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The accuracy of novel antigen rapid diagnostics for SARS-CoV-2: a living systematic review and meta-analysis.

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ABSTRACT

Background: SARS-CoV-2 antigen rapid diagnostic tests (Ag-RDTs) are increasingly being integrated in testing strategies around the world. Studies of the Ag-RDTs have shown variable performance. In this systematic review and meta-analysis, we assessed the clinical accuracy (sensitivity and specificity) of commercially available Ag-RDTs.

Methods and Results: We registered the review on PROSPERO (Registration number: CRD42020225140). We systematically searched multiple databases (PubMed, Web of Science Core Collection, medRvix and bioRvix, FIND) for publications evaluating the accuracy of Ag-RDTs for SARS-CoV-2 up until April 30th, 2021. Descriptive analyses of all studies were performed and when more than four studies were available, a random-effects meta-analysis was used to estimate pooled sensitivity and specificity in comparison to reverse transcriptase polymerase chain reaction testing. We assessed heterogeneity by subgroup analyses, and rated study quality and risk of bias using the QUADAS 2 assessment tool. From a total of 14,254 articles, we included 133 analytical and clinical studies resulting in 214 clinical accuracy data sets with 112,323 samples. Across all meta-analyzed samples, the pooled Ag-RDT sensitivity was 71.2% (95% confidence interval [CI] 68.2 to 74.0) and increased to 76.3% (CI 73.1 to 79.2) if analysis was restricted to studies that followed the Ag-RDT manufacturers' instructions. The LumiraDx showed the highest sensitivity with 88.2% (CI 59.0 to 97.5). Of instrument-free Ag-RDTs, Standard Q nasal performed best with 80.2% sensitivity (CI 70.3 to 87.4). Across all Ag-RDTs sensitivity was markedly better on samples with lower Ct-values, i.e., <20 (96.5%, CI 92.6 to 98.4) and <25 (95.8%, CI 92.3 to 97.8), in comparison to those with Ct ≥25 (50.7%, CI 35.6 to 65.8) and ≥30 (20.9%, CI 12.5 to 32.8). Testing in the first week from symptom onset resulted in substantially higher sensitivity (83.8%, CI 76.3 to 89.2) compared to testing after one week (61.5%, CI 52.2 to 70.0). The best Ag-RDT sensitivity was found with anterior nasal sampling (75.5%, CI 70.4 to 79.9) in comparison to other sample types (e.g., nasopharyngeal 71.6%, CI 68.1 to 74.9) although CIs were overlapping. Concerns of bias were raised across all data sets, and financial support from the manufacturer was reported in 24.1% of data sets. Our analysis was limited by the included studies' heterogeneity in design and reporting, making it difficult to draw conclusions from.

Conclusion: In this study we found that Ag-RDTs detect the vast majority of cases within the first week of symptom onset and those with high viral load. Thus, they can have high utility for diagnostic purposes in the early phase of disease, making them a valuable tool to fight the spread of SARS-CoV-2. Standardization in conduct and reporting of clinical accuracy studies would improve comparability and use of data.

AUTHOR SUMMARY

Why was this study done?

- Antigen rapid diagnostic tests (Ag-RDTs) are considered an important diagnostic tool to fight the spread of SARS-CoV-2
- An increasing number of Ag-RDTs is offered on the market, and a constantly growing body of literature evaluating their performance is available
- To inform decision makers about the best test to choose, an up to date summary of their performance is needed

What did the researchers do and find?

- On a weekly basis, we search multiple data bases for evaluations of Ag-RDTs detecting SARS-CoV-2 and post the results on www.diagnosticsglobalhealth.org
- Based on the search results up until April 30th, 2021, we conducted a systematic review and meta-analysis, including a total of 133 clinical and analytical accuracy studies
- Across all meta-analyzed studies, when Ag-RDTs were performed according to manufacturers' recommendations, they showed a sensitivity of 76.3% (CI 73.1 to 79.2), with the LumiraDx (sensitivity 88.2%, CI 59.0 to 97.5) and of the instrument-free Ag-RDT Standard Q (74.9% sensitivity, CI 69.3 to 79.7) performing best.
- Across all Ag-RDTs, sensitivity increased to 95.8% (CI 92.3 to 97.8) when restricting the analysis to samples with high viral loads (i.e., a Ct-value <25) and to 83.8% (CI 76.3 to 89.2) when tests were performed on patients within the first week after symptom onset

What do these findings mean?

- Ag-RDTs detect the vast majority of cases within the first week of symptom onset and those with high viral load. Thus, they can have high utility for diagnostic purposes in the early phase of disease
- Out of all assessed tests, the Lumira Dx showed the highest accuracy. The Standard Q was the best performing test when only considering those that don't require an instrument
- A standardization of reporting methods for clinical accuracy studies would enhance future test-comparisons

ABBREVIATIONS

Ag-RDT	= antigen rapid diagnostic test
AN/MT	= anterior nasal or mid-turbinate
BAL/TW	= bronchoalveolar lavage or throat wash
CI	= confidence interval
Ct-value	= cycle threshold value
FIND	= Foundation for Innovative New Diagnostics
FP	= false positive
FN	= false negative
IFU	= instructions for use
LRT	= lower respiratory tract
ML	= milliliter
N	= sample size
NP	= nasopharyngeal
OP	= oropharyngeal
PFU	= plaque forming units
RT-PCR	= reverse transcriptase polymerase chain reaction
TP	= true positive
TN	= true negative
VTM/UTM	= viral or universal transport medium

INTRODUCTION

As the COVID-19 pandemic continues around the globe, antigen rapid diagnostic tests (Ag-RDTs) for SARS-CoV-2 are seen as an important diagnostic tool to fight the virus' spread [1,2]. The number of Ag-RDTs on the market is increasing constantly [3]. Initial data from independent evaluations suggests that the performance of SARS-CoV-2 Ag-RDTs may be lower than what is reported by the manufacturers. In addition, Ag-RDT accuracy seems to vary substantially between tests [4-6].

With the increased availability of Ag-RDTs, an increasing number of independent validations have been published. Such evaluations differ widely in their quality, methods and results, making it difficult to assess the true performance of the respective tests [7]. To inform decision makers on the best choice of individual tests, an aggregated, widely available and frequently updated assessment of the quality, performance and independence of the data is urgently necessary. While other systematic reviews have been published, they only include data up until Nov 2020 [8-11], exclude preprints [12], or were industry sponsored [13]. In addition, only one assessed the quality of studies in detail, with data up until Nov, 2020 [7,11].

With our systematic review and meta-analysis, we aim to close this gap in the literature and link to a website (www.diagnosticsglobalhealth.org) that is regularly updated.

METHODS

We developed a study protocol following standard guidelines for systematic reviews [14,15], which is available in the Supplement (S15). We have also completed the PRISMA checklist, which can be found in the Supplement (S1_PRISMA_Checklists) as well. Furthermore, we registered the review on PROSPERO (Registration number: CRD42020225140).

SEARCH STRATEGY

We performed a search of the databases PubMed, Web of Science, medRxiv and bioRxiv using search terms that were developed with an experienced medical librarian (MauG) using combinations of subject headings (when applicable) and text-words for the concepts of the search question. The main search terms were "Severe Acute Respiratory Syndrome Corona-virus 2", "COVID-19", "Betacoronavirus", "Coronavirus" and "Point of Care Testing". The full list of search terms is available in the Supplement (S2). We also searched the FIND website (https://www.finddx.org/sarscov2-eval-antigen/) for relevant studies manually. We performed the search up until April 30th, 2021. No language restrictions were applied.

INCLUSION CRITERIA

We included studies evaluating the accuracy of commercially available Ag-RDTs to establish a diagnosis of a SARS-CoV-2 infection against reverse transcriptase polymerase chain reaction (RT-PCR) or cell culture as reference standard. We included all study populations irrespective of age, presence of symptoms, or the study location. We considered cohort studies, nested cohort studies, case-control or cross-sectional studies and randomized studies. We included both peer reviewed publications and preprints.

We excluded studies in which patients were tested for the purpose of monitoring or ending quarantine. Also, publications with a population size smaller than 10 were excluded. Although the

size threshold of 10 is arbitrary, such small studies are more likely to give unreliable estimates of sensitivity or specificity.

INDEX TESTS

Ag-RDTs for SARS-CoV-2 aim to detect infection by recognizing viral proteins. Most Ag-RDTs use specific labeled antibodies attached to a nitrocellulose matrix strip, to capture the virus antigen. Successful binding of the antibodies to the antigen is either detected visually (through the appearance of a line on the matrix strip (lateral flow assay)) or requires a specific reader for fluorescence detection. Microfluidic enzyme-linked immunosorbent assays have also been developed. Ag-RDTs typically provide results within 10 to 30 minutes [6].

REFERENCE STANDARD

Viral culture detects viable virus that is relevant for transmission but is available in research settings only. Since RT-PCR tests are more widely available and SARS-CoV-2 RNA (as reflected by RT-PCR cycle threshold (Ct) value) highly correlates with SARS-CoV-2 antigen quantities, we considered it an acceptable reference standard for the purposes of this systematic review [16]. It is of note that there is currently no international standard for the classification of viral load available.

STUDY SELECTION AND DATA EXTRACTION

Two reviewers (LEB and CE, LEB and SS or LEB and MB) reviewed the titles and abstracts of all publications identified by the search algorithm independently, followed by a full-text review for those eligible, to select the articles for inclusion in the systematic review. Any disputes were solved by discussion or by a third reviewer (CMD).

A full list of the parameters extracted is included in the Supplement (S14) and the data extraction file is available upon request. Studies that assessed multiple Ag-RDTs or presented results based on differing parameters (e.g., various sample types) were considered as individual data sets.

184 At first, four authors (SK, CE, SS, MB) extracted five randomly selected papers in parallel to align
185 data extraction methods. Afterwards, data extraction and the assessment of methodological quality
186 and independence from test manufacturers (see below) were performed by one author per paper
187 (SK, CE, SS, MB) and controlled by a second (LEB, SK, SS, MB). Any differences were resolved by dis-
188 cussion or by consulting a third author (CMD).
189
190 STUDY TYPES
191 We differentiated between clinical accuracy studies (performed on clinical samples) or analytical
192 accuracy studies (performed on spiked samples with a known quantity of virus). Analytical accuracy
193 studies can differ widely in methodology, impeding an aggregation of their results. Thus, while we
194 extracted the data for both kinds of studies, we only considered data from clinical accuracy studies as
195 eligible for the meta-analysis. Separately, we summarized the results of analytical studies and com-
196 pared them with the results of the meta-analysis for individual tests.
197
198 ASSESSMENT OF METHODOLOGICAL QUALITY
199 The quality of the clinical accuracy studies was assessed by applying the QUADAS-2 tool [17].
200 The tool evaluates four domains: patient selection, index test, reference standard, and flow and tim-
201 ing. For each domain, the risk of bias is analyzed using different signaling questions. Beyond the risk
202 of bias, the tool also evaluates the applicability of the study of each included study to the research
203 question for every domain. The QUADAS 2 tool was adjusted to the needs of this review and can be
204 found in the Supplement (S3).
205
206 ASSESSMENT OF INDEPENDENCY FROM MANUFACTURERS
207 We examined whether a study received financial support from a test manufacturer (including
208 the free provision of Ag-RDTs), whether any study author was affiliated with a test manufacturer, or
209 a respective conflict of interest was declared. Studies were judged not to be independent from the

test manufacturers if at least one of these aspects was present, otherwise they were considered to be independent.

STATISTICAL ANALYSIS AND DATA SYNTHESIS

We extracted raw data from the studies and recalculated performance estimates where possible based on the extracted data. The raw data can be found in the Supplement (S4). We prepared forest plots for the sensitivity and specificity of each test and visually evaluated the heterogeneity between studies. If four or more data sets were available with at least 20 positive RT-PCR samples per data set for a predefined analysis, a meta-analysis was performed. We report point estimates of sensitivity and specificity for SARS-CoV-2 detection compared to the reference standard along with 95% confidence intervals (CI) using a bivariate model (implemented with the 'reitsma' command from the R package "mada" version 0.5.10). When there were less than four studies for an index test, only a descriptive analysis was performed and accuracy ranges were reported. In sub-group analyses where papers presented data only on sensitivity, a univariate random-effects inverse variance meta-analysis was done (using the 'metagen' command from the R package "meta" version 4.11-0). We predefined the following subgroups for meta-analysis: by Ct-value range, by sampling and testing procedure in accordance with manufacturer's instructions as detailed in the instructions for use (henceforth called IFU-conforming) vs. not IFU-conforming, age (<18; ≥18), sample type, by presence or absence of symptoms, symptom duration (<7 days vs. ≥7 days), by viral load and by type of RT-PCR used.

In an effort to use as much of the heterogeneous data as possible, the cut-offs for the Ct-value groups were relaxed by 2-3 points within each range. The <20 group included values reported up to ≤20, the <25 group included values reported as ≤24 or <25 or 20-25, the <30 group included values from ≤29 to ≤33 and 25-30. The ≥25 group included values reported as ≥25 or 25-30, the ≥30 group included values from ≥30 to ≥35. For categorization by sample type, we assessed (1) nasopharyngeal (NP) alone or combined with other (e.g., oropharyngeal (OP)), (2) OP alone, (3) anterior nasal or mid-

236 turbinate (AN/MT), (4) a combination of bronchial alveolar lavage and throat wash (BAL/TW) or (5)
237 saliva. For categorization by age, the pediatric group included values reported as <16 or <18, whereas
238 values reported as ≥16 or ≥18 were included in the adult group. Analyses were preformed using R
239 4.0.3 (R Foundation for Statistical Computing, Vienna, Austria).

240 We aimed to do meta-regression to examine the impact of covariates including symptom dura-
241 tion and Ct-value range. We also performed the Deeks' test for funnel-plot asymmetry as recom-
242 mended to investigate publication bias for diagnostic test accuracy meta-analyses ([18], using the
243 'midas' command in Stata version 15); a p-value<□0.10 for the slope coefficient indicates significant
244 asymmetry.

245

246 SENSITIVITY ANALYSIS

247 Two types of sensitivity analyses were planned: an estimation of sensitivity and specificity ex-
248 cluding case-control studies, and estimation of sensitivity and specificity excluding non-peer-
249 reviewed studies. We compared the results of each sensitivity analysis against overall results to as-
250 sess the potential bias introduced by considering case-control studies and non-peer reviewed stud-
251 ies.

RESULTS

SUMMARY OF STUDIES

The systematic search resulted in 14,254 articles. After removing duplicates, 8,921 articles were screened, and 266 papers were considered eligible for full-text review. Of these, 148 were excluded because they did not present primary data [13,19-131] or the Ag-RDT was not commercially available [16,132-164], leaving 133 studies to be included in the systematic review (Fig 1) [4,165-296].

At the end of the data extraction process, 37 studies were still in preprint form [4,171,173,174,177,180,190,192,201,204,205,207,211,214-216,218,220,222,223,225,227,231,233,234,238,240,244,247,253,257,265,267,284,287,290,293]. All studies were written in English, except for two in Spanish [175,280]. Out of the 133 studies, nine reported analytical accuracy [173,191,198,208,227,256,274,275,282] and the remaining 124 reported clinical accuracy.

The clinical accuracy studies were divided into 214 data sets, while the nine analytical accuracy studies accounted for 62 data sets. A total of 61 different Ag-RDTs were evaluated (48 lateral flow with visual readout, twelve requiring an automated reader), with 56 being assessed in a clinical accuracy study. 39 studies reported data for more than one test and 19 studies of these conducted a head-to-head assessment, i.e., testing at least two Ag-RDTs on the same sample or participant. The reference method was RT-PCR in all except one study, which used viral culture [281].

The most common reasons for testing were the occurrence of symptoms (55/19.9% of data sets), screening independent of symptoms (19/6.9%) and close contact to a SARS-CoV-2 confirmed case (10/3.6%). In 79 (28.6%) of the data sets, persons were tested due to more than one of the reasons mentioned before and for 163 (59.1%) the reason for testing was unclear.

In total, 113,242 Ag-RDTs were performed, 112,323 (99.2%) in clinical accuracy studies and 919 (0.8%) in analytical accuracy studies. In the clinical accuracy studies, the mean number of samples per study was 525 (Range 16 to 6,954). Only 4,752 (4.2%) tests were performed on pediatric samples and 21,351 (18.9%) on samples from adults. For the remaining 87,139 (76.9%) samples it was not

specified whether they originate from adults or children. Symptomatic patients comprised 36,981 (32.7%) samples, 32,799 (29.0%) samples originated from asymptomatic patients, and for 42,462 (38.4%) samples the patient's symptom status could not be identified. The most common sample type evaluated was NP and mixed NP/OP (67,036 samples, 59.2%), followed by AN/MT (27,045 samples, 23.9%). There was substantially less testing done for the other sample types, with 6,254 (5.5%) tests done from OP samples, 1,351 (1.2%) from saliva, 219 (0.2%) from BAL/TW and for 11,337 (10.0%) tests we could not tell the type of sample.

Of the data sets assessing clinical accuracy, 89 (41.6%) performed testing according to the manufacturers' recommendations (i.e., IFU-conforming), while 100 (46.7%) were not IFU-conforming and for 25 (11.7%) it was unclear. The most common deviations from the IFU were (1) use of samples that were prediluted in transport media not recommended by the manufacturer (80 data sets; seven unclear), (2) use of banked samples (60 data sets; 14 unclear) and (3) a sample type that was not recommended for Ag-RDTs (17 data sets; 8 unclear).

A summary of the tests evaluated in clinical accuracy studies, including study author, sample size, sample type, sample condition and IFU conformity, can be found in Table 1. The Panbio test by Abbott Rapid Diagnostics (Germany; henceforth called Panbio) was reported the most frequently with 39 (18.2%) data sets and 28,089 (25.0%) tests, while Standard Q test by SD Biosensor (South Korea; distributed in Europe by Roche, Germany; henceforth called Standard Q) was assessed in 37 (17.3%) data sets with 16,820 (15.0%) tests performed. Detailed results for each clinical accuracy study are available in the Supplement (S 4).

METHOLOGICAL QUALITY OF STUDIES

The findings on study quality using the QUADAS 2 tool are presented in Fig 2. In 190 (88.8%) data sets a relevant patient population was assessed. However, for only 44 (20.6%) of the data sets the patient selection was considered representative of the setting and population chosen (i.e., they

avoided inappropriate exclusions, a case-control design and enrollment occurred consecutive or randomly).

The conduct and interpretation of the index tests was considered to have low risk for introduction of bias in 113 (52.8%) of data sets (through e.g., appropriate blinding of persons interpreting the visual read-out). However, for 99 (46.3%) of data sets sufficient information to clearly judge the risk of bias was not provided. In only 89 (41.6%) of data sets the Ag-RDTs were performed according to IFU, while 100 (46.7%) were not IFU-conforming, potentially impacting the diagnostic accuracy (for 25 (11.7%) of data sets the IFU status was unclear).

In 81 (37.9%) of data sets the reference standard was performed before the Ag-RDT, or the operator conducting the reference standard was blinded to the Ag-RDT results, resulting in a low risk of bias. In almost all other data sets (132/61.7%) this risk could not be assessed due to missing data. The applicability of the reference test was judged to be of low concern for all data sets, as cell culture or RT-PCR are expected to adequately define the target condition.

In 209 (97.7%) data sets, the sample for the index test and reference test were obtained at the same time, while this was unclear in five (2.3%). All samples included in a data set were applied to the same type of RT-PCR in 145 (67.8%) data sets, while different types of RT-PCR were used within the same data set in 50 (23.4%) data sets. For 19 (8.9%), it was unclear. Furthermore, for 11 (5.1%) of data sets, there was a concern that not all selected patients were included in the analysis.

Finally, 32 (24.1%) of the studies received financial support from the Ag-RDT manufacturer and in another nine (6.8%) employment of the authors by the manufacturer of the Ag-RDT studied was indicated. Overall, a conflict of interest was found in 33 (24.8%) of the studies.

DETECTION OF SARS-COV-2 INFECTION

Out of 214 clinical data sets (from 124 studies), 20 were excluded from the meta-analysis, as they included less than 20 RT-PCR positive samples. Further 21 data sets were missing either sensitivity or specificity and were only considered for univariate analyses. Across the remaining 173 data

sets, including any test and type of sample, the pooled sensitivity and specificity were 71.2% (95%CI 68.2 to 74.0) and 98.9% (95%CI 98.6 to 99.1), respectively. If testing was performed in conformity with IFU, sensitivity increased to 76.3% (95%CI 73.1 to 79.2) compared to not IFU-conforming testing with a sensitivity of 65.9% (95%CI 60.6 to 70.8). Pooled specificity was similar in both groups (99.1% (95% CI 98.8-99.4)and 98.3% (95% CI 97.7 to 98.8), respectively).

ANALYSIS OF SPECIFIC TESTS

Based on 119 data sets with 71,424 tests performed, we were able to perform bivariate meta-analysis of the sensitivity and specificity for twelve different Ag-RDTs (Fig 3A). Across these, pooled estimates of sensitivity and specificity on all samples were 72.1% (95%CI 68.8 to 75.3) and 99.0% (95% CI 98.7 to 99.2), which were very similar to the overall pooled estimate across all meta-analyzed data sets (71.2% and 98.9%, above).

The highest pooled sensitivity was found for the SARS-CoV-2 Antigen Test by LumiraDx (United Kingdom; henceforth called LumiraDx) and the Lumipulse G SARS-CoV-2 Ag by Fujirebio (Japan; henceforth called Lumipulse G) with 88.2% (95% CI 59.0 to 97.5) and 87.2% (95% CI 78.0 to 92.9), respectively. The Sofia SARS Antigen FIA by QUIDEL (California, US; henceforth called Sofia) had a pooled sensitivity with 77.4% (95% CI 74.2 to 80.3). Of the non-instrument tests, the Standard Q and the Standard Q nasal test by SD Biosensor (South Korea; distributed in Europe by Roche, Germany; henceforth called Standard Q nasal) performed best with a pooled sensitivity of 74.9% (95% CI 69.3 to 79.7) and 80.2% (95% CI 70.3 to 87.4), respectively. The pooled sensitivity for Panbio was 71.8% (95%CI 65.4 to 77.5). From all Ag-RDTs, the COVID-19 Ag Respi-Strip by Coris BioConcept (Belgium; henceforth called Coris) had the lowest pooled sensitivity of 40.0% (95% CI 28.7 to 52.4).

The pooled specificity was above 98% for all of the tests, except for the Standard F by SD Biosensor (South Korea) and Lumipulse G with specificities of 97.7% (95% CI 96.6 to 98.5) and 96.7% (95% CI 88.6 to 99.1), respectively. Hierarchical summary receiver-operating characteristic for Standard Q and LumiraDx are available in the Supplement (S6).

Three Ag-RDTs did not have sufficient data to allow for a bivariate meta-analysis, wherefore a univariate analysis was conducted (Fig 3B). For the INNOVA SARS-CoV-2 Antigen Rapid Qualitative Test by Innova Medical Group (California, US) this resulted in a pooled sensitivity and specificity of 76.1% (95% CI 68.1 to 84.1) and 99.4% (95% CI 98.7 to 100), respectively. For the NADAL by NAL von Minden (Germany) and the COVID-19 Rapid Antigen Visual Read by SureScreen (United Kingdom), sufficient data was only available to analyze sensitivity, resulting in polled sensitivity estimates of 58.4% (95% CI 29.2 to 87.6) and 58.0% (95% CI 38.3 to 77.6) and, respectively.

The remaining 35 Ag-RDTs did not present sufficient data for neither a uni- nor a bivariate meta-analysis. However, 9/35 have results presented in more than one data set and are summarized in Table 2. Herein, the widest ranges of sensitivity were found for the ESPLINE SARS-CoV-2 by Fujirebio (Japan) with sensitivity reported between 8.1% and 80.7%, and the RIDA®QUICK SARS-CoV-2 Antigen by R-Biopharm (Germany) with sensitivity between 39.2% and 77.6%, both with three data sets each. In contrast, two other test with two data sets each showed the least variability in sensitivity: the Zhuhai Encode Medical Engineering, SARS-CoV-2 Antigen Rapid Test (China) reported sensitivity between 74.0% and 74.4% and the COVID-19 Rapid Antigen Flourescent by SureScreen (UK) reported sensitivity between 60.3% and 69.0%. However, for both tests both data sets originated from the same studies. Overall, the lowest sensitivity range was reported for the SARS-CoV-2 Antigen Rapid Test by MEDsan (Germany) with 36.5% to 45.2% across two data sets. The specificity ranges were above 96% for most of the tests. A notable outlier was the 2019-nCov Antigen Rapid Test Kit by Shenzhen Bioeasy Biotechnology (China; henceforth called Bioeasy), reporting the worst with a specificity as low as 85.6% in one study. Forest plots for the data sets for each Ag-RDT are provided in the Supplement (S5). The remaining 26 Ag-RDTs that were evaluated in one data set only are included in Table 1 and Supplement (S5).

In total, 16 studies accounting for 53 data sets conducted head-to-head clinical accuracy evaluations of different tests using the same sample(s) from the same participant. These data sets are underlined in Table 1; 15 such studies included more than 100 samples, and one study included too few

samples to draw clear conclusions [286]. Four studies performed their head-to-head evaluation as per manufacturers' instructions and on symptomatic patients. Across three of them, the Standard Q (sensitivity 73.2% to 91.2%) and the Standard Q nasal (sensitivity 82.5% to 91.2%) showed a similar range of sensitivity [207,215,271]. The fourth reported a sensitivity of 56.4% (95% CI 44.7 to 67.6) for the Biocredit Covid-19 Antigen rapid test kit by RapiGEN (South Korea; henceforth called Rapigen) and 52.6% (95% CI 40.9 to 64) for the SGTi-flex COVID-19 Ag by Sugentech (South Korea) [233].

All other head-to-head comparisons were not IFU-conforming. In one of these, the Rapid COVID-19 Ag Test by Healgen (sensitivity 77.1%) performed better than the Standard Q and Panbio (sensitivity 69.8% and 67.7%, respectively) [178]. In contrast to the overall findings of the meta-analysis above, two other head-to-head studies found that both the Standard Q (sensitivity 43.6% and 49.4) and Panbio (sensitivity 38.6% and 44.6%) had lower performance than the CLINITEST® Rapid COVID-19 Antigen Test by Siemens Healthineers (Germany; henceforth called Clinitest), which reported sensitivities 51.5% and 54.9% [167,279]. However, another study found both the Standard Q and Panbio (sensitivity 81.0% and 82.9%, respectively) to have a higher accuracy than the Sofia (sensitivity 80.4%) [196].

SUBGROUP ANALYSIS

The results are presented in Fig 4. Detailed results for the subgroup analysis are available in the Supplement (S7 to 11).

Subgroup analysis by Ct-values

High sensitivity was achieved for Ct-values <20 with 96.5% (95% CI 92.6 to 98.4). The pooled sensitivity for Ct-values <25 was markedly better at 95.8% (95% CI 92.3 to 97.8) compared to the group with Ct ≥ 25 at 50.7% (95% CI 35.6 to 65.8). A similar pattern was observed when the Ct-values were analyzed using cut-offs <30 or ≥30, resulting in a sensitivity of 79.9% (95% CI 70.3 to 86.9) and 20.9% (95% CI 12.5 to 32.8), respectively (Fig 4A).

In addition, it was possible to meta-analyze test specific pooled sensitivity for the Panbio: 97.7% sensitivity (95% CI 95.3 to 98.9) for Ct-value <20, 95.8% (95% CI 92.3 to 97.8) for Ct-value <25 and 83.4% (95% CI 69.1 to 91.9) for Ct-value <30. For Ct-value ≥25 sensitivity was 61.2% (95% CI 38.8 to 79.7) and 30.5% (95% CI 16.0 to 50.4) for Ct-value ≥30. For the other Ag-RDTs only limited data was available, which is presented in the supplements (S10).

Subgroup analysis by IFU conformity

The summary results are presented in Fig 4B. When assessing only studies with an IFU-conforming testing, pooled sensitivity from 81 datasets with 49,643 samples was 76.3% (95% CI 73.1 to 79.2). When not IFU-conforming sampling (75 data sets, 31,416 samples) was performed sensitivity decreased to 65.9% (95% CI 60.6 to 70.8).

For five tests it was possible to calculate pooled sensitivity estimates only including data sets with an IFU-conforming testing: Panbio (sensitivity of 76.5% (95% CI 69.5 to 82.3); 17 data sets, 12,856 samples), Standard Q (sensitivity of 79.3% (95% CI 73.5 to 84.1); 15 data sets, 6,584 samples), BinaxNOW (sensitivity of 61.8% (95% CI 48.0 to 74.0); 4 data sets, 8,163 samples), Rapigen (sensitivity of 67.1% (95% CI 50.4 to 80.4); 4 data sets, 1,934 samples) and Standard Q nasal (sensitivity of 83.8% (95% CI 77.8 to 88.4); 5 data sets, 683 samples). Specificity was above 98.6% for all tests.

In contrast, when the Panbio (14 data sets, 9,233 samples) and Standard Q (14 data sets, 4,714 samples) tests were not performed according to IFU, pooled sensitivity decreased to 64.3% (95% CI 50.9 to 75.8) and 67.4 (95% CI 57.2 to 76.2), respectively.

Subgroup analysis by sample type

Most data sets evaluated NP or combined NP/OP swabs (122 data sets and 59,810 samples) as the sample type for the Ag-RDT. NP or combined NP/OP swabs achieved a pooled sensitivity of 71.6% (95% CI 68.1 to 74.9). Data sets that used AN/MT swabs for Ag-RDTs (32 data sets and 25,814 samples) showed a summary estimate for sensitivity of 75.5% (95% CI 70.4 to 79.9). This was confirmed

433 by two studies that reported direct head-to-head comparison of NP and MT samples from the same
434 participants using the same Ag-RDT (Standard Q), where the two sample types showed equivalent
435 performance [271,272]. Analysis of performance with an OP swab (seven data sets, 5,165 samples),
436 showed pooled sensitivity of only 53.1% (95%CI 40.9 to 65.0). Saliva swabs (four data sets, 1,088
437 samples) showed the lowest pooled sensitivity with only 37.9% (95% CI 11.8 to 73.5) (Fig 4C).
438 We were not able to perform a subgroup meta-analysis for BAL/TW due to insufficient data as
439 there was only one study with 73 samples evaluating the Rapigen, Panbio and Standard Q [286].
440 However, BAL/TW would in any case be considered an off-label use.
441
442 **Subgroup analysis in symptomatic and asymptomatic patients**
443 Within the data sets possible to meta-analyze, 17,964 (54.1%) samples were from symptomatic
444 and 15,228 (45.9%) from asymptomatic patients. The pooled sensitivity for symptomatic patients was
445 markedly different compared to asymptomatic patients with 76.7% (95% CI 70.6 to 81.9) vs. 52.5%
446 (95% CI 43.7 to 61.1). Specificity was 99% for both groups (Figu 4D). Median Ct-values differed in
447 symptomatic and asymptomatic patients. For those studies where it was possible to extract a median
448 Ct-value, it ranged from 20.5 to 27.0 in symptomatic [170,207,226,258,271,272] and from 27.2 to
449 30.5 in asymptomatic [170,201,258] patients.
450
451 **Subgroup analysis comparing symptom duration**
452 Data were analyzed for 5,538 patients with symptoms less than 7 days, but very limited data
453 were available for patients with symptoms ≥ 7 days (397 patients). The pooled sensitivity for patients
454 with onset of symptoms <7 days was 83.8% (95% CI 76.3 to 89.2) which is markedly higher than the
455 61.5% (95% CI 52.2 to 70.0) sensitivity for individuals tested ≥ 7 days from onset of symptoms (Fig
456 4D).
457
458 **Subgroup analysis by age**

459 For adult patients, it was possible to pool estimates across 3,837 samples, whereas the pediatric
460 group included 7,326 samples. Sensitivity and specificity were 64.3% (95% CI 54.7 to 72.9) and 99.4%
461 (95% CI 98.9 to 99.7) in mostly symptomatic patients <18 years. In patients ≥18, sensitivity increased
462 to 74.8% (95% CI 66.5 to 81.6), while the specificity was similar (98.7%, 95% CI 97.2 to 99.4) (Fig 4E).
463
464 **Subgroup analysis by type of RT-PCR and viral load**
465 We were not able to perform a meta-analysis for the subgroups by type of RT-PCR or viral load
466 (viral copies/mL) due to insufficient data.
467 In 152 (71.0%) of the data sets only one type of RT-PCR was used, whereas 37 (17.3%) tested
468 samples in the same data set using different RT-PCRs. For 25 (11.7%) of the data sets the type of RT-
469 PCR was not reported. The Cobas® SARS-CoV-2 Test from Roche (Germany) was used most frequently
470 in 63 (29.4%) of the data sets, followed by the Allplex® 2019 n-CoV Assay from Seegene in 41 (19.2%)
471 and the SARS CoV-2 assay from TaqPath in 20 (9.3%) of the data sets
472 Median sensitivity in samples with viral load of >5 log 10 copies/ml was 72.4% (range 46.9 to
473 100), 97.8% (range 71.4 to 100) for >6 log 10 copies/ml and 100% (range 93.8 to 100) for >7 log 10
474 copies/ml, showing that the sensitivity increases with increasing viral load.
475
476 **Meta regression**
477 We were not able to perform a meta-regression due to the considerable heterogeneity in re-
478 porting sub-groups, which resulted in too few studies with sufficient data for comparison.
479
480 **Publication Bias**
481 The result of the Deeks' test (p=0.001) shows significant asymmetry in the funnel plot for all datasets
482 with complete results. This indicates there may be publication bias from studies with small sample
483 sizes. However, when looking at publications specifically for LumiraDx (p=0.567), Standard Q
484 (p=0.23), and Panbio (p=0.35), the results do not show significant asymmetry in the funnel plots,

485 indicating these tests may have less publication bias. All funnel plots are listed in the Supplement
486 (S12).
487
488 COMPARISON WITH ANALYTICAL STUDIES
489 The nine analytical studies were divided into 63 data sets, evaluating 23 different Ag-RDTs. Only
490 seven studies reported a samples size, wherein 833 (90.6%) samples originated from NP swabs and
491 for 86 (9.4%) the sample type was unclear. One of the two studies not reporting sample size used
492 saliva samples [198], while the other used the sample type specified in the respective Ag-RDT's IFU
493 [173].
494 Overall, the reported analytical sensitivity (limit of detection) in the studies resembled the re-
495 sults of the meta-analysis presented above. Rapigen (limit of detection (LOD) in log10 copies per
496 swab: 10.2) and Coris (LOD 7.46) were found to perform worse than Panbio (LOD 6.6 to 6.1) and
497 Standard Q (LOD 6.8 to 6.0), whereas the Clinitest (LOD 6.0) and the BinaxNOW by Abbott (LOD 4.6
498 to 4.9) performed even better [191,256,282]. Similar results were found in another study, where the
499 Standard Q showed the lowest LOD (detecting virus up to what is an equivalent Ct-value of 26.3 to
500 28.7), when compared to that of Rapigen and Coris (detecting virus up to what is an equivalent Ct-
501 value of only 18.4 for both) [208,274,275]. However, another study found the Panbio, Standard Q,
502 Coris and BinaxNOW to have a similar LOD of $5.0*10^3$ plaque forming units (pfu) /milliliter (ml), but
503 the ESPLINE SARS-CoV-2 by Fujirebio (Japan), the COVID-19 Rapid Antigen Test by MOLOGIC (United
504 Kingdom) and the Sure Status COVID-19 Antigen Card Test by Premier Medical Corporation (India) to
505 perform markedly better (LOD 2.5 to $5.0*10^2$ pfu/ml) [173]. An overview of all LODs reported in the
506 studies can be found in the Supplement (S13)
507
508 SENSITIVITY ANALYSIS
509 When the data sets from case control studies (25/173) were excluded, the estimated sensitivity
510 did not differ greatly, with a value of 70.9% (95% CI 67.7 to 73.9) compared to 71.2% (95% CI 68.2 to

511 74.0) in the overall analysis with no change in pooled specificity. When excluding the data sets from
512 pre-prints (64/173), sensitivity decreased slightly to 67.2% (95% CI 62.9 to 71.3) compared to the
513 overall analysis.

DISCUSSION

In this comprehensive systematic review and meta-analysis, we have summarized the data of 133 studies evaluating the accuracy of 61 different Ag-RDTs. Across all meta-analyzed samples, our results show a pooled sensitivity and specificity of 71.2% (95% CI 68.2 to 74.0) and 98.9% (95% CI 98.6 to 99.1). Over half of the studies did not perform the Ag-RDT in accordance with the test manufacturers' recommendation or the performance was unknown, which negatively impacted the sensitivity. When considering only IFU-conforming studies, the sensitivity increased to 76.3% (95% CI 73.1 to 79.2). While we found the sensitivity to vary across specific tests, the specificity was consistently high.

The two Ag-RDTs that have been approved through the WHO emergency use listing procedure, Abbott Panbio and SD Biosensor Standard Q (distributed by Roche in Europe), have not only drawn the largest research interest, but also perform at or above average when comparing their pooled accuracy to that of all Ag-RDTs (sensitivity of 71.8% for Panbio and of 74.9% for Standard Q). The Standard Q nasal demonstrated an even higher pooled sensitivity (80.2% compared to the NP test), although this is likely due to variability in populations tested, as head-to-head performance showed a comparable sensitivity. Three other Ag-RDTs showed an even higher accuracy with sensitivities ranging from 77.4% to 88.2% (namely Sofia, Lumipulse G and LumiraDX), but were only assessed on relatively small samples sizes (ranging from 1,373 to 3,532) and all required an instrument/reader.

Not surprisingly, lower Ct-values, the RT-PCR semi-quantitative correlate for a high virus concentration, resulted in a significantly higher Ag-RDT sensitivity than higher Ct-values (pooled sensitivity 96.5% and 95.8% for ct-values <20 and <25 vs. 50.7% and 20.9% for ct-values ≥25 and ≥30). This confirms prior data that suggested that antigen concentrations and Ct-values were highly correlated in NP samples [16]. Ag-RDTs also showed a higher sensitivity in patients within 7 days after symptom onset compared to patients later in the course of the disease (pooled sensitivity 83.8% vs. 61.5%),

which is to be expected given that samples from patients within the first week after symptom onset have been shown to contain the highest virus concentrations [297]. In line with this, studies reporting an unexpectedly low overall sensitivity either shared a small population size with an on average high Ct-value [230,273,288] or performed the Ag-RDT not as per IFU, e.g., using saliva or prediluted samples [167,170,203,248,279]. In contrast, studies with an unusually high Ag-RDT sensitivity were based on study populations with a low median Ct-value, between 18 and 22 [189,255,284].

Our analysis also found that the accuracy of Ag-RDTs is substantially higher in symptomatic patients than in asymptomatic (pooled sensitivity 76.7% vs. 52.5%). This is not surprising as studies that enrolled symptomatic patients showed a lower range of median Ct-values (i.e., higher viral load), than studies enrolling asymptomatic patients. Given that other studies found symptomatic and asymptomatic patients to have comparable viral loads [298,299], the differences found in our analysis are likely explained by the varied time in the course of the disease at which testing is performed in asymptomatic patients presenting for one-time screening testing. As symptoms start in the early phase of the disease when viral load is still high, studies testing only symptomatic patients have a higher chance of including patients with high viral loads. In contrast, study populations drawn from asymptomatic patients only have a higher chance of including patients at any point of disease (i.e., including late in disease, when PCR is still positive, but viable virus is rapidly decreasing) [300].

With regards to the sampling and testing procedure, we found Ag-RDTs to perform similarly across upper-respiratory swab samples (e.g., NP and AN/MT), particularly when considering the most reliable comparisons from head-to-head studies.

Similar to previous assessment [7], the methodological quality of the included studies revealed a very heterogenous picture. In the future, aligning the design of clinical accuracy studies to common agreed upon minimal specifications (e.g., by WHO or European Center of Disease Control) and reporting the results in a standardized way [301] would improve data quality and comparability.

The main strengths of our study lie in its comprehensive approach and continuous updates. By linking this review to our website www.diagnosticsglobalhealth.org, we strive to equip decision makers with the latest research findings on Ag-RDTs for SARS-CoV-2 and, to the best of our knowledge, are the first in doing so. At least once per week the website is updated by continuing the literature search and process described above. We plan to update the meta-analysis on a monthly basis and publish it on the website. Furthermore, our study used rigorous methods as both the study selection and data extraction were performed by one author and independently validated by a second, we conducted blinded pilot extractions before of the actual data extraction, and we prepared a detailed interpretation guide for the QUADAS-2 tool.

The study may be limited by the inclusion of both preprints and peer-reviewed literature, which could affect the quality of the data extracted. However, we aimed to balance this potential effect by applying a thorough assessment of all clinical studies included, utilizing the QUADAS-2 tool and performing a sensitivity analysis excluding preprint manuscripts. In addition, the studies included in our analysis varied widely in the reported range of viral loads, limiting the comparability of their results. To control for this, we analyzed the Ag-RDTs' performance at different levels of viral load. Finally, even though we are aware that further data exits from other sources, for example from governmental research institutes exists [302], such data could not be included as sufficient detail describing the methods and results are not publicly available.

CONCLUSION

In summary, it can be concluded that there are Ag-RDTs available that have high sensitivity, particularly when performed in the first week of illness when viral load is high, and excellent specificity. However, our analysis also highlights the variability in results between tests (which is not reflected in the manufacturer reported data), indicating the need for independent validations. Furthermore, the analysis highlights the importance of performing tests in accordance with the manufacturers' recommended procedures, and in alignment with standard diagnostic evaluation and reporting guidelines. The accuracy achievable by the best-performing Ag-RDTs, combined with the rapid turn-around time compared to RT-PCR, suggests that these tests could have a significant impact on the pandemic if applied in thoughtful testing and screening strategies.

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1564 *Table 1:* Clinical accuracy data for Ag-RDTs against SARS-CoV-2

Author	Study location	Sample type	Sample condition	IFU conform	Sample size	Sensitivity	Specificity
AAZ, COVID-VIRO® (LFA)							
[287] Schwob, a35.3	Switzerland	NP	fresh	yes	324	84.1% (95% CI 76.9-89.7)	100% (95% CI 98.0*-100*)
Abbott, BinaxNOW™ (LFA)							
[224] Pollock, f17.1	USA	AN	fresh	yes	2308	77.4% (95% CI 72.2-82.1)	99.4% (95% CI 99.0-99.7)
[283] Pilarowski, a29.1	USA	AN/MT	fresh	yes	878	57.7% (95% CI 36.9*-76.6*)	100%* (95% CI 99.6*-100*)
[197] James, f23.1	USA	AN	fresh	yes	2339	56.6% (95% CI 48.3*-64.6*)	99.9% (95% CI 99.6*-100)
[217] Okoye, f51.1	USA	MT	fresh	yes	2645	53.3% (95% CI 37.9*-68.3*)	100% (95% CI 99.9-100)
Abbott, Panbio™ (LFA)							
[175] Domínguez Fernández, f49.1	Spain	unclear	fresh	unclear	30	95.0% (95% CI 75.1*-99.9*)	100% (95% CI 69.2*-100*)
[250] Alemany, a02.1	Spain	NP	banked	no	919	93.4% (95% CI 91.5-95.0)	100% (95% CI 95.8-100)
[184] FINDdx, f42.2	Germany	NP	fresh	yes	281	90.9% (95% CI 78.3*-97.5*)	99.2% (95% CI 97.0-99.9*)
[276] Merino-Amador, a25.1	Spain	NP	fresh	yes	958	90.5% (95% CI 87.0*-93.4*)	98.8% (95% CI 97.6*-99.5*)
[267] Krüger, a52.1	Germany	NP	fresh	yes	1034	87.5% (95% CI 79.6*-93.2*)	99.9% (95% CI 99.4-100)
[287] Schwob, a35.2	Switzerland	NP	fresh	yes	271	86.1% (95% CI 78.6-91.7)	100% (95% CI 97.6*-100*)
[235] Stokes, f65.1	Canada	NP	fresh	yes	1641	86.2%* (95% CI 81.5*-90.1*)	99.9% (95% CI 99.5-100)
[252] Berger, a05.1	Switzerland	NP	fresh	yes	535	85.5% (95% CI 78.0-91.2)	100% (95% CI 99.1-100)
[177] Faíco-Filho, f63.1	Brazil	NP	fresh	yes	127	84.3% (95% CI 73.6*-91.9*)	98.2%* (95% CI 90.6*-100*)
[196] Jääskeläinen, f50.3	Finland	NP	banked	no	190	82.9%* (95% CI 76.0*-88.5*)	100% (95% CI 90.7*-100*)
[247] Abdulrahman, a01.1	Bahrain	AN/MT	fresh	no	4183	82.1% (95% CI 79.2-84.8)	99.1% (95% CI 98.8-99.4)
[263] Gremmels, a12.2	Netherlands	NP	fresh	yes	208	81.0% (95% CI 69.1*-89.8*)	100% (95% CI 97.5-100)
[214] Ngo Nsoga, f28.1	Switzerland	OP	fresh	no	402	81.0% (95% CI 74.2-86.6)	99.1% (95% CI 96.9-99.9)
[245] Yin, f82.2	Belgium	NP	fresh	yes	101	80.8% (95% CI 68.1-89.2)	not provided
[249] Albert, a03.1	Spain	NP	fresh	yes	412	79.6% (95% CI 66.5*-89.4*)	100% (95% CI 99.0-100)
[250] Alemany, a02.2	Spain	AN/MT	banked	no	487	79.5% (95% CI 71.0-86.4)	98.6%* (95% CI 96.9-99.6)
[258] Fenollar, a11.1	France	NP	fresh	yes	341	75.5% (95% CI 69.0*-81.2*)	94.9% (95% CI 89.8*-97.9*)
[270] Linares, a20.1	Spain	NP	fresh	unclear	255	73.3% (95% CI 60.3*-83.9*)	100% (95% CI 98.1*-100*)
[263] Gremmels, a12.1	Netherlands	NP	fresh	yes	1367	72.7*% (95% CI 64.5-79.9)	100% (95% CI 99.7-100)
[192] Halfon, f18.1	France	NP	unclear	no	200	72.0% (95% CI 62.1*-80.5*)	99.0% (95% CI 94.6*-100)
[253] Bulilete, a07.1	Spain	NP	fresh	yes	1362*	71.4% (95% CI 63.2*-78.7)	99.8% (95% CI 99.4-99.9)
[165] Akingba, f30.1	Southafrica	NP	fresh	unclear	657*	69.7%* (95% CI 61.5*-77.0*)	99.4%* (95% CI 98.3*-99.9*)

[174] Del Vecchio, f66.1	Italy	unclear	fresh	unclear	1441	68.9% (95% CI 55.7-80.1)	99.9% (95% CI 99.6-100)
[178] Favresse, f31.2	Belgium	NP	fresh	no	188	67.7% (95% CI 57.4-76.9)	100% (95% CI 96.1-100)
[257] Drevinek, a10.1	Czech Republic	NP	fresh	yes	591	66.4% (95% CI 59.8*-72.5*)	100% (95% CI 99.0-100)
[205] L'Huillier, f72.1	Switzerland	NP	fresh	yes	822	65.5%* (95% CI 56.3*-74.0)	99.9%* (95% CI 99.2*-100)
[221] Pérez-García, f52.2	Spain	NP	banked	no	320	60.0% (95% CI 52.2-67.4)	100% (95% CI 97.6-100)
[248] Agullo, a56.1	Spain	NP	fresh	yes	652*	57.6%* (95% CI 48.7*-66.1*)	99.8% (95% CI 98.9*-100)
[267] Krüger, a52.2	Germany	OP	fresh	no	74	50.0% (95% CI 1.3-98.7)	100% (95% CI 94.9-100)
[286] Schildgen, a33.2	Germany	BAL/TW	unclear	no	73	50.0% (95% CI 34.2*-65.8*)	77.4% (95% CI 58.9*-90.4*)
[292] Torres, a37.1	Spain	NP	fresh	yes	634	48.1% (95% CI 36.7*-59.6*)	100% (95% CI 99.3-100)
[244] Wagenhäuser, f89.2	Germany	OP	fresh	no	1029	46.7% (95% CI 24.8-69.9)	99.6% (95% CI 99.0-99.9)
[243] Villaverde, f55.1	Spain	NP	fresh	yes	1620	45.4% (95% CI 34.1-57.2)	99.8% (95% CI 99.4-99.9)
[248] Agullo, a56.2	Spain	AN/MT	fresh	no	659	44.7% (95% CI 36.1-53.6)	100% (95% CI 99.3*-100)
[279] Olearo, a54.2	Germany	OP	unclear	no	184	44.0%* (95% CI 33.2*-55.3*)	100% (95% CI 96.4*-100)
[170] Caruana, f34.2	Switzerland	NP	fresh	no	532	41.2% (95% CI 32.1*-50.8*)	99.5% (95% CI 98.3*-99.9*)
[167] Baro, f33.1	Spain	NP	banked	no	286	38.6% (95% CI 29.1-48.8)	99.5% (95% CI 97.0-100)
[248] Agullo, a56.3	Spain	saliva	fresh	no	610	23.1% (95% CI 16.0*-31.7*)	100% (95% CI 99.2*-100)
[213] Muhi, f90.1	Australia	NP	fresh	yes	2413	not provided	100% (95% CI 99.7-100)
Abbott, Panbio™ (nasal sampling) (LFA)							
[184] FINDdx, f42.1	Germany	AN/MT	fresh	yes	281	86.4% (95% CI 72.6*-94.8*)	99.2% (95% CI 97.0-99.9*)
Access Bio, CareStart™ COVID-19 Antigen Test (LFA)							
[225] Pollock, f59.1	USA	AN	fresh	yes	1498	57.7% (95% CI 51.1-64.1)	98.3% (95% CI 97.5-99.0)
Assure Tech, Ecotest COVID-19 Antigen Rapid Test (LFA)							
[194] Homza, f87.1	Czech Republic	NP	fresh	yes	318	75.7% (95% CI 66.5-83.5)	96.7% (95% CI 93.3-98.7)
Becton, Dickinson and Company, BD Veritor™ (requires reader)							
[281] Pekosz, a28.1	USA	NP	fresh	no	251	96.4% (95% CI 81.7*-99.9*)	98.7% (95% CI 96.1-99.7)
[293] Van der Moeren, a39.1	Netherlands	MT/OP	banked	no	351*	94.1% (95% CI 71.1-100)	100% (95% CI 98.9-100)
[190] Marti, f46.2	USA	AN	fresh	unclear	unknown	93.8% (95% CI 79.2*-99.2*)	not provided
[245] Yin, f82.1	Belgium	NP	fresh	yes	177	87.7% (95% CI 80.0-92.7)	not provided
[296] Young, a43.1	USA	NP	banked	no	251	76.3%* (95% CI 59.8*-88.6*)	99.5%* (95% CI 97.4*-99.9*)
[202] Kilic, f71.1	USA	AN	fresh	yes	1384	66.4% (95% CI 57.0-74.9)	98.8% (95% CI 98.1-99.3)
[231] Schuit, f64.1	Netherlands	NP	fresh	no	2678	63.9% (95% CI 57.4-70.1)	99.6% (95% CI 99.3-99.8)
[170] Caruana, f34.4	Switzerland	NP	fresh	no	532	41.2% (95% CI 32.1*-50.8*)	99.8%* (95% CI 98.7*-100*)
Becton, Dickinson and Company, Hometest (LFA)							

[234] Stohr, f45.1	Netherlands	AN	fresh	unclear	1604	48.9% (95% CI 41.3*-56.5*)	99.9% (95% CI 99.5-100)
Beijing Savant Biotechnology, SARS-CoV-2 detection kit (LFA)							
[295] Weitzel, a41.3	Chile	NP/OP	banked	no	109	16.7% (95% CI 9.2*-26.8*)	100% (95% CI 88.8*-100)
Biotime, COVID-19 Antigen Test Cassette (LFA)							
[232] Seitz, f68.1	Austria	saliva	fresh	yes	40	44.4% (95% CI 21.5*-69.2*)	100% (95% CI 84.6*-100*)
Bionote, NowCheck® (LFA)							
[185] FINDdx, f91.1	Brazil	AN	fresh	yes	218	89.9% (95% CI 81.0*-95.5*)	98.6% (95% CI 94.9-99.8*)
[185] FINDdx, f91.2	Brazil	NP	fresh	yes	218	89.9% (95% CI 81.0*-95.5*)	98.6% (95% CI 94.9-99.8*)
[259] FINDdx, a61.1	Brazil	NP	fresh	yes	400	89.2% (95% CI 81.5*-94.5*)	97.3% (95% CI 94.8-98.8*)
[228] Rottenstreich, f53.1	Israel	NP	unclear	unclear	1326	55.6% (95% CI 21.2-86.3)	100% (95% CI 99.7-100)
Biotical Health, SARS-CoV-2 Ag Card (LFA)							
[178] Favresse, f31.1	Belgium	NP	fresh	no	188	66.7% (95% CI 56.3-76.0)	98.9% (95% CI 94.1-99.9)
CerTest Biotec, SARS-CoV-2 one step test card (LFA)							
[221] Pérez-García, f52.1	Spain	NP	banked	no	320	53.5% (95% CI 45.7-61.2)	100% (95% CI 97.6-100)
Coris BioConcept, COVID-19 Ag Respi-Strip (LFA)							
[245] Yin, f82.3	Belgium	NP	fresh	yes	135	80.0% (95% CI 69.2-87.7)	not provided
[277] Mertens, a48.1	Belgium	NP	banked	no	328	57.6% (95% CI 48.7*-66.1*)	99.5% (95% CI 97.2*-100*)
[269] Lambert-Niclot, a18.1	France	NP	fresh	no	138	50.0% (95% CI 39.5-60.5)	100% (95% CI 92.0*-100)
[4] Krüger, a17.3	Germany/England	NP/OP	unclear	no	417	50.0% (95% CI 21.5*-78.5)	95.8% (95% CI 93.4-97.4)
[172] Ciotti, f24.1	Italy	NP	fresh	unclear	50	30.8% (95% CI 17.0-47.6)	100% (95% CI 71.5-100)
[288] Scohy, a34.1	Belgium	NP	fresh	no	148	30.2% (95% CI 21.7-39.9)	100% (95% CI 91.6*-100*)
[294] Veyrenche, a40.1	France	NP	fresh	no	65	28.9%* (95% CI 16.4*-44.3*)	100% (95% CI 83.2-100)
Denka, Quick Navi (LFA)							
[237] Takeuchi, f12.1	Japan	NP	fresh	unclear	1186	86.7% (95% CI 78.6-92.5)	100% (95% CI 99.7-100)
[238] Takeuchi, f60.1	Japan	AN	fresh	unclear	862	72.5% (95% CI 58.3-84.1)	100% (95% CI 99.5*-100)
DiaSorin, LIAISON® SARS-CoV-2 Ag (LFA)							
[206] Lefever, f70.1	Belgium	NP	banked	no	414	67.6%* (95% CI 60.8*-74.0*)	100% (95% CI 98.3*-100)
Dräger, Antigen Test SARS-CoV-2 (LFA)							
[218] Osmanodja, f79.1	Germany	NP/OP	fresh	yes	379	88.6% (95% CI 78.7-94.9)	99.7% (95% CI 98.2-100)
E25Bio, Rapid Diagnostic Test (LFA)							
[223] Pickering, f73.2	United Kingdom	AN/OP	banked	no	200	75.0% (95% CI 65.3*-83.1*)	86% (95% CI 77.6*-92.1*)
EcoDiagnostica, COVID-19 Ag (LFA)							
[180] Filgueiras, f14.1	Brazil	NP	fresh	unclear	150	69.1% (95% CI 55.2*-80.9*)	98.8% (95% CI 93.5*-100)
Fujirebio, ESPLINE® SARS-CoV-2 (LFA)							
[290] Takeda, a50.1	Japan	NP	unclear	no	162	80.6%* (95% CI 68.6*-89.6*)	100%* (95% CI 96.4*-100*)
[186] FINDdx, f92.1	Germany	NP/OP	fresh	no	723	78.6% (95% CI 69.8*-85.8*)	100% (95% CI 99.4-100)

[230] Sberna, f83.1	Italy	saliva	unclear	unclear	136	8.1% (95% CI 2.7-17.8)	100% (95% CI 95.1-100)
Fujirebio, Lumipulse® G SARS-CoV-2 Ag (requires reader)							
[189] Gili, f57.2	Italy	NP	banked	no	226	100% (95% CI 96.0*-100*)	92.1% (95% CI 90.7*-93.4*)
[189] Gili, f57.1	Italy	NP	fresh	no	1738	90.5% (95% CI 82.8*-95.6*)	91.6% (95% CI 85.5*-95.7*)
[193] Hirotsu, f47.1	Japan	NP	banked	no	1033	92.5% (95% CI 79.6*-98.4*)	100%* (95% CI 99.6*-100*)
[168] Basso, f10.1	Italy	NP	fresh	yes	234	81.6% (95% CI 71.9*-89.1*)	93.9%* (95% CI 88.7*-97.2*)
[166] Asai, f74.1	Japan	saliva	unclear	yes	305	77.8% (95% CI 65.5*-87.3*)	98.3% (95% CI 95.8*-99.5*)
[168] Basso, f10.2	Italy	saliva	fresh	yes	223	41.3% (95% CI 30.4-52.8)	98.6% (95% CI 95.0-99.8)
Guangzhou Wondfo Biotech, 2019-nCoV Antigen Test (LFA)							
[183] FINDdx, f41.1	Switzerland	NP	fresh	yes	328	85.7% (95% CI 73.8*-93.6*)	100% (95% CI 98.7*-100*)
Humasis, COVID-19 Ag Test (LFA)							
[169] Bruzzone, f86.2	Italy	unclear	banked	no	21	85.7% (95% CI 63.7*-97*)	not provided
Healgen, Rapid COVID-19 Ag Test (LFA)							
[178] Favresse, f31.3	Belgium	NP	fresh	no	188	77.1% (95% CI 67.4-85.1)	96.7% (95% CI 90.8-99.3)
ichroma, COVID-19 AG (requires reader)							
[181] FINDdx, f39.1	Switzerland	NP	fresh	yes	232	73.2% (95% CI 57.1*-85.8*)	100% (95% CI 98.0-100)
Innova Medical Group, INNOVA SARS-CoV-2 Antigen Rapid Qualitative Test (LFA)							
[223] Pickering, f73.1	United Kingdom	AN/OP	banked	no	200	89.0% (95% CI 81.2*-94.4*)	99.0% (95% CI 94.6-100)
[195] Houston, f25.1	United Kingdom	NP	fresh	yes	242	86.4% (95% CI 81.9*-90.2*)	95.1% (95% CI 92.7*-96.9*)
[223] Pickering, f73.10	United Kingdom	AN/OP	banked	no	23	82.6% (95% CI 61.2*-95.0*)	not provided
[223] Pickering, f73.11	United Kingdom	AN/OP	banked	no	23	82.6% (95% CI 61.2*-95.0*)	not provided
[222] Peto, f21.1	United Kingdom	unclear	unclear	unclear	6954	not provided	99.7% (95% CI 99.5*-99.8*)
[222] Peto, f21.4	United Kingdom	unclear	unclear	unclear	198	78.8% (95% CI 72.4-84.3)	not provided
[223] Pickering, f73.12	United Kingdom	AN/OP	banked	no	23	78.3% (95% CI 56.3*-92.5*)	not provided
[223] Pickering, f73.8	United Kingdom	AN/OP	banked	no	110	78.2% (95% CI 69.3*-85.5*)	not provided
[222] Peto, f21.3	United Kingdom	unclear	unclear	unclear	223	70.0% (95% CI 63.5-75.9)	not provided
[246] Young, f56.1	United Kingdom	NP	fresh	unclear	803	62.1%*(95% CI 55.3*-68.7*)	100% (95% CI 99.4-100)
[222] Peto, f21.2	United Kingdom	unclear	unclear	unclear	372	57.5% (95% CI 52.3-62.6)	not provided
[179] Ferguson, f85.1	United Kingdom	AN	fresh	yes	720	3.2% (95% CI 0.6-15.6)	100% (95% CI 99.5-100)
JOYSBIO Biotechnology, COVID-19 Antigen Rapid Test Kit (LFA)							
[182] FINDdx, f40.1	Switzerland	NP	fresh	yes	265	70.5% (95% CI 54.8*-83.2*)	99.1% (95% CI 96.8*-99.9*)
[194] Homza, f87.2	Czech Republic	NP	fresh	yes	225	57.8% (95% CI 46.9-68.1)	98.5% (95% CI 94.8-99.8)
Lab Care Diagnostics, PathoCatch/ACCUCARE SARS-CoV-2 Antigen Test (LFA)							
[239] Thakur, f88.1	India	NP	fresh	yes	677	34.5% (95% CI 24.5-45.6)	99.8% (95% CI 99.1-100)

Lepu Medical, SARS-CoV-2 Antigen Rapid Test Kit (LFA)							
[167] Baro, f33.4	Spain	NP	banked	no	286	45.5% (95% CI 35.6-55.8)	89.2% (95% CI 83.8-93.3)
Liming Bio, SARS-CoV-2 Ag-RDT (LFA)							
[295] Weitzel, a41.2	Chile	NP/OP	banked	no	19	0% (95% CI 0-29.9)	90.0% (95% CI 59.6-98.2)
LumiraDx, COVID-19 SARS-CoV-2 Antigen Test (requires reader)							
[176] Drain, f43.1	UK/US	AN	fresh	yes	257	97.6% (95% CI 91.6*-99.7*)	96.6% (95% CI 92.6*-98.7*)
[176] Drain, f43.2	UK/US	NP	fresh	yes	255	97.5% (95% CI 86.8*-99.9*)	97.7% (95% CI 94.7-99.2*)
[204] Krüger, f58.1	Germany	MT	fresh	yes	761	82.2% (95% CI 75.0*-88.0*)	99.3% (95% CI 98.3-99.7)
[169] Bruzzone, f86.6	Italy	unclear	banked	no	23	69.6% (95% CI 47.1*-86.8*)	not provided
[203] Kohmer, f32.4	Germany	NP	fresh	no	100	50.0% (95% CI 38.1-61.9)	100% (95% CI 86.8-100)
[211] Micocci, f77.1	United Kingdom	NP	fresh	unclear	241	75.0%* (95% CI 34.9*-96.8*)	96.1%* (95% CI 92.7*-98.2*)
MEDsan®, SARS-CoV-2 Antigen Rapid Test (LFA)							
[279] Olearo, a54.3	Germany	OP	unclear	no	184	45.2%* (95% CI 34.3*-56.5)	97.0% (95% CI 91.5-99.4*)
[244] Wagenhäuser, f89.3	Germany	OP	fresh	yes	3221	36.5% (95% CI 24.7*-49.6*)	99.6% (95% CI 99.3-99.8)
MOLOGIC, COVID-19 Rapid Antigen Test (LFA)							
[187] FINDdx, f93.1	Germany	AN/NMT	fresh	yes	665	90.7% (95% CI 85.7*-94.4*)	100% (95% CI 99.2-100)
NAL von minden, NADAL (LFA)							
[188] FINDdx, f94.1	Switzerland	NP	fresh	yes	462	88.4% (95% CI 78.4*-94.9*)	99.2% (95% CI 97.8-99.7)
[236] Strömer, f11.1	Germany	NP	banked	no	124	63.7%* (95% CI 54.6*-72.2*)	not provided
[244] Wagenhäuser, f89.1	Germany	OP	fresh	yes	806	56.5% (95% CI 34.5*-76.8*)	100% (95% CI 99.5-100)
[203] Kohmer, f32.3	Germany	NP	fresh	no	100	24.3% (95% CI 15.1-35.7)	100% (95% CI 86.8-100)
NanoEntek, FREND™ COVID-19 Ag (requires reader)							
[169] Bruzzone, f86.7	Italy	unclear	banked	no	60	93.3% (95% CI 83.8*-98.2*)	not provided
NDFOS, ND COVID-19 Ag Test (LFA)							
[194] Homza, f87.3	Czech Republic	NP	fresh	yes	191	70.1% (95% CI 58.6-80.0)	56.1% (95% CI 46.4-65.4)
Ortho Clinical Diagnostics, VITROS® SARS-CoV-2 Antigen Test (requires reader)							
[178] Favresse, f31.5	Belgium	NP	fresh	no	188	83.3% (95% CI 74.4-90.2)	100% (95% CI 96.1-100)
Precision Biosensors, Exdia COVID-19 Ag (requires reader)							
[170] Caruana, f34.3	Switzerland	NP	fresh	no	532	48.3% (95% CI 38.8*-57.8*)	99.5% (95% CI 98.3*-99.9*)
PRIMA, COVID-19 Antigen Rapid Test (LFA)							
[169] Bruzzone, f86.3	Italy	unclear	banked	no	50	66.0% (95% CI 51.2*-78.8*)	not provided
QUIDEL, Sofia SARS Antigen FIA (requires reader)							
[284] Porte, a32.1	Chile	NP/OP	banked	no	64	93.8% (95% CI 79.2*-99.2*)	96.9% (95% CI 83.8*-99.9*)
[196] Jääskeläinen, f50.1	Finland	NP	banked	no	188	80.4% (95% CI 73.1*-86.5*)	100% (95% CI 91.2*-100*)
[251] Beck, a04.1	USA	NP	fresh	yes	346	77.0% (95% CI 64.5*-86.8*)	99.6% (95% CI 98.1*-100*)
[265] Herrera, a46.1	USA	unclear	unclear	unclear	1172	76.8% (95% CI	99.2% (95% CI

						72.6-80.5)	98.2-99.7)
[190] Marti, f46.1	USA	MT	fresh	unclear	427	72.0% (95% CI 56.3*-84.7*)	99.7%* (95% CI 98.6*-100*)
RapiGEN, Biocredit Covid-19 Antigen Detection Kit (LFA)							
[289] Shrestha, a36.1	Nepal	NP	fresh	yes	113	85.0% (95% CI 71.7*-93.8*)	100% (95% CI 94.6*-100*)
[260] FINDdx, a62.1	Brazil	NP	fresh	yes	476	74.4% (95% CI 65.5*-82.0*)	98.9%* (95% CI 97.2-99.7*)
[295] Weitzel, a41.1	Chile	NP/OP	banked	no	109	62.0% (95% CI 50.4*-72.7*)	100% (95% CI 88.4*-100)
[233] Shidlovskaya, f61.1	Russia	NP	fresh	yes	106	56.4% (95% CI 44.7-67.6)	100% (95% CI 87.7-100)
[260] FINDdx, a62.2	Germany	ONP	fresh	yes	1239	52.0% (95% CI 31.3*-72.2*)	100% (95% CI 99.7-100)
[169] Bruzzone, f86.4	Italy	unclear	banked	no	23	39.1% (95% CI 19.7*-61.5*)	not provided
[286] Schildgen, a33.1	Germany	BAL/TW	unclear	no	73	33.3% (95% CI 19.6*-49.6*)	87.1% (95% CI 70.2*-96.4*)
[200] Kenyeres, f84.1	Hungary	NP	fresh	no	37	8.1% (95% CI 1.7*-21.9*)	not provided
R-Biopharm, RIDA®QUICK SARS-CoV-2 Antigen (LFA)							
[291] Toptan, a55.1	Germany	NP/OP	banked	no	67	77.6% (95% CI 64.7*-87.5*)	100% (95% CI 66.4*-100*)
[291] Toptan, a55.2	Germany	unclear	banked	no	70	50.0% (95% CI 31.9*-68.1*)	100% (95% CI 90.8*-100*)
[203] Kohmer, f32.1	Germany	NP	fresh	no	100	39.2% (95% CI 28.0-51.2)	96.2% (95% CI 80.4-99.9)
Roche, Elecsys® SARS-CoV-2 Antigen Test (requires reader)							
[216] Nörz, f78.1	Germany	NP/OP	banked	no	3139	60.2% (95% CI 55.2-65.1)	99.9% (95% CI 99.6-100)
Roche, SARS-CoV-2 Rapid Antigen Test (LFA)							
[240] Thell, f81.1	Austria	unclear	fresh	unclear	591	80.3% (95% CI 74.3-85.4)	99.1% (95% CI 97.4-99.8)
SD Biosensor, Standard F (requires reader)							
[284] Porte, a32.2	Chile	NP/OP	banked	no	64	90.6% (95% CI 75.0*-98.0*)	96.9% (95% CI 83.8*-99.9*)
[169] Bruzzone, f86.5	Italy	unclear	banked	no	60	86.7% (95% CI 75.4*-94.1*)	not provided
[261] FINDdx, a63.1	Brazil	NP	fresh	yes	453	77.5% (95% CI 69.0*-84.6*)	97.9% (95% CI 95.7-99.2*)
[261] FINDdx, a63.2	Germany	ONP	fresh	yes	676	69.2% (95% CI 52.4*-83.0*)	96.9% (95% CI 95.2-98.0)
[257] Drevinek, a10.2	Czech Republic	NP	fresh	yes	591	62.3% (95% CI 55.6*-68.7*)	99.5% (95% CI 98.0-99.9)
[219] Osterman, f20.1	Germany	NP/OP	unclear	no	360	60.9% (95% CI 53.5*-67.8*)	97.8% (95% CI 95.7-99.0*)
[273] Liotti, a22.1	Italy	NP	banked	no	359	47.1% (95% CI 37.1-57.1)	98.4% (95% CI 96.0-99.6)
SD Biosensor / Roche, Standard Q (LFA)							
[255] Chaimayo, a57.1	Thailand	NP/OP	banked	no	454	98.3% (95% CI 91.1-100)	98.7% (95% CI 97.1-99.6)
[169] Bruzzone, f86.1	Italy	unclear	banked	no	16	93.8% (95% CI 71.7-98.9)	not provided
[201] Kerneis, f69.1	France	NP	fresh	unclear	1109	94.2%* (95% CI 87.0*-98.1*)	99.0% (95% CI 98.2*-99.5*)
[287] Schwob, a35.1	Switzerland	NP	fresh	yes	333	92.9% (95% CI 86.4-96.9)	100% (95% CI 98.3*-100*)
[215] Nikolai, f35.3	Germany	NP	fresh	yes	96	91.2% (95% CI 76.3*-98.1*)	100% (95% CI 94.2-100)
[252] Berger, a05.2	Switzerland	NP	fresh	yes	529	89.0% (95% CI 83.7-93.1)	99.7% (95% CI 98.4-100)

[262] FINDdx, a64.1	Brazil	NP	fresh	yes	400	88.7% (95% CI 81.1*-94.0*)	97.6% (95% CI 95.2-99.0*)
[286] Schildgen, a33.3	Germany	BAL/TW	unclear	no	73	88.1% (95% CI 74.4*-96.0*)	19.4% (95% CI 7.5*-37.5*)
[207] Lindner, f15.1	Germany	NP	fresh	yes	139	85.0% (95% CI 70.2*-94.3*)	99.1% (95% CI 94.9*-100*)
[266] Igl□i, a15.1	Netherlands	NP	fresh	yes	970	84.9% (95% CI 79.0*-89.8*)	99.5% (95% CI 98.7-99.9*)
[264] Gupta, a13.1	India	NP	fresh	yes	330	81.8% (95% CI 71.4*-89.7*)	99.6% (95% CI 97.8-99.9)
[196] Jääskeläinen, f50.2	Finland	NP	banked	no	198	81.0% (95% CI 74.0*-86.8*)	100% (95% CI 91.2*-100*)
[242] Turcato, f09.1	Italy	NP	fresh	unclear	3410	80.3% (95% CI 74.4*-85.3*)	99.1% (95% CI 98.7*-99.4*)
[272] Lindner, a21.2	Germany	NP	fresh	yes	289	79.5% (95% CI 63.5*-90.7*)	99.6% (95% CI 97.8-100)
[245] Yin, f82.4	Belgium	NP	fresh	yes	65	78.3% (95% CI 58.1-90.3)	not provided
[4] Krüger, a17.1	Germany/England	NP/OP	unclear	no	1263	76.6% (95% CI 62.0*-87.7*)	99.3% (95% CI 98.6-99.7*)
[212] Möckel, f19.1	Germany	NP/OP	fresh	yes	271	75.3% (95% CI 65.0*-83.8*)	100% (95% CI 98.0*-100)
[272] Lindner, a21.1	Germany	AN/MT	fresh	no	289	74.4% (95% CI 57.9*87.0*)	99.2% (95% CI 97.1-99.9*)
[271] Lindner, a53.1	Germany	NP	fresh	yes	180	73.2%* (95% CI 57.1*-85.8*)	99.3% (95% CI 96.0-100)
[229] Salvagno, f54.1	Italy	NP	unclear	no	321	72.5% (95% CI 64.6-79.5)	99.4% (95% CI 96.8-100)
[254] Cerutti, a08.1	Italy	NP	unclear	no	185	72.1% (95% CI 62.5*-80.5*)	100% (95% CI 95.6*-100*)
[212] Möckel, f19.2	Germany	NP/OP	fresh	yes	2020	72.0% (95% CI 50.6*-87.9*)	99.4% (95% CI 96.9*-100*)
[268] Krüttgen, a16.1	Germany	NP	banked	no	150	70.7% (95% CI 59.0*-80.6*)	96.0% (95% CI 88.8*-99.2*)
[278] Nalumansi, a27.1	Uganda	NP	fresh	yes	262	70.0% (95% CI 59.4*-79.2*)	92.4%* (95% CI 87.4*-95.9*)
[220] Pena, f36.1	Chile	NP	fresh	yes	842	69.9% (95% CI 58.0*-80.1*)	99.6% (95% CI 98.9-99.9)
[178] Favresse, f31.4	Belgium	NP	fresh	no	188	69.8% (95% CI 59.6-78.8)	100% (95% CI 96.1-100)
[219] Osterman, f20.2	Germany	NP/OP	unclear	no	386	64.5% (95% CI 58.3*-70.3*)	97.7% (95% CI 95.6-98.9*)
[194] Homza, f87.4	Czech Republic	NP	fresh	yes	139	61.9% (95% CI 45.6-76.4)	99.0% (95% CI 94.4-100)
[231] Schuit, f64.2	Netherlands	NP	fresh	yes	1596	62.9% (95% CI 54.0-71.1)	99.5% (95% CI 98.9-99.8)
[226] Ristic, f44.1	Serbia	NP	fresh	unclear	120	58.1% (95% CI 42.1-73.0)	100% (95% CI 95.3*-100*)
[199] Kannian, f26.1	India	saliva	unclear	no	37	55.6%* (95% CI 35.3*-74.5*)	100% (95% CI 69.2*-100*)
[279] Olearo, a54.1	Germany	OP	unclear	no	184	48.8%* (95% CI 37.7*-60.0*)	100% (95% CI 96.4*-100)
[167] Baro, f33.3	Spain	NP	banked	no	286	43.6% (95% CI 33.7-53.8)	96.2% (95% CI 92.4-98.5)
[203] Kohmer, f32.2	Germany	NP	fresh	no	100	43.2% (95% CI 31.8*-55.3)	100% (95% CI 86.8-100)
[170] Caruana, f34.1	Switzerland	NP	fresh	no	532	41.2% (95% CI 32.1*-50.8*)	99.8%* (95% CI 98.7*-100*)
[254] Cerutti, a08.2	Italy	NP	fresh	no	145	40.0% (95% CI 5.3*-85.3*)	100% (95% CI 97.4*-100*)
[171] Caruana, f75.1	Switzerland	NP	fresh	unclear	116	28.6% (95% CI 3.7*-71.0*)	98.2% (95% CI 93.5*-99.8*)
SD Biosensor / Roche, Standard Q (nasal sampling) (LFA)							

[215] Nikolai, f35.4	Germany	MT	fresh	yes	96	91.2% (95% CI 76.3*-98.1*)	98.4% (95% CI 91.3*-100*)
[215] Nikolai, f35.2	Germany	MT	fresh	yes	132	86.1% (95% CI 70.5*-95.3*)	100% (95% CI 96.2*-100*)
[215] Nikolai, f35.1	Germany	AN	fresh	yes	132	86.1% (95% CI 70.5*-95.3*)	100% (95% CI 96.2*-100*)
[207] Lindner, f15.2	Germany	MT	fresh	yes	180	82.5% (95% CI 67.2*92.7*)	100% (95% CI 96.5-100)
[234] Stohr, f45.2	Netherlands	AN	fresh	unclear	1611	61.5% (95% CI 54.2*-68.4*)	99.7% (95% CI 99.3-99.9)
[271] Lindner, a53.2	Germany	AN	fresh	yes	179	80.5% (95% CI 65.1*-91.2*)	98.6% (95% CI 94.9-99.8*)
Shenzhen Lvshiyuan Biotechnology, Green Spring® SARS-CoV-2-Antigen-Schnelltest-Set (LFA)							
[223] Pickering, f73.4	United Kingdom	AN/OP	banked	no	200	77.0% (95% CI 67.5*-84.8*)	98.0% (95% CI 93.0-99.8*)
Shenzen Bioeasy Biotechnology, 2019-nCov Antigen Rapid Test Kit (requires reader)							
[285] Porte, a31.1	Chile	NP/OP	banked	no	127	93.9% (95% CI 86.3*-98.0*)	100% (95% CI 92.1*-100*)
[295] Weitzel, a41.4	Chile	NP/OP	banked	no	111	85.0% (95% CI 75.3*-92.0*)	100% (95% CI 88.8*-100)
[282] Parada-Ricart, a58.1	Spain	NP	fresh	yes	172	73.1%* (95% CI 52.2*-88.4*)	85.6%* (95% CI 78.9*-90.9*)
[4] Krüger, a17.2	Germany	NP/OP	fresh	no	727*	66.7% (95% CI 41.7-84.8)	93.1% (95% CI 91.0-94.8)
Siemens Healthineers, CLINITEST® Rapid COVID-19 Antigen Test (LFA)							
[241] Torres, f29.1	Spain	NP	fresh	yes	178	80.2% (95% CI 70.6*-87.8*)	100% (95% CI 95.8-100)
[241] Torres, f29.2	Spain	NP	fresh	yes	92	60.0% (95% CI 38.7*-78.9*)	100% (95% CI 94.6-100)
[279] Olearo, a54.4	Germany	OP	unclear	no	170	54.8%* (95% CI 43.5*-65.7*)	100% (95% CI 95.8*-100)
[167] Baro, f33.2	Spain	NP	banked	no	286	51.5% (95% CI 41.3-61.6)	98.4% (95% CI 95.3-99.7*)
SIENNA, COVID-19 Antigen Rapid Test (LFA)							
[209] Bouassa, f67.1	France	NP	banked	no	100	90.0% (95% CI 82.4*-95.1*)	100% (95% CI 92.9*-100)
Sugentech, SGTi-flex COVID-19 Ag (LFA)							
[233] Shidlovskaya, f61.2	Russia	NP	fresh	yes	106	52.6% (95% CI 40.9-64.0)	96.4% (95% CI 81.7-99.9)
SureScreen, COVID-19 Rapid Antigen Visual Read (LFA)							
[223] Pickering, f73.14	United Kingdom	AN/OP	banked	no	23	74.0%* (95% CI 51.6*-89.8*)	not provided
[223] Pickering, f73.3	United Kingdom	AN/OP	banked	no	200	65.0% (95% CI 54.8*-74.3*)	100% (95% CI 96.4*-100*)
[223] Pickering, f73.15	United Kingdom	AN/OP	banked	no	23	65.2% (95% CI 42.7*-83.6*)	not provided
[223] Pickering, f73.13	United Kingdom	AN/OP	banked	no	23	61.0%* (95% CI 38.5*-80.3*)	not provided
[167] Baro, f33.5	Spain	NP	banked	no	286	28.8% (95% CI 20.2-38.6)	97.8% (95% CI 94.5-99.4)
SureScreen, COVID-19 Rapid Antigen Flourescent (requires reader)							
[223] Pickering, f73.6	United Kingdom	AN/OP	banked	no	200	69.0% (95% CI 59.0*-77.9*)	98.0% (95% CI 93-99.8*)
[223] Pickering, f73.7	United Kingdom	AN/OP	banked	no	141	60.3% (95% CI 51.7*-68.4*)	not provided
VivaCheck, VivaDiag™ SARS-CoV-2 Ag Rapid Test (LFA)							
[194] Homza, f87.5	Czech Republic	NP	fresh	yes	268	41.8% (95% CI 31.5-52.6)	96.0% (95% CI 92.0-98.4)
Zhuhai Encode Medical Engineering, SARS-CoV-2 Antigen Rapid Test (LFA)							
[223] Pickering,	United Kingdom	AN/OP	banked	no	200	74.0% (95% CI	100% (95% CI

	f73.5						64.3*-82.3*)	96.4*-100)
	[223] Pickering, f73.9	United Kingdom	AN/OP	banked	no	90	74.4% (95% CI 64.2*-83.1*)	not provided

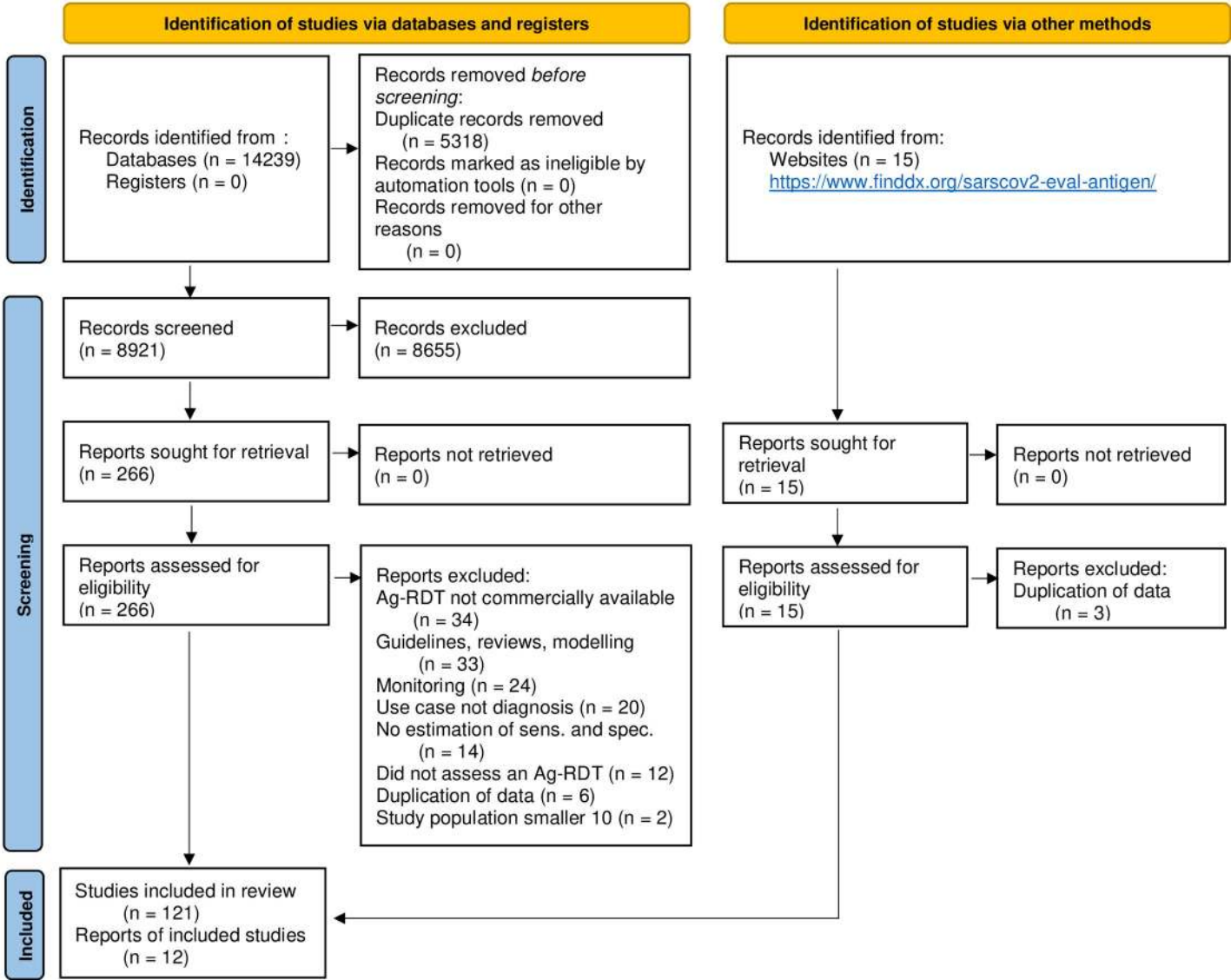
Caption: * Values differ from those provided in the respective manuscript due to missing or contradictory data. A list including the original data can be found in the Supplement (S4).
Data sets from an underlined author have not undergone peer-review yet (time of data extraction, 28.12.2020).
In data sets with underlined sample sizes the samples were used in head-to-head studies, performing different Ag-RDTs on the same patient.
Naming convention column "author": number in brackets relates to the list of sources. Letters behind the author's last name differentiates the data set from other data sets by the same author.
IFU = instructions for use; NP = nasopharyngeal; OP = oropharyngeal; AN = anterior nasal; MT = mid turbine; LRT = lower respiratory tract; BAL/TW = bronchoalveolar lavage and throat wash; CI = confidence interval.

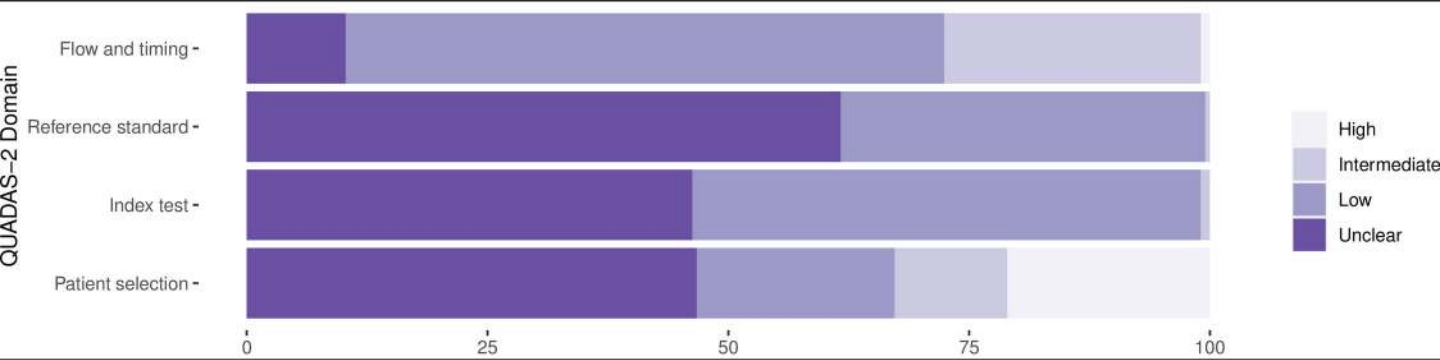
Table 2: Summary clinical accuracy data for major Ag-RDTs not included in the meta-analysis

Manufacturer, Ag-RDT	Number of data sets	Sensitivity range	Specifcity range	Comments
Bionote, NowCheck® (LFA)	3	55.6% to 89.9%	97.3% to 100%	- Two of the studies were IFU-conform, where-as IFU-conformity for the study reporting 55.6% sensitivity was unclear
Denka, Quick Navi (LFA)	2	72.5% to 86.7%	100%*	- Both studies were conducted on fresh sam-ples, but for the one reporting 72.5% IFU-conformity was unclear
Fujirebio, ESPLINE® SARS-CoV-2 (LFA)	3	8.1% to 80.7%	100%*	- The data set reporting 8.1% sensitivity used saliva samples (not IFU-conform) and the ma-jority of samples showed a Ct-value > 25
JOYSBIO Biotechnology, COVID-19 Antigen Rapid Test Kit (LFA)	2	57.8% to 70.5%	98.5% to 99.1%	- The datasets used NP and AN samples, re-spectively. Both were performed by IFU on symptomatic people or high-risk contacts
MEDsan®, SARS-CoV-2 Antigen Rapid Test (LFA)	2	36.5% to 45.2%	97% to 99.6%	- Both studies were conducted on OP samples, which is IFU-conforming for this test
R-Biopharm, RIDA®QUICK SARS-CoV-2 Antigen (lateral flow assay)	3	39.2% to 77.6%	96.2% to 100%	- Two data sets originate from the same study and no study was conducted as per IFU - The data set reporting 39.2% included only asymptomatic persons with Ct-values between 22.1 and 36.4
Shenzen Bioeasy Bio-technology, 2019-nCov Antigen Rapid Test Kit (requires reader)	4	66.7% to 93.9%	85.6% to 100%	- The data set reporting 85.6% specificity was conducted IFU-conforming - The data sets reporting highest sensitivity were drawn from just symptomatic patients, for the others symptomatic patients made up more than two thirds of the study population
SureScreen, COVID-19 Rapid Antigen Flourescent (requires reader)	2	60.3% to 69.0%	98%*	- Both datasets originate from the same study and were conducted not IFU-conforming on stored samples
Zhuhai Encode Medical Engineering, SARS-CoV-2 Antigen Rapid Test (LFA)	2	74.0% to 74.4%	100%*	- Both datasets originate from the same study, a retrospective head-to-head comparison - Stored AN/MT samples were assessed

Caption: * only one data set for specificity was provided
IFU = instructions for use; Ag-RDT = antigen rapid diagnostic test; NP = nasopharyngeal; OP = oropharyngeal; AN = anterior nasal; MT = mid-turbinate.

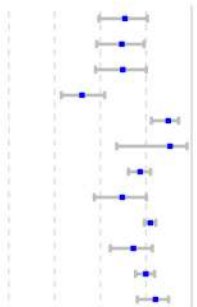
PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources

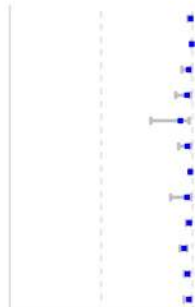



QUADAS–2 Domain
Flow and timing
Reference standard
Index test
Patient selection
0
25
50
75
100
High
Intermediate
Low
Unclear

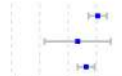

QUADAS−2 Domain
Reference standard
Index test
Patient selection
0
25
50
75
100
High
Intermediate
Low
Unclear

Test assessed	N datasets	Total Sample Size	Pooled Sensitivity (95% CI)	Pooled Specificity (95% CI)
BD Veritor	6	6661	63.5% (49.3–75.8)	99.5% (98.8–99.8)
BinaxNOW	4	8163	61.8% (48–74)	99.8% (99.5–99.9)
CLINITEST	4	740	62.3% (47.4–75.2)	98.9% (97.1–99.6)
Coris	5	729	40% (28.7–52.4)	98.5% (95.4–99.5)
Lumipulse G	5	3532	87.2% (78–92.9)	96.7% (88.6–99.1)
LumiraDx	4	1373	88.2% (59–97.5)	98.6% (96.2–99.5)
Panbio	35	24472	71.8% (65.4–77.5)	99.4% (99.1–99.7)
Rapigen	6	2116	62% (46.7–75.2)	98.5% (94–99.6)
Sofia	5	2197	77.4% (74.2–80.3)	99.1% (98.3–99.5)
Standard F	6	2692	68.1% (55.5–78.5)	97.7% (96.6–98.5)
Standard Q	33	16478	74.9% (69.3–79.7)	98.6% (97.8–99.2)
Standard Q nasal	6	2271	80.2% (70.3–87.4)	99% (97.7–99.6)

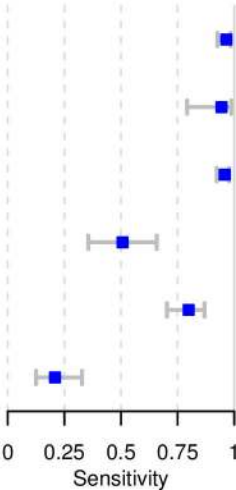




Test assessed	Sensitivity N datasets	Sensitivity Total Sample Size	Pooled Sensitivity (95% CI)	Specificity N datasets	Specificity Total Sample Size	Pooled Specificity (95% CI)
Innova	10	2686	76.1% (68.1–84.1)	4	8668	99.4% (98.7–100)
Nadal	4	1492	58.4% (29.2–87.6)			
SureScreen V	4	269	65.9% (58.4–73.3)			

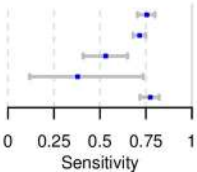


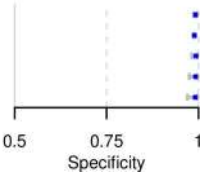
Ct Values	N datasets	Total Sample Size	Pooled Sensitivity (95% CI)
<20	22	741	96.5% (92.6–98.4)
>=20	12	598	94.4% (79.2–98.7)
<25	47	3004	95.8% (92.3–97.8)
>=25	24	987	50.7% (35.6–65.8)
<30	37	2879	79.9% (70.3–86.9)
>=30	29	509	20.9% (12.5–32.8)



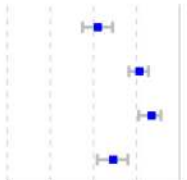
Testing procedure	N datasets	Total Sample Size	Pooled Sensitivity (95% CI)	Pooled Specificity (95% CI)
IFU	81	49643	76.3% (73.1–79.2)	99.1% (98.8–99.4)
non–IFU	75	31416	65.9% (60.6–70.8)	98.3% (97.7–98.8)
unclear	17	14288	67.1% (55.8–76.7)	99.4% (99.2–99.6)

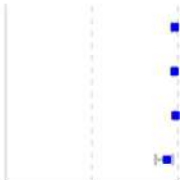
Sample type	N datasets	Total Sample Size	Pooled Sensitivity (95% CI)	Pooled Specificity (95% CI)
AN/MT	32	25814	75.5% (70.4–79.9)	99.2% (98.7–99.5)
NP	122	59810	71.6% (68.1–74.9)	98.9% (98.5–99.1)
OP	7	5165	53.1% (40.9–65)	99.3% (98.2–99.7)
saliva	4	1088	37.9% (11.8–73.5)	99.2% (97.5–99.7)
unclear	5	3251	77.4% (71.8–82.2)	99.1% (97–99.7)





Symptoms	N datasets	Total Sample Size	Pooled Sensitivity (95% CI)	Pooled Specificity (95% CI)
Asymptomatic	25	15228	52.5% (43.7–61.1)	99.1% (98.3–99.5)
Symptomatic	38	17964	76.7% (70.6–81.9)	99% (98.5–99.4)
Symptoms <7 days	12	5538	83.8% (76.3–89.2)	99.3% (99–99.6)
Symptoms >=7 days	10	397	61.5% (52.2–70)	96.8% (93.5–98.5)





	N datasets	Total Sample Size	Pooled Sensitivity (95% CI)	Pooled Specificity (95% CI)
Age <18 years	7	3837	64.3% (54.7–72.9)	99.4% (98.9–99.7)
Age >=18 years	16	7326	74.8% (66.5–81.6)	98.7% (97.2–99.4)