Philippine COVID-19 Living Clinical Practice Guidelines
Institute of Clinical Epidemiology, National Institutes of Health, UP Manila
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EVIDENCE SUMMARY

Among patients suspected to have COVID-19, how accurate are rapid antigen tests compared to RT-PCR for the diagnosis of COVID-19?

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RECOMMENDATION

We suggest the use of rapid antigen test for the diagnosis of symptomatic individuals suspected of COVID-19 as an alternative to RT-PCR if all the following conditions are met: *(Low certainty of evidence; Weak recommendation)*

a. Individuals are in the early phase of illness (less than or equal to 7 days from onset of symptoms)
b. Testing kits demonstrated sensitivity of more than or equal to 80% AND have very high specificity of more than or equal to 97%

We suggest against the use of rapid antigen test for screening purposes. *(Low certainty of evidence; Weak recommendation)*

We suggest against the use of saliva as specimen for rapid antigen test in patients suspected of COVID-19 infection. *(Low certainty of evidence; Weak recommendation)*

We suggest against the use of rapid antigen tests alone in asymptomatic patients suspected of COVID-19 infection. *(Low certainty of evidence; Weak recommendation)*

We suggest the use of rapid antigen tests for the diagnosis of individuals suspected of COVID-19 during the setting of an outbreak provided that all the following conditions are met: *(Very low certainty of evidence; Weak recommendation)*

a. Individuals are in the early phase of illness (less than or equal to 7 days from onset of symptoms); AND

b. Testing kits demonstrated sensitivity of more than or equal to 80% AND have very high specificity of more than or equal to 97%.

There is insufficient evidence to recommend for or against the use of repeat antigen testing for screening or diagnosis of COVID-19. *(Very low certainty of evidence)*

A negative rapid antigen test should be confirmed with an RT-PCR in settings or situations wherein COVID-19 is highly suspected (e.g., symptomatic or asymptomatic close contacts of probable or confirmed COVID-19 individuals).

Consensus Issues

The panel was unanimous against (1) the use of rapid antigen test for screening purposes, (2) the use of saliva as specimen for rapid antigen tests, and (3) the use of rapid antigen test alone in asymptomatic patients suspected of COVID-19 infection due to the observed lower sensitivity of these tests under such conditions. A unanimous decision on the insufficiency of evidence to recommend for or against the use of repeat antigen testing was also made.

Majority of the panelists agreed that the following conditions should be met when using rapid antigen tests:

a. Individuals are in the early phase of illness, because antigen tests perform best during this period; and
b. Testing kits have a sensitivity of more than or equal to 80% and specificity of more than or equal to 97%, because the quality of the test kit should be ensured.

One of eleven panelists raised a concern on the specified sensitivity and specificity of the testing kits, as these are based on the Health Technology Assessment Council (HTAC) of the local Department of Health (DOH).

A weak recommendation on the use of rapid antigen tests for diagnosing COVID-19 suspects during outbreaks was made based on nine observational studies with unclear patient selection, conduct of reference standard, and patient flow and timing. The risk of exposure was an important consideration for the panel, citing that it is not cost-effective to test everyone during an outbreak. However, the risk stratification of participants was not specified in any of the studies.

PREVIOUS RECOMMENDATION

We recommend the use of rapid antigen test in patients suspected of COVID-19 infection meeting all the following conditions: *(Moderate quality of evidence; Strong recommendation)*

Symptomatic AND
Early phase ≤7 days from onset of symptoms AND
Specific brands that demonstrated sensitivity ≥ 80% and have very high specificity (≥ 97-100%)

We recommend against the use of saliva as a specimen for rapid antigen test in patients suspected of COVID19 infection. *(Moderate quality of evidence; Strong recommendation)*

We recommend against the use of rapid antigen tests alone in asymptomatic patients suspected of COVID-19 infection*. (Moderate to high quality of evidence; Strong recommendation)*

Previous Consensus Issues
There were only two studies that used saliva as a specimen for rapid antigen test, which produced a pooled sensitivity of 17% (95% CI 13-23%) and a pooled specificity of 99% (95% CI 99-100%). Given the current evidence on the very low sensitivity for saliva, qualifying which specimen is used for a rapid antigen test is necessary.

What's new in this version?

- There are 124 new observational studies added to the initial studies evaluated in the previous evidence summary.
- New evidence on the use of antigen tests in special populations (children, healthcare workers), in the setting of an outbreak, as well as repeated/serial antigen testing was included in this review.
- Subgroup analysis was applied on the effect of cycle threshold values and additional test brands.
- Evidence on costs and resource implications of antigen testing was added.
- The certainty of evidence was downgraded due to risk of bias issues and inconsistencies across evaluations resulting in a change of draft statements to *"suggest"* from *"recommend"*.

Key Findings

- A total of 164 observational studies assessed the diagnostic accuracy of rapid antigen tests (RAgTs) against reverse transcriptase - polymerase chain reaction (RT-PCR) as the reference standard. Studies included different test brands, specimen types and timing of collection, symptom status, cycle threshold (CT) values, and populations, namely impatiens, children, and healthcare workers among others.
- The overall sensitivity of RAgTs is moderate at 0.71 (95% CI 0.68-0.73) while specificity is excellent at 0.995 (95% CI 0.993-0.996). This was comparable to the data of the previous evidence summary with pooled sensitivity of 0.72 (95% CI 0.64-0.78) and specificity of 0.99 (95% CI: 0.99-1.0).
- On subgroup analysis, RAgT showed higher sensitivity when used in symptomatic individuals (Sn 0.74, 95% CI 0.71-0.78), when conducted during the early phase or first week of illness (Sn 0.79, 95% CI 0.75-0.82), in positive specimens with Ct value <25 (Sn 0.94, 95% CI 0.92-0.96), and in other Ct thresholds considered as "high" viral load (Sn 0.89, 95% CI 0.0.85-0.92). Pooled sensitivity of commonly used specimen types falls between 65% to 79%. FDA-approved RAgT brands have pooled sensitivities ranging from 0-90% with improved performance of commonly used RAgT brands when used in symptomatic individuals.
- In outbreak settings, RAgT use remained to have an excellent specificity (Sp 0.966, 95% CI 0.997 - 0.999) with a similar sensitivity (Sn 0.68, 95% CI 0.45-0.84) but with less precise estimates.
- The overall certainty of evidence was low because of serious risk of bias in all domains (high and unclear risk in patient selection, conduct of index test and reference standard, and flow and timing) and serious inconsistency. Despite performing pre-specified subgroup analyses, significant heterogeneity was still observed. In certain subgroup analyses, such as use of RAgT in outbreak settings and saliva specimens, certainty of evidence was further downgraded to very low due to imprecision attributed to wide interval estimates.

Introduction

Reverse-transcriptase polymerase chain reaction (RT-PCR) test remains to be the gold standard in the diagnosis of COVID-19. Despite excellent diagnostic accuracy, RT-PCR-based assays are not entirely practical for all testing scenarios due to its need for additional specialized equipment, specialized training of laboratory-based staff, and high cost. On the other hand, rapid antigen tests (RAgTs) detect the presence of specific viral antigens with a faster turnaround time which may be performed at the point of care, are simple to use, requiring shorter training, and are relatively less expensive compared to RT-PCR tests.[1] If sufficiently accurate, RAgT can facilitate

timely decisions concerning the need for isolation, monitoring, treatment and contact tracing activities.[2]

The previous review by Burog et al in March 2021 showed that the pooled sensitivity and specificity of 30 studies and 10 evaluation reports on RAgTs were 0.72 (95% CI 0.64-0.78; I^2=95.77) and 0.99 (95% CI 0.99-1.0; I2=93.16) respectively.[3] Therefore, RAgT use was only recommended strictly for symptomatic individuals during the early phase of illness using brands with at least moderate sensitivity (≥ 0.80) and high specificity (≥ 0.97 - 1.00).

With the addition of more RAgTs available for use in COVID-19 screening and diagnosis, this update investigated the diagnostic accuracy of RAgTs and compared it with that of the previous review. This can influence changes in the recommendations guiding current clinical practice.

Review Methods

We searched MEDLINE for studies published until September 30, 2021 using subject headings combined with free text terms related to COVID-19 or SARS-CoV-2 and rapid antigen tests/testing, with no language limits or method filters. Appendix 2 shows the detailed search.

Preprint studies were identified using the COVID-19 Living Evidence Database (https://zika.ispm.unibe.ch/assets/data/pub/search_beta/) with "antigen" as the search term. This database is updated daily and includes preprints from medRxiv and bioRxiv, as well as published articles from EMBASE and PubMed. The Cochrane COVID-19 Study Register (covid-19.cochrane.org/) was also searched using "antigen" as a search term. Search for related links and journals was also carried out. Bibliography sections of the included studies were reviewed for relevant articles that might be missed by database search.

To supplement the initial search yield, available data on RAgT from FIND SARS-CoV-2 Diagnostic pipeline (https://www.finddx.org/covid-19/dx-data/) was accessed. Reported sensitivity and specificity estimates from the package inserts of RagTs approved by the Philippine FDA were also retrieved but were not included in the main analysis. Relevant clinical trials were searched on clinicaltrials.gov and the WHO International Clinical Trials Registry Platform (ICTRP). Local publications such as health technology assessments on the use of RAgTs were also sought. Methodological qualities of the diagnostic studies were assessed by independent reviewers using the QUADAS-2 instrument.

Heterogeneity was determined by visual inspection of forest plot of study evaluations and summary receiver operating characteristic (SROC) plot. Because of anticipated heterogeneity across studies, pooled sensitivity and specificity estimates were derived by stratifying studies according to test brand, CT value used, presence of symptoms, timing of specimen collection, and special populations such as children and healthcare workers. Summary estimates for sensitivity and specificity with 95% confidence intervals were derived using a random-effects bivariate binomial model [4] fitted as a generalized linear mixed effect model using the *metandi* and *gllam* commands in Stata/MP 13.0.[5] When only fewer than four studies were available for pooling, summary estimates were computed externally through a web-based app (MetaDTA v2.01; https://crsu.shinyapps.io/dta_ma/).[6,7] Results were graphically displayed in SROC curves with the summary operating points and 95% confidence regions as well as coupled forest plots.

Sensitivity analysis was performed by removing studies with low methodologic quality or with risk of bias issues in certain QUADAS-2 domains, and subsequently assessing their impact on overall diagnostic accuracy estimates.

Out of 802 titles and abstracts screened, we retrieved 198 full-text articles relevant to the key question. Removal of duplicate copies (e.g. 40 studies included in the initial RAgT review which were already available) and articles with incomplete or no data yielded 124 new studies that were appraised and included for final analysis in this update of the evidence summary.

Results

Characteristics of included studies

In addition to the 40 studies evaluated in the previous evidence review, 124 new published articles were appraised and analyzed, yielding in a total of 164 included observational studies [8-171] involving 235,546 samples. Using RT-PCR as reference standard, 25 different RAgT brands approved by the Philippine Food and Drug Administration (FDA) were evaluated. Included studies looked into screening and diagnosis of symptomatic and asymptomatic patients, employees, healthcare workers and students in both community and hospital settings. Appendix 3 shows a summary of the characteristics of included studies.

Methodological quality of included studies

The overall methodological quality of the included studies was rated as low. In < 50% of included studies, high and unclear risk of bias were seen in all domains particularly in the patient selection and conduct of both index test and reference standard. Issues on applicability, on the other hand, were documented in < 25% of studies. Certainty of evidence was downgraded to very low when only studies on outbreak settings were pooled due to the presence of imprecision. Appendix 4 shows a detailed assessment of the risk of bias of included studies.

Diagnostic accuracy of RAgT

A. Overall diagnostic accuracy

Across 164 studies, the pooled sensitivity of RAgTs was found to be moderate at 0.71 (95% CI 0.68-0.73). Pooled specificity was excellent at 0.995 (95% CI 0.994-0.996). Visual examination of forest plots and SROC plot indicated highly heterogeneous sensitivity estimates across studies. Figure 1 shows the SROC plot.

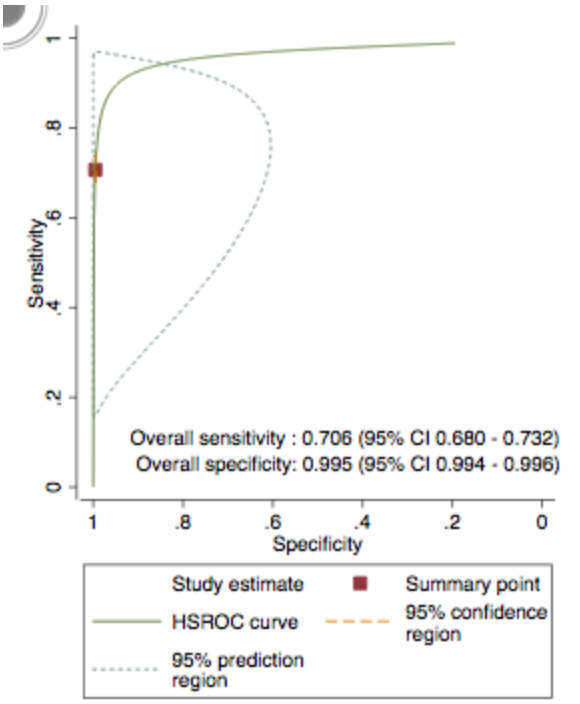

Figure 1. Summary receiver operating characteristic (SROC) plot showing the summary sensitivity and specificity point (165 studies / 272 evaluations). The 95% prediction region reflects heterogeneity in test accuracy across studies.

B. Subgroup Analysis

Table 1 shows the sensitivity of self-administered RAgTs per subgroup.

Table 1. Subgroup Analysis for Sensitivity of RAgTs

Variable	Current Review		Previous Review
	Studies/ Evaluations (Samples)	Sensitivity (95% CI)	Sensitivity (95% CI)
OVERALL	272 (235,794)	**0.71** (0.68, 0.73)	0.72 (0.64, 0.78)
Special Populations			
Children	11 (5,101)	**0.79** (0.70, 0.86)	Not evaluated
Healthcare workers	5 (1,554)	**0.82** (0.64, 0.92)	Not evaluated
Presence of symptoms			
Symptomatic	79 (45,523)	**0.74** (0.71, 0.78)	0.78 (0.69, 0.86)
Asymptomatic	55 (72,858)	**0.56** (0.51, 0.62)	0.51 (0.39, 0.63)
Timing of testing in relation to symptoms			
Early	54 (28,591)	**0.79** (0.75, 0.82)	0.71 (0.44, 0.89)
Mixed	44 (69,501)	**0.70** (0.65, 0.74)	0.81 (0.76, 0.85)
Late	23 (4,307)	**0.47** (0.39, 0.55)	0.65 (0.57, 0.71)
Test brand and presence of symptoms			
Panbio™ Ag-RDT (Abbott)	39 (29,764)	**0.72** (0.67, 0.77)	0.76 (0.61, 0.86)
●*Symptomatic*	17 (6,551)	**0.77** (0.72, 0.82)	Not evaluated
●*Asymptomatic*	11 (2,642)	**0.52** (0.45, 0.59)	Not evaluated
Standard Q COVID-19 Ag Test (SD Biosensor)	30 (24,102)	**0.72** (0.66, 0.78)	0.77 (0.58, 0.94)
●*Symptomatic*	12 (4,439)	**0.75** (0.68, 0.81)	Not evaluated
●*Asymptomatic*	7 (2,903)	**0.65** (0.59, 0.70)	Not evaluated
Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)	16 (12,351)	**0.71** (0.61, 0.80)	0.66 (0.55, 0.75)
●*Symptomatic*	3 (452)	**0.83** (0.62, 0.94)	Not evaluated
●*Asymptomatic*	6 (6,070)	**0.80** (0.57, 0.93)	Not evaluated
BinaxNOW SARS-CoV-2 (Abbott)	13 (39,177)	**0.63** (0.50, 0.74)	0.90 (0.66, 0.93)
●*Symptomatic*	8 (3,425)	**0.81** (0.73, 0.87)	Not evaluated

●*Asymptomatic*	5 (6,771)	**0.61** (0.52, 0.69)	Not evaluated
Sofia SARS Antigen Fluorescent Immunoassay (Quidel)	8 (7,343)	**0.75** (0.67, 0.81)	0.70 (0.53, 0.85)
●*Symptomatic*	8 (3,798)	**0.78** (0.71, 0.84)	Not evaluated
●*Asymptomatic*	2 (2,564)	**0.58** (0.48, 0.67)	Not evaluated
Standard F Covid19 Ag FIA (SD Biosensor)	7 (4,396)	**0.72** (0.41, 0.91)	0.64 (0.40, 0.85)
●*Symptomatic*	3 (667)	**0.75** (0.43, 0.92)	Not evaluated
●*Asymptomatic*	1 (2,340)	**0.65** (0.54, 0.75)	Not evaluated
Biocredit COVID-19 Ag test (RapiGEN)	7 (827)	**0.54** (0.39, 0.69)	0.55 (0.38, 0.71)
●*Symptomatic*	2 (132)	**0.50** (0.27, 0.73)	Not evaluated
●*Asymptomatic*	1 (27)	**0.33** (0.20, 0.50)	Not evaluated
COVID-19 Rapid Antigen Test (BD Veritor)	5 (5,183)	**0.68** (0.54, 0.79)	0.76 (00.60, 0.89)
●*Symptomatic*	3 (821)	**0.83** (0.72, 0.91)	Not evaluated
●*Asymptomatic*	1 (2,317)	**0.59** (0.51, 0.66)	Not evaluated
Coronavirus Ag Rapid Test Cassette (Healgen Scientific)	3 (715)	**0.84** (0.77, 0.90)	0.77 (0.67, 0.85)
●*Symptomatic*	1 (332)	**0.79** (0.72, 0.86)	Not evaluated
VITROS Immunodiagnostic Products SARS-CoV-2 Antigen test (Ortho Clinical Diagnostics)	2 (336)	**0.78** (0.72, 0.84)	0.80 (0.74, 0.90)
NADAL COVID-19 Rapid Antigen Test (Nal Von Minden)	2 (931)	**0.74** (0.45, 0.91)	Not evaluated
AFIAS COVID-19 Ag (AFC) (Menarini)	2 (1,049)	**0.42** (0.38, 0.47)	Not evaluated
SARS-CoV-2 Antigen Rapid Test Kit (Lepu Medical)	1 (286)	**0.46** (0.36, 0.56)	Not evaluated
CareStart COVID-19 Antigen Test (Access Bio)	1 (286)	**0.46** (0.34, 0.45)	Not evaluated
Encode SARS-CoV-2 Antigen Rapid Test Device (Zhuhai Encode Medical Engineering)	1 (200)	**0.74** (0.64, 0.82)	Not evaluated
Elecsys SARS-CoV-2 Antigen assay (Roche)	1 (3,143)	**0.60** (0.55, 0.65)	Not evaluated
SIENNA COVID-19 Antigen Rapid Test Cassette	1 (150)	**0.90** (0.82, 0.95)	Not evaluated
GenBody COVAG025 Rapid Antigen Test	1 (130)	**0.90** (0.73, 0.98)	Not evaluated

Humasis COVID-Ag Test COVID-19 Antigen (Humasis)	1 (21)	**0.90** (0.70, 0.99)	Not evaluated
NowCheck COVID-19 Ag Test (Bionote)	1 (1,326)	**0.56** (0.21, 0.86)	0.89 (0.81, 0.95)
StrongStep Rapid Antigen Test (Liming)	1 (19)	**0** (0, 0.34)	Not evaluated
Huaketai SARS-CoV-2 Rapid Antigen Test (Savant)	1 (109)	**0.17** (0.09, 0.27)	0.17 (0.09, 0.27)
SARS-CoV-2 Antigen Rapid Test Kit (JOYSBIO)	1 (225)	**0.58** (0.47, 0.68)	Not evaluated
ichromaTM COVID-19 Ag (Boditech)	1 (966)	**0.41** (0.37, 0.46)	Not evaluated
CT value			
Low (<25)	40 (6,906)	**0.94** (0.92, 0.96)	Not evaluated
High (>25)	35 (5,076)	**0.39** (0.38, 0.42)	Not evaluated
Other Ct thresholds for 'higher' viral load	27 (14,398)	**0.89** (0.85, 0.92)	Not evaluated
Other Ct thresholds for 'lower' viral load	18 (1,996)	**0.29** (0.20-0.41)	Not evaluated
Specimen type			
Exhaled breath	1 (105)	**0.92** (0.64, 1.0)	Not evaluated
Nasopharyngeal and Saliva	1 (343)	**0.91** (0.76, 0.98)	Not evaluated
Nasal (anterior nares and mid-turbinate)	24 (51,399)	**0.79** (0.74, 0.83)	0.84 (0.66, 0.93)
Nasopharyngeal	99 (111,446)	**0.71** (0.68, 0.75)	0.72 (0.65, 0.78)
Nasopharyngeal and Oropharyngeal	35 (38,387)	**0.65** (0.59, 0.71)	0.65 (0.47, 0.79)
Oropharyngeal	3 (8,568)	**0.59** (0.42, 0.73)	Not evaluated
Saliva	7 (6,148)	**0.57** (0.22, 0.86)	0.17 (0.13, 0.23)
Nasal and Oropharyngeal	1 (18,457)	**0.49** (0.47, 0.51)	Not evaluated
Sputum	1 (45)	**0.11** (0.04, 0.24)	Not evaluated
In Outbreak Settings			
Overall	9 (6805)	**0.68** (0.45 - 0.84)	Not evaluated
• Symptomatic	3 (398)	**0.14 - 0.89**	Not evaluated
• Asymptomatic	3 (1142)	**0.22 - 0.92**	Not evaluated
Methodological quality			
Studies with low risk of bias	83 (73,469)	**0.75** (0.71, 0.79)	Not evaluated

Studies with high risk of bias	96 (88 252)	**0.64** (0.58, 0.69)	Not evaluated
Studies with unclear risk of bias	93 (74 073)	**0.73** (0.68. 0.77)	Not evaluated

By special population

The evidence summary update incorporated analysis of RAgT use in special populations. The pooled sensitivity of RAgT use in children was 0.79 (95% CI 0.70-0.86; n=5,101; 11 studies) while pooled sensitivity was 0.82 (95% CI 0.64-0.92; n=1,554; 5 studies) when used among healthcare workers. Though RAgT use in both populations showed high performance, more trials may be needed to substantiate recommendations for these specific populations.

By presence of symptoms

The use of RAgT in symptomatic individuals showed higher pooled sensitivity (Sn=0.74, 95% CI 0.71-0.78; n=45,523; 79 studies) compared to that of asymptomatic individuals (Sn=0.56, 95% CI 0.51-0.62; n=72 858; 55 studies). This is consistent with previous estimates showing higher sensitivity of RAgT in symptomatic individuals (Sn 0.78, 95% CI 0.69-0.86) compared to asymptomatic individuals (Sn 0.51, 95% CI 0.39-0.63).

By time of testing in relation to symptom onset

When RAgt was used either during the early (0-7 days) or late phase (>7 days) from symptom onset, the pooled sensitivity was 0.70 (95% CI 0.65-0.74; n=69,501; 44 studies). The pooled sensitivity increased to 0.79 (95% CI 0.75-0.82; n=28,591; 54 studies) when RAgT was used in the early phase of illness and decreased to 0.47 (95% CI 0.39-0.55; n=4,307; 23 studies) when RAgT was used during the late phase of the disease.

By test brand

Moderate performance was demonstrated by the five most commonly used RAgT brands, namely Abbott Panbio (Sn 0.72, 95% CI 0.65-0.77; n=29,764; 39 studies), SD biosensor Standard Q COVID-19 Ag (Sn 0.72, 95% CI 0.66-0.78; n=24,102; 30 studies), Roche SARS-CoV-2 Rapid Antigen Test (Sn 0.71, 95% CI 0.61-0.80; n=12,351; 16 studies), Abbott BinaxNOW CoVID-19 Antigen Card (Sn 0.63, 95% CI 0.50-0.74; n=39 177; 13 studies) and Quidel Sofia SARS Antigen Fluorescent Immunoassay (Sn 0.75, 95% CI 0.67-0.81, n=7,343; 8 studies).

Subgroup analysis showed improved diagnostic performance of the above RAgT brands when used with symptomatic individuals as pooled sensitivity increased in the range of 0.75 (95% CI 0.68-0.81; SD biosensor Standard Q COVID-19 Ag) to 0.83 (95% CI 0.62-0.94; Roche SARS-CoV-2 Rapid Antigen Test).

Though highest sensitivity was documented in the RAgT brands SIENNA COVID-19 Antigen Rapid Test (Sn 0.90, 95% CI 0.82-0.95; n=150; 1 study), GenBody COVAG025 Rapid Antigen Test (Sn 0.90, 95% CI 0.73- 0.98; n=130; 1 study) and Humasis COVID-Ag Test (Sn 0.90, 95% CI 0.70- 0.99; n=21; 1 study), their use in a limited number of samples warrant more trials to further validate their clinical utility.

By cycle threshold (Ct) value of RT-PCR

RAgTs demonstrated excellent performance in positive RT-PCR specimens having Ct value ≤25 with pooled sensitivity at 0.94 (95% CI 0.92-0.96; n=6,906; 40 studies). Studies that used Ct cutoff values other than 25 still showed better performance when samples had higher viral loads (i.e., lower Ct values) with a sensitivity of 0.89 (95% CI 0.85-0.92; n=14,398; 27 studies) versus 0.29 (95% CI 0.20-0.41; n=1996; 18 studies) when used in those with “low” viral load.

By specimen type

RAgT using exhaled breath samples showed the highest sensitivity (Sn 0.92, 95% CI 0.64-1.00; n=105; 1 study). This was followed by samples from combined nasopharyngeal and saliva (Sn 0.91, 95% CI 0.76-0.98; n=343; 1 study). However, the use of these specimens was limited to single studies with imprecise estimates.

The more commonly used specimen types, namely nasal, nasopharyngeal, combined nasopharyngeal and oropharyngeal, have moderate sensitivities. RAgTs had a pooled sensitivity of 0.79 (95% CI 0.74-0.82; n=51,399; 24 studies) when used in nasal specimens, 0.71 (95% CI 0.67-0.74; n=111,446; 102 studies) when used in nasopharyngeal specimens, and 0.65 (95% CI 0.59-0.71; n=38,387; 35 studies) when used in combined nasopharyngeal and oropharyngeal specimens.

Sputum as a specimen type had the lowest sensitivity (Sn 0.11, 95% CI 0.04-0.24; n=45; 1 study). Seven studies using saliva as the specimen type demonstrated poor sensitivity at 0.57 (95% CI 0.22-0.86; n=6,148). This result is consistent with the findings of the previous review.

By serial/repeat testing

Two observational studies with unclear risk of bias provided data on repeat testing. In the study of Shah et al., repeat antigen testing of anterior nasal specimen using Abbott BinaxNOW CoVID-19 Antigen Card in a community setting taken within 30 minutes from the initial evaluation showed an improved sensitivity from 0.77 (95% CI 0.72-0.82) to 0.81 (95% CI 0.77-0.86). This study tested a total of 2110 patients, 1190 (56%) of which were symptomatic. [148]

Using the same specimen type and RAgT brand, McKay and colleagues employed 3 rounds of serial testing over a 13-day period (every 4-5 days) among nursing home residents and staff using RT-PCR as reference standard. Majority of the subjects were asymptomatic (451/532 or 84.7%). Sensitivity was inconsistent across different test rounds: 1st round at 0.74 (95% CI 0.59-0.86), 2nd round at 0.63 (95% CI 0.47-0.78), and 3rd round at 0.67 (95% CI 0.41-0.88) respectively. On the other hand, specificity remained high throughout the study with a range of 0.97 to 1.0.[106]

During outbreak settings

The authors identified nine observational studies [23, 24, 27, 47, 93, 106, 112, 130, 159] that involved settings or scenarios wherein rapid antigen testing was compared to RT-PCR testing in the context of an outbreak. Six out of the nine studies consisted of a mixed population of asymptomatic and symptomatic. In studies during outbreaks and surges, rapid antigen tests had a pooled sensitivity of 0.68 (95% CI 0.45-0.84) which was similar to the overall pooled sensitivity of included studies but with less precise estimates. Pooled specificity remained excellent at 0.996 (95% CI 0.997-0.999). Certainty of evidence of the pooled studies on outbreak settings was downgraded to very low due to the presence of imprecision.

I. In Symptomatic Individuals

Three studies [23, 106, 112] provided specific data on symptomatic subjects. The three studies tested subjects within the early and late phases of illness with RT-PCR as the reference standard. A summary sensitivity estimate was not calculated due to the small number of studies and the variability in the test brands and specimens used. Sensitivity ranged from 0.14 to 0.89. When the

study with the lowest sensitivity estimate and high risk of bias [112] was excluded from analysis, sensitivity ranged from 0.76 to 0.89.

In the study by Bianco et al., 231 individuals reported at least one COVID-19 symptom and were tested using LumiraDx™ SARS-CoV-2 Antigen Test with RT-PCR as the reference standard. Sensitivity and specificity were high at 0.89 (95% CI 0.0.84-0.93) and 0.88 (95% CI 0.73-0.97) respectively.

Among residents and staff of a nursing home in the study by Mckay et al., 79 paired specimens were evaluated using the BinaxNOW COVID-19 Ag Card, which showed moderate sensitivity of 0.76 (95% CI 0.58-0.89) but excellent specificity of 1.00 (95% CI 0.92-1.0)

Nagura-Ikeda reported the lowest sensitivity estimate of 0.14 (95% CI 0.07-0.27) and specificity of 1.00 (95% CI 0.8-1.0) from collected saliva specimens of 88 individuals using the Espline SARS-CoV2 (Fujirebio) Rapid Antigen Test.

II. In Asymptomatic Individuals

Three studies [23, 106, 112] provided data on asymptomatic subjects. A summary sensitivity estimate was not calculated due to the small number of studies and the variability in the test brands and specimens used. Sensitivity ranged from 0.22 to 0.92. When the study with the lowest sensitivity estimate [112] and high risk of bias was excluded from analysis, sensitivity ranged from 0.65 to 0.92.

The lowest sensitivity estimate of 0.22 (95% CI 0.03-0.6) was obtained from the study by Nagura-Ikeda et al. [112] which used saliva specimens and had high risk of bias. The remaining two observational studies used nasal specimens and showed higher sensitivities but had unclear risk of bias. In the study by Bianco et. al, 676 subjects underwent rapid antigen testing using LumiraDx™ SARS-CoV-2 Antigen Test with RT PCR as the reference standard. Sensitivity and specificity were high at 0.92 (95% CI 0.85-0.97) and 0.92 (95% CI 0.90-0.94) respectively. A total of 451 paired specimens from asymptomatic residents and staff of a nursing home were evaluated in a study by Mckay et al. The BinaxNOW COVID-19 Ag Card was used for testing which showed poor sensitivity of 0.65 (95% CI 0.53-0.76) but excellent specificity of 0.98 (95% CI 0.96-0.99).

C. Sensitivity Analysis

RAgT showed an improved overall sensitivity when only studies with low risk of bias (high methodological quality) were included in the analysis (pooled Sn 0.75, 95% CI 0.71-0.79; n=73,469). This estimate appears to be comparable to that of studies with unclear risk of bias (Sn 0.73, 95% CI 0.68-0.77; n=74 073). In contrast, studies with high risk of bias in any of the four QUADAS-2 domains (patient selection, index test, reference standard, flow interval) produced significantly lower sensitivity estimates (pooled Sn 0.64, 95% CI 0.58-0.69; n=88,252).

Ongoing Studies on RAgT

As of November 2021, there were 24 ongoing trials [172-195] on the use of RAgTs for COVID-19 registered at ClinicalTrials.gov. Most of the trials compare the accuracy of RAgTs to RT PCR. Specimen type and brands used across the trials are varied. There are trials exploring the potential of RAgTs for screening and surveillance in various settings (i.e. workplace, airports, mass gatherings, community).

Other Considerations

With the increase in RAgT use, some studies have explored the economic advantage brought by testing. A cost-benefit study by Diel and Nienhaus in Germany have shown that the implementation of the Sofia SARS Antigen FIA test saved on average about 210 euros as compared to clinical-judgment only. Furthermore, with a high prevalence rate of 15.6% in the same study population, point-of-care COVID-19 antigen testing reduced average costs of hospitalized patients by 213 euros per tested patient.[196]

Another study has explored the economic effects of home-based RAgT in the United States of America. Despite the imperfections of home testing for COVID-19, the epidemic modeling done has shown that home-based RAgT can reduce transmission of infection and mortality at a justifiable cost.[197] No local economic evaluation study has been performed on RAgTs to date.

As there are numerous COVID-19 tests available, authorized organizations namely Philippine Food and Drug Administration (FDA) and the Research Institute for Tropical Medicine (RITM) were tasked to evaluate commercially manufactured COVID-19 tests to ensure the quality of the tests in the local setting. [198] The Philippine FDA-approved brands are constantly being updated because of this evaluation. Among the brands included in this review, Panbio™ Ag-RDT (Abbott), Sofia SARS Antigen Fluorescent Immunoassay (Quidel), and NowCheck COVID-19 Ag Test (Bionote) have passed the performance evaluation as of August 2, 2021.[199] In an advisory dated September 13, 2021, caution was advised on the use of COVID-19 Rapid Antigen Test (BD Veritor), NADAL COVID-19 Rapid Antigen Test (Nal Von Minden), and SARS-CoV-2 Antigen Rapid Test Kit (JOYSBIO) as these brands have failed the performance evaluation.[200] Standard Q COVID-19 Ag Test (SD Biosensor) was listed under the tests being recalled for the low performance in the evaluation and for failure to explain the non-conformance of the product to the specifications declared last August 2, 2021.[201] The company distributing ichroma COVID-19 Ag voluntarily surrendered their authorization to market the product as of June 18, 2021.[202]

The Department of Health (DOH) issued a memorandum dated September 1, 2021 which strictly placed a price cap of Php 960 for RAgT in all testing and clinical laboratories.[203] Unit cost of the different brands of RAgT kit in the market ranges from Php 250 to Php 1,600. Table 2 lists the available unit cost of RAgT kits locally. Automated RAgTs are much more costly than the manually interpreted RAgT.

Table 2. Unit Price of RAgT Kits

Test Brand	Unit Cost
Sofia SARS Antigen Fluorescent Immunoassay (Quidel)	Php 1 600 (32 USD)
VITROS Immunodiagnostic Products SARS-CoV-2 Antigen test (Ortho Clinical Diagnostics)	Php 1 067 (21 USD)
COVID-19 Rapid Antigen Test (BD Veritor)	Php 907 (18 USD)
SIENNA COVID-19 Antigen Rapid Test Cassette	Php 750 (15 USD)
Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)	Php 705 (14 USD)
GenBody COVAG025 Rapid Antigen Test	Php 503 (10 USD)
CareStart COVID-19 Antigen Test (Access Bio)	Php 605 (12 USD)

Standard Q COVID-19 Ag Test (SD Biosensor)	Php 550
Panbio™ Ag-RDT (Abbott) 1000-4975 tests (40-199 boxes)	Php 520 (13 USD)
NADAL COVID-19 Rapid Antigen Test (Nal Von Minden)	Php 349 (€ 6)
BinaxNOW SARS-CoV-2 (Abbott)	Php 250 (5 USD)
Coronavirus Ag Rapid Test Cassette (Healgen Scientific)	Php 680 (£ 10)

Recommendations from Other Groups

Table 3 summarizes the recommendations from different agencies, countries, and organizations regarding the use of rapid antigen tests.

Table 3. Summary of Recommendations from Other Groups

Agency	Recommendation	Date
Department of Health Health Technology Assessment Council [204]	The HTAC **does not recommend the use of rapid antigen tests** for indiscriminate use in mass screening, for return-to-work clearance and for COVID-19 diagnosis in individuals with low index of suspicion (i.e., asymptomatic and no history of exposure). Rapid antigen tests are currently recommended **by HTAC only for very specific purposes:** ● For **targeted screening and diagnosis of suspected and probable cases of COVID-19** (i.e., with a high index of suspicion), meeting the clinical and/or epidemiologic criteria in the hospital or community settings. ● For **testing of patients in the hospital setting**, where the turnaround time is critical, to guide patient cohort management to minimize transmission of COVID-19 among healthcare workers and other patients. (Hospitals are high-risk settings among healthcare workers and patients.) Otherwise, use RT-PCR in case of elective procedures; ● For **targeted screening and diagnosis of suspect and probable cases of COVID-19** (as defined above) in presumptive outbreaks where the result of the RT-PCR test of one suspect has not yet been released and in settings where RT-PCR is not immediately available or when delayed release of result or prolonged turnaround time is expected (i.e., more than 48 hours). ● For local border screening at points of entry **for individuals travelling from areas with a high daily positivity rate averaged over a seven-day period (i.e., >10%) or as reported by the DOH-Epidemiology Bureau** based on its periodic updates of prevalence rate/positivity rate; and, ● For **international border screening** at points of entry, always assume a high prevalence/positivity rate. A periodic update every month of prevalence rate/positivity rate per country is also suggested. It is recommended that the RT-PCR or RAgT test be used for screening of all incoming individuals in accordance with existing protocol and testing guidelines. Facility- or home-based quarantine shall also be implemented together with RT-PCR or Rapid Antigen testing.	Apr 30, 2021
Infectious Disease Society of America [205]	**Recommendation 1**: For symptomatic individuals suspected of having COVID-19, the IDSA panel suggests using standard NAAT (either rapid RT-PCR or laboratory-based NAAT) over rapid Ag tests (*conditional recommendation based on moderate certainty in test accuracy of rapid Ag test and very low certainty in comparative test accuracy of rapid RT-PCR* versus *rapid Ag tests*) **Recommendation 2**: For asymptomatic individuals with risk for exposure to SARS-CoV-2 infection, the IDSA panel suggests using a single standard NAAT (either rapid RT-PCR or laboratory-based NAAT) over a single rapid Ag test (*conditional recommendation based on moderate certainty in test accuracy of rapid Ag tests and very low certainty in comparative test accuracy of rapid RT-PCR* versus *rapid Ag tests*) **Recommendation 3**: For asymptomatic individuals with risk for exposure to SARS-CoV-2 infection, the IDSA panel suggests a single (i.e., one-time)	May 5, 2021

	standard NAAT (either rapid RT-PCR or laboratory-based NAAT) rather than a strategy of two consecutive rapid Ag tests (*conditional recommendation based on moderate certainty in test accuracy of molecular testing and an evidence gap to inform the test accuracy of a strategies using repeat Ag testing*) **Recommendation 4**: In asymptomatic individuals with risk for exposure to SARS-CoV-2 infection, the IDSA panel suggests neither for nor against using single (i.e., one-time) rapid Ag testing over no testing (evidence gap to inform the utility of Ag testing compared to no testing) **Recommendation 5**: In asymptomatic individuals with risk for exposure to SARS-CoV-2 infection, the IDSA panel suggests neither for nor against using repeat rapid Ag testing over no testing (*evidence gap to inform the utility of a strategy of Ag testing compared to no testing)*.	
World Health Organization [206]	WHO recommends the use of Ag-RDTs that meet minimum performance requirements of ≥ 80% sensitivity and ≥ 97% specificity. Ag-RDTs are less sensitive than NAAT, particularly in asymptomatic populations, but careful selection of cohorts for testing can mitigate this limitation. Ag-RDTs should be prioritized for use in symptomatic individuals meeting the case definition for COVID-19, and to test asymptomatic individuals at high risk of infection, including contacts and health workers, particularly in settings where NAAT testing capacity is limited.	Oct 6, 2021
American Academy of Pediatrics [207]	Patients with symptoms consistent with COVID-19 should be tested without delay using either a NAAT (including PCR) or antigen test. The appropriate test for delayed testing of asymptomatic exposed patients is the PCR and not the rapid antigen. Testing for active SARS-CoV-2 infection using NAATs or antigen-based tests is not generally recommended for asymptomatic patients who have previously tested positive within the past 3 months.	Sep 9, 2021

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Appendix 1: Evidence to Decision

FACTORS	JUDGEMENT						RESEARCH EVIDENCE/ADDITIONAL CONSIDERATIONS
Problem	No	Yes (8)					
Certainty of Evidence	High	Moderate (3)	Low (6)	Very low			Overall, the studies included are of low methodological quality due to risk of bias issues and high heterogeneity among included evaluations.
Accuracy	Very Accurate	Accurate (7)	Inaccurate (2)	Very Inaccurate			Across 164 studies, the pooled sensitivity of RAgTs was found to be moderate at 0.71 (95%CI: 0.68-0.73). Pooled specificity was excellent at 0.995 (95%CI: 0.993-0.996).
Values	Important uncertainty or variability (1)	Possibly important uncertainty or variability (7)	Possibly NO important uncertainty or variability (1)	No important uncertainty or variability			
Resources Required	Uncertain	Large cost (1)	Moderate Cost (6)	Negligible cost	Moderate savings (1)	Large savings	Unit cost of the different brands of rapid antigen test kit in the market ranges from Php 250 to Php 1600.
Certainty of evidence of required resources	No included studies (1)	Very low (1)	Low (5)	Moderate (1)	High (1)		In the Philippines, the Department of Health issued a memorandum dated September 1, 2021 strictly placing a price cap of Php 960 for rapid antigen testing in all testing and clinical laboratories.
Cost effectiveness	No included studies (6)	Favors RT-PCR (1)	Does not favor either RAgT or RT-PCR	Favors RAgT (2)			No local economic evaluation studies are available as of press time on comparing rapid antigen tests and RT-PCR.
Equity	Uncertain (4)	Reduced	Probably no impact	Increased (5)			
Acceptability	Uncertain (1)	No (1)	Yes (7)				
Feasibility	Uncertain	No	Yes (9)				

Appendix 2: Search Yield and Results

Search	Query	Results	Time
#10	Search **#1 AND #8** Filters: **from 1000/1/1 - 2021/9/30** Sort by: **Most Recent**	802	04:57:47
#9	Search **#1 AND #8** Sort by: **Most Recent**	874	04:56:30
#8	Search **#7 OR #2** Sort by: **Most Recent**	18,609	04:56:20
#7	Search **#5 OR #6** Sort by: **Most Recent**	18,608	04:56:13
#6	Search: **rapid antigen test* OR "rapid antigen detection test" OR radt OR radts OR rdt OR rdts OR (antigen* n3 detect*)** Sort by: **Most Recent**	18,555	04:56:06
#5	Search **#3 and #4** Sort by: **Most Recent**	171	04:55:58
#4	Search: **(test OR tests OR detect* OR diagnos* OR kit OR kits OR assay*)** Sort by: **Most Recent**	11,628,285	04:55:41
#3	Search: **((rapid OR point-of-care OR "point of care" OR poc OR poct) n3 antigen))** Sort by: **Most Recent**	204	04:55:27
#2	Search: **"COVID-19 Ag Respi-Strip" OR "BIOCREDIT COVID-19 Ag" OR "STANDARD F COVID-19 Ag" OR "STANDARD Q COVID-19 Ag" OR "Bioeasy 2019-nCoV Ag"** Sort by: **Most Recent**	25	04:55:19
#1	Search: **("Coronavirus Infections"[Mesh] OR novel coronavirus OR NCOV OR "COVID-19"[Supplementary Concept] OR covid19 OR covid 19 OR covid-19 OR "severe acute respiratory syndrome coronavirus 2"[Supplementary Concept] OR severe acute respiratory syndrome coronavirus 2 OR SARS2 OR SARS 2 OR SARS COV2 OR SARS COV 2 OR SARS-COV-2)** Sort by: **Most Recent**	205,257	04:55:11

Appendix 3. Characteristics of Included Studies

Study		Setting	RAgT Brand	Test Specimen	Population	Sample Size	Reference Standard	
							Test	Specimen
1	Okoye 2021	USA	BinaxNOW COVID-19 Antigen Card (Abbott)	NP	Asymptomatic university students	2638	RT PCR	Nasal
2	Oh 2021	Korea	STANDARD Q COVID19 Ag (SD Biosensor)	NP	Patients admitted in the study hospital	118	RT PCR	NP
3	Lindner 202105	Germany	STANDARD Q COVID19 Ag (SD Biosensor)	MT + NP	Symptomatic patients at ambulatory testing facility	146	RT PCR	NP + OP
4	Lindner 202104	Germany	STANDARD Q COVID19 Ag (SD Biosensor)	MT	Symptomatic patients at ambulatory testing facility	287	RT PCR	NP + OP
5	Ishii 2021	Japan	ESPLINE SARS-CoV-2 (Fujirebio)	NP + Saliva	COVID and non-COVID patients admitted	271	RT PCR	NP
6	Baro 2021	Spain	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Unexposed asymptomatics during third wave in Spain	286	RT PCR	NP
7	Stokes 2021	Canada	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Symptomatic individuals	1786	RT PCR	NP
8	Torres 202101	Spain	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Asymptomatic close contacts	634	RT PCR	NP
9	Torres 202102	Spain	CLINITEST Rapid COVID-19 Antigen Test (Siemens)	NP	Symptomatic individuals and asymptomatic close contacts	270	RT PCR	NP
10	Torres 202102	Netherlands	COVID-19 Rapid Antigen Test (BD Veritor)	NP	Non-hospitalized symptomatic patients	351	RT PCR	NP
11	Yokota 2021	Japan	Lumipulse SARS-CoV-2 Antigen Kit (Fujirebio)	NP + Saliva	Inpatients and Outpatients	343	RT PCR	NP
12	Igloi 2021	Netherlands	Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)	NP	Symptomatic or close contact	970	RT PCR	NP + OP
13	Courtellemont 2021	France	COVID-VIRO Antigen Rapid Test (AAZ)	NP	Asymptomatic and hospitalized	248	RT PCR	NP
14	Olearo 2021	Germany	STANDARD Q COVID19 Ag (SD Biosensor) Panbio COVID-19 Ag Rapid Test (Abbott) SARS-CoV-2 Antigen Rapid Test (MedSan GmbH) CLINITEST Rapid COVID-19 Antigen Test (Siemens)	NP + OP	Asymptomatic and hospitalized	184	RT PCR	NP + OP
15	Jaaskelainen 2021	Finland	Sofia SARS Antigen Fluorescent Immunoassay (Quidel)	NP	Symptomatic	188	RT-PCR	NP

			STANDARD Q COVID19 Ag (SD Biosensor)			198		
			Panbio COVID-19 Ag Rapid Test (Abbott)			190		
16	Adnan 2021	Bangladesh	Rapid In-house ELISA (Bangladesh)	NP	No data	339	RT-PCR	NP
17	Pollock 2021a	USA	BinaxNOW COVID-19 Antigen Card (Abbott)	Nasal	Symptomatic patients	2,482	RT-PCR	Nasal
18	Pollock 2021b	USA	CareStart COVID-19 Antigen Test (Access Bio)	Nasal	Symptomatic patients	1,603	RT-PCR	Nasal
19	Peña-Rodríguez 2021	Mexico	STANDARD Q COVID19 Ag (SD Biosensor)	NP	Symptomatic, asymptomatic, exposed contacts (3-5 days)	369	RT-PCR	NP + OP
20	Chiu 2021	USA	INDICAID COVID-19 rapid antigen test (PHASE)	Nasal	Symptomatic participants	698	RT PCR	Nasal
		HongKong			Asymptomatic participants	22994	RT PCR	Nasal + OP
21	Shaikh 2021	USA	BinaxNOW COVID-19 Antigen Card (Abbott)	Nasal	Symptomatic children	199	RT PCR	Nasal
22	Laandas 2021	Norway	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Community and outbreak setting	4,857	RT-PCR	NP
23	Boum 2021	Cameroon	STANDARD Q COVID19 Ag (SD Biosensor)	NP	Hospitalized, asymptomatic volunteers, exposed contacts	1,195	RT-PCR	NP
24	Pickering 2021	UK	Innova Rapid SARS-CoV-2 Antigen Test (Xiamen Biotime Biotechnology)	NP	Trained personnels; community settings, inpatients and outpatients	200	RT PCR	NP
			Spring Healthcare SARS-CoV-2 Antigen Rapid Test Cassette (Shanghai ZJ Bio-Tech)					
			E25Bio Rapid Diagnostic Test (E25Bio)					
			Encode SARS-CoV-2 Antigen Rapid Test Device (Zhuhai Encode Medical Engineering)					
			COVID-19 Coronavirus Rapid Antigen Test Cassette (Surescreen)					
			COVID-19 Coronavirus Rapid Antigen Test Cassette (Surescreen)					
25	Sood 2021	USA	BinaxNOW COVID-19 Antigen Card (Abbott)	Nasal	Children less than 18 years	783	RT-PCR	OP

26	Matsuda 2021	Mexico	Ecotest COVID-19 Rapid Antigen Test (Verify) Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Symptomatic patients	112	RT-PCR	NP + OP
27	Bello-Chavolla 2021	Mexico	STANDARD Q COVID19 Ag (SD Biosensor)	NP	Community setting: COVID suspects	193824	RT-PCR	NP
28	Kyritsi 2021	Greece	Rapid Test Ag 2019-nCoV (PROGNOSIS, BIOTECH)	NP	Hospital setting	624	RT-PCR	NP
29	Iqbal 2021	Pakistan	Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)	NP	Hospital setting: COVID suspects	170	RT-PCR	NP
30	Nikolai 2021	Germany	STANDARD Q COVID19 Ag (SD Biosensor)	Nasal + MT	Community setting: COVID suspects from ambulatory facility	228	RT-PCR	NP
31	Caruana 2021	Switzerland	Exdia COVID-19 Antigen Test (Precision-Bio) STANDARD Q COVID19 Ag (SD Biosensor) Panbio COVID-19 Ag Rapid Test (Abbott) COVID-19 Rapid Antigen Test (BD Veritor)	NP	Symptomatic and asymptomatic ER patients	532	RT-PCR	NP
32	Martin-Sanchez 2021	Spain	Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)	NP	Community setting: population-based screening of asymptomatic individuals	881	RT-PCR	NP
33	Maniscalco 2021	Italy	Inflammacheck device (Exhalation technology LTD)	Exhaled breath condensate	Hospital setting: COVID suspects, convalescent patients, asymptomatic with high risk of COVID, asymptomatic with low risk of COVID	105	RT-PCR	NP
34	Merino-Amador 2021	Spain	CLINITEST Rapid COVID-19 Antigen Test (Siemens)	NP	Hospital setting: COVID suspects with exposure < 7 days or early symptoms	450	RT-PCR	NP
35	Hauser 2021	Germany	LIAISON SARS-CoV-2 Antigen Assay (DiaSorin)	NP	Hospitalized patients	196	RT-PCR	NP
36	Osterman 2021	Germany	Lumipulse SARS-CoV-2 Antigen Kit (Fujirebio) Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics) LIAISON SARS-CoV-2 Antigen Assay (DiaSorin)	NP	Hospital setting: patients from ER or clinics	410	RT-PCR	NP

			SARS-CoV-2 Ag ELISA (Euroimmun)					
37	Andreani 2021	France	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Community settings: patients and personnels in a diagnostic facility	239	RT-PCR	NP
			STANDARD Q COVID19 Ag (SD Biosensor)					
			Certest SARS-CoV-2 one step card test (Theradiag)					
			Orient Gene Coronavirus Ag rapid cassette (Menarini)					
			Espline SARS-CoV-2 (Fujirebio)					
			Lumipulse SARS-CoV-2 Antigen Kit (Fujirebio)					
38	Salvagno 2021	Italy	Espline SARS-CoV-2 (Fujirebio)	NP	Community settings: patients with confirmed COVID	174	RT-PCR	NP
39	Lhuillier 2021	Switzerland	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Community and hospital setting: Children	822	RT-PCR	NP
40	Korenkov 2021	Germany	STANDARD Q COVID19 Ag (SD Biosensor)	NP + OP	Hospital setting: COVID suspect and Trained personnel screening	2028	RT-PCR	NP + OP
41	Bachman 2021	USA	Open-access lateral flow assay	Anterior nares	Community settings: COVID suspects in clinics	170	RT PCR	Anterior nares + NP
			Sofia SARS Antigen Fluorescent Immunoassay (Quidel)					
			BinaxNOW COVID-19 Antigen Card (Abbott)					
			Meso Scale Discovery MESO Quick-Plex SQ 120 (MSD)					
			Open-access lateral flow assay					
			Sofia SARS Antigen Fluorescent Immunoassay (Quidel)					
			BinaxNOW COVID-19 Antigen Card (Abbott)					
			Meso Scale Discovery MESO Quick-Plex SQ 120 (MSD)					
42	Nomoto 2021	Japan	Lumipulse SARS-CoV-2 Antigen Kit (Fujirebio)	NP	Hospital setting: inpatients	100	RT-PCR	NP

43	Kruger 2021	Germany	LumiraDx SARS-CoV-2 Antigen (LumiraDx)	MT	Community settings: COVID suspects in Drive-in testing site and ambulatory care facility	761	RT-PCR	NP
44	Kahn 2021	Germany	Standard F Covid19 Ag FIA (SD Biosensor)	OP	Community settings; Individuals at point-of-care facilities	3110	RT-PCR	OP
45	Escriva 2021	Spain	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Community settings: nursing home residents and employees	448	RT-PCR	NP
46	Norz 2021	Germany	Elecsys SARS-CoV-2 Antigen assay (Roche)	NP + OP	Hospital settings: multicenter routine diagnostic	3139	RT-PCR	NP and OP
47	Mboma 2021	Germany	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Hospitalized patients and accompanying relatives	3,686	RT-PCR	NP
48	Stohr 2021	The Netherlands	COVID-19 Rapid Antigen Test (BD Veritor) Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)	NP	Community settings	3,201	RT PCR	NP and OP
49	Allan-Blitz 2021	USA	BinaxNOW COVID-19 Antigen Card (Abbott)	AN + OP	Community setting	15,304	RT-PCR	NP + OP + AN
50	Cassuto 2021	France	COVID-VIRO Antigen Rapid Test (AAZ)	NP	Symptomatic adult volunteers	234	RT-PCR	NP
51	Agarwal 2021	India	STANDARD Q COVID19 Ag (SD Biosensor)	NP	Hospitalized patients and asymptomatic contacts	467	RT-PCR	NP
52	Hartard 2021	France	LIAISON SARS-CoV-2 Antigen Assay (DiaSorin)	NP	Mass screening of hospitalized patients	378	RT-PCR	NP
53	Kobayashi 2021	Japan	Lumipulse SARS-CoV-2 Antigen Kit (Fujirebio)	NP + saliva	Samples from hospitals and public health centers in Japan	10,422	RT-PCR	NP
54	Wagenhauser 2021	Germany	NADAL COVID-19 Rapid Antigen Test (Nal Von Minden) Panbio COVID-19 Ag Rapid Test (Abbott) SARS-CoV-2 Antigen Rapid Test (MedSan GmbH)	OP	Mass screening of all hospitalized patients	5,056	RT-PCR	OP
55	Amer 2021	Egypt	STANDARD Q COVID19 Ag (SD Biosensor)	NP + OP	Community and hospital setting: COVID suspects Trained personnels	83	RT-PCR	NP + OP
56	Montero 2021	Spain	Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)	NP + OP	Community setting: asymptomatic adults in a semi-closed community	2543	RT-PCR	NP + OP

57	Ferte 2021	France	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Community setting: symptomatic and asymptomatic students	688	RT-PCR	NP
58	Leixner 2021	Austria	AMP Rapid Test SARS-CoV-2 Ag (AMP)	NP	Hospital setting: symptomatic patients presenting at the ER	392	RT-PCR	NP + OP
59	Soleimani 2021	Belgium	BioSpeedia COVID19Speed-Antigen Test (Institut Pasteur) Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Community settings: COVID suspects or with exposure	401	RT-PCR	NP
60	Kiro 2021	India	Standard F Covid19 Ag FIA (SD Biosensor)	NP	Hospital setting: admitted patients and OPD patients from COVID screening	354	RT-PCR	NP
61	Garcia 2021	Spain	Panbio COVID-19 Ag Rapid Test (Abbott) Standard F Covid19 Ag FIA (SD Biosensor)	NP	Community settings	356	RT-PCR	NP
62	Seynaeve 2021	Belgium	COVID-19 Ag Respi-Strip (Coris Bioconcept) Coronavirus Ag Rapid Test Cassette (Healgen Scientific)	NP	Hospitalized patients	100	RT PCR	NP
63	Nsoga 2021	Nsoga	Panbio COVID-19 Ag Rapid Test (Abbott)	OP	Hospitalized patients	402	RT-PCR	NP
64	Eleftheriou 2021	Greece	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	hospitalized pediatric patients (< 16 years old) symptomatic and high risk for infection based on regional epidemiologic data	744	RT-PCR	NP
65	Fiñana 2021	UK	Innova Rapid SARS-CoV-2 Antigen Test (Xiamen Biotime Biotechnology)	NP + OP	Adults >18 years old; asymptomatic: community setting	5504	RT-PCR	NP + OP
66	Kurihara 2021	Japan	Quick Chaser Auto SARS-CoV-2 (Mizuhomedy)	NP	community: individuals that possibly contracted SARS-Cov2; referred by clinics, health centers and healthcare workers for testing	1401	RT PCR	NP
67	Ifko 2021	Slovenia	NADAL COVID-19 Rapid Antigen Test (Nal Von Minden)	NP	Long-term healthcare facility: Elderly 65 - 95 yrs old with at least one symptom of COVID	125	RT-PCR	NP

68	Karon 2021	USA	COVID-19 Rapid Antigen Test (BD Veritor)	NP	residual phosphate buffered saline samples of symptomatic and asymptomatic patients	347	RT-PCR	NP
69	Abusrewil 2021	Libya	10 brands: Fluorecare, Espline, Rapigen, Assut, Orient Gene, AMP, Acon, Abbot, Certest Biotec, Bioperfectus	NP	community setting: clinical features suggestive of COVID-19 or a history of close contact with COVID-19 positive patients	231	RT-PCR	NP
70	Orsi 2021	Italy	FREND Antigen Test (NanoEntek)	NP	Hospitalized patients	110	RT-PCR	NP
71	Brihn 2021	USA	Sofia SARS Antigen Fluorescent Immunoassay (Quidel)	Anterior Nares	Symptomatic and asymptomatic patients	2039	RT-PCR	NP
72	Osmanodja 2021	Germany	Dräger Antigen Test SARS-CoV-2 (Dräger)	Anterior Nares	Community setting	379	RT-PCR	NP + OP
73	Bornemann 2021	Germany	Sofia SARS Antigen Fluorescent Immunoassay (Quidel)	NP	Community setting	1404	RT-PCR	NP
74	Holzner 2021	Germany	STANDARD Q COVID19 Ag (SD Biosensor)	NP	Community setting	2375	RT-PCR	NP
75	Pena 2021	Chile	STANDARD Q COVID19 Ag (SD Biosensor)	NP	Community setting	842	RT-PCR	NP
76	Donapetry 2021	Spain	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Children	440	RT-PCR	NP
77	Cento 2021	Italy	LumiraDx™ SARS-CoV-2 Antigen Test	NP	Community setting	960	RT-PCR	NP
78	Klein 2021	Germany	Panbio COVID-19 Ag Rapid Test (Abbott)	NP + MT	community: symptomatic adults and high risk contact of confirmed case in SARS-Cov-2-drive in testing center:	290	RT-PCR	NP
79	Frediani 2021	USA	BinaxNOW COVID-19 Antigen Card (Abbott)	Anterior Nares	community: community-based and hospital based testing center: age > 7 yrs old (adults and pedia) symptomatic within 7 days from onset	341	RT-PCR	NP
80	Schuit 2021	Netherlands	COVID-19 Rapid Antigen Test (BD Veritor) Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)	NP + OP	Close contacts, asymptomatic individuals requesting for a COVID-19 test	2678	RT-PCR	NP + OP
81	Wachinger	Germany	STANDARD Q COVID19 Ag (SD Biosensor)	NP	Asymptomatic patients in hospitals, presenting for elective surgeries, OPD	1596	RT-PCR	Unspecified

82	Fourati 2021	France	COVID-19 Ag Respi-Strip (Coris Bioconcept) STANDARD Q COVID19 Ag (SD Biosensor) Panbio COVID-19 Ag Rapid Test (Abbott) COVID-VIRO Antigen Rapid Test (AAZ) NG-test SARS-CoV-2 Ag (NG-Biotech) BIOSYNEX COVID-19 Ag BSS-(Biosynex SA)	NP	COVID-19 patients	626	RT-PCR	NP
83	Leli 2021	Italy	LumiraDx™ SARS-CoV-2 Antigen Test	Nasal	Hospital (presenting in emergency department)	792	RT-PCR	NP
84	Sahuquillo 2021	Spain	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Hospital setting: pediatric ER; Symptomatic children aged 0-14 yrs	357	RT-PCR	NP
85	Kanauija 2021	India	COVID-19 Ag Respi-Strip (Coris Bioconcept)	NP	hospital setting (adult communicable disease ward); symptomatic adults and asymptomatic contacts	484	RT-PCR	NP
86	Dierks 2021	Germany	LumiraDx™ SARS-CoV-2 Antigen Test	NP	Hospital setting: employee of University Medical Center	444	RT-PCR	NP
87	Jung 2021	France	BIOSYNEX COVID-19 Ag BSS (Biosynex SA)	NP	hospital setting: ER & primary pediatric care center; age < 18	308	RT-PCR	NP
88	Tsai 2021	Taiwan	Vstrip COVID-19 Antigen Rapid Test (Panion & BF Biotech)	NP	Hospital setting: COVID suspects but no mention whether symptomatic or asymptomatic	61	RT-PCR	NP
89	Jegerlehner 2021	Switzerland	Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)	NP	community setting: COVID testing facility; adults>18 yrs symptomatic and those suspected of exposure to infected	1462	RT-PCR	NP
90	Thakur 2021	India	Immune-chromatographic lateral flow assay PathoCatch/ACCUCARE (Lab Care Diagnostics)	NP	Community settings (Preoperative)	677	RT-PCR	NP + OP
91	Kim 2021	South Korea		NP		130	RT-PCR	NP

		India	GenBody COVAG025 Rapid Antigen Test		Hospital setting: patients visited or admitted in the hospital	200		
92	Bruzzone 2021	Italy	STANDARD Q COVID19 Ag (SD Biosensor)	NP	Hospital setting: retrospective analysis of swab samples in laboratory	321	RT-PCR	NP
			Humasis COVID-Ag Test COVID-19 Antigen (Humasis)					
			Rapid Test Prima Professional (Prima Lab)					
			BIOCREDIT COVID-19 Ag test (RapiGEN, Inc)					
			Standard F Covid19 Ag FIA (SD Biosensor)					
			LumiraDx™ SARS-CoV-2 Antigen Test					
			FREND Antigen Test (NanoEntek)					
93	Nordgren 2021	Sweden	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Community setting: Symptomatic individuals	332	RT-PCR	NP
			Coronavirus Ag Rapid Test Cassette (Healgen Scientific)					
94	Bianco 2021	Italy	LumiraDx™ SARS-CoV-2 Antigen Test	Nasal	Hospital setting: patients in adult and pedia ER and Trained personnels	907	RT-PCR	NP
95	Kolwijck 2021	Netherlands	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Hospital setting: Trained personnel at least 16 years old	433	RT-PCR	NP and OP
96	Ford 2021	USA	Sofia SARS Antigen Fluorescent Immunoassay (Quidel)	MT	Community setting: students, faculty and employee of University	1051	RT-PCR	MT
97	Kweon 2021	Korea	AFIAS COVID-19 Ag (AFC) (Menarini; Florence, Italy)	NP	Hospital setting: Mixed COVID19 and non-COVID19 patients	322	RT-PCR	NP
			ichromaTM COVID-19 Ag (Boditech)					
98	Berger 2021	Switzerland	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Hospital setting:COVID suspects at least 16 years old consulting in the hospital	535	RT-PCR	NP
			STANDARD Q COVID19 Ag (SD Biosensor)			529		
99	Van Honacker 2021	Belgium	BIOSYNEX COVID-19 Ag BSS (Biosynex SA)	NP	Hospital setting: COVID suspect and non-COVID with other respiratory isolates	100	RT-PCR	NP
			Biotical SARS-CoV-2 Ag Card (Biotical Health)			100		

			Coronavirus AG Rapid test cassette (Zhejiang Orient Gene Biotech Co., Zhejiang, China)			98		
			Panbio COVID-19 Ag Rapid Test (Abbott)			97		
			STANDARD Q COVID19 Ag (SD Biosensor)			98		
			STANDARD Q COVID19 Ag (SD Biosensor)			4207		
100	Bouassa 2021	France	SIENNA COVID-19 Antigen Rapid Test Cassette	NP	Hospital setting: retrospective study of archived NP swabs	150	RT-PCR	NP
101	Caruana 2021	Switzerland	STANDARD Q COVID19 Ag (SD Biosensor)	NP	Hospital setting: asymptomatic adults hospitalized in medical and surgical wards	116	RT-PCR	NP
102	Baccani 2021	Italy	Lumipulse SARS-CoV-2 Antigen Kit (Fujirebio)	NP	Hospital setting: inpatients in 3 Tuscan hospitals	201	RT-PCR	NP
			Standard F Covid19 Ag FIA (SD Biosensor)			93		
			AFIAS COVID-19 Ag (AFC) (Menarini; Florence, Italy)			81		
103	Koeleman 2021	Netherlands	Certest SARS-CoV-2 (Certest Biotec S.L., Spain)	NP and OP	Hospital setting: symptomatic ER patients, nursing home residents and Trained personnels	80	RT-PCR	NP and OP
			Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)			80		
			Romed Coronavirus Ag Rapid Test (Romed, The Netherlands)			80		
			Romed Coronavirus Ag Rapid Test (Romed, The Netherlands)			900		
104	Kruger 2021	Germany	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Community setting: patients in drive-in testing site and ambulatory testing facility	1108	RT-PCR	NP and OP
105	Denina 2021	Italy	LumiraDx™ SARS-CoV-2 Antigen Test	Nasal	Hospital setting: children admitted at the ER and hospital	191	RT-PCR	NP
107	Stokes 202109	USA	BinaxNOW COVID-19 Antigen Card (Abbott)	Anterior nares	Hospital setting: Asymptomatic pre-surgery	997	RT-PCR	NP

107	Halfon 2021	France	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Community setting: patients screened in the laboratory	200	RT-PCR	NP
108	Paul 2021	India	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen test (Ortho Clinical Diagnostics)	NP + OP	Hospital setting: symptomatic patients in OPD	148	RT-PCR	NP and OP
			Angcard® COVID-19 rapid Antigen Test kit (Angstrom® Biotech Pvt. Ltd., Alwar, Rajasthan, India)	NP				
109	Von Ahnen 2021	Germany	Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)	NP	Hospital setting: screening of all employees	919	RT-PCR	NP
110	Shah 2021	USA	BinaxNOW COVID-19 Antigen Card (Abbott)	Anterior nares	Community setting: patients recruited from community testing site	2110	RT-PCR	Anterior nares
111	McKay 2021	USA	BinaxNOW COVID-19 Antigen Card (Abbott)	Anterior Nares	Community setting: residents and employees of nursing home	532	RT-PCR	Mixed
112	Abdelrazik 2021	Egypt	BIOCREDIT COVID-19 Ag test (RapiGEN, Inc)	NP	Patients and HCW, patient contacts	310	RT-PCR	NP
113	Albert 2020	Spain	Panbio COVID-19 Ag Rapid Test (Abbott)	NP or OP	COVID 19 test centre	497	RT-PCR	NP
114	Alemany 2020	Spain	Panbio COVID-19 Ag Rapid Test (Abbott)	NP or OP	Symptomatic patients, close contacts, preventive screening of unexposed asymptomatics	1406	RT-PCR	NP or MT
115	Asai 2021	Japan	Lumipulse SARS-CoV-2 Antigen Kit (Fujirebio)	Saliva	Suspected patients	305	RT-PCR	Saliva
116	Billaud 2020	France	Panbio COVID-19 Ag Rapid Test (Abbott)	NP or OP	Contacts	462	RT-PCR	NP or OP
117	Blairon 2020	Belgium	COVID-19 Ag Respi-Strip (Coris Bioconcept)	NP or OP	Laboratory-based	56	RT-PCR	NP
118	Bulilete 2021	Spain	Panbio COVID-19 Ag Rapid Test (Abbott)	NP	Symptomatic patients and close contacts	1369	RT-PCR	NP
119	Caputo 2021	Italy	Lumipulse SARS-CoV-2 Antigen Kit (Fujirebio)	NP	Clinical suspect, screening or contacts	4266	RT-PCR	NP
120	Cerutti 2020	Italy	STANDARD Q COVID19 Ag (SD Biosensor)	NP	Mixed	256	RT-PCR	NP
121	Chaimayo 2020	Thailand	STANDARD Q COVID19 Ag (SD Biosensor)	NP + OP	Covid-19 suspects	454	RT-PCR	NP + OP
122	Ciotti 2021	Italy	COVID-19 Ag Respi-Strip (Coris Bioconcept)	NP	Covid-19 suspects	50	RT-PCR	NP

123	Diao 2020	China	2019-nCoV Ag Fluorescence Rapid Test Kit (Bioeasy)	NP or OP	Unclear	239	RT-PCR	NP
124	Favresse 2021	Belgium	Biotical SARS-CoV-2 Ag Card (Biotical Health)	NP	Symptomatic and asymptomatic subjects	188	RT-PCR	NP
			Panbio COVID-19 Ag Rapid Test (Abbott)					
			Coronavirus Ag Rapid Test Cassette (Healgen Scientific)					
			Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)					
			VITROS Immunodiagnostic Products SARS-CoV-2 Antigen test (Ortho Clinical Diagnostics)					
125	Fenollar 2020	France	Panbio COVID-19 Ag Rapid Test (Abbott)	NP or OP	Symptomatic patients	182	RT-PCR	NP
					Asymptomatic contacts	159		
126	Fourati 2020	France	COVID-19 Ag Respi-Strip (Coris Bioconcept)	NP or OP	Laboratory-based	629	RT-PCR	NP
			STANDARD Q COVID19 Ag (SD Biosensor)			628		
			Panbio COVID-19 Ag Rapid Test (Abbott)			632		
			BIOSYNEX COVID-19 Ag BSS (Biosynex SA)			634		
			COVID-VIRO Antigen Rapid Test (AAZ)			632		
127	Gili 2021	Italy	Lumipulse SARS-CoV-2 Antigen Kit (Fujirebio)	NP	Screening population	1340	RT-PCR	NP
128	Gremmels 2020	Netherlands	Panbio COVID-19 Ag Rapid Test (Abbott)	NP or OP	COVID-19 test centre	1367	RT-PCR	NP
129	Gupta 2020	India	STANDARD Q COVID19 Ag (SD Biosensor)	NP or OP	COVID-19 test centre	330	RT-PCR	NP + OP
130	Herrera 2020	USA	Sofia SARS Antigen Fluorescent Immunoassay (Quidel)	NP	Symptomatic and asymptomatic healthcare workers	1172	RT-PCR	NP
131	Hirotsu 2020	Japan	Lumipulse SARS-CoV-2 Antigen Kit (Fujirebio)	NP	Hospital setting: infected and noninfected patients	313	RT-PCR	NP
132	Homza 2021	Czech Republic	SARS-CoV-2 Antigen Rapid Test Kit (JOYSBIO [Tianjin Biotechnology Co., China])	NP	COVID-19 test centre	225	RT-PCR, viral culture	NP
			Ecotest COVID-19 Antigen Rapid Test (Assure Tech, Hangzhou, China)			179		

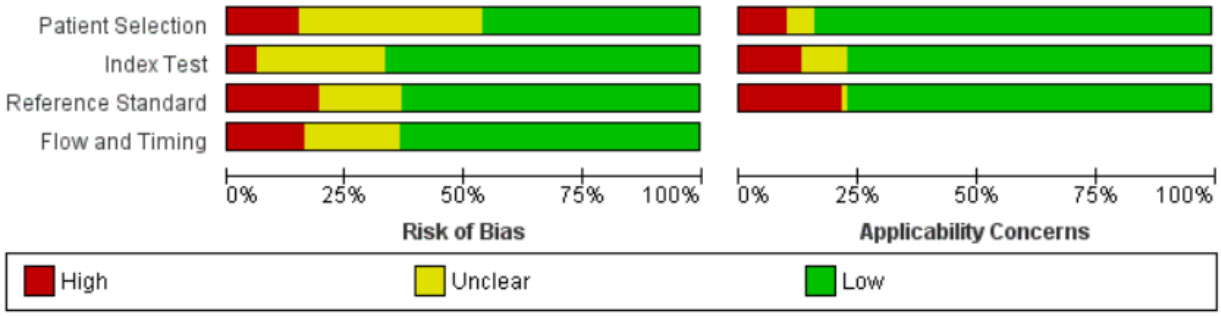
			STANDARD Q COVID19 Ag (SD Biosensor)			72		
			Immupass VivaDiag SARS-CoV-2 Ag Rapid Test (VivaChek Biotech [Hangzhou] Co., China)			268		
			ND COVID-19 Ag test (NDFOS, Eumseong, Korea)			91		
133	James 2021	USA	BinaxNOW COVID-19 Antigen Card (Abbott)	NP	Symptomatic and asymptomatic patients	2339	RT-PCR	Nasal swab
134	Kruger 2020	Germany	2019-nCoV Ag Fluorescence Rapid Test Kit (Bioeasy)	NP + OP	COVID-19 test centre	712	RT-PCR	NP + OP
			COVID-19 Ag Respi-Strip (Coris Bioconcept)			409		
			STANDARD Q COVID19 Ag (SD Biosensor)			1216		
135	Kruttgen 2020	Germany	Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)	NP	Admitted patients in the hospital	150	RT-PCR	NP
136	Lambert-Niclot 2020	France	COVID-19 Ag Respi-Strip (Coris Bioconcept)	NP or OP	Laboratory-based	138	RT-PCR	NP
137	Linares 2020	Spain	Panbio COVID-19 Ag Rapid Test (Abbott)	NP or OP	Hospital A&E	255	RT-PCR	NP
138	Liotti 2020	Italy	Standard F Covid19 Ag FIA (SD Biosensor)	NP or OP	Laboratory-based	359	RT-PCR	NP
139	Mak 2020	China	BIOCREDIT COVID-19 Ag test (RapiGEN, Inc)	Mixed respiratory samples	COVID-confirmed patients	368	RT-PCR	d respiratory sam
140	Mertens 2020	Belgium	COVID-19 Ag Respi-Strip (Coris Bioconcept)	NP or OP	Laboratory-based	328	RT-PCR	NP
141	Mockel 2021	Germany	Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)	NP + OP	COVID19 suspect adults in the emergency department	271	RT-PCR	NP
142	Muhi 2021	Australia	Panbio COVID-19 Ag Rapid Test (Abbott)	Nasal	Hospital	2602	RT-PCR + Viral culture	NP + OP
143	Nagura-Ikeda 2020	Japan	Espline SARS-CoV-2 (Fujirebio)	Saliva	Mixed	103	RT-PCR	Saliva
144	Nalumansi 2020	Uganda	STANDARD Q COVID19 Ag (SD Biosensor)	NP	COVID-19 suspects and low-risk volunteers	262	RT-PCR	NP
145	Nash 2020	USA	E25Bio Rapid Diagnostic Test (E25Bio)	NP or OP	Laboratory-based	190	RT-PCR	NP + OP
146	Osterman 022021	Germany	STANDARD Q COVID19 Ag (SD Biosensor)	NP + OP	Symptomatic patients in the ER	681	RT-PCR	NP + OP
			Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)			771		

147	Porte 2020a	Chile	2019-nCoV Ag Fluorescence Rapid Test Kit (Bioeasy)	NP + OP	Hospital A&E	127	RT-PCR	NP + OP
148	Porte 2020b	Chile	Sofia SARS Antigen Fluorescent Immunoassay (Quidel)	NP + OP	COVID-19 test centre	64	RT-PCR	NP + OP
			Standard F Covid19 Ag FIA (SD Biosensor)	NP + OP	COVID-19 test centre	64	RT-PCR	
149	Pray 2021	USA	Sofia SARS Antigen Fluorescent Immunoassay (Quidel)	Anterior Nares	students, faculty & staff of university campus	1098	RT-PCR	Anterior Nares
150	Prince-Guerra 2021	USA	BinaxNOW COVID-19 Antigen Card (Abbott)	Anterior Nares	10 years and older receiving testing for COVID 19	4904	RT-PCR	NP
151	Ristic 2021	Serbia	STANDARD Q COVID19 Ag (SD Biosensor)	NP	triage ambulance of primary and tertiary outpatients healthcare facility; 14 - 91 yrs old	120	RT-PCR	NP
152	Rottenstreich 2021	Israel	NowCheck COVID-19 Ag Test (Bionote)	NP	Asymptomatic women admitted for delivery	1326	RT-PCR	NP
153	Schildgen 2020	Germany	BIOCREDIT COVID-19 Ag test (RapiGEN, Inc)	Mixed	Laboratory based: specimens with confirmed PCR results	73	RT-PCR	Mixed
			Panbio COVID-19 Ag Rapid Test (Abbott)					
			Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)					
154	Scohy 2020	Belgium	COVID-19 Ag Respi-Strip (Coris Bioconcept)	NP	Laboratory-based: NP specimen for COVID testing with available data on symptomatology of some specimen	148	RT-PCR	NP
155	Seitz 2021	Austria	COVID- 19 Antigen Test Cassette [hypersensitive colloidal gold] (Xiamen Zhongsheng Langjie Biotechnology Co., Ltd)	Saliva	healthy citizens of Vienna, Austria were invited to participate in a vo- luntary SARS-CoV-2 mass screening	40	RT-PCR	gargle sample
156	Shrestha 2020	Nepal	BIOCREDIT COVID-19 Ag test (RapiGEN, Inc)	NP or OP	close contacts of confirmed COVID 19	113	RT-PCR	NP
157	Takeda 2020	Japan	Espline SARS-CoV-2 (Fujirebio)	NP or OP	Laboratory-based: specimens for COVID testing	162	RT-PCR	NP
158	Turcato 2020	Italy	STANDARD Q COVID19 Ag (SD Biosensor)	NP	ER consults (COVID related and non-COVID complains) and contacts of COVID infected persons	3410	RT-PCR	NP

159	Uwamino 2021	Japan	Espline SARS-CoV-2 (Fujirebio)	NP and saliva	Adults for COVID testing	117	RT-PCR	NP and saliva
160	Veyrenche 2020	France	COVID-19 Ag Respi-Strip (Coris Bioconcept)	NP or OP	Inpatients, symptomatic adults and healthcare worker	65	RT-PCR	NP
161	Weitzel 2020	Chile	BIOCREDIT COVID-19 Ag test (RapiGEN, Inc)	NP + OP	symptomatic individuals	109	RT-PCR	NP + OP
			StrongStep Rapid Antigen Test (Liming)			19		
			Huaketai SARS-CoV-2 Rapid Antigen Test (Savant)			109		
			2019-nCoV Ag (Shenzhen Bioeasy Biotech)			111		
			COVID-19 Rapid Antigen Test (BD Veritor)			251		
162	Young 2020	USA	COVID-19 Rapid Antigen Test (BD Veritor)	NP or OP	18 years old and above with symptoms	251	RT-PCR	NP or OP
163	Pilarowski 2020	USA	BinaxNOW COVID-19 Antigen Card (Abbott)	Anterior Nares	symptomatic and asymptomatic individuals	3302	RT-PCR	Anterior Nares
164	PHE 2020	United Kingdom	Innova Rapid SARS-CoV-2 Antigen Test (Xiamen Biotime Biotechnology)	NP + OP	Hospital in-patient; contacts; patients in COVID-19 test center	3168	RT-PCR	NP + OP

RT PCR: Reverse Transcriptase – Polymerase Chain Reaction; NP: Nasopharyngeal; OP: Oropharyngeal.

Appendix 4. Risk of Bias and Applicability Concerns of Included Studies



Appendix 5. Characteristics of Ongoing Studies

NCT Number	Title	Population	Interventions	Comparator	Outcomes
NCT04878068	Study to Evaluate the Performance of the Therma COVID-19 Rapid Antigen Test for Detection of SARS-CoV-2	12 years old and above aat COVID-19 testing centre	Device: Theram COVID-19 Rapid Antigen Test; Saliva sample	RT PCR	Establish Performance of Therma COVID-19 Rapid Antigen Test, Participant Feedback, User Feedback
NCT04750629	Clinical Evaluation of a Point-of-Care (POC), COVID-19 Rapid Antigen Test (CoviDx™)	1 year old and above suspected of SARS-Cov-2	Device: POC CoviDx™ Rapid Antigen Test	SARS-Cov-2 RT-PCR	Sensitivity of SARS-CoV-2 antigen in nasal swab as compared to a high-sensitive SARS-CoV-2 RT-PCR granted Emergency Use Authorization (EUA) by the FDA
NCT05045846	Diagnostic Accuracy of Rapid Antigen Test Based on Anterior Nasal Swab Compared With RT-PCR for SARS-CoV-2 Detection.	18 years old and above who have self-booked appointment at COVID testing centre	Rapid Antigen Test Based on Anterior Nasal Swab	RT-PCR	Accuracy of anterior nasal swab in rapid antigen (Ag)-tests
NCT04733170	Clinical Performance Evaluation of KnowNow SARS-CoV-2 Test for the Detection of COVID-19 Antigen	18 years old and above suspected with COVID-19	Diagnostic Test: KnowNow SARS-CoV-2 Rapid Antigen Test	RT-PCR	Assess clinical diagnostic performance of the KnowNow SARS-CoV-2 Rapid Antigen Test, Efficacy to assess the test compared to the reference test method; Usability Questionnaire to evaluate the use of the test with 2 saliva collection methods
NCT04689399	Sensitivity and Specificity of SARS-CoV-2 Rapid Antigen Test Compared to RT-PCR Test	18 years old above with appointment at COVID-a9 testing center	Diagnostic Test: Standard Q COVID-19 Ag - test, produced by SD Biosensor INC.	RT PCR	Sensitivity and specificity of the rapid antigen test of COVID-19 Economic analyses PCR analysis on nasopharyngeal swabs
NCT04716088	Rapid Antigen Testing for SARS-CoV-2 Among Healthcare Workers to Prevent Spread of COVID-19	18 years old and above healthcare workers	Repeated Rapid antigen test for SARS CoV2	RT PCR	SARS CoV2 infection
NCT04894760	Evaluation of a COVID-19 Rapid Diagnostic Test in ER	18 years old and above with	Diagnostic Test: Rapid Antigen Test (PanBio Ag test)	RT PCR	Diagnostic accuracy

	Departments in Mexico: a Multi-center Study	respiratory symptoms visiting the ER			
NCT04403906	Somerset and South Essex Coronavirus Antigen Testing	18 years old and above with clinical indication for COVID testing	Diagnostic Test: PCL COV05 - COVID 19 Ag Rapid FIA test (Rapid Antigen Test)	RT PCR	To compare the result of SARS-COV2 PCR test to PCL rapid antigen test Number of technically failed samples due to test issues. Time taken for PCL Antigen test result
NCT04839094	Dry Versus Wet Nasopharyngeal Rapid Test for the Detection of COVID-19.	18 years old and above hospitalized with a confirmed SARS-Cov-2 infection	Diagnostic Test: rapid antigen testing; nasopharyngeal vs saliva samples	RT PCR	Diagnostic assessment Limit of detection determination.
NCT04665193	An Approach to Screening for COVID-19 at Vancouver Airport	Adults with ticket to board a flight from Vancouver International Airport	Rapid Antigen Test	none	COVID-19 status; effectiveness and feasibility of rapid antigen test in airport screening
NCT05074017	COVAG - Covid-19 Antigen Study - the Diagnostic Efficacy of SARS-CoV-2 Rapid Detection Tests	18 years old and above at testing centers in whom RT- PCR testing for SARS-CoV-2 is medically indicated or requested	2 rapid antigen tests	RT PCR	Sensitivity of the rapid antigen tests
NCT04568356	A Clinical Evaluation of COVID-19 Rapid Point of Care Antigen Tests	18 years old and above suspected with COVID	Diagnostic Test: Direct Antigen Tests for COVID-19; nasopharyngeal, nasal and saliva samples	RT PCR	Percent Positive Agreement and Negative Percent Agreement
NCT04896710	COVID-19 Rapid Testing for Self-Administration Among an Asymptomatic Sample	16 Years to 80 Years Asymptomatic	Device: SD Biosensor RAT; self-administered	professional administered SD Biosensor RAT	Concordance Ability of rapid antigen test to detect COVID-19 positive Acceptability of self-administration

NCT04977050	The Role of Frequent Point-of-care Molecular Workplace Surveillance for Miners	18 Years and above miners	Diagnostic Test: Quidel quickvue antigen test for COVID-19	RT PCR	Screening test (molecular) Diagnostic test (RT-PCR) Serologic antibody test
NCT05047900	The Impact of SARS-CoV-2 Rapid Antigen Testing Kit Screening in Bangkok Community	10 years and older in any Bangkok community	Routine Use of Rapid antigen testing kit	Did not routinely use Rapid antigen testing kit	Incidence rate of COVID19 infection Incidence rate of severe COVID19 infection Incidence of COVID19 infection in COVID19 vaccinated and unvaccinated people sensitivity and specificity of rapid antigen testing kit
NCT04808921	Performance Evaluation of SARS-COV-2 (Covid-19) Antigen Rapid Test	Child and adults clinically suspected of COVID 19	Diagnostic Test: Xiamen Wiz Biotech Co., Ltd. SARS-CoV-2 Antigen Rapid Test	RT PCR	Percent Positive Agreement and Negative Percent Agreement
NCT04348864	COVID-19 Diagnostic Self-testing Using Virtual Point-of-care	18 years old and above suspected or clinically diagnosed with COVID	Diagnostic Test: COVID-19 Antigen/Antibody Rapid Testing, mobile device image capture and telemedicine support Self-test interpretation	RT PCR; Expert Clinical Interpretation of results	Clinical accuracy of the antibody and antigen rapid tests compared to LAMP/PCR-based test result Clinical accuracy of the antibody and antigen rapid tests based on Clinical diagnosis Self-test interpretation of result vs expert clinical image interpretation of result Ease of self-testing procedure
NCT04805840	Sensitivity of Frequent SARS-CoV-2 (COVID-19) Rapid Antigen Testing Regimen	18 years old and above healthy volunteers	Frequent testing of CoV-SCAN rapid COVID-19 antigen test	RT PCR	Sensitivity of CoV-SCAN daily testing regimen Specificity of CoV-SCAN daily testing regimen Time from CoV-SCAN positive to PCR positive result
NCT04898127	Antigen Rapid Test Screening to Prevent SARS-CoV-2 Transmission (COVID-19) at Mass Gathering Events.	18 - 45 years old volunteers	Diagnostic Test: SARS-CoV-2 antigen rapid test Rapid test before access to mass gathering event (concert), provided the test result is negative.	RT PCR	SARS-CoV-2 infection Clinical COVID-19 disease Hospital admissions False positive rapid test

NCT04877002	Performance Study of SONA Saliva C-19 Rapid Test	18 years old and above presenting with COVID symptoms at the ER	Diagnostic Test: Sona Saliva C-19 Rapid Test	RT PCR	Percent Positive Agreement and Negative Percent Agreement
NCT04926779	Open Label, Single-Center Study Utilizing BIOZEK COVID-19 Antigen Rapid Test	18 years old and above with COVID-19 symptoms and close contacts	Diagnostic Test: Biozek Covid-19 Antigen Rapid Test (Saliva)	RT PCR	Sensitivity and Specificity of Biozek Covid-19 Antigen Rapid Test (Saliva) Sensitivity and Specificity of Biozek Covid-19 Antigen Rapid Test (Nasopharyngeal Swab)
NCT04805892	Open Label, Single-Center Study Utilizing BIOZEK COVID-19 Antigen Rapid Test.	18 years old and above with COVID-19 symptoms and close contacts	Diagnostic Test: BIOZEK COVID-19 Antigen Rapid Test; professional vs sel-collected	RT PCR	Sensitivity and Specificity of BIOZEK COVID-19 Antigen Rapid Test on a sample collected by healthcare professionals. Sensitivity and Specificity of BIOZEK COVID-19 Antigen Rapid Test on self-collected sample.
NCT04889365	COVID-19 Antigen Rapid Test Kit	18 years old and above with or without COVID-19 symptoms	Diagnostic Test: SG Diagnostics COVID-19 Antigen Rapid Test Kit	Diagnostic Test: Polymerase chain reaction (PCR) test	Sensitivity of SG Diagnostics COVID-19 Antigen Rapid Test Kit Specificity of SG Diagnostics COVID-19 Antigen Rapid Test Kit
NCT04872075	Study on Prevention of SARS-CoV-2 Transmission During a Large Indoor Gathering Event	18 to 45 years old healthy volunteers	Concert Attendees; Diagnostic Test: Rapid nasopharyngeal antigen test for Sars-Cov-2 Diagnostic Test: Saliva Sample	RT PCR; People staying at home	Number of participants with a positive salivary RT-PCR at day 7 after the date of the concert Number of participants in each group with a positive salivary RT-PCR the day of the concert Molecular analysis of transmission cluster

Appendix 6 GRADE Evidence Profile

A. OVERALL

Should rapid antigen test be used to diagnose COVID-19 in patients suspected to have COVID-19?

Patient or population: patients suspected to have COVID-19
Pooled sensitivity: 0.71 (95% CI: 0.68 to 0.73)
Pooled specificity: 0.99 (95% CI: 0.99 to 1.00)

Outcomes	No of studies (No of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 1,000 patients tested			Test Accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication Bias	Pre-test probability of 5%	Pre-test probability of 10%	Pre-test probability of 15%	
True positives (patients with COVID-19)	164 studies (43,943 patients)	Cross-sectional (cohort type accuracy study)	serious[a]	not serious	serious[b]	not serious	none	36 (34 to 37)	71 (68 to 73)	107 (102 to 110)	⊕⊕◯◯ Low
False negatives (patients incorrectly classified as not having COVID-19)								14 (13 to 16)	29 (27 to 32)	43 (40 to 48)	
True negatives (patients without COVID-19)	164 studies (191,573 patients)	Cross-sectional (cohort type accuracy study)	serious[a]	not serious	serious[b]	not serious	none	945 (943 to 946)	896 (894 to 896)	846 (844 to 847)	⊕⊕◯◯ Low
False positives (patients incorrectly classified as having COVID-19)								5 (4 to 7)	4 (4 to 6)	4 (3 to 6)	

CI: confidence interval

Explanations

a. High and unclear risk on all domains (patient selection, conduct of index text and reference standard and patient flow and timing)
b. High heterogeneity across studies (I^2 = 99% [99-100%])

B. SYMPTOMATIC

Question: Should rapid antigen test be used to diagnose COVID-19 in symptomatic individuals suspected of COVID-19?

Sensitivity	0.74 (95% CI: 0.71 to 0.78)
Specificity	-- (95% CI: -- to --)

Prevalences	5 %	10%	15%

Outcome	№ of studies (№ of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 1,000 patients tested			Test accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	pre-test probability of 5%	pre-test probability of 10%	pre-test probability of 15%	
True positives (patients with COVID-19)	79 studies 45523 patients	cross-sectional (cohort type accuracy study)	serious [a]	not serious	serious[a,b]	not serious	none	37 (36 to 39)	74 (71 to 78)	111 (107 to 117)	⨁⨁◯◯ Low
False negatives (patients incorrectly classified as not having COVID-19)								13 (11 to 14)	26 (22 to 29)	39 (33 to 43)	
True negatives (patients without COVID-19)	0 studies patients							0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	-
False positives (patients incorrectly classified as having COVID-19)								950 (950 to 950)	900 (900 to 900)	850 (850 to 850)	

Explanations

a. Unclear and high risk of bias in all domains (e.g. patient selection, conduct of index test and reference stand, and patient flow)
b. High heterogeneity (different timing of testing, test brands, specimen type)

Should rapid antigen test be used to diagnose COVID-19 in symptomatic individuals suspected of COVID-19?

Patient or population: symptomatic individuals suspected of COVID-19
Setting:
New test:rapid antigen test |**Cut-off value**:
Pooled sensitivity:0.74 (95% CI: 0.71 to 0.78) |**Pooled specificity**: not calculated

Test result	Number of results per 1,000 patients tested (95% CI)			Number of participants (studies)	Certainty of the Evidence (GRADE)
	Prevalence5% Typically seen in	**Prevalence10%** Typically seen in	**Prevalence15%** Typically seen in		
True positives	**37** (36 to 39)	**74** (71 to 78)	**111** (107 to 117)	45523 (79)	⨁⨁◯◯ **Low**[a,b]
False negatives	**13** (11 to 14)	**26** (22 to 29)	**39** (33 to 43)		
True negatives					-
False positives					

CI: confidence interval

Explanations

a. Unclear and high risk of bias in all domains (e.g. patient selection, conduct of index test and reference stand, and patient flow)
b. High heterogeneity (I^2 = 99% [99-100%])

C. ASYMPTOMATIC

Question: Should rapid antigen test be used to diagnose COVID-19 in asymptomatic individuals suspected of COVID-19?

Sensitivity	0.56 (95% CI: 0.51 to 0.62)
Specificity	-- (95% CI: -- to --)

Prevalences	5 %	10%	15%

Outcome	№ of studies (№ of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 1,000 patients tested			Test accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	pre-test probability of 5%	pre-test probability of 10%	pre-test probability of 15%	
True positives (patients with COVID-19)	55 studies 72858 patients	cross-sectional (cohort type accuracy study)	serious[a]	not serious	serious[b]	not serious	none	28 (26 to 31)	56 (51 to 62)	84 (77 to 93)	⨁⨁◯◯ Low
False negatives (patients incorrectly classified as not having COVID-19)								22 (19 to 24)	44 (38 to 49)	66 (57 to 73)	

Explanations

a. High and unclear risk of bias in all domains (e.g. patient selection, conduct of index test and reference standard, and patient flow and timing
b. High heterogeneity (different test brands, specimen types, timing of testing) (I^2 = 99% [99-100%])

Should rapid antigen test be used to diagnose COVID-19 in asymptomatic individuals suspected of COVID-19?

Patient or population: asymptomatic individuals suspected of COVID-19
Setting:
New test: rapid antigen test |**Cut-off value**: variable
Pooled sensitivity:0.56 (95% CI: 0.51 to 0.62) | **Pooled specificity**: not computed

Test result	Number of results per 1,000 patients tested (95% CI)			Number of participants (studies)	Certainty of the Evidence (GRADE)
	Prevalence 5% Typically seen in	**Prevalence 10%** Typically seen in	**Prevalence 15%** Typically seen in		
True positives	**28** (26 to 31)	**56** (51 to 62)	**84** (77 to 93)	72858 (55)	⨁⨁◯◯ **Low**[a,b]
False negatives	**22** (19 to 24)	**44** (38 to 49)	**66** (57 to 73)		
True negatives					-
False positives					

CI: confidence interval

Explanations

a. High and unclear risk of bias in all domains (e.g. patient selection, conduct of index test and reference standard, and patient flow and timing
b. High heterogeneity (I^2 = 99% [99-100%])

D. EARLY PHASE

Question: Should rapid antigen test be used to diagnose COVID-19 in in the early phase of illness in individuals suspected of COVID-19??

Sensitivity	0.79 (95% CI: 0.75 to 0.82)
Specificity	-- (95% CI: -- to --)

Prevalences	5 %	10%	15%

Outcome	№ of studies (№ of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 1,000 patients tested			Test accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	pre-test probability of 5%	pre-test probability of 10%	pre-test probability of 15%	
True positives (patients with COVID-19)	54 studies 28591 patients	cross-sectional (cohort type accuracy study)	serious[a]	not serious	serious[b]	not serious	none	40 (38 to 41)	79 (75 to 82)	119 (112 to 123)	⨁⨁◯◯ Low
False negatives (patients incorrectly classified as not having COVID-19)								10 (9 to 12)	21 (18 to 25)	31 (27 to 38)	

Explanations

a. High and unclear risk of bias in all domains (e.g. patient selection, conduct of index test and reference standard, and patient flow and timing
b. High heterogeneity (different test brands, symptom status, specimen) (I^2 = 99% [99-100%])

Should rapid antigen test be used to diagnose COVID-19 in in the early phase of illness in individuals suspected of COVID-19??

Patient or population: in the early phase of illness in individuals suspected of COVID-19?
Setting:
New test: rapid antigen test |**Cut-off value**: variable
Pooled sensitivity:0.79 (95% CI: 0.75 to 0.82) | **Pooled specificity**: not calculated

Test result	Number of results per 1,000 patients tested (95% CI)			Number of participants (studies)	Certainty of the Evidence (GRADE)
	Prevalence5% Typically seen in	**Prevalence10%** Typically seen in	**Prevalence15%** Typically seen in		
True positives	**40** (38 to 41)	**79** (75 to 82)	**119** (112 to 123)	28591 (54)	⨁⨁◯◯ **Low**[a,b]
False negatives	**10** (9 to 12)	**21** (18 to 25)	**31** (27 to 38)		
True negatives				(0)	-
False positives					

CI: confidence interval

Explanations

a. High and unclear risk of bias in all domains (e.g. patient selection, conduct of index test and reference standard, and patient flow and timing
b. High heterogeneity (I^2 = 99% [99-100%])

E. SALIVA SPECIMEN

Question: Should rapid antigen test using saliva as specimen be used to diagnose COVID-19 in individuals suspected of COVID-19?

Sensitivity	0.57 (95% CI: 0.22 to 0.86)
Specificity	Not calculated

Prevalences	5 %	10%	15%

Outcome	№ of studies (№ of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 1,000 patients tested			Test accuracy CoE	Importance
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	pre-test probability of 5%	pre-test probability of 10%	pre-test probability of 15%		
True positives (patients with COVID-19)	7 studies 6148 patients	cross-sectional (cohort type accuracy study)	serious[a]	not serious	serious[b]	serious[c]	none	28 (11 to 43)	57 (22 to 86)	85 (33 to 129)	⨁◯◯◯ Very low	
False negatives (patients incorrectly classified as not having COVID-19)								22 (7 to 39)	43 (14 to 78)	65 (21 to 117)		

Explanations

a. High and unclear risk of bias in all domains (e.g. patient selection, conduct of index test and reference standard, and patient flow and timing)
b. High heterogeneity (I^2 = 99% [99-100%])
c. Very wide estimates

Should rapid antigen test using saliva as specimen be used to diagnose COVID-19 in individuals suspected of COVID-19?

Patient or population: individuals suspected of COVID-19
Setting:
New test: rapid antigen test – saliva-based |**Cut-off value**: variable
Pooled sensitivity:0.57 (95% CI: 0.22 to 0.86)|**Pooled specificity**: not calculated

Test result	Number of results per 1,000 patients tested (95% CI)			Number of participants (studies)	Certainty of the Evidence (GRADE)
	Prevalence5% Typically seen in	**Prevalence10%** Typically seen in	**Prevalence15%** Typically seen in		
True positives	**28** (11 to 43)	**57** (22 to 86)	**85** (33 to 129)	6148 (7)	⨁◯◯◯ **Very low**[a,b,c]
False negatives	**22** (7 to 39)	**43** (14 to 78)	**65** (21 to 117)		
True negatives					
False positives					

CI: confidence interval

Explanations

a. High and unclear risk of bias in all domains (e.g. patient selection, conduct of index test and reference standard, and patient flow and timing)
b. High heterogeneity (I^2 = 99% [99-100%])
c. Very wide estimates

F. REPEAT TESTING

Question: Should repeat testing using rapid antigen tests be used to diagnose COVID-19 in individuals suspected of COVID-19?

Sensitivity	0.63 to 0.81
Specificity	Not calculated

Prevalences	5 %	10%	15%

Outcome	№ of studies (№ of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 1,000 patients tested			Test accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	pre-test probability of5%	pre-test probability of10%	pre-test probability of15%	
True positives (patients with COVID-19)	2 studies 4752 patients	cross-sectional (cohort type accuracy study)	serious[a]	not serious	serious[b]	serious[c]	none	32 to 41	63 to 81	95 to 122	⨁◯◯◯ Very low
False negatives (patients incorrectly classified as not having COVID-19)								9 to 18	19 to 37	28 to 55	

Explanations

a. Unclear risk of bias in patient selection and conduct of reference standard
b. Heterogenous studies with inconsistent sensitivity values (I^2 = 99% [99-100%])
c. Wide estimates seen especially in the study of Mckay et al.

Should repeat testing using rapid antigen tests be used to diagnose COVID-19 in individuals suspected of COVID-19?

Patient or population: individuals suspected of COVID-19
Setting:
New test: repeat antigen testing |**Cut-off value**:
Range of sensitivities:0.63 to 0.81| **Range of specificities** not calculated

Test result	Number of results per 1,000 patients tested (95% CI)			Number of participants (studies)	Certainty of the Evidence (GRADE)
	Prevalence5% Typically seen in	**Prevalence10%** Typically seen in	**Prevalence15%** Typically seen in		
True positives	32 to 41	63 to 81	95 to 122	4752 (2)	⨁◯◯◯ **Very low**[a,b,c]
False negatives	9 to 18	19 to 37	28 to 55		
True negatives	0 to 0	0 to 0	0 to 0	(0)	-
False positives	950 to 950	900 to 900	850 to 850		

CI: confidence interval

Explanations

a. Unclear risk of bias in patient selection and conduct of reference standard
b. Heterogenous studies with inconsistent sensitivity values
c. Wide estimates seen especially in the study of Mckay et al.

F. CHILDREN

Question: Should rapid antigen test be used to diagnose COVID-19 in children suspected of COVID-19?

Sensitivity	0.79 (95% CI: 0.70 to 0.86)
Specificity	0.99 (95% CI: 0.96 to 1.00)

Prevalences	5 %	10%	15%

Outcome	№ of studies (№ of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 1,000 patients tested			Test accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication bias	pre-test probability of5%	pre-test probability of10%	pre-test probability of15%	
True positives (patients with COVID-19)	11 studies 5101 patients	cross-sectional (cohort type accuracy study)	serious[a]	not serious	serious[b]	not serious	none	40 (35 to 43)	79 (70 to 86)	119 (105 to 129)	⨁⨁◯◯ Low
False negatives (patients incorrectly classified as not having COVID-19)								10 (7 to 15)	21 (14 to 30)	31 (21 to 45)	
True negatives (patients without COVID-19)	0 studies patients	cross-sectional (cohort type accuracy study)	serious[a]	not serious	not serious	not serious	none	945 (916 to 949)	896 (868 to 899)	846 (819 to 849)	⨁⨁⨁◯ Moderate
False positives (patients incorrectly classified as having COVID-19)								5 (1 to 34)	4 (1 to 32)	4 (1 to 31)	

Explanations

a. High and unclear risk of bias in all domains (e.g. patient selection, conduct of index test and reference standard, and patient flow and timing)
b. High heterogeneity (I^2 = 99% [99-100%])

Should rapid antigen test be used to diagnose COVID-19 in children suspected of COVID-19?

Patient or population: children suspected of COVID-19
Setting:
New test: rapid antigen tests |**Cut-off value**:
Pooled sensitivity:0.79 (95% CI: 0.70 to 0.86)|**Pooled specificity**:0.99 (95% CI: 0.96 to 1.00)

Test result	Number of results per 1,000 patients tested (95% CI)			Number of participants (studies)	Certainty of the Evidence (GRADE)
	Prevalence5% Typically seen in	**Prevalence10%** Typically seen in	**Prevalence15%** Typically seen in		
True positives	**40** (35 to 43)	**79** (70 to 86)	**119** (105 to 129)	5101 (11)	⨁⨁◯◯ **Low**[a,b]
False negatives	**10** (7 to 15)	**21** (14 to 30)	**31** (21 to 45)		
True negatives	**945** (916 to 949)	**896** (868 to 899)	**846** (819 to 849)	5101 (11)	⨁⨁⨁◯ **Moderate**[a]
False positives	**5** (1 to 34)	**4** (1 to 32)	**4** (1 to 31)		

CI: confidence interval

Explanations

a. High and unclear risk of bias in all domains (e.g. patient selection, conduct of index test and reference standard, and patient flow and timing)
b. High heterogeneity

G. OUTBREAK SETTINGS

Should rapid antigen test be used to diagnose COVID-19 in individuals suspected of COVID-19 during outbreaks?

Patient or population: individuals suspected to have COVID-19 (includes both symptomatic and asymptomatic patients)
Range of sensitivity: 0.14 to 0.89
Range of specificity: 0.88 to 1.0

Outcomes	No of studies (No of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 1,000 patients tested			Test Accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication Bias	Pre-test probability of 5%	Pre-test probability of 10%	Pre-test probability of 15%	
True positives (patients with COVID-19)	3 studies (398 patients)	Cross-sectional (cohort type accuracy study)	very serious[a]	not serious	serious[b]	serious[c]	none	7 to 45	14 to 89	21 to 134	⊕◯◯◯ Very low
False negatives (patients incorrectly classified as not having COVID-19)								5 to 43	11 to 86	16 to 129	
True negatives (patients without COVID-19)	3 studies (398)	Cross-sectional (cohort type accuracy study)	very serious[a]	not serious	serious[b]	not serious	none	836 to 950	792 to 900	748 to 850	⊕⊕◯◯ Low
False positives (patients incorrectly classified as having COVID-19)								0 to 114	0 to 108	0 to 102	

CI: confidence interval

Explanations

a. Majority of included studies have high risk of bias most notably in the patient selection, conduct of reference standard, and patient flow and timing
b. High heterogeneity across studies (different timing of testing, test brands, specimen type) - $I^2 = 99\%$
c. Wide confidence intervals

Should rapid antigen test be used to diagnose COVID-19 in asymptomatic individuals during outbreaks?

Patient or population: asymptomatic individuals in an outbreak setting
Range sensitivity: 0.64 to 0.92
Range specificity: 0.92 to 0.98

Outcomes	No of studies (No of patients)	Study design	Factors that may decrease certainty of evidence					Effect per 1,000 patients tested			Test Accuracy CoE
			Risk of bias	Indirectness	Inconsistency	Imprecision	Publication Bias	Pre-test probability of 5%	Pre-test probability of 10%	Pre-test probability of 15%	
True positives (patients with COVID-19)	2 studies (1,127 patients)	Cross-sectional (cohort type accuracy study)	serious[a]	not serious	serious[b]	serious[c]	none	32 to 46	64 to 92	96 to 138	⊕◯◯◯ VeryLow
False negatives (patients incorrectly classified as not having COVID-19)								4 to 18	8 to 36	12 to 54	
True negatives (patients without COVID-19)	2 studies (1,127 patients)	Cross-sectional (cohort type accuracy study)	serious[a]	not serious	serious[b]	not serious	none	874 to 931	828 to 882	782 to 833	⊕⊕◯◯ Low
False positives (patients incorrectly classified as having COVID-19)								19 to 76	18 to 72	17 to 68	

CI: confidence interval

Explanations

a. Unclear issues on patient selection domain
b. High heterogeneity across studies (different test brands, different timing of testing)
c. few studies, wide confidence interval

Appendix 7. Forest Plots

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Schildgen 2020 [C]	10	12	0	1	1.00 [0.69, 1.00]	0.08 [0.00, 0.36]
Matsuda 2021 [B]	9	2	0	31	1.00 [0.66, 1.00]	0.94 [0.80, 0.99]
Cassuto 2021	31	0	1	202	0.97 [0.84, 1.00]	1.00 [0.98, 1.00]
Courtellemont 2020	97	20	4	127	0.96 [0.90, 0.99]	0.86 [0.80, 0.91]
Pilarowski 2021 [C]	124	1	6	540	0.95 [0.90, 0.98]	1.00 [0.99, 1.00]
Van Der Moeren 202105	16	0	1	334	0.94 [0.71, 1.00]	1.00 [0.99, 1.00]
Denina 2021	16	14	1	160	0.94 [0.71, 1.00]	0.92 [0.87, 0.96]
Porte 2020a	77	0	5	45	0.94 [0.86, 0.98]	1.00 [0.92, 1.00]
Porte 2020b [A]	30	1	2	31	0.94 [0.79, 0.99]	0.97 [0.84, 1.00]
Alemany 2020	388	0	31	27	0.93 [0.90, 0.95]	1.00 [0.87, 1.00]
Orsi 2021	50	0	4	56	0.93 [0.82, 0.98]	1.00 [0.94, 1.00]
Bachman 2021 [D]	84	4	8	78	0.91 [0.84, 0.96]	0.95 [0.88, 0.99]
Bachman 2021 [C]	84	5	8	72	0.91 [0.84, 0.96]	0.94 [0.85, 0.98]
Nikolai 2021 [B]	31	0	3	62	0.91 [0.76, 0.98]	1.00 [0.94, 1.00]
Pollock 202104	116	1	12	376	0.91 [0.84, 0.95]	1.00 [0.99, 1.00]
Porte 2020b [B]	29	1	3	31	0.91 [0.75, 0.98]	0.97 [0.84, 1.00]
Turcato 2021 [A]	152	20	17	802	0.90 [0.84, 0.94]	0.98 [0.96, 0.99]
Osmanodja 2021	62	1	7	203	0.90 [0.80, 0.96]	1.00 [0.97, 1.00]
Bianco 2021	176	4	21	30	0.89 [0.84, 0.93]	0.88 [0.73, 0.97]
Klein 2021	66	3	8	189	0.89 [0.80, 0.95]	0.98 [0.96, 1.00]
Kurihara 2021	32	0	4	825	0.89 [0.74, 0.97]	1.00 [1.00, 1.00]
Jung 2021	29	4	4	271	0.88 [0.72, 0.97]	0.99 [0.96, 1.00]
Stokes 202103 [B]	268	2	37	1334	0.88 [0.84, 0.91]	1.00 [0.99, 1.00]
Stokes 202103 [A]	121	2	17	5	0.88 [0.81, 0.93]	0.71 [0.29, 0.96]
Ifko 2021	20	12	3	90	0.87 [0.66, 0.97]	0.88 [0.80, 0.94]
Kruger 2021	79	1	12	620	0.87 [0.78, 0.93]	1.00 [0.99, 1.00]
Kolwijck 2021 [A]	39	0	6	388	0.87 [0.73, 0.95]	1.00 [0.99, 1.00]
Nikolai 2021 [A]	31	0	5	96	0.86 [0.71, 0.95]	1.00 [0.96, 1.00]
Bachman 2021 [B]	79	3	13	75	0.86 [0.77, 0.92]	0.96 [0.89, 0.99]
Cento 2021	297	17	50	596	0.86 [0.81, 0.89]	0.97 [0.96, 0.98]
Chiu 2021 [A]	64	14	11	260	0.85 [0.75, 0.92]	0.95 [0.92, 0.97]
Weitzel 2020 [D]	68	0	12	31	0.85 [0.75, 0.92]	1.00 [0.89, 1.00]
Kahn 2021	34	17	6	192	0.85 [0.70, 0.94]	0.92 [0.87, 0.95]
Lindner 202105 [B]	34	1	6	105	0.85 [0.70, 0.94]	0.99 [0.95, 1.00]
Shaikh 2021	39	16	7	137	0.85 [0.71, 0.94]	0.90 [0.84, 0.94]
Schuit 2021 [A]	32	1	6	180	0.84 [0.69, 0.94]	0.99 [0.97, 1.00]
Homza 2021 [B]	72	2	14	46	0.84 [0.74, 0.91]	0.96 [0.86, 0.99]
Bachman 2021 [A]	75	2	15	77	0.83 [0.74, 0.90]	0.97 [0.91, 1.00]
James 2021 [A]	20	0	4	91	0.83 [0.63, 0.95]	1.00 [0.96, 1.00]
Jaaskelainen 2021 [C]	126	0	26	48	0.83 [0.76, 0.89]	1.00 [0.93, 1.00]
Chiu 2021 [B]	62	10	13	264	0.83 [0.72, 0.90]	0.96 [0.93, 0.98]
Lindner 202105 [A]	33	2	7	104	0.82 [0.67, 0.93]	0.98 [0.93, 1.00]
Nomoto 2021	66	1	14	19	0.82 [0.72, 0.90]	0.95 [0.75, 1.00]
Kruger 202108	113	3	24	346	0.82 [0.75, 0.88]	0.99 [0.98, 1.00]
Kruger 2020(c)	32	7	7	972	0.82 [0.66, 0.92]	0.99 [0.99, 1.00]
Matsuda 2021 [A]	18	1	4	43	0.82 [0.60, 0.95]	0.98 [0.88, 1.00]
Bachman 2021 [G]	89	0	20	60	0.82 [0.73, 0.88]	1.00 [0.94, 1.00]
Jaaskelainen 2021 [B]	128	0	30	40	0.81 [0.74, 0.87]	1.00 [0.91, 1.00]
Leli 2021	64	2	15	126	0.81 [0.71, 0.89]	0.98 [0.94, 1.00]
Bulilete 2021	70	2	17	588	0.80 [0.71, 0.88]	1.00 [0.99, 1.00]
Jaaskelainen 2021 [A]	119	0	29	40	0.80 [0.73, 0.86]	1.00 [0.91, 1.00]
Pray 2021 [A]	32	2	8	185	0.80 [0.64, 0.91]	0.99 [0.96, 1.00]
Albert 2020	43	0	11	358	0.80 [0.66, 0.89]	1.00 [0.99, 1.00]
Nordgren 2021 [B]	124	45	32	131	0.79 [0.72, 0.86]	0.74 [0.67, 0.81]
Lindner 202104 [B]	31	1	8	247	0.79 [0.64, 0.91]	1.00 [0.98, 1.00]
Fenollar 2020(a)	144	0	38	0	0.79 [0.72, 0.85]	Not estimable
Bachman 2021 [H]	87	1	23	59	0.79 [0.70, 0.86]	0.98 [0.91, 1.00]
Ford 2021	30	1	8	180	0.79 [0.63, 0.90]	0.99 [0.97, 1.00]
Ferte 2021	26	0	7	99	0.79 [0.61, 0.91]	1.00 [0.96, 1.00]
Shah 2021	221	2	60	907	0.79 [0.73, 0.83]	1.00 [0.99, 1.00]
Linares 2020	39	0	11	133	0.78 [0.64, 0.88]	1.00 [0.97, 1.00]
Asai 2021	49	4	14	238	0.78 [0.66, 0.87]	0.98 [0.96, 1.00]
Donapetry 2021	14	0	4	422	0.78 [0.52, 0.94]	1.00 [0.99, 1.00]
Homza 2021 [E]	45	18	13	23	0.78 [0.65, 0.87]	0.56 [0.40, 0.72]
Herrera 2020	352	6	107	707	0.77 [0.73, 0.80]	0.99 [0.98, 1.00]
Kanauija 2021	113	2	35	221	0.76 [0.69, 0.83]	0.99 [0.97, 1.00]
Young 2020	29	1	9	212	0.76 [0.60, 0.89]	1.00 [0.97, 1.00]

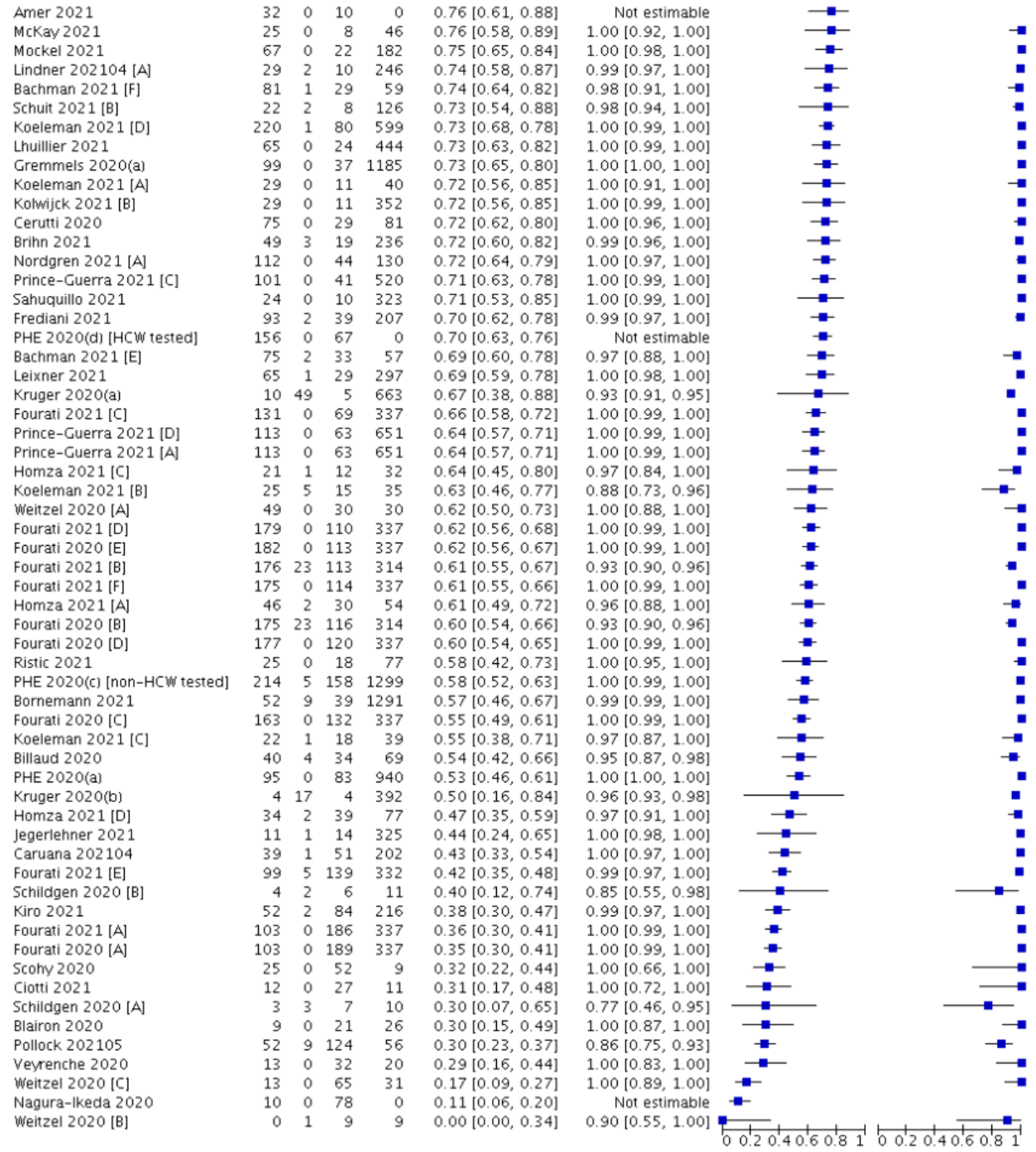


Figure 1. Sensitivity and specificity of RAgT in symptomatic individuals

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Martin-Sanchez 2021	214	3	7	657	0.97 [0.94, 0.99]	1.00 [0.99, 1.00]
Pilarowski 2021 [D]	14	1	1	855	0.93 [0.68, 1.00]	1.00 [0.99, 1.00]
Schildgen 2020 [C]	11	12	2	2	0.85 [0.55, 0.98]	0.14 [0.02, 0.43]
Montero 2021	35	8	14	2486	0.71 [0.57, 0.83]	1.00 [0.99, 1.00]
Pena 2021	51	3	22	766	0.70 [0.58, 0.80]	1.00 [0.99, 1.00]
Pollock 202104	110	11	54	1628	0.67 [0.59, 0.74]	0.99 [0.99, 1.00]
Schuit 2021 [B]	60	6	41	1307	0.59 [0.49, 0.69]	1.00 [0.99, 1.00]
Schuit 2021 [A]	105	8	74	2130	0.59 [0.51, 0.66]	1.00 [0.99, 1.00]
Rottenstreich 2021	5	0	4	1317	0.56 [0.21, 0.86]	1.00 [1.00, 1.00]
Okoye 2021	24	0	21	2593	0.53 [0.38, 0.68]	1.00 [1.00, 1.00]
Pollock 202105	83	12	82	1080	0.50 [0.42, 0.58]	0.99 [0.98, 0.99]
Pray 2021 [B]	7	14	10	840	0.41 [0.18, 0.67]	0.98 [0.97, 0.99]
Schildgen 2020 [B]	5	4	8	10	0.38 [0.14, 0.68]	0.71 [0.42, 0.92]
Prince-Guerra 2021 [B]	44	4	79	2465	0.36 [0.27, 0.45]	1.00 [1.00, 1.00]
Schildgen 2020 [A]	4	1	9	13	0.31 [0.09, 0.61]	0.93 [0.66, 1.00]
Nagura-Ikeda 2020	2	0	13	0	0.13 [0.02, 0.40]	Not estimable
Osmanodja 2021	0	0	1	105	0.00 [0.00, 0.97]	1.00 [0.97, 1.00]
PHE 2020(e)	0	1	0	537	Not estimable	1.00 [0.99, 1.00]
Von Ahnen 2021	12	0	1	906	0.92 [0.64, 1.00]	1.00 [1.00, 1.00]
Bianco 2021	93	44	8	531	0.92 [0.85, 0.97]	0.92 [0.90, 0.94]
Kruger 2021	12	0	2	374	0.86 [0.57, 0.98]	1.00 [0.99, 1.00]
Shrestha 2020	40	0	7	66	0.85 [0.72, 0.94]	1.00 [0.95, 1.00]
Chiu 2021 [C]	32	18	6	22938	0.84 [0.69, 0.94]	1.00 [1.00, 1.00]
Alemany 2020	93	5	24	365	0.79 [0.71, 0.86]	0.99 [0.97, 1.00]
Kruger 202108	7	1	2	262	0.78 [0.40, 0.97]	1.00 [0.98, 1.00]
Klein 2021	12	1	4	293	0.75 [0.48, 0.93]	1.00 [0.98, 1.00]
Jegerlehner 2021	81	1	35	994	0.70 [0.61, 0.78]	1.00 [0.99, 1.00]
Gupta 2020	9	1	4	113	0.69 [0.39, 0.91]	0.99 [0.95, 1.00]
Shah 2021	33	5	15	829	0.69 [0.54, 0.81]	0.99 [0.99, 1.00]
Amer 2021	2	1	1	1	0.67 [0.09, 0.99]	0.50 [0.01, 0.99]
Gremmels 2020(a)	2	0	1	34	0.67 [0.09, 0.99]	1.00 [0.90, 1.00]
McKay 2021	46	7	25	373	0.65 [0.53, 0.76]	0.98 [0.96, 0.99]
Wachinger 2021	170	26	94	1306	0.64 [0.58, 0.70]	0.98 [0.97, 0.99]
Kurihara 2021	30	2	17	491	0.64 [0.49, 0.77]	1.00 [0.99, 1.00]
Brihn 2021	49	9	32	1642	0.60 [0.49, 0.71]	0.99 [0.99, 1.00]
Halfon 2021	20	0	15	0	0.57 [0.39, 0.74]	Not estimable
Bulilete 2021	30	0	23	82	0.57 [0.42, 0.70]	1.00 [0.96, 1.00]
Kanauija 2021	23	0	18	72	0.56 [0.40, 0.72]	1.00 [0.95, 1.00]
Billaud 2020	13	1	12	289	0.52 [0.31, 0.72]	1.00 [0.98, 1.00]
James 2021 [B]	66	3	62	2093	0.52 [0.43, 0.60]	1.00 [1.00, 1.00]
Baro 2021 [B]	52	3	49	182	0.51 [0.41, 0.62]	0.98 [0.95, 1.00]
Turcato 2021 [B]	27	10	27	2355	0.50 [0.36, 0.64]	1.00 [0.99, 1.00]
Homza 2021 [C]	4	0	4	64	0.50 [0.16, 0.84]	1.00 [0.94, 1.00]
Linares 2020	5	0	5	62	0.50 [0.19, 0.81]	1.00 [0.94, 1.00]
Leli 2021	26	20	28	303	0.48 [0.34, 0.62]	0.94 [0.91, 0.96]
Torres 202101	38	0	41	555	0.48 [0.37, 0.60]	1.00 [0.99, 1.00]
Kahn 2021	20	25	22	2273	0.48 [0.32, 0.64]	0.99 [0.98, 0.99]
Homza 2021 [E]	9	31	10	41	0.47 [0.24, 0.71]	0.57 [0.45, 0.69]
Homza 2021 [A]	6	0	7	0	0.46 [0.19, 0.75]	Not estimable
Baro 2021 [D]	46	20	55	165	0.46 [0.36, 0.56]	0.89 [0.84, 0.93]
Fenollar 2020(b)	10	7	12	130	0.45 [0.24, 0.68]	0.95 [0.90, 0.98]
Ford 2021	7	14	9	802	0.44 [0.20, 0.70]	0.98 [0.97, 0.99]
Baro 2021 [C]	44	7	57	178	0.44 [0.34, 0.54]	0.96 [0.92, 0.98]
Lhuillier 2021	13	0	17	259	0.43 [0.25, 0.63]	1.00 [0.99, 1.00]
Cerutti 2020	2	0	3	140	0.40 [0.05, 0.85]	1.00 [0.97, 1.00]
Finana 2021	28	3	42	5431	0.40 [0.28, 0.52]	1.00 [1.00, 1.00]
Homza 2021 [B]	8	5	12	154	0.40 [0.19, 0.64]	0.97 [0.93, 0.99]
Baro 2021 [A]	39	1	62	184	0.39 [0.29, 0.49]	0.99 [0.97, 1.00]
Ferte 2021	7	0	13	536	0.35 [0.15, 0.59]	1.00 [0.99, 1.00]
Thakur 2021	29	1	55	592	0.35 [0.24, 0.46]	1.00 [0.99, 1.00]
Caruana 202104	8	0	16	215	0.33 [0.16, 0.55]	1.00 [0.98, 1.00]
Baro 2021 [E]	29	4	72	181	0.29 [0.20, 0.39]	0.98 [0.95, 0.99]
Scohy 2020	4	0	10	31	0.29 [0.08, 0.58]	1.00 [0.89, 1.00]
Caruana 202105	2	2	5	107	0.29 [0.04, 0.71]	0.98 [0.94, 1.00]
Homza 2021 [D]	4	5	13	93	0.24 [0.07, 0.50]	0.95 [0.88, 0.98]
Stokes 202109	0	1	6	990	0.00 [0.00, 0.46]	1.00 [0.99, 1.00]

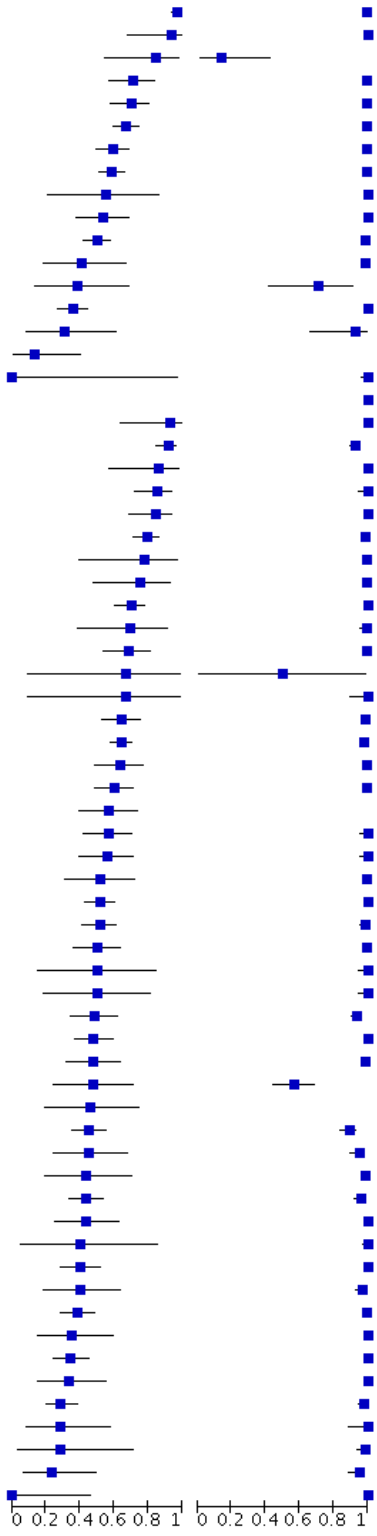
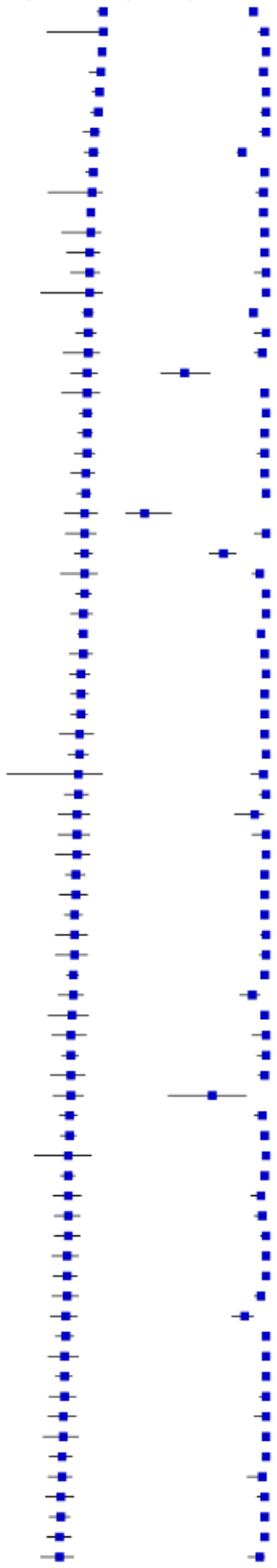


Figure 2. Sensitivity and specificity of RAgT in asymptomatic individuals

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Gili 2021	90	130	0	1518	1.00 [0.96, 1.00]	0.92 [0.91, 0.93]
Ishii 2021 [D]	8	1	0	123	1.00 [0.63, 1.00]	0.99 [0.96, 1.00]
Kobayashi 2021 [A]	304	0	1	4615	1.00 [0.98, 1.00]	1.00 [1.00, 1.00]
Chaimayo 2021	59	5	1	389	0.98 [0.91, 1.00]	0.99 [0.97, 1.00]
Kobayashi 2021 [B]	111	3	3	5272	0.97 [0.93, 0.99]	1.00 [1.00, 1.00]
Courtellemont 2021	117	0	4	127	0.97 [0.92, 0.99]	1.00 [0.97, 1.00]
Kim 2021 [B]	94	0	6	100	0.94 [0.87, 0.98]	1.00 [0.96, 1.00]
Sood 2021	127	99	9	539	0.93 [0.88, 0.97]	0.84 [0.81, 0.87]
Merino-Amador 2021	179	2	13	256	0.93 [0.89, 0.96]	0.99 [0.97, 1.00]
Maniscalco 2021	12	1	1	91	0.92 [0.64, 1.00]	0.99 [0.94, 1.00]
Alemany 2020	872	5	79	450	0.92 [0.90, 0.93]	0.99 [0.97, 1.00]
Ishii 2021 [C]	22	1	2	460	0.92 [0.73, 0.99]	1.00 [0.99, 1.00]
Yokota 2021	31	2	3	307	0.91 [0.76, 0.98]	0.99 [0.98, 1.00]
Seynaeve 2021 [C]	41	0	4	50	0.91 [0.79, 0.98]	1.00 [0.93, 1.00]
Ishii 2021 [A]	10	0	1	260	0.91 [0.59, 1.00]	1.00 [0.99, 1.00]
Bianco 2021	269	48	29	561	0.90 [0.86, 0.93]	0.92 [0.90, 0.94]
Bouassa 2021	90	0	10	50	0.90 [0.82, 0.95]	1.00 [0.93, 1.00]
Kim 2021 [A]	27	2	3	98	0.90 [0.73, 0.98]	0.98 [0.93, 1.00]
Van Honacker 2021 [A]	52	21	6	18	0.90 [0.79, 0.96]	0.46 [0.30, 0.63]
Agarwal 2021	26	2	3	436	0.90 [0.73, 0.98]	1.00 [0.98, 1.00]
Pilarowski 2021 [A]	211	3	26	3062	0.89 [0.84, 0.93]	1.00 [1.00, 1.00]
Berger 2021 [B]	170	1	21	337	0.89 [0.84, 0.93]	1.00 [0.98, 1.00]
Pickering 2021 [A]	89	1	11	99	0.89 [0.81, 0.94]	0.99 [0.95, 1.00]
Osmanodja 2021	62	1	8	308	0.89 [0.79, 0.95]	1.00 [0.98, 1.00]
Karon 2021 [D]	174	0	23	150	0.88 [0.83, 0.92]	1.00 [0.98, 1.00]
Schildgen 2020 [C]	37	25	5	6	0.88 [0.74, 0.96]	0.19 [0.07, 0.37]
Seynaeve 2021 [D]	44	0	6	50	0.88 [0.76, 0.95]	1.00 [0.93, 1.00]
Andreani 2021 [F]	109	32	15	83	0.88 [0.81, 0.93]	0.72 [0.63, 0.80]
Baccani 2021 [A]	29	7	4	161	0.88 [0.72, 0.97]	0.96 [0.92, 0.98]
Karon 2021 [C]	164	0	23	150	0.88 [0.82, 0.92]	1.00 [0.98, 1.00]
Kruger 2021	92	1	14	1001	0.87 [0.79, 0.93]	1.00 [0.99, 1.00]
Caputo 2021	436	102	67	3661	0.87 [0.83, 0.90]	0.97 [0.97, 0.98]
Klein 2021	78	4	12	486	0.87 [0.78, 0.93]	0.99 [0.98, 1.00]
Berger 2021 [A]	106	0	18	411	0.85 [0.78, 0.91]	1.00 [0.99, 1.00]
Kyritsi 2021	141	1	24	458	0.85 [0.79, 0.90]	1.00 [0.99, 1.00]
Igloi 2021	158	4	28	780	0.85 [0.79, 0.90]	0.99 [0.99, 1.00]
Hartard 2021	39	2	7	330	0.85 [0.71, 0.94]	0.99 [0.98, 1.00]
Escriva 2021	99	0	18	331	0.85 [0.77, 0.91]	1.00 [0.99, 1.00]
Tsai 2021	5	1	1	54	0.83 [0.36, 1.00]	0.98 [0.90, 1.00]
Favresse 2021 [E]	80	0	16	92	0.83 [0.74, 0.90]	1.00 [0.96, 1.00]
Van Honacker 2021 [C]	48	3	10	37	0.83 [0.71, 0.91]	0.93 [0.80, 0.98]
Van Honacker 2021 [E]	48	0	10	40	0.83 [0.71, 0.91]	1.00 [0.91, 1.00]
Eleftheriou 2021	42	0	9	693	0.82 [0.69, 0.92]	1.00 [0.99, 1.00]
Kruger 202108	120	4	26	611	0.82 [0.75, 0.88]	0.99 [0.98, 1.00]
Gupta 2020	63	1	14	252	0.82 [0.71, 0.90]	1.00 [0.98, 1.00]
Nsoga 2021	136	2	32	232	0.81 [0.74, 0.87]	0.99 [0.97, 1.00]
Gremmels 2020(b)	51	0	12	145	0.81 [0.69, 0.90]	1.00 [0.97, 1.00]
Takeda 2020	50	0	12	100	0.81 [0.69, 0.90]	1.00 [0.96, 1.00]
Holzner 2021	367	8	89	1816	0.80 [0.77, 0.84]	1.00 [0.99, 1.00]
Nash 2020	80	8	20	82	0.80 [0.71, 0.87]	0.91 [0.83, 0.96]
Lindner 202104 [B]	31	1	8	247	0.79 [0.64, 0.91]	1.00 [0.98, 1.00]
Van Honacker 2021 [D]	45	0	12	40	0.79 [0.66, 0.89]	1.00 [0.91, 1.00]
Bruzzone 2021 [A]	199	0	54	68	0.79 [0.73, 0.84]	1.00 [0.95, 1.00]
Salvagno 2021	47	1	13	113	0.78 [0.66, 0.88]	0.99 [0.95, 1.00]
Amer 2021	54	5	15	9	0.78 [0.67, 0.87]	0.64 [0.35, 0.87]
Karon 2021 [B]	153	4	44	146	0.78 [0.71, 0.83]	0.97 [0.93, 0.99]
Pollock 202104	226	12	66	2004	0.77 [0.72, 0.82]	0.99 [0.99, 1.00]
Muhi 2021	17	1	5	2580	0.77 [0.55, 0.92]	1.00 [1.00, 1.00]
Shah 2021	258	7	76	1769	0.77 [0.72, 0.82]	1.00 [0.99, 1.00]
Favresse 2021 [C]	74	3	22	89	0.77 [0.67, 0.85]	0.97 [0.91, 0.99]
Pickering 2021 [B]	77	2	23	98	0.77 [0.68, 0.85]	0.98 [0.93, 1.00]
Abusrewil 2021 [A]	83	0	25	123	0.77 [0.68, 0.84]	1.00 [0.97, 1.00]
Pena-Rodriguez 2021	79	0	25	265	0.76 [0.67, 0.84]	1.00 [0.99, 1.00]
Torres 202102	88	0	28	154	0.76 [0.67, 0.83]	1.00 [0.98, 1.00]
Homza 2021 [B]	81	7	26	204	0.76 [0.66, 0.83]	0.97 [0.93, 0.99]
Pickering 2021 [C]	75	14	25	86	0.75 [0.65, 0.83]	0.86 [0.78, 0.92]
Soleimani 2021][B]	174	0	58	169	0.75 [0.69, 0.80]	1.00 [0.98, 1.00]
Kurihara 2021	62	2	21	1316	0.75 [0.64, 0.84]	1.00 [0.99, 1.00]
Landaas 2021	186	3	64	3738	0.74 [0.69, 0.80]	1.00 [1.00, 1.00]
Pickering 2021 [D]	74	0	26	100	0.74 [0.64, 0.82]	1.00 [0.96, 1.00]
Paul 2021 [A]	72	0	26	50	0.73 [0.64, 0.82]	1.00 [0.93, 1.00]
Linares 2020	44	0	16	195	0.73 [0.60, 0.84]	1.00 [0.98, 1.00]
Gremmels 2020(a)	101	0	38	1228	0.73 [0.64, 0.80]	1.00 [1.00, 1.00]
Iqbal 2021	92	1	35	42	0.72 [0.64, 0.80]	0.98 [0.88, 1.00]
Halfon 2021	72	1	28	99	0.72 [0.62, 0.81]	0.99 [0.95, 1.00]
Kanaujia 2021	136	2	53	293	0.72 [0.65, 0.78]	0.99 [0.98, 1.00]
Bullete 2021	100	2	40	670	0.71 [0.63, 0.79]	1.00 [0.99, 1.00]
Kruttgen 2020	53	3	22	72	0.71 [0.59, 0.81]	0.96 [0.89, 0.99]



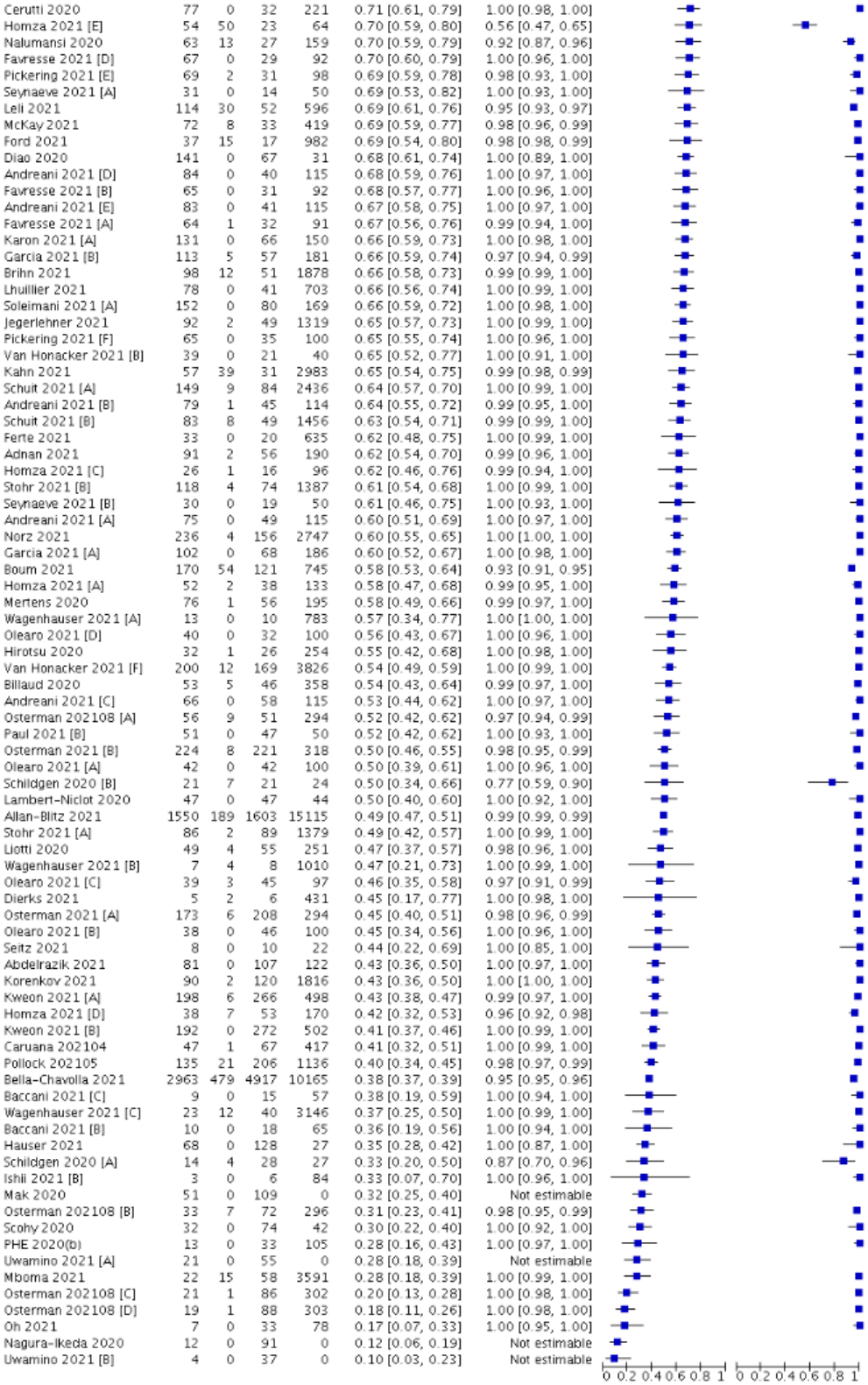
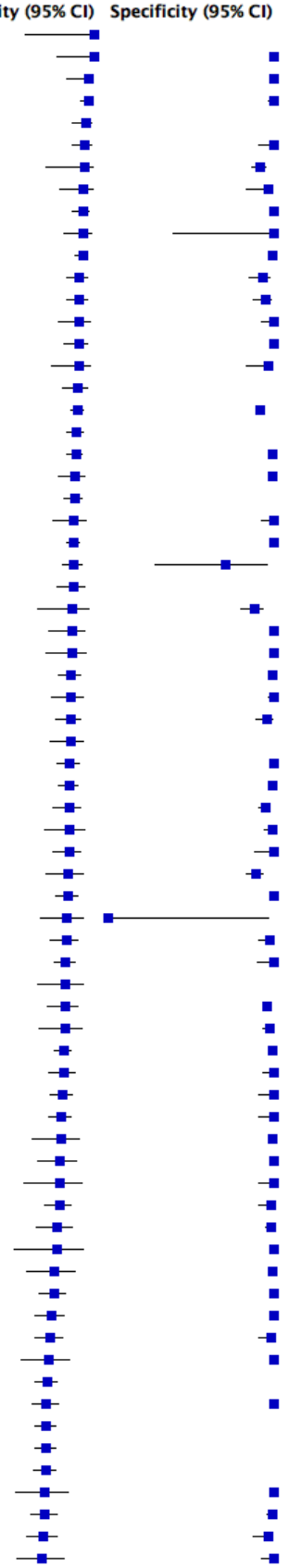


Figure 3. Sensitivity and specificity of RAgT in individuals with mixed symptoms or unreported

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Kim 2021 [A]	7	0	0	0	1.00 [0.59, 1.00]	Not estimable
Muhi 2021	15	0	0	156	1.00 [0.78, 1.00]	1.00 [0.98, 1.00]
Cassuto 2021	31	0	1	202	0.97 [0.84, 1.00]	1.00 [0.98, 1.00]
Courtellemont 2021	117	0	4	127	0.97 [0.92, 0.99]	1.00 [0.97, 1.00]
Kim 2021 [B]	64	0	3	0	0.96 [0.87, 0.99]	Not estimable
Porte 2020a	72	0	4	42	0.95 [0.87, 0.99]	1.00 [0.92, 1.00]
Denina 2021	16	14	1	160	0.94 [0.71, 1.00]	0.92 [0.87, 0.96]
Porte 2020b [A]	30	1	2	31	0.94 [0.79, 0.99]	0.97 [0.84, 1.00]
Pollock 202104	104	0	7	335	0.94 [0.87, 0.97]	1.00 [0.99, 1.00]
Nomoto 2021	44	0	3	4	0.94 [0.82, 0.99]	1.00 [0.40, 1.00]
Merino-Amador 2021	179	2	13	256	0.93 [0.89, 0.96]	0.99 [0.97, 1.00]
Bachman 2021 [C]	84	5	8	72	0.91 [0.84, 0.96]	0.94 [0.85, 0.98]
Bachman 2021 [D]	84	4	8	78	0.91 [0.84, 0.96]	0.95 [0.88, 0.99]
Seynaeve 2021 [C]	41	0	4	50	0.91 [0.79, 0.98]	1.00 [0.93, 1.00]
Kruger 2021	69	1	7	533	0.91 [0.82, 0.96]	1.00 [0.99, 1.00]
Porte 2020b [B]	29	1	3	31	0.91 [0.75, 0.98]	0.97 [0.84, 1.00]
Garcia 2021 [B]	66	0	7	0	0.90 [0.81, 0.96]	Not estimable
Bianco 2021	269	48	29	561	0.90 [0.86, 0.93]	0.92 [0.90, 0.94]
Kweon 2021 [A]	135	0	16	0	0.89 [0.83, 0.94]	Not estimable
Berger 2021 [B]	170	1	21	337	0.89 [0.84, 0.93]	1.00 [0.98, 1.00]
Osmanodja 2021	62	1	8	308	0.89 [0.79, 0.95]	1.00 [0.98, 1.00]
Kweon 2021 [B]	135	0	18	0	0.88 [0.82, 0.93]	Not estimable
Seynaeve 2021 [D]	44	0	6	50	0.88 [0.76, 0.95]	1.00 [0.93, 1.00]
Stokes 202103 [B]	268	2	37	1334	0.88 [0.84, 0.91]	1.00 [0.99, 1.00]
Stokes 202103 [A]	121	2	17	5	0.88 [0.81, 0.93]	0.71 [0.29, 0.96]
Garcia 2021 [A]	64	0	9	0	0.88 [0.78, 0.94]	Not estimable
Ifko 2021	20	12	3	90	0.87 [0.66, 0.97]	0.88 [0.80, 0.94]
Kolwijck 2021 [A]	39	0	6	388	0.87 [0.73, 0.95]	1.00 [0.99, 1.00]
Linares 2020	32	0	5	846	0.86 [0.71, 0.95]	1.00 [1.00, 1.00]
Kruger 202108	102	2	16	303	0.86 [0.79, 0.92]	0.99 [0.98, 1.00]
Gupta 2020	49	0	8	134	0.86 [0.74, 0.94]	1.00 [0.97, 1.00]
Bachman 2021 [B]	79	3	13	75	0.86 [0.77, 0.92]	0.96 [0.89, 0.99]
McKay 2021	48	0	8	0	0.86 [0.74, 0.94]	Not estimable
Berger 2021 [A]	106	0	18	411	0.85 [0.78, 0.91]	1.00 [0.99, 1.00]
Kyritsi 2021	141	1	24	458	0.85 [0.79, 0.90]	1.00 [0.99, 1.00]
Chiu 2021 [A]	64	14	11	260	0.85 [0.75, 0.92]	0.95 [0.92, 0.97]
Lindner 202105 [B]	34	1	6	105	0.85 [0.70, 0.94]	0.99 [0.95, 1.00]
Weitzel 2020 [D]	68	0	12	31	0.85 [0.75, 0.92]	1.00 [0.89, 1.00]
Shaikh 2021	39	16	7	137	0.85 [0.71, 0.94]	0.90 [0.84, 0.94]
Escriva 2021	99	0	18	331	0.85 [0.77, 0.91]	1.00 [0.99, 1.00]
Amer 2021	31	1	6	0	0.84 [0.68, 0.94]	0.00 [0.00, 0.97]
Bachman 2021 [A]	75	2	15	77	0.83 [0.74, 0.90]	0.97 [0.91, 1.00]
Jaaskelainen 2021 [C]	126	0	26	38	0.83 [0.76, 0.89]	1.00 [0.91, 1.00]
Halfon 2021	29	0	6	0	0.83 [0.66, 0.93]	Not estimable
Chiu 2021 [B]	62	10	13	264	0.83 [0.72, 0.90]	0.96 [0.93, 0.98]
Lindner 202105 [A]	33	2	7	104	0.82 [0.67, 0.93]	0.98 [0.93, 1.00]
Shah 2021	199	2	44	684	0.82 [0.76, 0.87]	1.00 [0.99, 1.00]
Bachman 2021 [G]	89	0	20	60	0.82 [0.73, 0.88]	1.00 [0.94, 1.00]
Jaaskelainen 2021 [B]	128	0	30	40	0.81 [0.74, 0.87]	1.00 [0.91, 1.00]
Jaaskelainen 2021 [A]	119	0	29	40	0.80 [0.73, 0.86]	1.00 [0.91, 1.00]
Kruger 2020(c)	28	7	7	907	0.80 [0.63, 0.92]	0.99 [0.98, 1.00]
Albert 2020	43	0	11	358	0.80 [0.66, 0.89]	1.00 [0.99, 1.00]
Ristic 2021	19	0	5	39	0.79 [0.58, 0.93]	1.00 [0.91, 1.00]
Bachman 2021 [H]	87	1	23	59	0.79 [0.70, 0.86]	0.98 [0.91, 1.00]
Asai 2021	49	4	14	238	0.78 [0.66, 0.87]	0.98 [0.96, 1.00]
Donapetry 2021	14	0	4	422	0.78 [0.52, 0.94]	1.00 [0.99, 1.00]
Young 2020	29	1	9	212	0.76 [0.60, 0.89]	1.00 [0.97, 1.00]
Torres 202102	88	0	28	154	0.76 [0.67, 0.83]	1.00 [0.98, 1.00]
Gremmels 2020(a)	75	0	26	846	0.74 [0.65, 0.82]	1.00 [1.00, 1.00]
Bachman 2021 [F]	81	1	29	59	0.74 [0.64, 0.82]	0.98 [0.91, 1.00]
Kolwijck 2021 [B]	29	0	11	352	0.72 [0.56, 0.85]	1.00 [0.99, 1.00]
Fourati 2021 [B]	143	0	57	0	0.71 [0.65, 0.78]	Not estimable
Prince-Guerra 2021 [C]	101	0	41	520	0.71 [0.63, 0.78]	1.00 [0.99, 1.00]
Fourati 2020 [E]	142	0	58	0	0.71 [0.64, 0.77]	Not estimable
Fourati 2021 [D]	142	0	58	0	0.71 [0.64, 0.77]	Not estimable
Fourati 2020 [B]	141	0	58	0	0.71 [0.64, 0.77]	Not estimable
Sahuquillo 2021	24	0	10	323	0.71 [0.53, 0.85]	1.00 [0.99, 1.00]
Frediani 2021	93	2	39	207	0.70 [0.62, 0.78]	0.99 [0.97, 1.00]
Bachman 2021 [E]	75	2	33	57	0.69 [0.60, 0.78]	0.97 [0.88, 1.00]
Seynaeve 2021 [A]	31	0	14	50	0.69 [0.53, 0.82]	1.00 [0.93, 1.00]



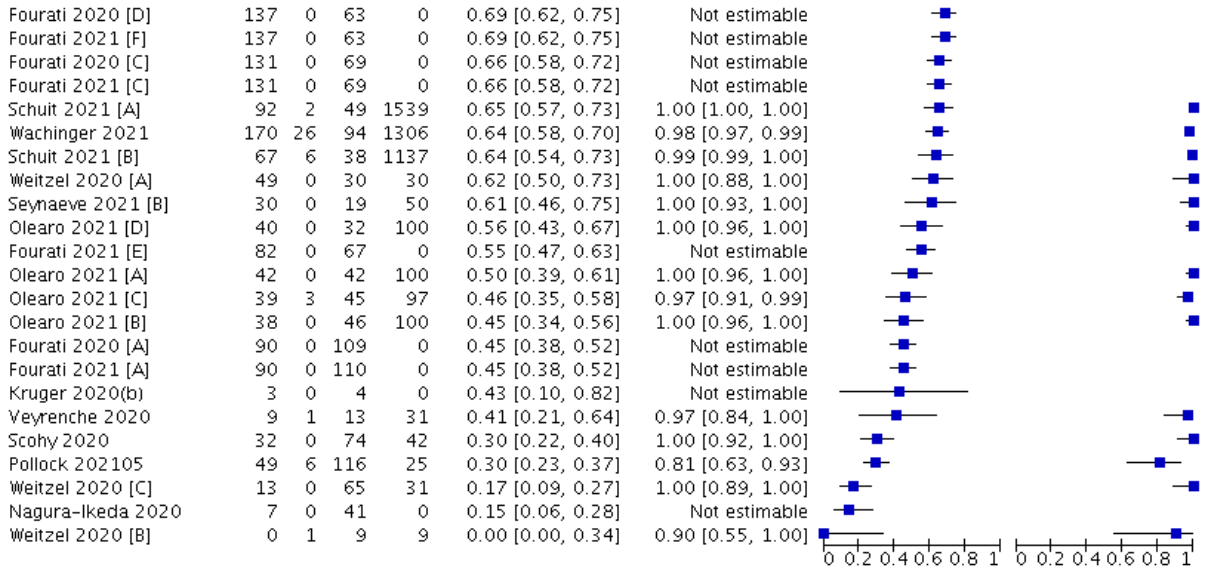


Figure 4. Sensitivity and specificity of RAgT in early testing (0-7 days after symptom onset)

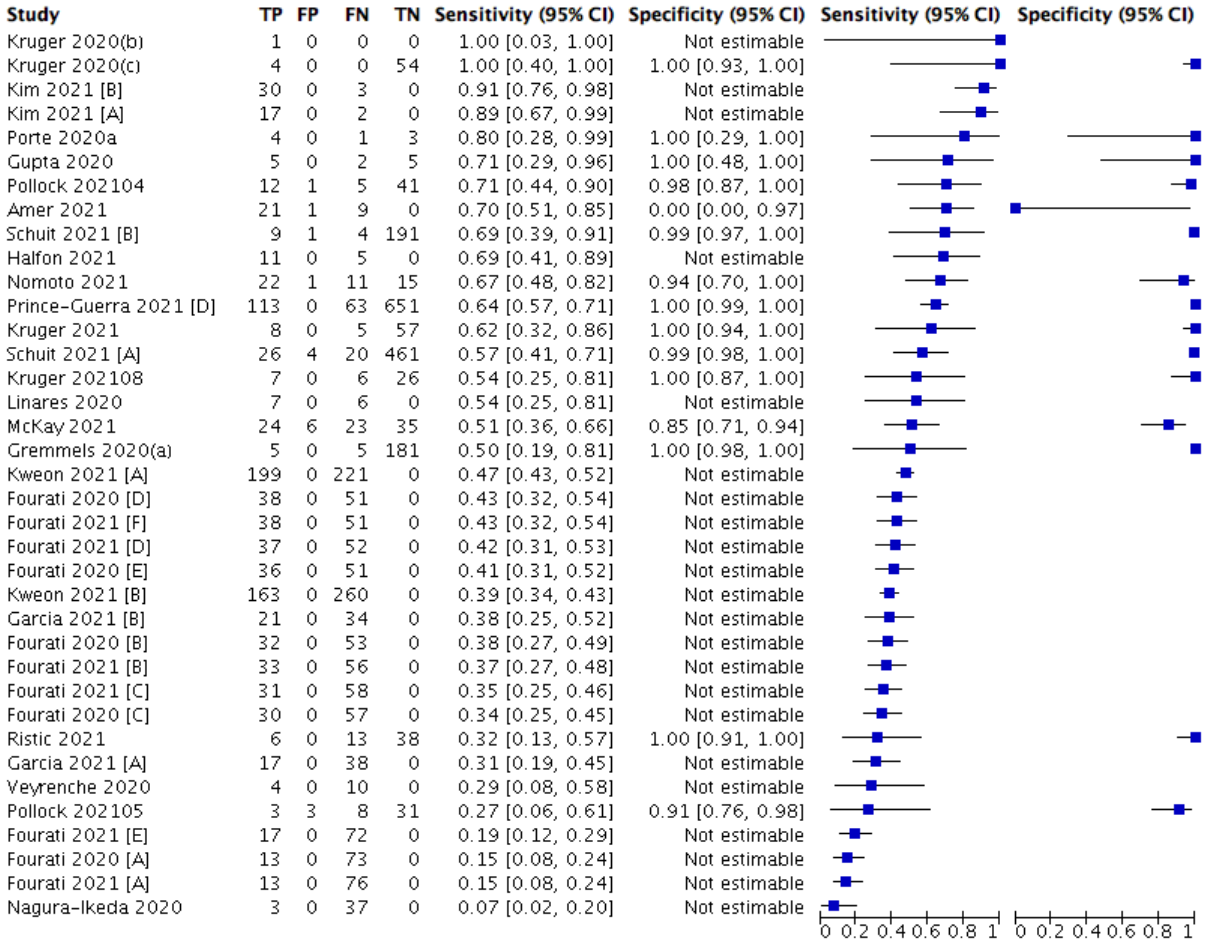


Figure 5. Sensitivity and specificity of RAgT in late testing (> 7 days)

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Denina 2021	16	14	1	160	0.94 [0.71, 1.00]	0.92 [0.87, 0.96]
Sood 2021	127	99	9	539	0.93 [0.88, 0.97]	0.84 [0.81, 0.87]
Jung 2021	29	4	4	271	0.88 [0.72, 0.97]	0.99 [0.96, 1.00]
Shaikh 2021	39	16	7	137	0.85 [0.71, 0.94]	0.90 [0.84, 0.94]
Eleftheriou 2021	42	0	9	693	0.82 [0.69, 0.92]	1.00 [0.99, 1.00]
Donapetry 2021	14	0	4	422	0.78 [0.52, 0.94]	1.00 [0.99, 1.00]
Sahuquillo 2021	24	0	10	323	0.71 [0.53, 0.85]	1.00 [0.99, 1.00]
Pollock 202104	94	7	41	786	0.70 [0.61, 0.77]	0.99 [0.98, 1.00]
Lhuillier 2021	78	0	41	703	0.66 [0.56, 0.74]	1.00 [0.99, 1.00]
Albert 2020	5	0	3	77	0.63 [0.24, 0.91]	1.00 [0.95, 1.00]
Pollock 202105	26	7	20	200	0.57 [0.41, 0.71]	0.97 [0.93, 0.99]

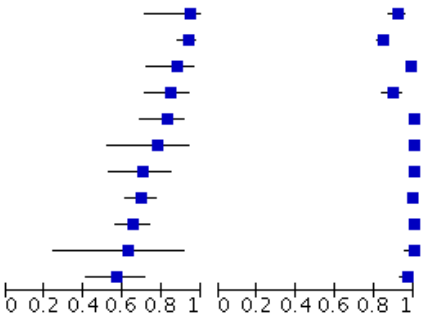


Figure 6. Sensitivity and specificity of RAgT in special population - children

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Matsuda 2021 [B]	9	2	0	31	1.00 [0.66, 1.00]	0.94 [0.80, 0.99]
Von Ahnen 2021	12	0	1	906	0.92 [0.64, 1.00]	1.00 [1.00, 1.00]
Matsuda 2021 [A]	18	1	4	43	0.82 [0.60, 0.95]	0.98 [0.88, 1.00]
Amer 2021	54	5	15	9	0.78 [0.67, 0.87]	0.64 [0.35, 0.87]
Dierks 2021	5	2	6	431	0.45 [0.17, 0.77]	1.00 [0.98, 1.00]

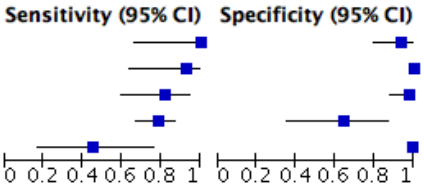


Figure 7. Sensitivity and specificity of RAgT in special population - healthcare workers

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Bianco 2021	176	4	21	30	0.89 [0.84, 0.93]	0.88 [0.73, 0.97]
McKay 2021	25	0	8	46	0.76 [0.58, 0.89]	1.00 [0.92, 1.00]

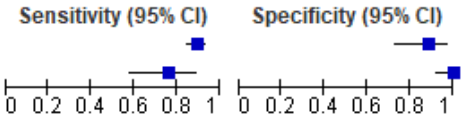


Figure 8. Sensitivity and specificity of RAgT use in symptomatic individuals in an outbreak settings

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Bianco 2021	93	44	8	531	0.92 [0.85, 0.97]	0.92 [0.90, 0.94]
McKay 2021	46	7	25	373	0.65 [0.53, 0.76]	0.98 [0.96, 0.99]

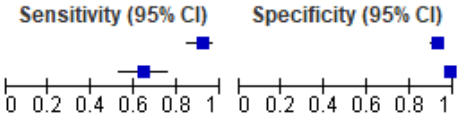


Figure 9. Sensitivity and specificity of RAgT use in asymptomatic individuals in an outbreak settings

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Matsuda 2021 [B]	9	2	0	31	1.00 [0.66, 1.00]	0.94 [0.80, 0.99]
Alemany 2020	872	5	79	450	0.92 [0.90, 0.93]	0.99 [0.97, 1.00]
Stokes 202103 [B]	268	2	37	1334	0.88 [0.84, 0.91]	1.00 [0.99, 1.00]
Stokes 202103 [A]	121	2	17	5	0.88 [0.81, 0.93]	0.71 [0.29, 0.96]
Kruger 2021	92	1	14	1001	0.87 [0.79, 0.93]	1.00 [0.99, 1.00]
Klein 2021	78	4	12	486	0.87 [0.78, 0.93]	0.99 [0.98, 1.00]
Kolwijck 2021 [A]	39	0	6	388	0.87 [0.73, 0.95]	1.00 [0.99, 1.00]
Berger 2021 [A]	106	0	18	411	0.85 [0.78, 0.91]	1.00 [0.99, 1.00]
Escriva 2021	99	0	18	331	0.85 [0.77, 0.91]	1.00 [0.99, 1.00]
Jaaskelainen 2021 [C]	126	0	26	38	0.83 [0.76, 0.89]	1.00 [0.91, 1.00]
Eleftheriou 2021	42	0	9	693	0.82 [0.69, 0.92]	1.00 [0.99, 1.00]
Gremmels 2020(b)	51	0	12	145	0.81 [0.69, 0.90]	1.00 [0.97, 1.00]
Nsoga 2021	136	2	32	232	0.81 [0.74, 0.87]	0.99 [0.97, 1.00]
Albert 2020	43	0	11	358	0.80 [0.66, 0.89]	1.00 [0.99, 1.00]
Fenollar 2020(a)	144	0	38	0	0.79 [0.72, 0.85]	Not estimable
Van Honacker 2021 [D]	45	0	12	40	0.79 [0.66, 0.89]	1.00 [0.91, 1.00]
Donapetry 2021	14	0	4	422	0.78 [0.52, 0.94]	1.00 [0.99, 1.00]
Muhi 2021	17	1	5	2580	0.77 [0.55, 0.92]	1.00 [1.00, 1.00]
Abusrewil 2021 [H]	10	0	3	10	0.77 [0.46, 0.95]	1.00 [0.69, 1.00]
Soleimani 2021][B]	174	0	58	169	0.75 [0.69, 0.80]	1.00 [0.98, 1.00]
Landaas 2021	186	3	64	3738	0.74 [0.69, 0.80]	1.00 [1.00, 1.00]
Linares 2020	44	0	16	195	0.73 [0.60, 0.84]	1.00 [0.98, 1.00]
Gremmels 2020(a)	101	0	38	1228	0.73 [0.64, 0.80]	1.00 [1.00, 1.00]
Kolwijck 2021 [B]	29	0	11	352	0.72 [0.56, 0.85]	1.00 [0.99, 1.00]
Halfon 2021	72	1	28	99	0.72 [0.62, 0.81]	0.99 [0.95, 1.00]
Nordgren 2021 [A]	112	0	44	130	0.72 [0.64, 0.79]	1.00 [0.97, 1.00]
Bulilete 2021	100	2	40	670	0.71 [0.63, 0.79]	1.00 [0.99, 1.00]
Sahuquillo 2021	24	0	10	323	0.71 [0.53, 0.85]	1.00 [0.99, 1.00]
Favresse 2021 [B]	65	0	31	92	0.68 [0.57, 0.77]	1.00 [0.96, 1.00]
Lhuillier 2021	79	0	40	703	0.66 [0.57, 0.75]	1.00 [0.99, 1.00]
Ferte 2021	33	0	20	635	0.62 [0.48, 0.75]	1.00 [0.99, 1.00]
Andreani 2021 [A]	75	0	49	115	0.60 [0.51, 0.69]	1.00 [0.97, 1.00]
Garcia 2021 [A]	102	0	68	186	0.60 [0.52, 0.67]	1.00 [0.98, 1.00]
Fourati 2021 [C]	162	0	127	337	0.56 [0.50, 0.62]	1.00 [0.99, 1.00]
Fourati 2020 [C]	163	0	132	337	0.55 [0.49, 0.61]	1.00 [0.99, 1.00]
Billaud 2020	53	5	46	358	0.54 [0.43, 0.64]	0.99 [0.97, 1.00]
Schildgen 2020 [B]	21	7	21	24	0.50 [0.34, 0.66]	0.77 [0.59, 0.90]
Torres 202101	38	0	41	555	0.48 [0.37, 0.60]	1.00 [0.99, 1.00]
Wagenhauser 2021 [B]	7	4	8	1010	0.47 [0.21, 0.73]	1.00 [0.99, 1.00]
Fenollar 2020(b)	10	7	12	130	0.45 [0.24, 0.68]	0.95 [0.90, 0.98]
Olearo 2021 [B]	38	0	46	100	0.45 [0.34, 0.56]	1.00 [0.96, 1.00]
Baro 2021 [A]	39	1	62	184	0.39 [0.29, 0.49]	0.99 [0.97, 1.00]
Mboma 2021	22	15	58	3591	0.28 [0.18, 0.39]	1.00 [0.99, 1.00]

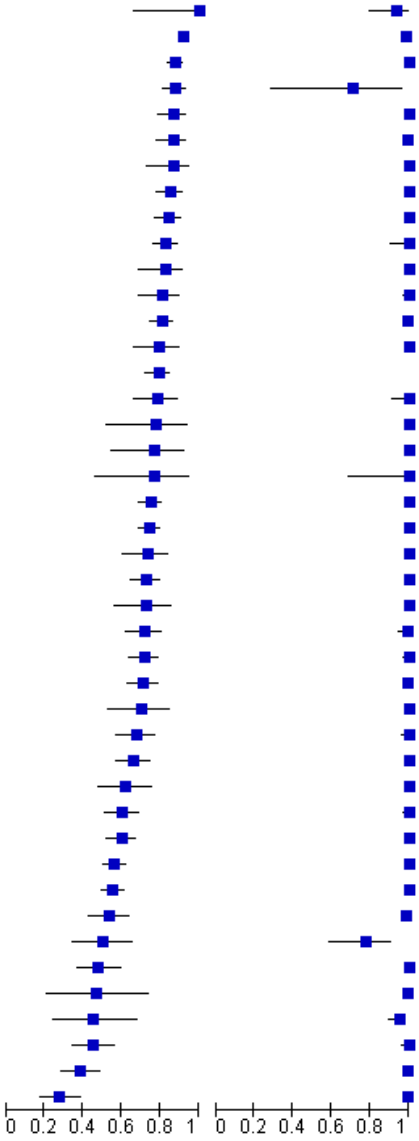


Figure 10. Sensitivity and specificity of Panbio™ Ag-RDT (Abbott)

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Chaimayo 2021	59	5	1	389	0.98 [0.91, 1.00]	0.99 [0.97, 1.00]
Nikolai 2021 [B]	31	0	3	62	0.91 [0.76, 0.98]	1.00 [0.94, 1.00]
Turcato 2021 [A]	152	20	17	802	0.90 [0.84, 0.94]	0.98 [0.96, 0.99]
Agarwal 2021	26	2	3	436	0.90 [0.73, 0.98]	1.00 [0.98, 1.00]
Berger 2021 [B]	170	1	21	337	0.89 [0.84, 0.93]	1.00 [0.98, 1.00]
Nikolai 2021 [A]	31	0	5	96	0.86 [0.71, 0.95]	1.00 [0.96, 1.00]
Lindner 202105 [B]	34	1	6	105	0.85 [0.70, 0.94]	0.99 [0.95, 1.00]
Van Honacker 2021 [E]	48	0	10	40	0.83 [0.71, 0.91]	1.00 [0.91, 1.00]
Lindner 202105 [A]	33	2	7	104	0.82 [0.67, 0.93]	0.98 [0.93, 1.00]
Gupta 2020	63	1	14	252	0.82 [0.71, 0.90]	1.00 [0.98, 1.00]
Jaaskelainen 2021 [B]	128	0	30	40	0.81 [0.74, 0.87]	1.00 [0.91, 1.00]
Holzner 2021	367	8	89	1816	0.80 [0.77, 0.84]	1.00 [0.99, 1.00]
Lindner 202104 [B]	31	1	8	247	0.79 [0.64, 0.91]	1.00 [0.98, 1.00]
Bruzzone 2021 [A]	199	0	54	68	0.79 [0.73, 0.84]	1.00 [0.95, 1.00]
Amer 2021	54	5	15	9	0.78 [0.67, 0.87]	0.64 [0.35, 0.87]
Kruger 2020(c)	36	9	11	1207	0.77 [0.62, 0.88]	0.99 [0.99, 1.00]
Pena-Rodriguez 2021	79	0	25	265	0.76 [0.67, 0.84]	1.00 [0.99, 1.00]
Lindner 202104 [A]	29	2	10	246	0.74 [0.58, 0.87]	0.99 [0.97, 1.00]
Cerutti 2020	77	0	32	221	0.71 [0.61, 0.79]	1.00 [0.98, 1.00]
Nalumansi 2020	63	13	27	159	0.70 [0.59, 0.79]	0.92 [0.87, 0.96]
Pena 2021	51	3	22	766	0.70 [0.58, 0.80]	1.00 [0.99, 1.00]
Wachinger 2021	170	26	94	1306	0.64 [0.58, 0.70]	0.98 [0.97, 0.99]
Andreani 2021 [B]	79	1	45	114	0.64 [0.55, 0.72]	0.99 [0.95, 1.00]
Homza 2021 [C]	26	1	16	96	0.62 [0.46, 0.76]	0.99 [0.94, 1.00]
Fourati 2021 [B]	176	23	113	314	0.61 [0.55, 0.67]	0.93 [0.90, 0.96]
Fourati 2020 [B]	175	23	116	314	0.60 [0.54, 0.66]	0.93 [0.90, 0.96]
Boum 2021	170	54	121	745	0.58 [0.53, 0.64]	0.93 [0.91, 0.95]
Ristic 2021	25	0	18	77	0.58 [0.42, 0.73]	1.00 [0.95, 1.00]
Van Honacker 2021 [F]	200	12	169	3826	0.54 [0.49, 0.59]	1.00 [0.99, 1.00]
Turcato 2021 [B]	27	10	27	2355	0.50 [0.36, 0.64]	1.00 [0.99, 1.00]
Olearo 2021 [A]	42	0	42	100	0.50 [0.39, 0.61]	1.00 [0.96, 1.00]
Osterman 2021 [A]	173	6	208	294	0.45 [0.40, 0.51]	0.98 [0.96, 0.99]
Korenkov 2021	90	2	120	1816	0.43 [0.36, 0.50]	1.00 [1.00, 1.00]
Caruana 202105	2	2	5	107	0.29 [0.04, 0.71]	0.98 [0.94, 1.00]
Oh 2021	7	0	33	78	0.17 [0.07, 0.33]	1.00 [0.95, 1.00]

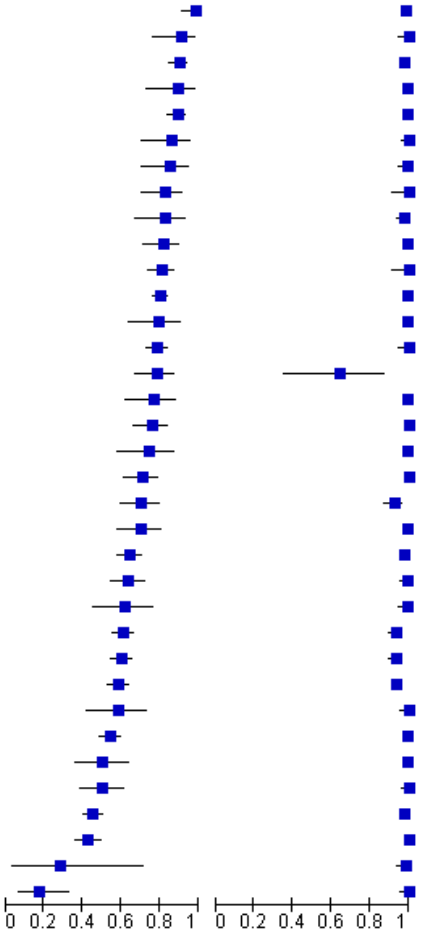


Figure 11. Sensitivity and specificity of Standard Q COVID-19 Ag Test (SD Biosensor)

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Martin-Sanchez 2021	214	3	7	657	0.97 [0.94, 0.99]	1.00 [0.99, 1.00]
Von Ahnen 2021	12	0	1	906	0.92 [0.64, 1.00]	1.00 [1.00, 1.00]
Schildgen 2020 [C]	37	25	5	6	0.88 [0.74, 0.96]	0.19 [0.07, 0.37]
Igloi 2021	158	4	28	780	0.85 [0.79, 0.90]	0.99 [0.99, 1.00]
Mockel 2021	67	0	22	182	0.75 [0.65, 0.84]	1.00 [0.98, 1.00]
Iqbal 2021	92	1	35	42	0.72 [0.64, 0.80]	0.98 [0.88, 1.00]
Montero 2021	35	8	14	2486	0.71 [0.57, 0.83]	1.00 [0.99, 1.00]
Kruttgen 2020	53	3	22	72	0.71 [0.59, 0.81]	0.96 [0.89, 0.99]
Favresse 2021 [D]	67	0	29	92	0.70 [0.60, 0.79]	1.00 [0.96, 1.00]
Jegerlehner 2021	92	2	49	1319	0.65 [0.57, 0.73]	1.00 [0.99, 1.00]
Schuit 2021 [B]	83	8	49	1456	0.63 [0.54, 0.71]	0.99 [0.99, 1.00]
Koeleman 2021 [B]	25	5	15	35	0.63 [0.46, 0.77]	0.88 [0.73, 0.96]
Stohr 2021 [B]	118	4	74	1387	0.61 [0.54, 0.68]	1.00 [0.99, 1.00]
Osterman 2021 [B]	224	8	221	318	0.50 [0.46, 0.55]	0.98 [0.95, 0.99]
Baro 2021 [C]	44	7	57	178	0.44 [0.34, 0.54]	0.96 [0.92, 0.98]
Osterman 202108 [B]	33	7	72	296	0.31 [0.23, 0.41]	0.98 [0.95, 0.99]

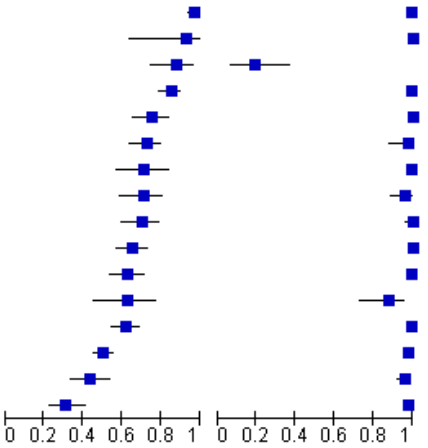


Figure 12. Sensitivity and specificity of Roche SARS-CoV-2 Rapid Antigen Test (Roche Diagnostics)

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Sood 2021	127	99	9	539	0.93 [0.88, 0.97]	0.84 [0.81, 0.87]
Bachman 2021 [C]	84	5	8	72	0.91 [0.84, 0.96]	0.94 [0.85, 0.98]
Pilarowski 2021 [A]	211	3	26	3062	0.89 [0.84, 0.93]	1.00 [1.00, 1.00]
Shaikh 2021	39	16	7	137	0.85 [0.71, 0.94]	0.90 [0.84, 0.94]
James 2021 [A]	20	0	4	91	0.83 [0.63, 0.95]	1.00 [0.96, 1.00]
Bachman 2021 [G]	89	0	20	60	0.82 [0.73, 0.88]	1.00 [0.94, 1.00]
Pollock 202104	226	12	66	2004	0.77 [0.72, 0.82]	0.99 [0.99, 1.00]
Shah 2021	258	7	76	1769	0.77 [0.72, 0.82]	1.00 [0.99, 1.00]
Prince-Guerra 2021 [C]	101	0	41	520	0.71 [0.63, 0.78]	1.00 [0.99, 1.00]
Frediani 2021	93	2	39	207	0.70 [0.62, 0.78]	0.99 [0.97, 1.00]
McKay 2021	72	8	33	419	0.69 [0.59, 0.77]	0.98 [0.96, 0.99]
Prince-Guerra 2021 [A]	113	0	63	651	0.64 [0.57, 0.71]	1.00 [0.99, 1.00]
Prince-Guerra 2021 [D]	113	0	63	651	0.64 [0.57, 0.71]	1.00 [0.99, 1.00]
Okoye 2021	24	0	21	2593	0.53 [0.38, 0.68]	1.00 [1.00, 1.00]
Allan-Blitz 2021	1550	189	1603	15115	0.49 [0.47, 0.51]	0.99 [0.99, 0.99]
Prince-Guerra 2021 [B]	44	4	79	2465	0.36 [0.27, 0.45]	1.00 [1.00, 1.00]
James 2021 [B]	3	62	2093	0	0.00 [0.00, 0.00]	0.00 [0.00, 0.06]
Stokes 202109	0	1	6	990	0.00 [0.00, 0.46]	1.00 [0.99, 1.00]

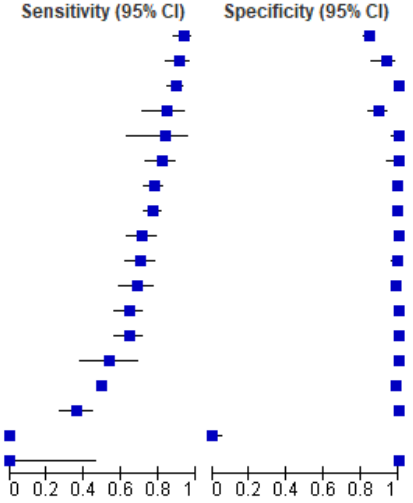


Figure 13. Sensitivity and specificity of Binax NOW SARS-CoV-2 (Abbott)

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Porte 2020b [A]	30	1	2	31	0.94 [0.79, 0.99]	0.97 [0.84, 1.00]
Bachman 2021 [B]	79	3	13	75	0.86 [0.77, 0.92]	0.96 [0.89, 0.99]
Jaaskelainen 2021 [A]	119	0	29	40	0.80 [0.73, 0.86]	1.00 [0.91, 1.00]
Pray 2021 [A]	32	2	8	185	0.80 [0.64, 0.91]	0.99 [0.96, 1.00]
Herrera 2020	352	6	107	707	0.77 [0.73, 0.80]	0.99 [0.98, 1.00]
Bachman 2021 [F]	81	1	29	59	0.74 [0.64, 0.82]	0.98 [0.91, 1.00]
Ford 2021	37	15	17	982	0.69 [0.54, 0.80]	0.98 [0.98, 0.99]
Brihn 2021	98	12	51	1878	0.66 [0.58, 0.73]	0.99 [0.99, 1.00]
Bornemann 2021	52	9	39	1291	0.57 [0.46, 0.67]	0.99 [0.99, 1.00]
Pray 2021 [B]	7	14	10	840	0.41 [0.18, 0.67]	0.98 [0.97, 0.99]

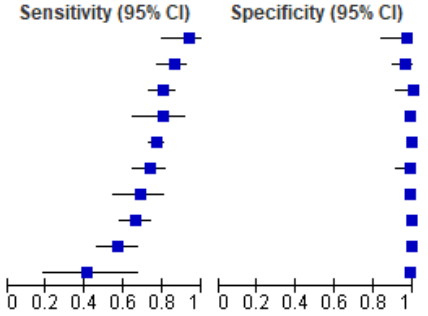


Figure 14. Sensitivity and specificity of Sofia SARS Antigen Fluorescent Immunoassay (Quidel)

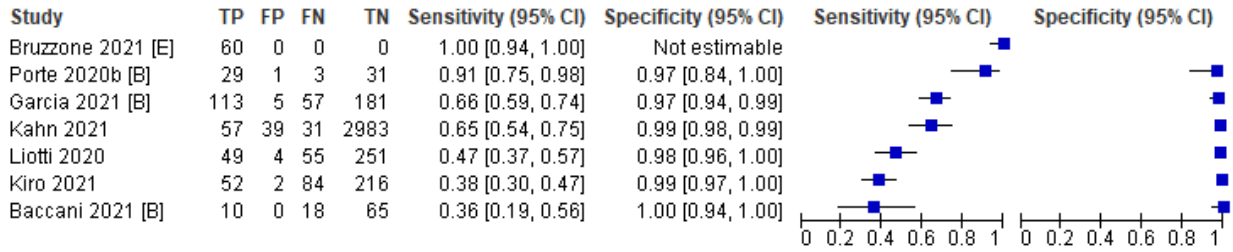


Figure 15. Sensitivity and specificity of Standard F Covid19 Ag FIA (SD Biosensor)

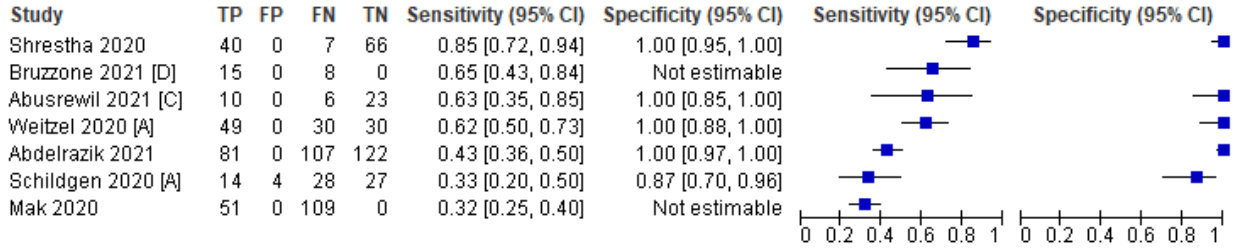


Figure 16. Sensitivity and specificity of Biocredit COVID-19 Ag test (RapiGEN)

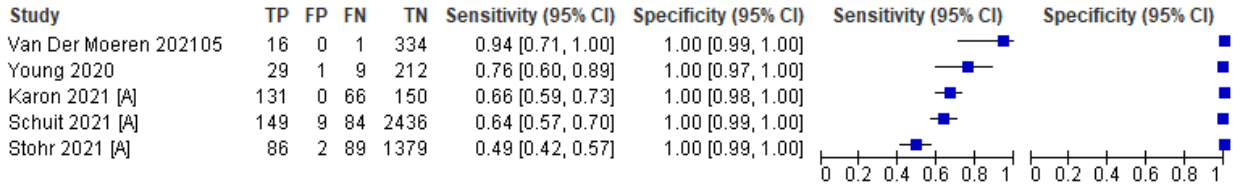


Figure 17. Sensitivity and specificity of COVID-19 Rapid Antigen Test (BD Veritor)

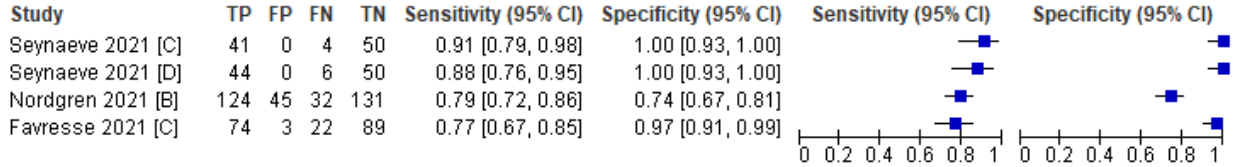


Figure 18. Sensitivity and specificity of Coronavirus Ag Rapid Test Cassette (Healgen Scientific)

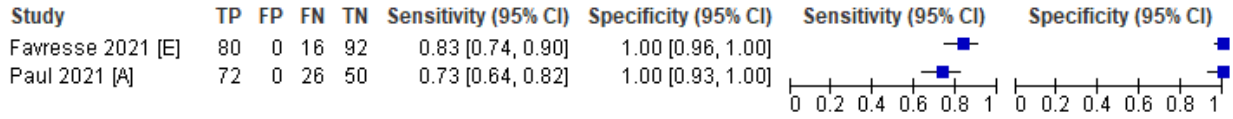


Figure 19. Sensitivity and specificity of VITROS Immunodiagnostic Products SARS-CoV-2 Antigen test (Ortho Clinical Diagnostics)

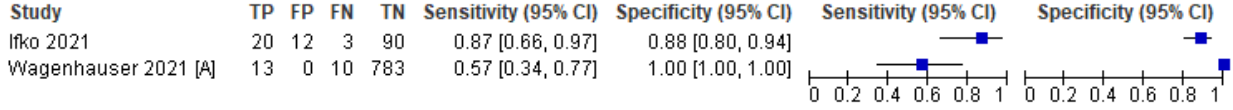


Figure 20. Sensitivity and specificity of NADAL COVID-19 Rapid Antigen Test (Nal Von Minden)

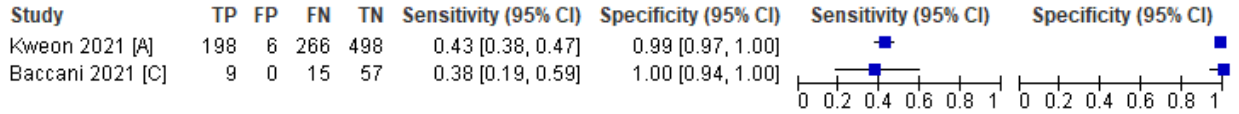


Figure 21. Sensitivity and specificity of AFIAS COVID-19 Ag (AFC) (Menarini)

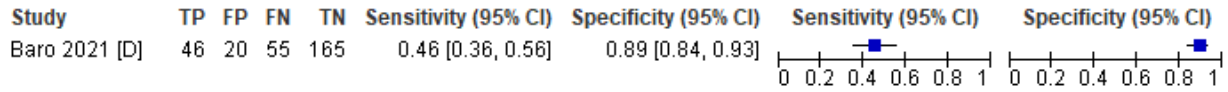


Figure 22. Sensitivity and specificity of SARS-CoV-2 Antigen Rapid Test Kit (Lepu Medical)

Figure 23. Sensitivity and specificity of CareStart COVID-19 Antigen Test (Access Bio)

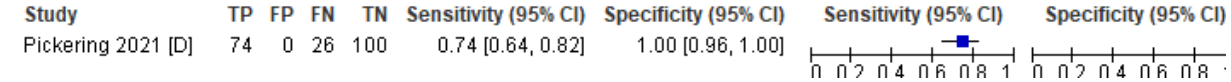


Figure 24. Sensitivity and specificity of Encode SARS-CoV-2 Antigen Rapid Test Device (Zhuhai Encode Medical Engineering)

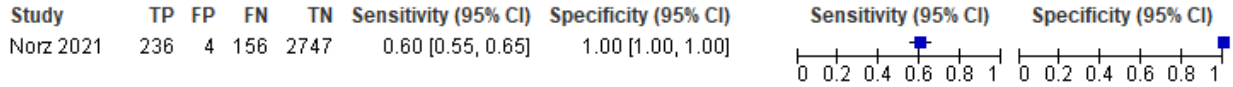


Figure 25. Sensitivity and specificity of Elecsys SARS-CoV-2 Antigen assay (Roche)

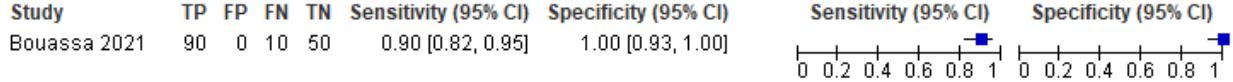


Figure 26. Sensitivity and specificity of SIENNA COVID-19 Antigen Rapid Test Cassette

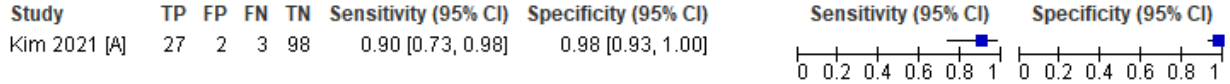


Figure 27. Sensitivity and specificity of GenBody COVAG025 Rapid Antigen Test

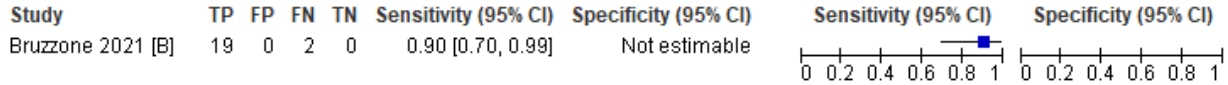


Figure 28. Sensitivity and specificity of Humasis COVID-Ag Test COVID-19 Antigen (Humasis)

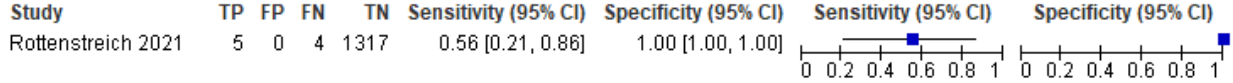


Figure 29. Sensitivity and specificity of NowCheck COVID-19 Ag Test (Bionote)

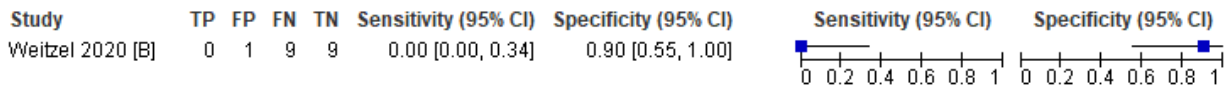


Figure 30. Sensitivity and specificity of StrongStep Rapid Antigen Test (Liming)

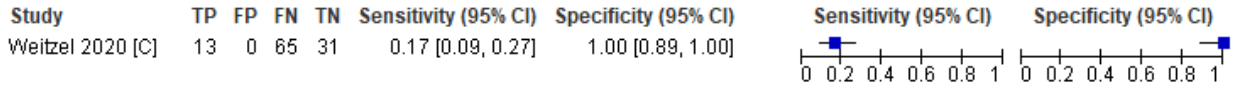


Figure 31. Sensitivity and specificity of Huaketai SARS-CoV-2 Rapid Antigen Test (Savant)

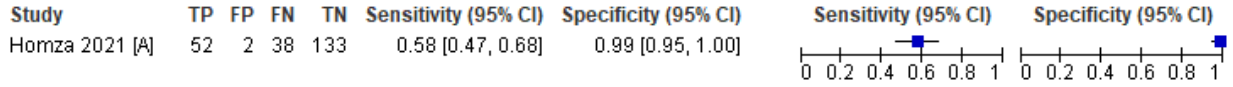


Figure 32. Sensitivity and specificity of SARS-CoV-2 Antigen Rapid Test Kit (JOYSBIO)

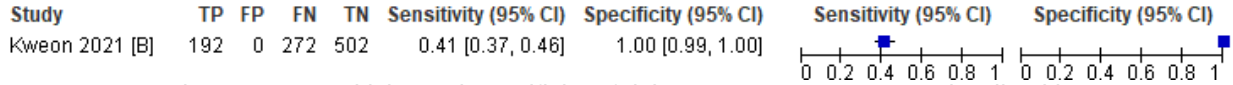


Figure 33. Sensitivity and specificity of ichromaTM COVID-19 Ag (Boditech)

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Van Honacker 2021 [C]	32	0	0	0	1.00 [0.89, 1.00]	Not estimable
Van Honacker 2021 [A]	32	0	0	0	1.00 [0.89, 1.00]	Not estimable
Van Honacker 2021 [E]	32	0	0	0	1.00 [0.89, 1.00]	Not estimable
Porte 2020b [B]	27	0	0	0	1.00 [0.87, 1.00]	Not estimable
Porte 2020b [A]	27	0	0	0	1.00 [0.87, 1.00]	Not estimable
Porte 2020a	52	0	0	0	1.00 [0.93, 1.00]	Not estimable
Takeda 2020	32	0	0	0	1.00 [0.89, 1.00]	Not estimable
Scohy 2020	10	0	0	0	1.00 [0.69, 1.00]	Not estimable
PHE 2020(b)	8	0	0	0	1.00 [0.63, 1.00]	Not estimable
Leixner 2021	33	0	0	0	1.00 [0.89, 1.00]	Not estimable
Jung 2021	23	0	0	0	1.00 [0.85, 1.00]	Not estimable
Kim 2021 [A]	15	0	0	0	1.00 [0.78, 1.00]	Not estimable
Kruger 2020(c)	18	0	0	0	1.00 [0.81, 1.00]	Not estimable
Fenollar 2020(b)	1	0	0	0	1.00 [0.03, 1.00]	Not estimable
Baccani 2021 [C]	5	0	0	0	1.00 [0.48, 1.00]	Not estimable
Baccani 2021 [B]	5	0	0	0	1.00 [0.48, 1.00]	Not estimable
Baccani 2021 [A]	5	0	0	0	1.00 [0.48, 1.00]	Not estimable
Weitzel 2020 [D]	54	0	0	0	1.00 [0.93, 1.00]	Not estimable
Jaaskelainen 2021 [B]	96	0	1	0	0.99 [0.94, 1.00]	Not estimable
Alemany 2020	557	0	6	0	0.99 [0.98, 1.00]	Not estimable
Jaaskelainen 2021 [A]	88	0	1	0	0.99 [0.94, 1.00]	Not estimable
PHE 2020(a)	58	0	1	0	0.98 [0.91, 1.00]	Not estimable
Kweon 2021 [B]	107	0	2	0	0.98 [0.94, 1.00]	Not estimable
Jaaskelainen 2021 [C]	90	0	2	0	0.98 [0.92, 1.00]	Not estimable
Kurihara 2021	44	0	1	0	0.98 [0.88, 1.00]	Not estimable
Garcia 2021 [B]	82	0	2	0	0.98 [0.92, 1.00]	Not estimable
Soleimani 2021][B]	151	0	5	0	0.97 [0.93, 0.99]	Not estimable
Van Honacker 2021 [D]	30	0	1	0	0.97 [0.83, 1.00]	Not estimable
Garcia 2021 [A]	81	0	3	0	0.96 [0.90, 0.99]	Not estimable
Fenollar 2020(a)	106	0	4	0	0.96 [0.91, 0.99]	Not estimable
Kweon 2021 [A]	105	0	4	0	0.96 [0.91, 0.99]	Not estimable
Halfon 2021	52	0	2	0	0.96 [0.87, 1.00]	Not estimable
Fourati 2020 [E]	125	0	5	0	0.96 [0.91, 0.99]	Not estimable
Fourati 2021 [D]	125	0	5	0	0.96 [0.91, 0.99]	Not estimable
Kruger 2021	69	0	3	0	0.96 [0.88, 0.99]	Not estimable
Van Honacker 2021 [F]	161	0	8	0	0.95 [0.91, 0.98]	Not estimable
Liotti 2020	20	0	1	0	0.95 [0.76, 1.00]	Not estimable
Hartard 2021	39	0	2	0	0.95 [0.83, 0.99]	Not estimable
Paul 2021 [A]	66	0	4	0	0.94 [0.86, 0.98]	Not estimable
Eleftheriou 2021	33	0	2	0	0.94 [0.81, 0.99]	Not estimable
Fourati 2021 [F]	122	0	8	0	0.94 [0.88, 0.97]	Not estimable
Fourati 2020 [D]	122	0	8	0	0.94 [0.88, 0.97]	Not estimable
Nordgren 2021 [B]	106	0	7	0	0.94 [0.88, 0.97]	Not estimable
Van Honacker 2021 [B]	30	0	2	0	0.94 [0.79, 0.99]	Not estimable
Montero 2021	30	0	2	0	0.94 [0.79, 0.99]	Not estimable
Fourati 2021 [B]	121	0	9	0	0.93 [0.87, 0.97]	Not estimable
Fourati 2020 [B]	118	0	9	0	0.93 [0.87, 0.97]	Not estimable
Hauser 2021	52	0	5	0	0.91 [0.81, 0.97]	Not estimable
Kim 2021 [B]	49	0	5	0	0.91 [0.80, 0.97]	Not estimable
Nash 2020	48	0	5	0	0.91 [0.79, 0.97]	Not estimable
Soleimani 2021 [A]	141	0	15	0	0.90 [0.85, 0.95]	Not estimable
Kruger 2020(a)	8	0	1	0	0.89 [0.52, 1.00]	Not estimable
Nordgren 2021 [A]	100	0	13	0	0.88 [0.81, 0.94]	Not estimable
Fourati 2020 [C]	113	0	17	0	0.87 [0.80, 0.92]	Not estimable
PHE 2020(c) [non-HCW tested]	92	0	14	0	0.87 [0.79, 0.93]	Not estimable
Veyrenche 2020	13	0	2	0	0.87 [0.60, 0.98]	Not estimable
Bulilete 2021	38	0	6	0	0.86 [0.73, 0.95]	Not estimable
Ford 2021	23	0	4	0	0.85 [0.66, 0.96]	Not estimable
Weitzel 2020 [A]	45	0	8	0	0.85 [0.72, 0.93]	Not estimable
Lambert-Niclot 2020	37	0	8	0	0.82 [0.68, 0.92]	Not estimable
Mertens 2020	65	0	23	0	0.74 [0.63, 0.83]	Not estimable
Fourati 2021 [A]	93	0	37	0	0.72 [0.63, 0.79]	Not estimable
Fourati 2020 [A]	91	0	37	0	0.71 [0.62, 0.79]	Not estimable
Finana 2021	25	0	11	0	0.69 [0.52, 0.84]	Not estimable
Fourati 2021 [C]	113	0	55	0	0.67 [0.60, 0.74]	Not estimable
Kruger 2020(b)	2	0	1	0	0.67 [0.09, 0.99]	Not estimable
Wachinger 2021	170	26	94	1306	0.64 [0.58, 0.70]	0.98 [0.97, 0.99]
Paul 2021 [B]	51	0	29	0	0.64 [0.52, 0.74]	Not estimable
Fourati 2021 [E]	81	0	49	0	0.62 [0.53, 0.71]	Not estimable
Thakur 2021	27	0	33	0	0.45 [0.32, 0.58]	Not estimable
Oh 2021	7	0	10	101	0.41 [0.18, 0.67]	1.00 [0.96, 1.00]
Weitzel 2020 [C]	11	0	41	0	0.21 [0.11, 0.35]	Not estimable

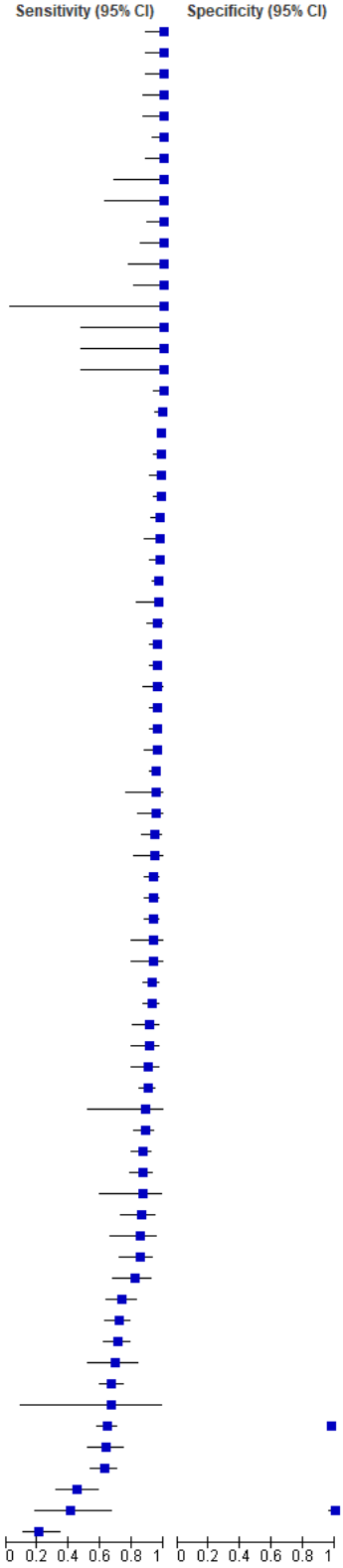


Figure 34. Sensitivity and specificity of RAgT if Ct value < 25

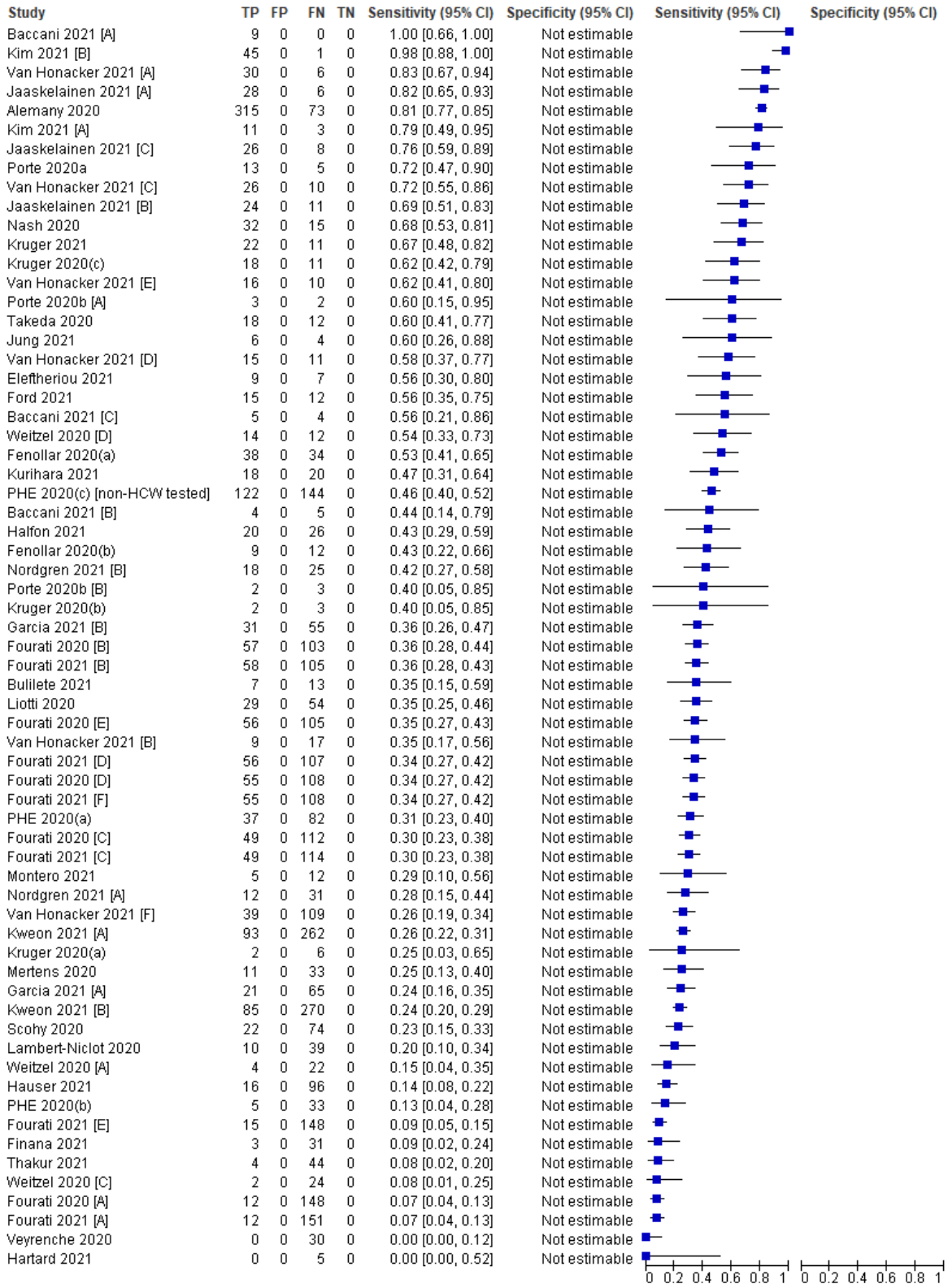


Figure 35. Sensitivity and specificity of RAgT if Ct value > 25

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Pilarowski 2021 [B]	171	43	0	3088	1.00 [0.98, 1.00]	0.99 [0.98, 0.99]
Bruzzone 2021 [A]	16	0	0	0	1.00 [0.79, 1.00]	Not estimable
Bruzzone 2021 [E]	60	0	0	0	1.00 [0.94, 1.00]	Not estimable
Bruzzone 2021 [G]	60	0	0	0	1.00 [0.94, 1.00]	Not estimable
Escriva 2021	116	0	1	331	0.99 [0.95, 1.00]	1.00 [0.99, 1.00]
Diao 2020	55	0	1	0	0.98 [0.90, 1.00]	Not estimable
Amer 2021	28	28	1	22	0.97 [0.82, 1.00]	0.44 [0.30, 0.59]
Klein 2021	52	0	2	0	0.96 [0.87, 1.00]	Not estimable
Bouassa 2021	74	0	3	0	0.96 [0.89, 0.99]	Not estimable
Takeda 2020	48	0	2	0	0.96 [0.86, 1.00]	Not estimable
Alemany 2020	813	0	35	0	0.96 [0.94, 0.97]	Not estimable
Jaaskelainen 2021 [A]	116	0	7	0	0.94 [0.89, 0.98]	Not estimable
Kruger 2021	87	0	6	0	0.94 [0.86, 0.98]	Not estimable
Abdelrazik 2021	71	0	5	0	0.93 [0.85, 0.98]	Not estimable
Osmanodja 2021	62	0	5	0	0.93 [0.83, 0.98]	Not estimable
Jaaskelainen 2021 [C]	116	0	10	0	0.92 [0.86, 0.96]	Not estimable
PHE 2020(b)	11	0	1	0	0.92 [0.62, 1.00]	Not estimable
Seynaeve 2021 [C]	41	0	4	50	0.91 [0.79, 0.98]	1.00 [0.93, 1.00]
Jaaskelainen 2021 [B]	120	0	12	0	0.91 [0.85, 0.95]	Not estimable
Cento 2021	126	0	13	0	0.91 [0.85, 0.95]	Not estimable
Bruzzone 2021 [B]	19	0	2	0	0.90 [0.70, 0.99]	Not estimable
Schuit 2021 [A]	137	20	15	2505	0.90 [0.84, 0.94]	0.99 [0.99, 1.00]
PHE 2020(a)	82	0	9	0	0.90 [0.82, 0.95]	Not estimable
Fenollar 2020(a)	137	0	16	0	0.90 [0.84, 0.94]	Not estimable
Soleimani 2021][B]	174	0	22	0	0.89 [0.84, 0.93]	Not estimable
Schuit 2021 [B]	79	12	12	1493	0.87 [0.78, 0.93]	0.99 [0.99, 1.00]
Baro 2021 [B]	26	0	4	0	0.87 [0.69, 0.96]	Not estimable
Nash 2020	65	0	13	0	0.83 [0.73, 0.91]	Not estimable
Baro 2021 [D]	25	0	5	0	0.83 [0.65, 0.94]	Not estimable
Baro 2021 [C]	25	0	5	0	0.83 [0.65, 0.94]	Not estimable
Fenollar 2020(b)	9	0	2	0	0.82 [0.48, 0.98]	Not estimable
Leli 2021	107	37	25	623	0.81 [0.73, 0.87]	0.94 [0.92, 0.96]
Holzner 2021	337	5	86	1033	0.80 [0.76, 0.83]	1.00 [0.99, 1.00]
Bruzzone 2021 [C]	39	0	11	0	0.78 [0.64, 0.88]	Not estimable
Soleimani 2021 [A]	152	0	44	0	0.78 [0.71, 0.83]	Not estimable
Baro 2021 [A]	23	0	7	0	0.77 [0.58, 0.90]	Not estimable
Adnan 2021	49	2	16	190	0.75 [0.63, 0.85]	0.99 [0.96, 1.00]
PHE 2020(c) [non-HCW tested]	166	0	56	0	0.75 [0.69, 0.80]	Not estimable
Bruzzone 2021 [F]	17	0	6	0	0.74 [0.52, 0.90]	Not estimable
Scohy 2020	24	0	10	0	0.71 [0.53, 0.85]	Not estimable
Baro 2021 [E]	21	0	9	0	0.70 [0.51, 0.85]	Not estimable
Seynaeve 2021 [A]	31	0	14	50	0.69 [0.53, 0.82]	1.00 [0.93, 1.00]
Okoye 2021	24	0	12	0	0.67 [0.49, 0.81]	Not estimable
Bruzzone 2021 [D]	15	0	8	0	0.65 [0.43, 0.84]	Not estimable
Liotti 2020	43	0	33	0	0.57 [0.45, 0.68]	Not estimable
Veyrenche 2020	13	0	17	0	0.43 [0.25, 0.63]	Not estimable
Oh 2021	7	0	19	92	0.27 [0.12, 0.48]	1.00 [0.96, 1.00]

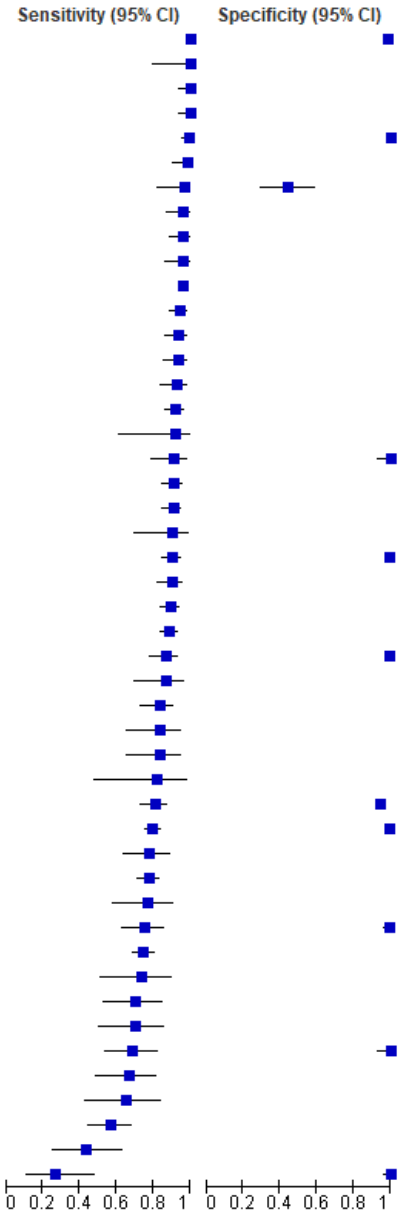


Figure 36. Sensitivity and specificity of RAgT if other Ct thresholds for 'higher' viral load

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Klein 2021	26	0	10	0	0.72 [0.55, 0.86]	Not estimable
Bouassa 2021	16	0	7	0	0.70 [0.47, 0.87]	Not estimable
Nash 2020	15	0	7	0	0.68 [0.45, 0.86]	Not estimable
Amer 2021	26	62	14	33	0.65 [0.48, 0.79]	0.35 [0.25, 0.45]
Alemany 2020	59	0	44	0	0.57 [0.47, 0.67]	Not estimable
Diao 2020	86	0	66	0	0.57 [0.48, 0.65]	Not estimable
Asai 2021	16	4	14	236	0.53 [0.34, 0.72]	0.98 [0.96, 1.00]
Jaaskelainen 2021 [C]	10	0	16	0	0.38 [0.20, 0.59]	Not estimable
Cento 2021	20	0	39	0	0.34 [0.22, 0.47]	Not estimable
Kruger 2021	4	0	8	0	0.33 [0.10, 0.65]	Not estimable
PHE 2020(c) [non-HCW tested]	48	0	102	0	0.32 [0.25, 0.40]	Not estimable
Jaaskelainen 2021 [B]	8	0	18	0	0.31 [0.14, 0.52]	Not estimable
Fenollar 2020(a)	7	0	22	0	0.24 [0.10, 0.44]	Not estimable
Liotti 2020	6	0	22	0	0.21 [0.08, 0.41]	Not estimable
Leli 2021	7	30	27	596	0.21 [0.09, 0.38]	0.95 [0.93, 0.97]
Takeda 2020	2	0	10	0	0.17 [0.02, 0.48]	Not estimable
PHE 2020(a)	13	0	74	0	0.15 [0.08, 0.24]	Not estimable
Jaaskelainen 2021 [A]	3	0	22	0	0.12 [0.03, 0.31]	Not estimable
Scohy 2020	8	0	64	0	0.11 [0.05, 0.21]	Not estimable
Fenollar 2020(b)	1	0	10	0	0.09 [0.00, 0.41]	Not estimable
PHE 2020(b)	2	0	32	0	0.06 [0.01, 0.20]	Not estimable
Veyrenche 2020	0	0	15	0	0.00 [0.00, 0.22]	Not estimable
Okoye 2021	0	0	9	0	0.00 [0.00, 0.34]	Not estimable

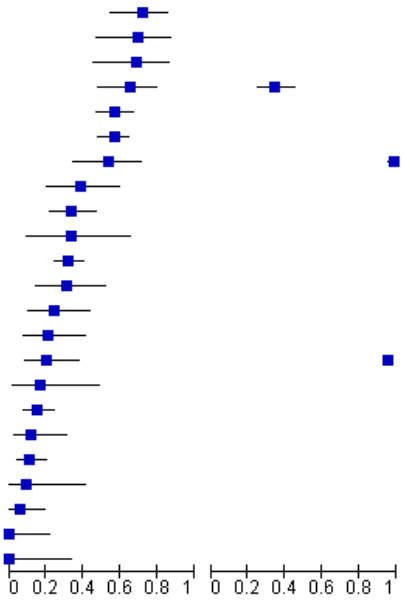


Figure 37. Sensitivity and specificity of RAgT if other Ct thresholds for 'lower' viral load

Saliva

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Ishii 2021 [D]	8	1	0	123	1.00 [0.63, 1.00]	0.99 [0.96, 1.00]
Kobayashi 2021 [B]	111	3	3	5272	0.97 [0.93, 0.99]	1.00 [1.00, 1.00]
Asai 2021	49	4	14	238	0.78 [0.66, 0.87]	0.98 [0.96, 1.00]
Seitz 2021	8	0	10	22	0.44 [0.22, 0.69]	1.00 [0.85, 1.00]
Mak 2020	18	0	27	0	0.40 [0.26, 0.56]	Not estimable
Ishii 2021 [B]	3	0	6	84	0.33 [0.07, 0.70]	1.00 [0.96, 1.00]
Nagura-Ikeda 2020	12	0	91	0	0.12 [0.06, 0.19]	Not estimable
Uwamino 2021 [B]	4	0	37	0	0.10 [0.03, 0.23]	Not estimable

Sputum

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Mak 2020	5	0	40	0	0.11 [0.04, 0.24]	Not estimable

NP + saliva

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Yokota 2021	31	2	3	307	0.91 [0.76, 0.98]	0.99 [0.98, 1.00]

Exhaled breath

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Maniscalco 2021	12	1	1	91	0.92 [0.64, 1.00]	0.99 [0.94, 1.00]

OP

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Nsoga 2021	136	2	32	232	0.81 [0.74, 0.87]	0.99 [0.97, 1.00]
Kahn 2021	57	39	31	2983	0.65 [0.54, 0.75]	0.99 [0.98, 0.99]
Wagenhauser 2021 [A]	13	0	10	783	0.57 [0.34, 0.77]	1.00 [1.00, 1.00]
Wagenhauser 2021 [B]	7	4	8	1010	0.47 [0.21, 0.73]	1.00 [0.99, 1.00]
Wagenhauser 2021 [C]	23	12	40	3146	0.37 [0.25, 0.50]	1.00 [0.99, 1.00]

Nasal + OP

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Allan-Blitz 2021	1550	189	1603	15115	0.49 [0.47, 0.51]	0.99 [0.99, 0.99]

Nasal (anterior nares + mid turbinate)

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Denina 2021	16	14	1	160	0.94 [0.71, 1.00]	0.92 [0.87, 0.96]
Sood 2021	127	99	9	539	0.93 [0.88, 0.97]	0.84 [0.81, 0.87]
Bachman 2021 [C]	84	5	8	72	0.91 [0.84, 0.96]	0.94 [0.85, 0.98]
Bachman 2021 [D]	84	4	8	78	0.91 [0.84, 0.96]	0.95 [0.88, 0.99]
Nikolai 2021 [B]	31	0	3	62	0.91 [0.76, 0.98]	1.00 [0.94, 1.00]
Bianco 2021	269	48	29	561	0.90 [0.86, 0.93]	0.92 [0.90, 0.94]
Pilarowski 2021 [A]	211	3	26	3062	0.89 [0.84, 0.93]	1.00 [1.00, 1.00]
Osmanodja 2021	62	1	8	308	0.89 [0.79, 0.95]	1.00 [0.98, 1.00]
Nikolai 2021 [A]	31	0	5	96	0.86 [0.71, 0.95]	1.00 [0.96, 1.00]
Bachman 2021 [B]	79	3	13	75	0.86 [0.77, 0.92]	0.96 [0.89, 0.99]
Chiu 2021 [A]	64	14	11	260	0.85 [0.75, 0.92]	0.95 [0.92, 0.97]
Shaikh 2021	39	16	7	137	0.85 [0.71, 0.94]	0.90 [0.84, 0.94]
Klein 2021	38	2	7	243	0.84 [0.71, 0.94]	0.99 [0.97, 1.00]
Chiu 2021 [C]	32	18	6	22938	0.84 [0.69, 0.94]	1.00 [1.00, 1.00]
Bachman 2021 [A]	75	2	15	77	0.83 [0.74, 0.90]	0.97 [0.91, 1.00]
Chiu 2021 [B]	62	10	13	264	0.83 [0.72, 0.90]	0.96 [0.93, 0.98]
Lindner 202105 [A]	33	2	7	104	0.82 [0.67, 0.93]	0.98 [0.93, 1.00]
Kruger 202108	120	4	26	611	0.82 [0.75, 0.88]	0.99 [0.98, 1.00]
Bachman 2021 [G]	89	0	20	60	0.82 [0.73, 0.88]	1.00 [0.94, 1.00]
Pray 2021 [A]	32	2	8	185	0.80 [0.64, 0.91]	0.99 [0.96, 1.00]
Bachman 2021 [H]	87	1	23	59	0.79 [0.70, 0.86]	0.98 [0.91, 1.00]
Pollock 202104	226	12	66	2004	0.77 [0.72, 0.82]	0.99 [0.99, 1.00]
Muhi 2021	17	1	5	2580	0.77 [0.55, 0.92]	1.00 [1.00, 1.00]
Shah 2021	258	7	76	1769	0.77 [0.72, 0.82]	1.00 [0.99, 1.00]
Lindner 202104 [A]	29	2	10	246	0.74 [0.58, 0.87]	0.99 [0.97, 1.00]
Bachman 2021 [F]	81	1	29	59	0.74 [0.64, 0.82]	0.98 [0.91, 1.00]
Prince-Guerra 2021 [C]	101	0	41	520	0.71 [0.63, 0.78]	1.00 [0.99, 1.00]
Frediani 2021	93	2	39	207	0.70 [0.62, 0.78]	0.99 [0.97, 1.00]
Bachman 2021 [E]	75	2	33	57	0.69 [0.60, 0.78]	0.97 [0.88, 1.00]
Leli 2021	114	30	52	596	0.69 [0.61, 0.76]	0.95 [0.93, 0.97]
Ford 2021	37	15	17	982	0.69 [0.54, 0.80]	0.98 [0.98, 0.99]
McKay 2021	2	0	1	134	0.67 [0.09, 0.99]	1.00 [0.97, 1.00]
Brihn 2021	98	12	51	1878	0.66 [0.58, 0.73]	0.99 [0.99, 1.00]
Prince-Guerra 2021 [A]	113	0	63	651	0.64 [0.57, 0.71]	1.00 [0.99, 1.00]
Prince-Guerra 2021 [D]	113	0	63	651	0.64 [0.57, 0.71]	1.00 [0.99, 1.00]
Pray 2021 [B]	7	14	10	840	0.41 [0.18, 0.67]	0.98 [0.97, 0.99]
Pollock 202105	135	21	206	1136	0.40 [0.34, 0.45]	0.98 [0.97, 0.99]
Prince-Guerra 2021 [B]	44	4	79	2465	0.36 [0.27, 0.45]	1.00 [1.00, 1.00]

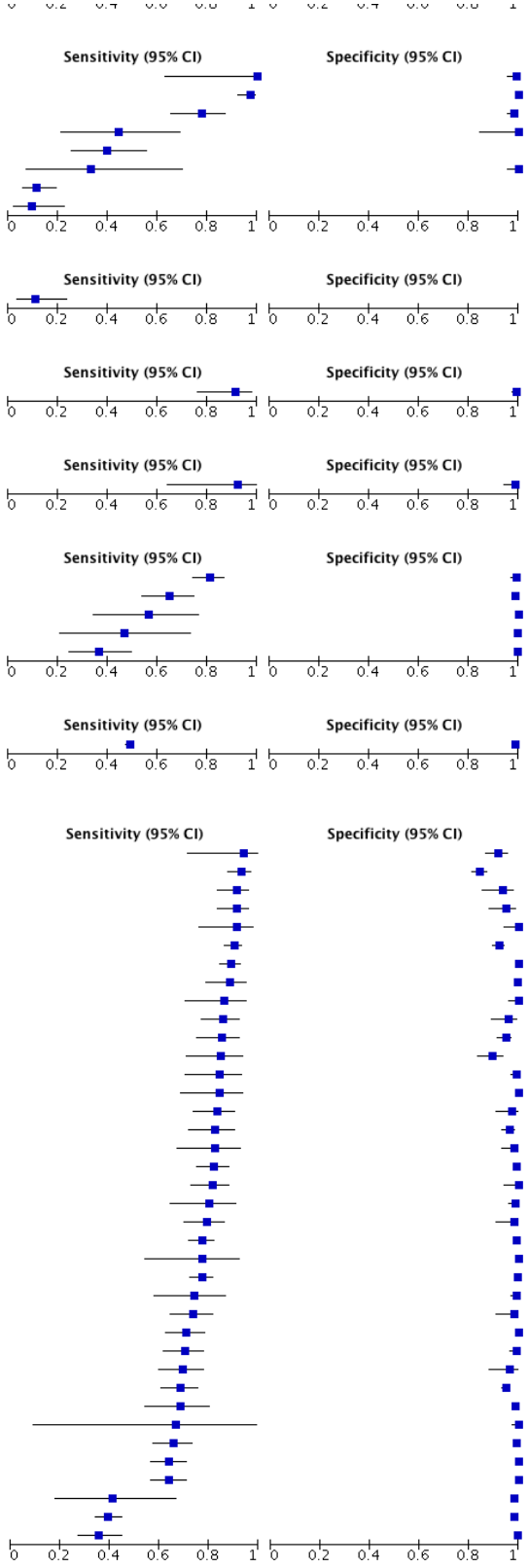


Figure 38. Sensitivity and specificity of RAgT per specimen ty