Soleimani et al.    | Belgium          | N   | nsp            | FIA                                                                                                   | 1. COVID19 speed-antigen test | 1. BioSpeedia                        | Up to 30/Up to 40/30–40 Rapid/detector | 401                           | 196   | 205      |
| Takeuchi et al.     | Japan            | N   | nsp            | LFIA                                                                                                   | Panbio™ COVID-19 Ag rapid test | 2. Abbott                            | Up to 30          | Rapid                                         | 862                           | 51    | 811      |
| Linares et al.      | Spain            | N   | nsp            | 1. LFIA 2. FIA                                           | Panbio™ COVID-19 Ag rapid test | 1. Abbott Rapid Diagnostics GmbH, Jena | Up to 20/Up to 30/20–30 1. Rapid | 356                           | 170   | 186      |
| Homza et al.        | Czech Republic   | N   | nsp            | 1. LFIA 2. FIA                                           | Panbio™ COVID-19 Ag rapid test | 2. SD Biosensor, Inc.                | Up to 20/Up to 30/20–30 Rapid/detector | 491                           | 164   | 327      |
| Van der Moeren et al| Netherlands       | N   | nsp-ts         | CLEIA                                                                                                  | 20–30 Rapid Test Device 2. D-Biosensor STANDARD F COVID-19 Ag | 1. Abbott Rapid Diagnostics GmbH, Jena | BD veritor system for rapid detection of SARS-CoV-2 (VRD) Becton-Dickinson and Company, USA | 978                           | 161   | 817      |
| Brihn et al.        | USA              | N   | nsp            | FIA                                                                                                    | Panbio™ COVID-19 Antigen Fluorescent Immunoassay | Quidel Corporation                | Up to 30          | Rapid/detector                                      | 2039                          | 149   | 1890     |
| Nordgren et al.     | Sweden           | N   | nsp            | LFIA/virus culture, data, 1. Panbio™ COVID-19 Ag Rapid, Test, 2. Zhejiang Orient Gene 1. Abbott 2. Healgien Biotech Coronavirus Ag rapid test cassette | Standard Q COVID-19 Ag       | SD Biosensor, Korea                  | Up to 20/Up to 40/20–30 Rapid | 462                           | 156   | 306      |
| Holzner et al.      | Germany          | N   | nsp            | LFIA                                                                                                   | Standard Q COVID-19 Ag       | SD Biosensor, Korea                  | Up to 30          | Rapid                                         | 2280                          | 456   | 1824     |
| Kim et al.          | Korea            | N   | nsp            | LFIA                                                                                                   | GenBody COVID-19 Ag test     | GenBody Inc.                         | Up to 40/20–30 Rapid | Rapid                                         | 330                           | 130   | 200      |
| Bianco et al.       | Italy            | N   | nsp            | LFIA                                                                                                   | LumiraDx™ SARS-CoV-2 Antigen Test | LumiraDx                           | 30–40            | Rapid/detector                                      | 907                           | 298   | 609      |
Table 1. Cont.

| Author           | Country of Study | Ag  | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                  | Kit Company                | Ct Values Tested | Signal Detection [Rapid (w/wo Detection)/Quick] | Total Individuals | Cases | Controls |
|------------------|------------------|-----|----------------|---------------------------------------|---------------------------|---------------------------|------------------|-----------------------------------------------|-------------------|-------|---------|
| Peña et al. [139] | Chile            | N   | nsp            | LFIA                                  | SARS-CoV-2 RAT            | SD Biosensor              | Up to 30         | Rapid                                         | 842               | 73    | 769     |
| Muhi et al. [140] | Australia        | N   | nsp            | LFIA/virus culture data               | PanBioTM COVID-19 Ag      | Abbott                    | Up to 40         | Rapid                                         | 189               | 26    | 163     |
| Uwamino et al. [141] | Japan           | N   | nsp            | LFIA/virus culture data               | Espline SARS-CoV-2 RAD    | FUJIREBIO, Tokyo, Japan   | Up to 40         | Rapid                                         | 117               | 25    | 92      |
| Thakur et al. [142] | India            | N   | nsp-ts         | LFIA                                  | PathoCatch                | ACCUCARE                  | 20–30            | Rapid                                         | 677               | 84    | 593     |
| Homza et al. [143] | Czech Republic   | N   | nsp            | LFIA/virus culture data               | 1. SARS-CoV-2 Antigen Rapid Test Kit 2. Ecotest COVID-19 Antigen Rapid Test 3. Standard Q COVID-19 Ag 4. Immupass VivaDiag™ SARS-CoV-2 Ag Rapid Test 5. ND COVID-19 Ag test | 1. JOYSBIO (Tianjin) Biotechnology Co., Ltd., Tianjin, China 2. Assure Tech, Hangzhou, China 3. SD Biosensor, Korea 4. VivaChek Biotech (Hangzhou) Co., Ltd., Hangzhou, China 5. ND Biosensor, Eumseong, Korea | Up to 40         | Rapid                                         | 1141              | 407   | 734     |
| Shah et al. [144] | USA              | N   | nsp            | LFIA                                  | BinaxNOW COVID-19 Ag      | Abbott                    | 20–30            | Rapid                                         | 2110              | 334   | 1776    |
| McKay [145]      | USA              | N   | nsp            | LFIA                                  | BinaxNOW Rapid Antigen Test | Abbott                    | Up to 40         | Rapid                                         | 532               | 105   | 427     |
| Yin et al. [146]  | Belgium          | N   | nsp            | LFIA                                  | 1. Panbio™ COVID-19 Ag Rapid Test Device 2. BD Veritor™ SARS-CoV-2 3. COVID-19 Ag Respi-Strip 4. SARS-CoV-2 Rapid Antigen Test | 1. Abbott Rapid Diagnostics, Germany 2. Becton-Dickinson and Company, USA 3. Coris BioConcept, Belgium 4. SD Biosensor, Republic of Korea | 30–40            | Rapid                                         | 760               | 722   | 38      |
### Table 1. Cont.

| Author         | Country of Study | Ag  | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                                                                 | Kit Company | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|----------------|------------------|-----|----------------|----------------------------------------|--------------------------------------------------------------------------|-------------|------------------|-----------------------------------------------|-------------------|-------|----------|
| Baro et al.    | Spain            | N   | nsp            | LFIA                                   | 1. PanBioTM COVID-19 Ag Rapid test                                       |             | Up to 30         | Rapid                                        | 286               | 101   | 185      |
|                |                  |     |                |                                        | 2. CLINITEST® Rapid COVID-19 Antigen Test                                 |             |                  |                                               |                   |       |          |
|                |                  |     |                |                                        | 3. SARS-CoV-2 Rapid Antigen Test                                         |             |                  |                                               |                   |       |          |
|                |                  |     |                |                                        | 4. SARS-CoV-2 Antigen Rapid Test Kit                                     |             |                  |                                               |                   |       |          |
|                |                  |     |                |                                        | 5. COVID-19 Coronavirus Rapid Antigen Test Cassette                        |             |                  |                                               |                   |       |          |
|                |                  |     |                |                                        | 1. Abbott                                                                 |             |                  | Up to 30 Rapid                                |                   |       |          |
|                |                  |     |                |                                        | 2. Siemens                                                                |             |                  |                                              |                   |       |          |
|                |                  |     |                |                                        | 3. Roche                                                                  |             |                  |                                              |                   |       |          |
|                |                  |     |                |                                        | 4. Lepu Medica                                                             |             |                  |                                              |                   |       |          |
|                |                  |     |                |                                        | 5. Surescreen                                                              |             |                  |                                              |                   |       |          |
|                |                  |     |                |                                        |                                                                         |             |                  |                                              |                   |       |          |
| Caputo et al.  | Italy            | N   | nsp-ts         | CLEIA                                  | Lumipulse G SARS-CoV-2 Ag                                                 |             | Up to 40         | Quick/detector                               | 4266              | 503   | 3763     |
| Kényeres et al.| Hungary          | N   | nsp            | LFIA                                   | BIOCREDIT COVID-19 Ag                                                     |             | Up to 30         | Rapid                                        | 37                | 37    | NA       |
| Hauser et al.  | Germany          | N   | nsp            | CLEIA/virus culture data               | LIAISON SARS-CoV-2 antigen test                                           |             | 20–30            | Detector                                     | 196               | 196   | 27       |
| Lefever et al. | Belgium          | N   | nsp            | LFIA/virus culture data                | Liaison antigen test                                                      |             | 20–30           | Rapid                                        | 410               | 200   | 210      |
| Zacharias et al.| Austria         | N   | nsp            | LFIA                                   | SARS-CoV-2 RAT                                                            |             | 30–40           | Rapid                                        | 30                | 24    | 6        |
| Oh et al.      | Korea            | N   | nsp            | LFIA                                   | Standard Q COVID-19 Ag                                                    |             | Up to 30         | Rapid                                        | 118               | 26    | 92       |
| Asai et al.    | Japan            | N   | nsp            | CLEIA                                  | LUMIPULSE SARS-CoV-2 antigen kit                                          |             | 30–40           | Detector                                     | 305               | 63    | 242      |
| Kweon et al.   | Korea            | N   | nsp            | LFIA                                   | 1. AFIAS COVID-19 Ag                                                      |             | Up to 30/Up to 40 | Rapid                                        | 167               | 167   | NA       |
### Table 1. Cont.

| Author                  | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                      | Kit Company                  | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|-------------------------|------------------|----|----------------|----------------------------------------|------------------------------|------------------------------|------------------|-----------------------------------------------|-------------------|-------|----------|
| Menchinelli et al. [156]| Italy            | N  | nsp            | CLEIA/virus culture data               | LUMIPULSE SARS-CoV-2 antigen kit | Fujirebio, Japan             | Up to 20/Up to 30/Up to 40/0–20/20–30/30–40 | Detector          | 594   | 194      | 400      |
| Sood et al. [157]       | USA              | N  | nsp            | LFIA                                   | BinaxNOW rapid antigen test  | Abbott                       | 20–30            | Rapid                          | 774   | 226   | 548      |
| Epstude et al. [158]    | Germany          | N  | nsp            | LFIA                                   | SARS-CoV-2 Rapid Antigen test | Roche®                       | Up to 40         | Rapid                          | 30    | 30    | NA       |
| Smith et al. [91]       | USA              | N  | nsp            | FIA/virus culture data                 | SARS Sofia FIA rapid antigen tests | Quidel                       | Up to 40         | Rapid/detector                | 286   | 286   | NA       |
| Berger et al. [159]     | Switzerland      | N  | nsp            | LFIA/virus culture data                | 1. PanbioTM COVID-19 Ag Rapid Test device 2. Standard Q Ag-RDT | 1. Abbott, 2. SD Biosensor, Roche | 20–30            | Rapid                          | 1064  | 315   | 749      |
| Matsuda et al. [160]    | Brazil           | N  | nsp            | LFIA                                   | 1. COVID-19 Ag ECO Test 2. Panbio COVID-19 Ag Rapid Test | 1. ECO Diagnóstica 2. Abbott, Ludwigshafen, Germany | Up to 40         | Rapid                          | 108   | 29    | 80       |
| Van Honacker et al. [161]| Belgium         | N  | nsp            | LFIA                                   | 1. COVID-19 ag BSS 2. SARS-CoV-2 Ag card 3. Coronavirus AG Rapid test cassette 4. Panbio COVID-19 Ag Rapid Test Device 5. SARS-CoV-2 Rapid Antigen test | 1. Biosynex, Fribourg, Switzerland 2. Biotal health, Madrid, Spain 3. Zhejiang Orient Gene Biotech Co., Zhejiang, China 4. Abbott, Ludwigshafen, Germany 5. SD Biosensor, Gyeonggi-do, Korea | Up to 20/Up to 30/Up to 40/0–20/20–30/30–40 | Rapid                          | 98    | 58    | 40       |
| Boum et al. [162]       | Cameroon         | N  | nsp            | LFIA                                   | SARS-CoV-2 Rapid Antigen test | SD Biosensor                  | 20–30            | Rapid                          | 1090  | 291   | 799      |
| Author          | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                               | Kit Company                                                                 | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|-----------------|------------------|----|----------------|--------------------------------------|----------------------------------------|--------------------------------------------------------------------------------|------------------|-----------------------------------------------|-------------------|-------|----------|
| Mboumba Bouassa et al. [163] | France           | N  | nsp            | LFIA                                 | SIENNA™ COVID-19 Antigen Rapid Test Cassette | Salofa Oy, Salo, Finland; manufactured under license of T&D Diagnostics Canada Pvt. Ltd., Halifax, Canada | Up to 20/Up to 40 Rapid | Rapid                                        | 150               | 100   | 50       |
| Stokes et al. [164] | Canada           | N  | 1. nsp 2. ts   | LFIA                                 | Panbio COVID-19 antigen Rapid Test Device | Abbott, IL, USA                                                                  | Up to 40 Rapid    | 1888                                          | 497               | 1391  |           |
| Landaa et al. [165] | Norway           | N  | nsp-ts         | LFIA                                 | Panbio™ COVID-19 Ag Rapid Test Device  | Abbott Up to 30/Up to 40/30–40 Rapid                                           | 3991             | 250                                           | 3741              |       |           |
| Takeuchi et al. [166] | Japan            | N  | nsp            | LFIA /virus culture data             | QuickNavi™-COVID19 Ag                  | Denka Co., Ltd., Tokyo, Japan Up to 40 Rapid                                    | 1186             | 105                                           | 1081              |       |           |
| Igloi et al. [167] | Netherlands       | N  | nsp            | LFIA /virus culture data             | Roche SD Biosensor SARS-CoV-2 rapid antigen test | Roche Diagnostics Up to 30/Up to 40/30–40 Rapid                                  | 970              | 186                                           | 784               |       |           |
| Masiá et al. [168] | Spain            | N  | 1. nsp 2. ts   | LFIA                                 | Panbio COVID-19 antigen Rapid Test Device | Abbott Rapid Diagnostic Jena GmbH, Jena, Germany Up to 40 Rapid                  | 2174             | 448                                           | 1726              |       |           |
| Jääskeläinen et al. [169] | Finland          | N  | nsp            | 1. FIA 2. LFIA /virus culture data   | 1. Quidel Sofia SARS FIA 2. Standard Q COVID-19 Ag test 3. PanbioTM | 1. Quidel, San Diego, CA 2. SD Biosensor, Republic of Korea 3. Abbott Diagnostic GmbH, Jena, Germany | Up to 30/Up to 40/30–40 1. Rapid/detector 2. Rapid 3. Rapid | 198                                           | 185   | 40       |
| Olearo et al. [170] | Germany          | N  | nsp            | LFIA /virus culture data             | 1. SARS-CoV-2 Rapid Antigen Test (Roche) 2. COVID-19 Rapid Test Device (Abbott) 3. MEDsan SARS-CoV-2 Antigen Rapid Test 4. CLINITEST Rapid COVID-19 Antigen Test | 1. Roche Diagnostics SD Biosensor Korea 2. Abbott Rapid Diagnostics Panbio Ltd. Australia 3. MEDsan GmbH Germany 4. Zhejiang Orient Biotech Co. China | Up to 40 Rapid | 184                                           | 84    | 100   |           |
| Author                      | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                                | Kit Company                                            | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|-----------------------------|------------------|----|----------------|----------------------------------------|-----------------------------------------|--------------------------------------------------------|------------------|-----------------------------------------------|-------------------|-------|----------|
| Toshiaki Ishii et al. [171] | Japan            | N  | 1. nsp         | 2. ts                                  | 1. LFIA                                 | 1. Espline® SARS-CoV-2 2. Lumipulse® SARS-CoV-2         | Up to 20/Up to 30/Up to 40/0–20/20–30/30–40         | 1. Rapid 2. Quick/detector | 893              | 44     | 849      |
| Peña-Rodríguez et al. [172] | Mexico           | N  | nsp            | LFIA                                  | STANDARD™ Q COVID-19 Ag Test            | SD BIOSENSOR                                           | Up to 40         | Rapid                                         | 369               | 104   | 265      |
| Gili et al. [173]           | Italy            | N  | nsp            | CLEIA                                  | Lumipulse® SARS-CoV-2 antigen assay    | Fujirebio, Inc., Tokyo, Japan                          | Up to 40         | Quick/detector                                | 1964              | 185   | 1779     |
| Pérez-García et al. [174]   | Spain            | N  | nsp            | LFIA                                  | 1. CerTest SARS-CoV-2 Ag One Step Card Test 2. Panbio COVID-19 Ag Rapid Test Device | 1. Certest Biotec S. L., Zaragoza, Spain 2. Abbot Rapid Diagnostics GmbH, Jena, Germany | Up to 30/Up to 40/30–40 | Rapid                                         | 320               | 170   | 150      |
| Kilic et al. [175]           | USA              | N  | nsp            | LFIA                                  | BD Veritor SARS-CoV-2                   | Becton, Dickinson, Sparks, MD, USA                     | Up to 40         | Rapid                                         | 1384              | 116   | 1268     |
| Drain et al. [176]           | USA              | N  | nsp            | FIA                                   | LumiraDx SARS-CoV-2 antigen test       | LumiraDx UK Ltd., Dumyat Business Park, Alloa, FK10 2PB, UK) | Up to 40         | Rapid/detector                                | 512               | 123   | 389      |
| Basso et al. [177]           | Italy            | N  | 1. nsp         | 2. ts                                  | 1. LFIA 2. LFIA 3. CLEIA               | 1. ESPLINE rapid test 2. COVID-19 Ag Rapid Test 3. Lumipulse G SARS-CoV-2 Ag | Up to 40         | 1. Rapid 2. Rapid 3. Quick/detector           | 234               | 87    | 147      |
| Pollock et al. [178]         | USA              | nsp | LFIA           | BinaxNOW COVID-19 Ag card              | Abbott Diagnostics Scarborough, Inc.    | Up to 30/Up to 40/30–40 | Rapid                                         | 2307              | 292   | 2015     |
| Ristić et al. [179]          | Serbia           | N  | nsp            | LFIA                                  | STANDARD Q COVID-19 Ag Test            | SD Biosensor, Gyeonggi-do, Korea                       | Up to 40         | Rapid                                         | 120               | 43    | 77       |
| Courtetlemont et al. [180]   | France           | N  | nsp            | LFIA                                  | COVID-VIRO®                            | AAZ, Boulogne Billancourt, France                     | Up to 30/Up to 40/30–40 | Rapid                                         | 248               | 121   | 127      |
| Author                  | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                                                                 | Kit Company                                                                                   | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|-------------------------|------------------|----|----------------|----------------------------------------|---------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|-------------------|-----------------------------------------------|-------------------|-------|----------|
| Thommes et al.          | Austria          | N  | nsp            | LFIA                                    | 1. Panbio™ COVID-19 Ag Rapid test                                       | 2. Novel Coronavirus (2019-nCov) Antigen Detection Kit                                    | Up to 30/Up to 40/Rapid 154 154 NA                             | Up to 30/Up to 40/30–40 Rapid 154 154 NA | 145 | 154 | NA       |
| González-Donapetry et al. | Spain            | N  | nsp            | LFIA                                    | 1. BD Veritor™ System for rapid detection of SARS-CoV-2                  | 2. CareStart™ COVID-19 Ag                                                               | Up to 40 Rapid 440 18 422 | Up to 40 Rapid 440 18 422 | 145 | 154 | NA       |
| Eshghifar et al.         | ?                | N  | ts             | LFIA                                    | 1. Panbio COVID-19 Ag Rapid Test Device                                 | 2. CareStart™ COVID-19 Antigen                                                            | Up to 40 Rapid 5 5 NA                                      | Up to 40 Rapid 5 5 NA                                        | 145 | 154 | NA       |
| Merino et al.           | Spain            | N  | nsp            | LFIA                                    | 1. Panbio™ COVID-19 Ag Rapid Test Device                                 | 2. CareStart™ COVID-19 Antigen                                                            | Up to 30/Up to 40/30–40 Rapid 154 154 NA                             | Up to 30/Up to 40/30–40 Rapid 154 154 NA | 145 | 154 | NA       |
| Author            | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name | Kit Company                           | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|-------------------|------------------|----|----------------|----------------------------------------|----------|---------------------------------------|-----------------|-----------------------------------------------|-------------------|-------|----------|
| Shao et al. [38]  | USA              | 1. N 2. S | nsp            | FET                                   | In-house |                                      | Up to 40        | NA/detector                                    | 38                | 28    | 10       |
| Bullete et al. [185] | Spain            | N  | nsp            | LFIA                                   | Panbio™ Ag-RDT | Abbott Diagnostic GmbH, Jena, Germany | Up to 40        | Rapid                                         | 1367              | 140   | 1222     |
| Torres et al. [186]  | Spain            | N  | nsp            | LFIA/virus culture data                | CLINITEST® Rapid COVID-19 Antigen Test | Siemens, Healthineers, Erlangen, Germany | Up to 40        | Rapid                                         | 270               | 116   | 154      |
| Lindner et al. [187]  | Germany          | N  | nsp            | LFIA                                   | STANDARD Q COVID-19 Ag Test | SD Biosensor, Inc., Gyeonggi-do, Korea | Up to 20/Up to 30/Up to 40/0–20/20–30/30–40 | Rapid | 179               | 41    | 138    |
| Hirotsu et al. [188]  | Japan            | N  | nsp            | CLEIA                                  | LUMIPULSE SARS-CoV-2 antigen test | Fujirebio, Inc., Tokyo, Japan | Up to 40        | Detector                                      | 1029              | 40    | 989      |
| Salvagno et al. [189]  | Italy            | N  | nsp-ts         | LFIA                                   | Roche SARS-CoV-2 Rapid Antigen Test | Roche Diagnostics, Basel, Switzerland | Up to 40        | Rapid                                         | 321               | 149   | 172      |
| Veyrenche et al. [190]  | France           | N  | nsp            | LFIA                                   | Coris COVID-19 Ag Respi-Strip | BioConcept | Up to 30/Up to 40/30–40 | Rapid | 65                | 45    | 20     |
| Porte et al. [191]   | Chile            | N  | nsp            | FIA                                    | 1. SOFIA SARS Antigen FIA 2. STANDARD F SARS-CoV-2 Ag FIA | 1. Quidel Corporation, San Diego, CA, USA 2. SD Biosensor Inc., Gyeonggi-do, Republic of Korea | Up to 40 | Rapid/detector | 64                | 32    | 32       |
| Dominguez Fernández et al. [192]  | Spain           | N  | nsp            | LFIA                                   | Panbio™ rapid antigens test device | Abbott | Up to 40 | Rapid | 30                | 20    | 10       |
| Kobayashi et al. [193]  | Japan            | N  | nsp            | LFIA                                   | 1. Lumipulse Presto SARS-CoV-2 Ag 2. Espline SARS-CoV-2 | 1. Fujirebio Inc., Tokyo, Japan 2. Fujirebio Inc., Tokyo, Japan | Up to 40 | 1. Quick/detector 2. Rapid | 300               | 100   | 200      |
| Houston et al. [194]   | UK               | N  | nsp            | LFIA                                   | Innova SARS-CoV-2 Antigen Rapid Qualitative Test | Lotus Global Company, London, UK | Up to 40 | Rapid | 728               | 280   | 448      |
| Author                  | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                      | Kit Company                          | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|------------------------|------------------|----|----------------|--------------------------------------|------------------------------|--------------------------------------|------------------|-----------------------------------------------|-------------------|-------|----------|
| Gremmels et al. [73]   | Netherlands/Aruba | N  | nsp            | LFIA                                 | Panbio™ COVID-19 antigen     | Abbott (Lake Country, IL, USA)       | Up to 40         | Rapid                                        | 1573              | 202   | 1371     |
| Ciotti et al. [195]    | Italy            | N  | nsp            | LFIA                                 | Coris COVID-19 Ag Respi-Strip| Coris BioConcept                    | Up to 40         | Rapid                                        | 50                | 39    | 11       |
| Okoye et al. [196]     | USA              | N  | nsp            | LFIA                                 | Abbott BinaxNOW COVID-19 antigen card | Abbott Diagnostics Scarborough, Inc.| Up to 20/Up to 30/Up to 40/0–20/20–30/30–40 | Rapid                         | 2638              | 45    | 2593     |
| Kurtulmus et al. [47]  | Turkey           | N  | urine          | UFT                                  | In-house                     | Up to 40                            | Rapid            | 201                                           | 86                | 115   |           |
| Saadi et al. [37]      | France           | N  | nsp            | 1. LFIA 2. LFIA 3. LC-MS              | 1. NG Test Ag 2. COVID-19 Ag Respi-Strip 3. In-house | 1. NG Biotech, France 2. Coris, Belgium | Up to 20/Up to 30/Up to 40/0–20/20–30/30–40 | 1. Rapid 2. Rapid 3. NA/detector | 19                | 12    | 7        |
| James et al. [197]     | USA              | N  | nsp            | LFIA                                 | BinaxNOW COVID-19 Ag Card tests | Abbott Diagnostics, Scarborough     | Up to 40         | Rapid                                        | 2339              | 152   | 2187     |
| Villaverde et al. [198]| Spain            | N  | nsp            | LFIA                                 | Panbio COVID-19 Ag Rapid Test| Abbott Rapid Diagnostic             | Up to 40         | Rapid                                        | 1620              | 77    | 1543     |
| Pekosz et al. [199]    | USA              | N  | nsp            | LFIA/virus culture data              | BD Veritor Antigen Test      | Becton, Dickinson and Company, BD Life Sciences-, San Diego, California | Up to 40         | Rapid                                        | 38                | 38    | NA       |
| Kohmer et al. [200]    | Germany          | N  | nsp            | LFIA/virus culture data              | 1. RIDA®QUICK SARS-CoV-2 Antigen 2. SARS-CoV-2 Rapid Antigen Test 3. NADAL® COVID-19 Ag Test (test cassette) 4. LumiraDx™ Platform SARS-CoV-2 Ag Test | 1. R-Biopharm AG, Darmstadt, Germany 2. Roche Diagnostics GmbH, Mannheim, Germany 3. Nal von Minden GmbH, Regensburg, Germany 4. LumiraDx GmbH, Cologne, Germany | Up to 40         | Rapid                                        | 100               | 74    | 26       |
Table 1. Cont.

| Author          | Country of Study | Ag   | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                  | Kit Company                          | Ct Values Tested | Signal Detection [Rapid (w/o w/v Detector)/Quick] | Total Individuals | Cases | Controls |
|-----------------|------------------|------|----------------|---------------------------------------|---------------------------|--------------------------------------|-----------------|------------------------------------------------|------------------|-------|----------|
| Prince-Guerra et al. [201] | USA   | N    | nsp            | LFIA /virus culture data               | BinxNOW COVID-19 Ag Card  | Abbott Diagnostics Scarborough, Inc. | Up to 40        | Rapid                                          | 3419             | 299   | 3120     |
| Möckel et al. [202]     | Germany | N    | nsp            | LFIA /virus culture data               | Roche SARS-CoV-2 rapid antigen test | SD Biosensor                   | Up to 40        | Rapid                                          | 271              | 89    | 182      |
| Rottenstreich et al. [203] | Israel | N    | nsp            | LFIA                                   | NowCheck COVID-19 Ag Test | Bionote Inc., Hwaseong-si, Republic of Korea | Up to 30/Up to 40/Up to 40 | Rapid                                          | 1326             | 9     | 1317     |
| Favresse et al. [204]   | Belgium | N    | nsp            | LFIA                                   | 1. Biotical SARS-CoV-2 Ag card 2. Panbio™ COVID-19 Ag Rapid Test Device 3. Coronavirus Ag Rapid Test Cassette 4. Roche SARS-CoV-2 Rapid Antigen Test 5. VITROS Immunodiagnostic Products SARS-CoV-2 Antigen test | Biotical Health, Madrid, Spain Abbott, Chicago, IL, USA Healgen Scientific, Houston, TX, USA Roche Diagnostics, Basel, Switzerland Ortho Clinical Diagnostics, Raritan, NJ, USA | Up to 20/Up to 30/Up to 40/30–40/30–40 | Rapid                                          | 188              | 96    | 92       |
| Osterman et al. [205]   | Germany | N    | nsp-ts         | LFIA                                   | 1. SARS-CoV-2 Rapid Antigen Test 2. STANDARD™ F COVID-19 Ag | SARS-CoV-2 Rapid Antigen Test | Up to 40        | 1. Rapid 2. Rapid/detector                     | 1572             | 826   | 746      |
| Pollock et al. [206]    | USA    | N    | nsp            | CLEIA/virus culture data               | MSD S-PLEX SARS-CoV-2 N assay | MSD Meso Scale Discovery [MSD] | Up to 40        | Quick/detector                                | 226              | 136   | 90       |
| Aoki et al. [207]       | Japan   | N    | nsp            | CLEIA                                  | Lumipulse® SARS-CoV-2 Ag | Fujirebio Inc., Tokyo, Japan | Up to 40        | Quick/detector                                | 548              | 30    | 518      |
| Torres et al. [208]     | Spain   | N    | nsp            | LFIA                                   | Panbio™ COVID-19 Ag        | Abbott Diagnostics, Jena, Germany | Up to 40        | Rapid                                          | 634              | 79    | 555      |
| Alemany et al. [209]    | Spain   | N    | nsp            | LFIA                                   | Panbio COVID-19 Ag Test    | Abbott Rapid Diagnostics, Germany | Up to 30/Up to 40/30–40 | Rapid                                          | 1406             | 951   | 455      |
| Author               | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name               | Kit Company                          | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|---------------------|------------------|----|----------------|----------------------------------------|------------------------|--------------------------------------|-----------------|-----------------------------------------------|------------------|-------|----------|
| Rastawicki et al.   | Poland           | N  | nsp            | FIA                                    | PCL COVID-19 Ag        | PCL Inc., Korea                      | Up to 40        | Rapid                                        | 42               | 36    | 6        |
| Yamamoto et al.     | Japan            | N  | nsp            | LFIA                                   | ESPLINE SARS-CoV-2     | Fujirebio Inc., Japan                | Up to 40        | Rapid                                        | 229              | 128   | 101      |
| Kashiwagi et al.    | Japan            | N  | 1. ts 2. nsp   | LFIA                                   | ESPLINE® SARS-CoV-2    | Fujirebio Inc., Tokyo                | Up to 40        | Rapid                                        | 6                | 4     | 2        |
| Pilarowski et al.   | USA              | N  | nsp            | LFIA /virus culture data               | BinaxNOW rapid antigen test | Abbott Diagnostics Scarborough, Inc. | Up to 30/Up to 40/30–40 | Rapid                                        | 871              | 26    | 845      |
| Aoki et al.         | Japan            | N  | nsp            | LFIA                                   | Espline® SARS-CoV-2    | Fujirebio Inc., Japan                | Up to 40        | Rapid                                        | 129              | 63    | 66       |
| Pray et al.         | Wisconsin        | N  | nsp            | FIA /virus culture data                | Sofia SARS Antigen     | Quidel Corporation                   | Up to 40        | Rapid/detector                               | 1098             | 57    | 1041     |
| Strömer et al.      | Germany          | N  | nsp            | LFIA /virus culture data               | 1. NADAL® COVID-19 Ag Test 2. Panbio™ COVID-19 Antigen | Nal von Minden GmbH, Moers, Germany Abbott Rapid Diagnostics, Germany | Up to 20/Up to 30/Up to 40/0–20/20–30/30–40 | Rapid                                        | 124              | 124   | NA       |
| Toptan et al.       | Germany          | N  | nsp-ts         | LFIA /virus culture data               | novel antigen test     | R-Biopharm                           | Up to 40        | Rapid                                        | 67               | 58    | 9        |
| Turcato et al.      | Italy            | N  | ts             | LFIA                                   | STANDARD Q COVID-19 Ag (R-Ag) | SD BIOSENSOR, KR                     | Up to 40        | Rapid                                        | 3410             | 223   | 3187     |
| Mak et al.          | Hong Kong        | N  | 1. nsp-ts 2. nsp 3. ts | LFIA /virus culture data | Panbio COVID-19 Ag Rapid Test Device | Abbott Rapid Diagnostics, Germany | Up to 20/Up to 30/Up to 40/0–20/20–30/30–40 | Rapid                                        | 35               | 8     | 27       |
| Zhang et al.        | China            | N  | nsp-ts         | LFIA                                   | SARS-CoV-2 N-protein test strip | Beijing Savant Biotechnology Co., Ltd. | Up to 40        | Rapid/detector                               | 547              | 247   | 300      |
| Agulló et al.       | Spain            | N  | 1. nsp 2. ts 3. nsp-ts | LFIA                                   | Panbio COVID-19 Ag-RDT | Abbott Rapid Diagnostics Jena GmbH, Jena, Germany | Up to 40        | Rapid                                        | 659              | 126   | 527      |
| Tanimoto et al.     | Japan            | N  | nsp            | LFIA                                   | ESPLINE SARS-CoV-2®    | Fujirebio Inc., Tokyo, Japan          | Up to 40        | Rapid                                        | 8                | 2     | 6        |
| Author                  | Country of Study | Ag    | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                                   | Kit Company                      | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|-------------------------|------------------|-------|----------------|---------------------------------------|--------------------------------------------|--------------------------------------|------------------|-----------------------------------------------|-------------------|-------|----------|
| Lindner et al. [223]    | Germany          | N     | nsp            | LFIA                                  | STANDARD Q COVID-19 Ag Test               | SD Biosensor, Inc., Gyeonggi-do, Korea | Up to 20/Up to 30/Up to 40/0–20/20–30/30–40 | Rapid            | 39    | 39       |
| Abdelrazik et al. [224] | Egypt            | N     | nsp            | LFIA                                  | BIOCREDIT COVID-19 Ag test               | RapiGEN Inc.                        | Up to 30/Up to 40/40–40 | Rapid            | 188   | 188      |
| Weitzel et al. [225]    | Chile            | N     | 1. nsp-ts 2. nsp | 1. LFIA 2. FIA 3. FIA | 1. Biocredit One Step SARS-CoV-2 Antigen Test 2. Huaketai New Coronavirus (SARS-CoV-2) N Protein Detection Kit (FIA) 3. Diagnostic Kit for 2019-Novel Coronavirus (2019-nCoV) | 1. RapiGen Inc., Anyang-si, Gyeonggi-do, Rep. of Korea 2. Savant Biotechnology Co., Beijing, China 3. Bioeasy Biotechnology Co., Shenzhen, China | Up to 40 | 1. Rapid 2. Rapid/detector 3. Rapid/detector | 111   | 80    | 31       |
| Winkel et al. [226]     | Netherlands      | N     | nsp            | LFIA                                  | PanbioTM COVID-19 Ag                     | Abbott                              | Up to 40 | Rapid            | 2390  | 63     | 2327     |
| Hoehl et al. [227]      | Germany          | N     | nsp            | LFIA                                  | RIDA® QUICK SARS80 CoV-2 Antigen test     | R-Biopharm                         | Up to 20 | Rapid            | 602   | 8      | 594      |
| Priya Kannian et al. [228] | India           | N     | nsp            | LFIA                                  | SARS-CoV2 antigen kit                    | SD Biosensor                       | Up to 40  | Rapid            | 30    | 20     | 10       |
| Lindner et al. [229]    | Germany          | N     | nsp            | LFIA                                  | STANDARD Q COVID-19 Ag Test              | SD Biosensor, Inc., Gyeonggi-do, Korea | Up to 40  | Rapid            | 146   | 40     | 106      |
| Filgueiras et al. [230] | Brazil           | N     | nsp            | LFIA                                  | SARS-CoV-2 rapid antigen test            | ECODiagnostica                     | Up to 40  | Rapid            | 139   | 55     | 84       |
| Peto et al. [231]       | UK               | N     | nsp-ts         | LFIA                                  | SARS-CoV-2 Antigen Rapid Qualitative Test | Innova                             | Up to 30  | Rapid            | 834   | 198    | 636      |
| Jakobsen et al. [232]   | Denmark          | N     | nsp            | LFIA                                  | STANDARD Q COVID-19 Ag test              | SD BIOSENSOR                       | Up to 40  | Rapid            | 4811  | 221    | 4590     |
Table 1. Cont.

| Author                | Country of Study | Ag  | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                                      | Kit Company                                      | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|-----------------------|------------------|-----|----------------|----------------------------------------|-----------------------------------------------|-------------------------------------------------|------------------|-----------------------------------------------|------------------|-------|----------|
| Miyakawa et al. [233] | Japan            | N   | nsp            | LFIA/virus culture data                | 1. SARS-CoV-2 Ag-RDT                           | YCU-FF, Abbott, Roche, SD Bio, Fujirebio         | Up to 40         | Rapid                                        | 108              | 45    | 63       |
| Torres et al. [186]   | Spain            | N   | nsp            | LFIA/virus culture data                | CLINITEST® Rapid 29 COVID-19 Antigen Test      | Siemens, Healthineers, Erlangen, German         | Up to 40         | Rapid                                        | 270              | 33    | 237      |
| Pollock et al. [234]  | Massachusetts    | N   | nsp            | LFIA                                   | Access Bio CareStart COVID-19 Antigen test     | Up to 30/Up to 40                               | Rapid            | 1498             | 234              | 1264  |
| Shidlovskaya et al.   | Russia           | N   | nsp            | LFIA/virus culture data                | 1. SGTI-flex COVID-19 Ag                       | SUGENTECH, INC, RapiGEN Inc.                    | Up to 40         | Rapid                                        | 106              | 14    | 92       |
| Faíco-Filho et al.    | Brazil           | N   | nsp            | LFIA                                   | Panbio™ COVID-19 Ag Rapid Test                 | Abbott                                          | Up to 30/Up to 40/30 Rapid | 127              | 70    | 57       |
| Schuit et al. [237]   | Netherlands      | N   | nsp            | LFIA/virus culture data                | 1. BD VeritorTM System Ag-RDT                  | Becton, Dickinson and Company, Franklin Lakes, NJ, USA | Up to 40         | Rapid                                        | 4274             | 365   | 4274     |
| Ducrest et al. [238]  | Switzerland      | N   | nsp            | LFIA                                   | COVIDia-Antigen                                | GaDia SA                                        | Up to 30         | Rapid                                        | 60               | 20    | 40       |
| Vecchio et al. [239]  | Italy            | N   | nsp            | LFIA                                   | Panbio™ COVID-19 Ag test                      | Abbott                                          | Up to 30         | Rapid                                        | 1441             | 61    | 1380     |
| Bonde et al. [240]    | Denmark          | N   | ts             | LFIA                                   | BD VERITOR Ag Rapid test                      | Becton-Dickinson and Company, USA               | Up to 30         | Rapid                                        | 809              | 65    | 744      |
| Igloi et al. [241]    | Netherlands      | N   | ts             | LFIA/virus culture data                | SARS-CoV-2 Rapid Antigen Test                 | Distributed by Roche (SD Biosensor)             | Up to 30         | Rapid                                        | 770              | 30    | 740      |
| Thell et al. [242]    | Austria          | N   | nsp            | LFIA                                   | SARS-CoV-2 Rapid Antigen Test                 | Roche Diagnostics                               | Up to 30         | Rapid                                        | 541              | 213   | 328      |
### Table 1. Cont.

| Author          | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name                                                                 | Kit Company           | Ct Values Tested | Ct Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|-----------------|------------------|----|----------------|----------------------------------------|--------------------------------------------------------------------------|-----------------------|------------------|-------------------------------------------|--------------------|-------|----------|
| Pollock et al.  | Massachusetts    | N  | nsp            | LFIA                                   | BinaxNOW COVID-19 Ag                                                     | Abbott                | Up to 30         | Rapid                       | 98                 | 98    | NA       |
| Hagbom et al.   | Sweden           | N  | ts             | LFIA/virus culture data                | 1. Rapid Response™ COVID-19 Antigen<br>2. DIAGNOS™ COVID-19 Antigen Saliva Test | 1. BioServ<br>2. DIAGNOS | Up to 30         | Rapid                       | 34                 | 15    | 19       |
| Thirion-Romero et al. [245] | Mexico | N  | nsp            | LFIA                                   | Panbio™                                                              | Abbott                | Up to 30         | Rapid                       | 1064               | 474   | 590      |
| Chiu et al.     | Hong Kong        | N  | nsp            | LFIA                                   | INDICAID™ Rapid Test                                                   | PHASE Scientific i   | Up to 30         | Rapid                       | 23,343             | 128   | 23,215   |
| Abusrewil et al. [247] | Libya     | N  | nsp            | LFIA                                   | 1. SARS-CoV-2 spike protein test<br>2. Shenzhen Microprofit Biotech Co<br>3. ESPLINE SARS-CoV-2<br>4. RapiGen COVID-19 Ag Detection Kit<br>5. Panbio™ COVID-19 Ag Rapid Test<br>6. Flowflex™ SARS-CoV-2 Antigen Rapid Test<br>7. Europe antigen testing COVID-19<br>8. Bioperfectus SARS-CoV-2 Antigen Rapid Test Kit<br>9. AMP Rapid Test SARS-CoV-2 Ag<br>10. Coronavirus ag rapid test cassette | 1. Fluorecare<br>2. Biotech<br>3. Fujirebio<br>4. Biocredit<br>5. Abbott<br>6. Acon<br>7. Assut<br>8. BIOPERFECTUS<br>9. AMP<br>10. Orient GENE | Up to 30/Up to 40 | Rapid | 231 | 83  | 145 |
| Author | Country of Study | Ag | Type of Sample | Ag Detection Method/Virus Culture Data | Kit Name | Kit Company | Ct Values Tested | Signal Detection [Rapid (w/wo Detector)/Quick] | Total Individuals | Cases | Controls |
|--------|------------------|----|----------------|----------------------------------------|----------|-------------|-----------------|---------------------------------|------------------|-------|----------|
| Muthamia et al. [248] | Kenya | N | nsp | LFIA | BD Veritor antigen test | Becton-Dickinson and Company, USA | Up to 20/Up to 30/0–20/20–30 | Rapid | 272 | 47 | 225 |
| Abdul-Mumin et al. [249] | Ghana | N | nsp | LFIA | STANDARD Q SARS-CoV-2 Ag Test | SD Biosensor | Up to 40 | Rapid | 193 | 42 | 151 |
| Akashi et al. [250] | Japan | N | nsp | LFIA | QuickNavi™-COVID19 Ag | Otsuka Pharmaceutical Co., Ltd. (Otsuka) and Denka Company | Up to 40 | Rapid | 96 | 96 | NA |
| Lindner et al. [251] | Germany | N | nsp | LFIA | 1. Espline SARS-CoV-2 2. Sure Status COVID-19 Antigen Card Test 3. Mologic COVID-19 Rapid Test | 1. Fujirebio Inc. 2. Premier Medical Corporation Private Limited 3. Fujirebio Inc | Up to 40 | Rapid | 329 | 329 | NA |
| Suliman et al. [252] | Massachusetts | N | nsp | LFIA | Access Bio CareStart™ COVID-19 RDT | CareStart | Up to 30 | Rapid | 631 | 37 | 594 |
| Bruins et al. [253] | Netherlands | N | nsp | LFIA | Panbio™ COVID-19 Ag Rapid Test | Abbott | Up to 30 | Rapid | 1101 | 84 | 917 |
| Ford et al. [254] | Wisconsin | N | nsp | LFIA/virus culture data | BinxNOW SARS-CoV-2 antigen test | Abbott Laboratories, Abbott Park, IL | Up to 40 | Rapid | 2110 | 334 | 1776 |
| Koskinen et al. [255] | Finland | N | nsp | LFIA/virus culture data | mariPOC SARS-CoV-2 Antigen Test | mariPOC | Up to 30 | Rapid/optional detector | 211 | 13 | 198 |
| Nikolai et al. [256] | Germany | N | nsp | LFIA | STANDARD Q COVID-19 Ag Test | SD Biosensor, Inc. Gyeonggi-do, Korea | Up to 40 | Rapid | 228 | 70 | 188 |
| Stohr et al. [257] | Netherlands | N | nsp | LFIA/virus culture data | 1. BD Veritor System for Rapid Detection of SARS-CoV-2 2. Roche SARS-CoV-2 antigen detection test | Becton Dickinson company, USA Roche, Switzerland | Up to 40 | Rapid | 3239 | 454 | 1528 |

LFIA: Lateral Flow Immunoassay; FIA: Fluorescence Immunoassay; CLEIA: Chemiluminescence Enzyme Immunoassay; FET: Field-Effect Transistors; Ag: Antigen; nsp: nasopharyngeal; ts: oropharyngeal/throat/saliva; Rapid: detection time 5–20 min (mainly 15) but never exceeding 30 min; Quick: detection time 30–35 min; Quick *: 60 min; w/wo: with/without; Detector: a detector in needed to read the developed signal; NA: Not applicable; NR: Not reported; Cases: SARS-CoV-2 positive samples according to RT-PCR; Controls: healthy individuals and RT-PCR negative (for SARS-CoV-2); Virus culture data: study that provides any kind of data on the correlation between virus culture [cytopathic effect, tissue culture infective dose 50% (TCID 50), limit of detection (LoD)], and rapid Antigen Test positivity, RNA copies number, Ct values of RT-PCR positive samples.
Table 2. Results of the multivariate meta-analysis for the different types of assays using different samples and stratified according to different cut-off rt-PCR values. Listed information includes the pooled sensitivity and specificity along with the 95% confidence intervals (NSP: pharyngeal, nasopharyngeal, nasal specimens, TS: throat, saliva, N: nucleocapsid protein, S: spike protein, M: membrane E: envelope, NS: nucleocapsid and Spike proteins).

| Sample        | Ag   | Method | Ct Values | Studies/Patients/Controls | Sensitivity (95% CI) | Specificity (95% CI) | Studies w/o Controls |
|---------------|------|--------|-----------|---------------------------|----------------------|----------------------|---------------------|
| NSP N         | LFIA | 0–20   | 41/7464/3945 | 0.945 (0.930, 0.961)      | 0.993 (0.987, 0.998) | 22                   |
| NSP N         | LFIA | 0–30   | 99/66,939/47,719 | 0.853 (0.826, 0.879)      | 0.991 (0.988, 0.995) | 44                   |
| NSP N         | LFIA | 0–40   | 207/88,088/69,415 | 0.702 (0.676, 0.727)      | 0.990 (0.987, 0.993) | 30                   |
| NSP N         | LFIA | 20–30  | 46/7817/4360 | 0.790 (0.739, 0.841)      | 0.987 (0.976, 0.998) | 35                   |
| NSP N         | LFIA | 30–40  | 71/5150/911  | 0.329 (0.265, 0.393)      | 0.999 (0.923, 0.995) | 51                   |
| TS N          | LFIA | 0–20   | 5/90/NA      | 0.805 (0.599, 1.000)      | -                     | 5                    |
| TS N          | LFIA | 0–30   | 10/2136/1756 | 0.636 (0.477, 0.795)      | 0.994 (0.989, 0.998) | 3                   |
| TS N          | LFIA | 0–40   | 23/10,249/9232 | 0.354 (0.238, 0.470)    | 0.996 (0.993, 0.998) | 12                   |
| TS N          | LFIA | 20–30  | 6/160/NA     | 0.412 (0.242, 0.593)      | -                     | 12                   |
| TS N          | LFIA | 30–40  | 4/44/NA      | 0.935 (0.880, 0.990)      | -                     | 3                    |
| NSP-TS N      | LFIA | 0–20   | 7/4240/3859  | 0.999 (0.000, 1.000)      | 0.999 (0.000, 1.000) | 6                    |
| NSP-TS N      | LFIA | 0–30   | 10/9229/8133 | 0.637 (0.592, 0.682)      | 0.997 (0.993, 0.999) | 10                   |
| NSP-TS N      | LFIA | 0–40   | 20/10,249/9232 | 0.354 (0.238, 0.470)    | 0.997 (0.993, 0.999) | 7                    |
| NSP-TS N      | LFIA | 20–30  | 6/1024/9232  | 0.412 (0.242, 0.593)      | -                     | 6                    |
| NSP-TS N      | LFIA | 30–40  | 4/44/NA      | 0.935 (0.880, 0.990)      | -                     | 3                    |
| NSP N         | FIA  | 0–20   | 3/97/NA      | 0.999 (0.000, 1.000)      | 0.999 (0.000, 1.000) | 6                    |
| NSP N         | FIA  | 0–30   | 10/2221/421  | 0.807 (0.726, 0.889)      | 0.997 (0.971, 1.000) | 6                    |
| NSP N         | FIA  | 0–40   | 29/36,425/33,718 | 0.707 (0.631, 0.783)    | 0.984 (0.970, 0.997) | 1                    |
| NSP N         | CLEIA | 0–20  | 1/136/NA      | 0.963 (0.774, 1.000)      | 0.997 (0.993, 0.999) | 1                    |
| NSP N         | CLEIA | 0–30  | 1/136/NA      | 0.963 (0.774, 1.000)      | 0.997 (0.993, 0.999) | 1                    |
| NSP N         | CLEIA | 0–40  | 3/396/NA     | 0.790 (0.637, 0.945)      | 0.997 (0.993, 0.999) | 1                    |
| NSP N         | other | 0–20  | 1/90/49      | 0.976 (0.928, 1.000)      | 0.857 (0.000, 1.000) | 0                    |
| NSP N         | other | 0–30  | 3/212/NA     | 0.976 (0.928, 1.000)      | 0.857 (0.000, 1.000) | 0                    |
| NSP N         | other | 0–40  | 4/73/NA      | 0.976 (0.928, 1.000)      | 0.857 (0.000, 1.000) | 0                    |
| NSP N         | other | 20–30 | 1/210/NA     | 0.984 (0.922, 1.000)      | 0.997 (0.970, 0.999) | 1                    |
| NSP N         | other | 30–40 | 4/73/NA      | 0.940 (0.847, 1.000)      | -                     | 2                    |
| NSP N         | other | 40–40 | 4/73/NA      | 0.940 (0.847, 1.000)      | -                     | 2                    |

Combining all major methods (LFIA, FIA and CLEIA) on NSP and TS samples, measuring both N and S antigens and stratified according to two Ct values (<30 and <40), the maximum sensitivity was estimated at 0.858 (95% CI 0.835, 0.881) for NSP samples positive for Ct < 30 (Table 3). The sensitivity using qPCR positive NSP samples for Ct < 40 is lower at 0.726 (95% CI 0.706, 0.746). Again, antigen testing of NSP samples outperformed that of TS samples for both Ct < 30 and Ct < 40 (0.637 (95% CI 0.478, 0.795) and 0.438 (95% CI: 0.332, 0.547), respectively). Specificity was very high in all meta-analyses (Table 3).
Table 3. Results of the multivariate meta-analysis performed cumulatively for methods and/or antigen tested, in <30 and <40 Ct values. Listed information includes the pooled sensitivity and specificity along with the 95% confidence intervals (NSP: pharyngeal, nasopharyngeal, nasal specimens, TS: throat, saliva, oropharyngeal, N: nucleocapsid protein, S: spike protein, M: membrane E: envelope, NS: nucleocapsid and Spike proteins).

| Sample | Ag | Method (LFIA, FIA, CLEIA) | Ct Values | Studies | Sensitivity (95% CI) | Specificity (95% CI) | Studies w/o Controls |
|--------|----|--------------------------|-----------|---------|----------------------|----------------------|----------------------|
| NSP NS | LFIA or FIA or CLEIA | 30         | 118       | 0.858 (0.835, 0.881) | 0.991 (0.987, 0.995) | 53                   |
| NSP NS | LFIA or FIA or CLEIA | 40         | 325       | 0.726 (0.706, 0.746) | 0.989 (0.987, 0.992) | 39                   |
| TS NS  | LFIA or FIA or CLEIA | 30         | 10        | 0.637 (0.478, 0.795) | 0.984 (0.989, 0.998) | 5                    |
| TS NS  | LFIA or FIA or CLEIA | 40         | 36        | 0.438 (0.332, 0.547) | 0.993 (0.987, 0.999) | 14                   |
| NSP NS | LFIA or FIA          | 30         | 114       | 0.854 (0.830, 0.878) | 0.991 (0.987, 0.995) | 50                   |
| NSP NS | LFIA or FIA          | 40         | 303       | 0.718 (0.697, 0.739) | 0.989 (0.987, 0.992) | 38                   |
| TS NS  | LFIA or FIA          | 30         | 10        | 0.637 (0.478, 0.795) | 0.994 (0.989, 0.998) | 5                    |
| TS NS  | LFIA or FIA          | 40         | 32        | 0.395 (0.285, 0.508) | 0.995 (0.993, 0.997) | 13                   |
| NSP NS | LFIA                 | 30         | 101       | 0.852 (0.825, 0.878) | 0.991 (0.987, 0.995) | 44                   |
| NSP NS | LFIA                 | 40         | 269       | 0.715 (0.692, 0.738) | 0.990 (0.987, 0.992) | 35                   |
| TS NS  | LFIA                 | 30         | 10        | 0.637 (0.478, 0.795) | 0.994 (0.989, 0.998) | 5                    |
| TS NS  | LFIA                 | 40         | 29        | 0.408 (0.292, 0.523) | 0.995 (0.993, 0.997) | 12                   |
| NSP NS | FIA                  | 30         | 13        | 0.868 (0.813, 0.924) | 0.991 (0.981, 1.000) | 6                    |
| NSP NS | FIA                  | 40         | 35        | 0.730 (0.674, 0.785) | 0.986 (0.976, 0.995) | 3                    |
| TS NS  | FIA                  | 30         | -         | -         | -                     | -                    |
| TS NS  | FIA                  | 40         | 2         | 0.162 (0.083, 0.242) | 0.984 (0.941, 1.000) | 1                    |
| NSP NS | CLEIA                | 30         | 4         | 0.977 (0.955, 0.998) | 0.995 (0.999, 1.000) | 3                    |
| NSP NS | CLEIA                | 40         | 23        | 0.816 (0.761, 0.870) | 0.979 (0.971, 0.988) | 1                    |
| TS NS  | CLEIA                | 30         | -         | -         | -                     | -                    |
| TS NS  | CLEIA                | 40         | 3         | 0.720 (0.380, 1.000) | 0.957 (0.889, 1.000) | 1                    |

To attain a better insight into how each method performs, we compared the meta-analysis results for the sensitivity and specificity of each method (LFIA, FIA, CLEIA) on NSP and TS samples for all antigens cumulatively (N plus S). As shown in Table 3, in terms of sensitivity, the laboratory CLEIA method outperforms the point of care (POC) methods (LFIA and FIA), the NSP samples outperform the TS samples, and the best results are obtained for samples identified positive with PCR for Ct < 30 (0.977 (95% CI: 0.955, 0.998) versus 0.408 (95% CI: 0.292, 0.523) and 0.162 (95% CI: 0.083, 0.242)) (Table 3).

Since the ultimate goal of a diagnostic method for SARS-CoV-2 is to identify an infected person regardless of the low viral load, we compared the overall sensitivity of rapid tests performed in points either of care or where virus surveillance is performed (LFIA or FIA) with laboratory methods (CLEIA) that show the highest sensitivity. As shown in Figure 2 (and Table 3), the overall (for Ct < 40) sensitivity of POC methods is about 10% lower than that of the CLEIA method for NSP samples (0.718 (95% CI: 0.478, 0.795) compared to 0.816 (95% CI: 0.761, 0.870)). Specificity was again high in all cases ranging from 0.957 (95% CI: 0.889, 1.000) to 0.995 (95% CI: 0.993, 0.997), although due to the small number of the included studies in some subgroups, these results may have some uncertainty (Table 3).

To investigate the validity of our stratification analysis according to Ct values (<30 and <40), we tried to explore the association between a patient/sample’s infectivity and positivity in POC antigen tests (LFIA and FIA) and PCR tests using data from the included studies. We found 51 studies (Table 1) that used a virus culture to address this issue; however, the results were presented in a plethora of different ways and could not be quantitatively synthesized and analyzed, due to different reported parameters. From them, ten studies used virus cultures to only test the viral load (RNA copies/mL) that a POC test could detect. The remaining 34 studies presented a combination of data such as the limit of detection (LoD) in terms of RNA copies/mL or per swab or in pfus/mL, tissue culture infection dose (TCID) (TCID50, TCID95%), sensitivity of POC tests in correlation with virus culture cytopathic effect (CPE) measured in different days and after zero, one or two passages. Nevertheless, sixteen studies [63,85,87,91,101,135,145,151,167,169,199,215–217,219,255] determined LoD Ct values ranging from 18.57 [219] to 34 [145], with most of them reporting Ct 30 as an average threshold for a POC test to be positive. Importantly, viral culture positivity (CPE),
though measured under various protocols (directly [87,91,101,135,143,145,200,216,241] and indirectly [141,169,201,215,241,254]), has been extensively used as a marker for sample infectivity. Furthermore, twelve studies [54,76,85,143,170,199,213,217,233,235,237,241] presented data providing LoD values for a POC tests ranging from $5 \times 10^3$ (Ct = 27.3 [63]) to $10^6$ RNA copies/swab (Ct = 30) [54,76]. Noteworthily, four studies on the CLEIA method [111,150,156,206] and four studies [41,44,46,47] on in-house tests also investigated virus infectivity in correlation with either Ct values or positivity of these tests, but these were not analyzed since they were not reporting on POC tests. Taken together, the above observations suggest that if SARS-CoV-2-infected cell culture positivity is an indicator of a patient/sample that is likely to be infectious [202,258,259], this infectivity better correlates with POC test positivity than rt-PCR positivity. As we show herein, POC test positivity corresponds better to PCR positivity for Ct < 30; thus, POC tests are more likely to detect infectious individuals than positive PCR tests.

**Figure 2.** Performance of POC (LFIA and FIA) and laboratory (CLEIA) antigen-based methods in terms of sensitivity. All included assays in the meta-analysis use samples with Ct < 40 and test cumulatively both the nucleocapsid and Spike antigen. Numbers above the bars depict sensitivity values/number of studies included in each meta-analysis.

Additional meta-analysis showed that the sensitivity of LFIA (on NSP samples) in symptomatic patients was higher than that in asymptomatic individuals, both for Ct < 30 and Ct < 40 (symptomatic: $0.823$ (95% CI: 0.765, 0.882) and $0.753$ (95% CI: 0.713, 0.794)—asymptomatic: $0.665$ (0.558, 0.772) and 0.561 (95% CI: 0.499, 0.622), respectively) (Table 4 and Figure 3). FIA assays seem to perform worse, but the meta-analysis estimates were
based on a smaller number of studies. Specificity was very high for both LFIA and FIA methods (~99%) (Table 4).

Table 4. Results of the meta-analysis for the different types of assays for symptomatic and asymptomatic patients. Listed information includes the pooled sensitivity and specificity along with the 95% confidence intervals. (NSP: pharyngeal, nasopharyngeal, nasal specimens, TS: throat, saliva, N: nucleocapsid protein, S: spike protein, NS: nucleocapsid and Spike proteins).

| Sample  | Ag | Method | Ct       | Studies | Sensitivity (95% CI) | Specificity (95% CI) | Studies w/o Controls |
|---------|----|--------|----------|---------|----------------------|----------------------|----------------------|
|         |    |        |          |         |                      |                      |                      |
| **SYMPTOMATIC INDIVIDUALS** |        |        |          |         |                      |                      |                      |
| NSP     | N  | LFIA   | 20       | 1       | 0.976 (0.911, 1.000) | -                    | 1                    |
| NSP     | N  | LFIA   | 30       | 21      | 0.823 (0.765, 0.882) | 0.993 (0.989, 0.997) | 7                    |
| NSP     | N  | LFIA   | 40       | 44      | 0.753 (0.713, 0.794) | 0.992 (0.987, 0.997) | 7                    |
| NSP     | N  | LFIA   | 20–30    | 2       | 0.881 (0.765, 0.996) | -                    | 2                    |
| NSP     | N  | LFIA   | 30–40    | 13      | 0.469 (0.228, 0.709) | 0.947 (0.880, 1.000) | 4                    |
| NSP     | N  | FIA    | 30       | 2       | 0.694 (0.509, 0.878) | 0.996 (0.993, 0.998) | 0                    |
| NSP     | N  | FIA    | 40       | 4       | 0.605 (0.292, 0.918) | 0.948 (0.827, 1.000) | 1                    |
| NSP     | N  | FIA    | 30–40    | 1       | 0.921 (0.868, 0.973) | 0.923 (0.000, 1.000) | 0                    |
| TS      | N  | LFIA   | 30       | 2       | 0.669 (0.119, 1.000) | 0.998 (0.994, 1.000) | 0                    |
| TS      | N  | LFIA   | 40       | 4       | 0.426 (0.029, 0.823) | 0.986 (0.977, 0.996) | 0                    |
| TS      | N  | LFIA   | 30–40    | 1       | 0.025 (0.000, 1.000) | 0.5 (0.000, 1.000)   | 0                    |
| TS      | N  | FIA    | 40       | 1       | 0.083 (0.000, 1.000) | -                    | 1                    |
| NSP-TS  | N  | LFIA   | 20       | 2       | 0.957 (0.889, 1.000) | -                    | 2                    |
| NSP-TS  | N  | LFIA   | 30       | 4       | 0.873 (0.788, 0.958) | 0.998 (0.993, 1.000) | 3                    |
| NSP-TS  | N  | LFIA   | 40       | 11      | 0.767 (0.695, 0.836) | 0.996 (0.992, 0.999) | 3                    |
| NSP-TS  | N  | LFIA   | 20–30    | 2       | 0.901 (0.795, 1.000) | -                    | 2                    |
| NSP-TS  | N  | LFIA   | 30–40    | 4       | 0.260 (0.142, 0.378) | 0.500 (0.000, 1.000) | 3                    |
| **ASYMPTOMATIC INDIVIDUALS** |        |        |          |         |                      |                      |                      |
| NSP     | N  | LFIA   | 30       | 15      | 0.665 (0.558, 0.772) | 0.992 (0.981, 1.000) | 6                    |
| NSP     | N  | LFIA   | 40       | 35      | 0.561 (0.499, 0.622) | 0.995 (0.992, 0.998) | 5                    |
| NSP     | N  | LFIA   | 20–30    | 1       | 0.371 (0.270, 0.471) | -                    | 1                    |
| NSP     | N  | LFIA   | 30–40    | 10      | 0.233 (0.061, 0.405) | 0.947 (0.880, 1.000) | 6                    |
| NSP     | N  | FIA    | 30       | 5       | 0.808 (0.714, 0.901) | 0.997 (0.989, 1.000) | 3                    |
| NSP     | N  | FIA    | 40       | 6       | 0.782 (0.614, 0.949) | 0.949 (0.904, 0.995) | 1                    |
| NSP     | N  | FIA    | 30–40    | 2       | 0.734 (0.253, 1.000) | 0.882 (0.774, 0.991) | 1                    |
| TS      | N  | LFIA   | 30       | 2       | 0.484 (0.000, 1.000) | 0.995 (0.986, 1.000) | 0                    |
| TS      | N  | LFIA   | 40       | 9       | 0.167 (0.034, 0.301) | 0.990 (0.974, 1.000) | 6                    |
| TS      | N  | LFIA   | 30–40    | 1       | 0.050 (0.000, 0.185) | 0.5 (0.000, 1.000)   | 0                    |
| TS      | N  | FIA    | 40       | 1       | 0.166 (0.000, 1.000) | 0.984 (0.941, 1.000) | 0                    |
| NSP-TS  | N  | LFIA   | 30       | 1       | 0.300 (0.136, 0.464) | 0.997 (0.000, 1.000) | 0                    |
| NSP-TS  | N  | LFIA   | 40       | 5       | 0.481 (0.291, 0.671) | 0.997 (0.995, 0.998) | 1                    |
| NSP-TS  | N  | LFIA   | 30–40    | 1       | 0.050 (0.000, 0.185) | 0.997 (0.000, 1.000) | 0                    |
| NSP-TS  | N  | FIA    | 40       | 1       | 0.850 (0.772, 0.928) | 0.984 (0.941, 1.000) | 0                    |
Figure 3. Performance of LFIA and FIA methods (N antigen-based) in terms of sensitivity on NSP samples in symptomatic vs. asymptomatic persons. Included assays in the meta-analysis are performed with positive samples for either Ct < 30 or Ct < 40. Numbers above the bars depict sensitivity values/number of studies included in each meta-analysis.

4. Discussion

Test-trace-isolate remains a fundamental strategy to control SARS-CoV-2 transmission. Compared to PCR methods, antigen detection tests do not require specialized laboratory equipment and are less expensive, thus allowing repeated and point-of-care testing on a wide scale [18]. Our meta-analysis, summarizing evidence from thousands of people with and without SARS-CoV-2 infection diagnosed with rt-PCR, and performing various comparisons, shows that the overall performance of AT is comparable to rt-PCR, at least in terms of specificity, with meta-analytic estimates around 99%, irrespective of the method used. Sensitivity is lower and seems to depend on viral concentration being increased if detected at lower PCR cycles (Ct values). AT are also more sensitive when used on NSP samples and in symptomatic individuals. These updated findings are in accordance with previous efforts to summarize the evidence in this field [260,261]. Current best practices in meta-analysis suggest that a frequent update should be performed, and there is active research regarding the identification of the actual time that an update is needed [262,263]. As a matter of fact, previous works include statistical methods and surveillance systems that will identify the need for an update of a published meta-analysis [264,265]. More recently, the concept of a “living” systematic review has emerged, in which the review is continuously updated, incorporating relevant new data as they become available. Such reviews may be particularly important in fields where research evidence is emerging rapidly [266,267], and clearly, the COVID-19 pandemic is a perfect example of a field where new research accumulates in an unprecedented way and an updated meta-analysis is needed.

The sensitivity of AT is good but not ideal, and thus rt-PCR remains the gold standard for diagnosis. Given the suboptimal sensitivity of antigen tests, there is a likelihood of false
negative results, which should be handled depending on the clinical and epidemiological circumstances. In general, confirmation of an AT result with rt-PCR in a laboratory is necessary when the result is not consistent with clinical and epidemiological information. Given their higher sensitivity among symptomatic people and in those with higher viral load (Ct < 30), ATs are expected to perform better when used for the diagnosis of SARS-CoV-2 infection in people with symptoms, in high-risk contacts of confirmed cases or in high-risk groups as health care workers with known exposure. Moreover, the sole detection of viral RNA with rt-PCR does not seem to overlap with patients’ infectiousness. Rather, POC (rapid) antigen tests that can only detect viral loads detectable with rt-PCR at Ct values <30 seem to more efficiently discriminate infectious SARS-CoV-2 carriers that should stay in isolation [202,255,258,259]. These findings are further supported by CDC recommendations, already posed by the end of 2020, which propose a Ct value of 33 as illustrative of contagiousness [204,268].

Proper interpretation of AT results is important not only for diagnosis but also for screening and surveillance purposes. This meta-analysis did not evaluate screening strategies that used AT. Nevertheless, it seems that AT can be used for regular screening of asymptomatic people in high-risk congregate settings, such as nursing homes, homeless shelters, detention facilities, etc., where the turnaround time of results is critical [269]. The fast identification of highly infected people in these facilities using rapid POC antigen tests will immediately inform infection prevention and control strategies and interventions, and consequently will significantly reduce onward transmission. Due to the lower sensitivity, screening in congregate high-risk settings but also mass screening may suffer from false negative results. Given the presumed direct correlation of rapid ATs’ positivity with patient’s infectivity, and the evidence that the effectiveness of screening depends more on frequency of testing and speed of reporting rather than on very high sensitivity [91,270], it seems that antigen tests can be used for repeated population screening.

In terms of specificity, AT performs extremely well, similarly to rt-PCR, thus minimizing the likelihood of false-positive results. However, false-positive results do occur, especially when the prevalence of SARS-CoV-2 infection in communities is low. This should be considered both in terms of diagnosis and when designing public health interventions or prevalence studies in low-prevalence settings because false positives result in a waste of resources (unnecessary isolation of cases and follow-up actions) and inaccurate estimations.

This meta-analysis is subject to the limitations of the individual studies. Bias and confounding at the study level cannot be easily addressed or corrected at the stage of meta-analysis. There are also issues that could affect the results and are usually not measured, reported, or addressed in studies that evaluate the accuracy of AT: storage and handling, reading of test results (time and interpretation), specimen collection and handling, time from specimen collection to testing, temperature of specimen, and potential cross-contamination, as was shown in the quality assessment of the research performed with the QUADAS tool.

We need to emphasize that the studies included in this meta-analysis were conducted before July 2021. Thus, data collection was completed at a time prior to the emergence of the Omicron variant and thus, the conclusions drawn from this work involve mainly the initial Wuhan strain, Alpha, Beta and Delta (to some extent) variants. A complete treatment of the question regarding the effectiveness of antigen tests against the newly emerged Omicron variant [271] would require a study of its own, but nevertheless we might be able to highlight some of the available evidence. Initially, there were concerns regarding the effectiveness of the tests [272], but the first report with the Abbott BinaxNow SARS-CoV-2 Rapid Antigen Assay provided evidence that it can be used efficiently [273]. Similar results were reported with another approved test (E25Bio, Inc., Cambridge, MA, USA, and Perkin Elmer, Waltham, MA, USA) in a comparison study of the Alpha, Gamma, Delta and Omicron variants [274], and for Panbio™ COVID-19 Ag Rapid Test [275]. Stanley and coworkers examined the analytical sensitivity of the Abbott BinaxNow, the AccessBio CareStart and LumiraDx antigen tests, and found that the level of detection was at least
as good for Omicron as for the initial Wuhan strain [276]. Finally, Deearin and coworkers measured the sensitivity of ten different lateral flow devices against the omicron variant and found that the analytical sensitivities of these ten kits were similar for both the Delta and Omicron variants [277]. All in all, even though more studies are needed, the available evidence suggests that the currently used ATs can be used efficiently for detecting the Omicron variant and large discrepancies in sensitivity due to its spread are not expected.

Finally, evaluation of different testing strategies in various settings is also urgently needed [278]. Moreover, the lack of an agreed, universal, standardized protocol starting from specimen collection and handling to performing and reading the test and to the way(s) that its performance is validated (rt-PCR (genes, Ct values) or cytopathic effects of virus cultures (reference virus strain) or RNA copies, etc. [140,279]) has also been revealed through our current systematic review and meta-analysis. Only in such uniform settings can accurate comparisons of methods and individual tests be performed in order to optimally track and manage SARS-CoV-2 infection in the global community.

### Supplementary Materials

The following supporting information can be downloaded at: https://www.mdpi.com/article/10.3390/diagnostics12061388/s1, Table S1: The QUADAS tool; File S1: QUADAS-2 assessment results for included studies.

### Author Contributions

Conceptualization: P.G.B., G.G.B. and P.I.K.; Methodology: P.I.K., G.K.N., P.G.B. and P.G.B.; Validation: G.G.B., G.K.N., P.I.K., A.T., M.P., H.M. and P.G.B.; Formal Analysis: A.T., P.G.B., G.G.B., P.I.K. and G.K.N.; Investigation: A.T., H.M., M.P., P.I.K. and G.G.B.; Resources, A.T. and G.G.B.; Data Curation: A.T., G.G.B. and P.I.K.; Writing—Original Draft Preparation: A.T. and G.G.B.; Writing—Review and Editing: P.I.K., H.M., M.P., G.K.N. and P.G.B.; Visualization: G.G.B. and P.I.K.; Supervision: G.G.B. and P.G.B. All authors have read and agreed to the published version of the manuscript.

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### Conflicts of Interest

The authors declare no conflict of interest.

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