Evidence check

19 April 2021

Rapid evidence checks are based on a simplified review method and may not be entirely exhaustive, but aim to provide a balanced assessment of what is already known about a specific problem or issue. This brief has not been peer-reviewed and should not be a substitute for individual clinical judgement, nor is it an endorsed position of NSW Health.

COVID-19 rapid testing

Evidence check question

What is the efficacy of rapid, point-of-care tests for COVID-19?

In brief

- Different types of rapid COVID-19 tests are available:
  - Antigen tests – identify constituent proteins of the virus
  - Molecular tests – detect the viral RNA (often referred to as nucleic acid tests)
  - Antibody tests – detect SARS-CoV-2-specific antibodies produced after a person is infected.
- This evidence check is focused on molecular and antigen tests which are used to diagnose current infection with SARS-CoV-2.
- Nucleic Acid Tests include reverse transcription-polymerase chain reaction (RT-PCR) which are considered the standard method for diagnosing COVID-19 disease; complemented by clinical and radiological features. There are very few true 'point-of-care' nucleic acid tests, but there are rapid nucleic acid tests.
- RT-PCR typically uses upper or lower respiratory tract specimens and takes up to six hours in a specialised laboratory; rapid nucleic acid testing (NAT) can provide results in approximately one hour. Turnaround times are impacted by the time required for a sample to be delivered to the laboratory and preanalytical data entry.
- Point-of-care antigen tests (not nucleic acid testing) provide results within minutes of the test being administered, facilitating rapid decisions about patient care. These tests can also extend testing to communities and populations that cannot readily access laboratory facilities.(1)
- Multiple manufacturers have produced rapid tests (Appendix 1). Most are specific to a specimen type, for example nasopharyngeal swab or saliva. The literature indicates differences in sensitivity and specificity across different products and reported results from independent evaluations tend to be lower than manufacturers' claims.
- A Cochrane systematic review of 22 studies of antigen and molecular tests concluded the evidence is not strong enough to determine how useful the tests are in clinical practice. Head-to-head comparisons are limited.(2)
- For antigen tests, most studies report low sensitivity and recommend against this type of test for COVID-19 diagnosis.(3, 4)
- A variation on antigen tests which detect within finger prick blood samples host response proteins, Myxovirus resistance protein A (MxA) (a marker of interferon-induced antiviral host

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response) and C reactive protein (CRP), have shown some promise. However, they are non-specific to COVID-19 and have limited value in comparison to nucleic acid testing.(5, 6)
- For molecular tests, the results are mixed with some products found to be of comparable sensitivity and specificity to the standard nucleic acid tests Xpert Xpress, COVIDNudge, NeuMoDx, SAMBA and RT-LAMP.(7-12)
- Less sensitive rapid antigen tests may have improved sensitivity if done frequently.

Limitations

Pre-peer review studies have not been included in this review. Different testing protocols are used throughout the literature, as well as differing definitions of what constitutes a rapid test. Some publications did not include in their results how long the test took. Implications of self-collection of tests, including the potential implications to public reporting of cases, are not explored in this review.

The methods for recording or interpreting the results of these tests may be rudimentary and often manual with no electronic repository available for collection or documentation into any patient result record. The expectation that these tests can be done at volume is not necessarily accurate given the manual requirements necessary.

Many studies are product specific and heterogeneous performance may limit our ability to assess the efficacy of the generic approach.

Background

Quantitative reverse transcription-PCR (RT-qPCR) assay for COVID-19 using upper and lower respiratory tract specimens (nasopharyngeal swab, throat swab and sputum) is considered the standard for diagnosing COVID-19.

Point-of-care testing may not necessarily be constituted by ‘close to patient’ ‘easy use’ or ‘simple platform’ devices. Rapid output devices are usually cartridge-based tests that can only be run serially on one instrument and take the full onboard run time for analysis. For example, a one-hour test takes one hour for one test after which you can run another one-hour test on another patient.

Point-of-care tests provide results within minutes of the test being administered, allowing for rapid decisions about patient care. It also provides the possibility to extend testing to geographically isolated communities and populations that cannot readily access onsite diagnostic services.(1)

Different types of rapid tests are being investigated for COVID-19:

- Antigen tests – these tests identify virus proteins, often using disposable single-use devices.(2)
- Molecular tests – these detect the virus’s genetic material, using small portable or table-top devices. Antigen and molecular tests use nose or throat samples.(2) With the rapid antigen test, some use their own bespoke swabs, meaning that they cannot be used for NAT or whole genome sequencing. This then requires another collection.
- Antibody tests – point-of-care COVID-19 serology tests detect human antibodies produced in the days and weeks after a person is infected. These are usually in a small plastic cartridge and require a blood specimen for testing.(13)

The timeframe to determine whether a test is ‘rapid’ varies across the literature. A Cochrane review defines rapid as test results are available within two hours of sample collection.(2)

Many rapid tests are being investigated for COVID-19, some of which are summarised in appendix 2.(14) On the 8 April 2020, the World Health Organisation released a scientific brief recommending that

at the time of publication, based on current evidence, the WHO recommends the use of these new point-of-care immunodiagnostic tests (antigen tests*)* only in research settings.(15)

In low prevalence settings negative predictive value and positive predictive values are weakened.

Note: a limited number of tests are now approved by the FDA (seven) as more performance data became available.

Assay performance in population screening versus disease diagnosis is uncertain.

Cost effectiveness (and billing processes) in the Australian context may be different to elsewhere.

Methods (Appendix 2)

PubMed was searched on 2 November 2020, to include studies published from 25 May 2020 onwards. This aligns with the dates searched in a published Cochrane review on rapid antigen and molecular tests. A weekly PubMed alert was set up, and results received on 9 November 2020 were also included in the review.

Prior to publication, the search was re-run to check for new developments. A total of 274 new articles were retrieved in the search including three systematic reviews. One of these systematic reviews was an update to the above-mentioned Cochrane review. The systematic reviews were included in table one and three below and in the brief summaries.

Results

Table 1 Both molecular and antigen tests

Source	Summary
Peer reviewed sources	
Both molecular and antigen	

Rapid, point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection
 	
Dinnes, et al. 2021
	• Cochrane systematic review including 78 study cohorts (described in 64 study reports, including 20 pre-prints), reporting results for 24,087 samples (7,415 with confirmed SARS-CoV-2).
	• Update to Dinnes, et al. 2020
	• Studies were predominately from Europe (n = 39) or North America (n = 20) and evaluated 16 antigen and five molecular assays.
	• Studies of antigen tests were of a higher methodological quality compared to studies of molecular tests.
	• Antigen tests:
	  ○ 48 studies reported 58 evaluations of antigen tests.
	  ○ Estimates of sensitivity varied considerably between studies, including differences between symptomatic (72.0%, 95% Confidence interval (CI): 63.7% - 79.0%; 37 evaluations; 15530 samples, 4410 cases) and asymptomatic patients (58.1%, 95% CI: 40.2% - 74.1%; 12 evaluations; 1581 samples, 295 cases).
	• Molecular tests:
	  ○ 30 studies reported 33 evaluations of five different rapid molecular tests.
	  ○ Sensitivities varied according to test brand.
	  ○ The average sensitivity of ID NOW was 73.0% (95% CI: 66.8% - 78.4%) and average specificity 99.7% (95% CI 98.7% - 99.9%; four evaluations; 812 samples, 222 cases). For Xpert Xpress, the average sensitivity was 100% (95% CI 88.1% - 100%) and average specificity 97.2% (95% CI: 89.4% - 99.3%; two evaluations; 100 samples, 29 cases).
	• Conclusions: The assays shown to meet appropriate criteria, such as the WHO's priority target product profiles for COVID-19 diagnostics (‘acceptable’ sensitivity ≥ 80% and specificity ≥ 97%), can be considered as a replacement for laboratory-based RT-PCR when immediate decisions about patient care must be made, or where RT-PCR cannot be delivered in a timely manner.

Source	Summary
Peer reviewed sources	
Point-of-care testing for the detection of SARS-CoV-2: a systematic review and meta-analysis Yoon, et al. 2021	• A systematic review including 26 studies describing a total of 3,243 samples. • PubMed, Embase, and Web of Science databases were searched for articles published till August 10, 2020. • The summary sensitivity and specificity were 0.94% (95% CI: 0.88% - 0.97%) and 1.00 (95% CI: 0.99% - 1.00%), respectively. • The area under the summary receiver operating characteristic curve was 1.00 (95% CI: 0.99% - 1.00%). • A pooled analysis based on the index test revealed a summary sensitivity and specificity of Cepheid Xpert Xpress SARS-CoV-2 (0.99% (95% CI: 0.97% - 1.00%) and 0.99% (95% CI: 0.94% - 1.00%, respectively)) and ID NOW COVID-19 (0.78% (95% CI: 0.74% - 0.82%) and 1.00% (95% CI: 0.98% - 1.00%), respectively). • Authors conclusions: point-of-care tests, especially molecular assays, have high sensitivity, specificity and overall diagnostic accuracy for detecting SARS-CoV-2.

Rapid, point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection
 	
Dinnes et al. 2020 (2)
	• A Cochrane systematic review of 22 studies, reporting on a total of 3,198 samples, of which 1,775 had confirmed COVID-19, to assess the diagnostic accuracy of point-of-care antigen and molecular-based tests, published before 25 May 2020.
	• Eight commercial tests (four antigen and four molecular) and one in-house antigen test.
	• Approximately two hours for detection.
	• Antigen tests:
	  ○ Sensitivity varied considerably across studies (from 0% - 94%): the average sensitivity was 56.2% (95% CI: 29.5% - 79.8%) and average specificity was 99.5% (95% CI: 98.1% - 99.9%; based on eight evaluations in five studies on 943 samples
	• Rapid molecular assays:
	  ○ Sensitivity showed less variation compared to antigen tests (from 68% - 100%), average sensitivity was 95.2% (95% CI: 86.7% - 98.3%) and specificity 98.9% (95% CI: 97.3% - 99.5%) based on 13 evaluations in 11 studies of on 2,255 samples.
	• Individual tests:
	  ○ Pooled results of individual tests for ID NOW (Abbott Laboratories) (five evaluations) and Xpert Xpress (Cepheid Inc) (six evaluations). Summary sensitivity for the Xpert Xpress assay (99.4%, 95% CI: 98.0% - 99.8%) was 22.6 (95% CI: 18.8% - 26.3%) percentage points higher than

Source	Summary
Peer reviewed sources	
	that of ID NOW (76.8%, (95% CI: 72.9% - 80.3%), whilst the specificity of Xpert Xpress (96.8%, 95% CI: 90.6% - 99.0%) was marginally lower than ID NOW (99.6%, 95% CI: 98.4% - 99.9%; a difference of -2.8% (95% CI: −6.4% - 0.8%). • Concludes that evidence is not strong enough to determine how useful the tests are in clinical practice.

Table 2 – Antigen tests

Source	Source
Peer reviewed sources	
Antigen	
Evaluation of rapid antigen test for detection of SARS-CoV-2 virus Ck Mak et al. 2020 (3)	• Cross-reactivity study to evaluate diagnostic use of a rapid antigen detection (RAD) test, in comparison to RT-PCR for detecting COVID-19, from 1 February 2020 to 21 April 2020 with 369 respiratory samples from individuals with COVID-19 infections. • Hong Kong. • BIOCREDIT COVID-19 AG kit. • RAD was 10^3 fold less sensitive than viral culture and 10^5 less sensitive than RT-PCR. The RAD test detected between 11.1% and 45.7% of RT-PCR-positive samples from COVID-19 patients. • Concludes that testing of patients suspected of COVID-19 infection with antigen-based assay may produce more false negative results in clinical practice.
Clinical Evaluation of Self-Collected Saliva by Quantitative Reverse Transcription-PCR (RT-qPCR), Direct RT-qPCR, Reverse Transcription-Loop-Mediated Isothermal Amplification, and a Rapid Antigen Test To Diagnose COVID-19 Nagura-Ikeda et al. 2020 (16)	• Performance evaluation of six molecular diagnostic tests and a rapid antigen test for COVID-19 detection, using self-collected saliva from 103 patients with COVID-19 infections, from 11 February to 13 May 2020. • Japan (in a hospital setting with patients in isolation for treatment of COVID-19). • On admission, a sterile tube was provided for the patients, and they were requested to self-collect saliva specimens (approximately 500 µl) by spitting into the tube. • Three rapid antigen detection tests: RT-qPCR kit (TaKaRa Bio Inc., Kusatsu, Japan), Ampdirect 2019 novel coronavirus detection kit (Shimadzu Corporation, Kyoto, Japan), and SARS-CoV-2 detection kit (Toyobo, Osaka, Japan). • Approximately 15 minutes detection. • Viral RNA was detected in 50.5% - 81.6% of the specimens by molecular diagnostic tests, and an antigen was detected in 11.7% of the specimens by the rapid antigen test. Viral RNA was detected at significantly higher percentages (65.6% - 93.4%) in specimens collected within nine days of symptom onset than in specimens collected after at least 10 days of symptoms (22.2% - 66.7%) and in specimens collected from asymptomatic patients (40.0% - 66.7%). • Concludes that the rapid antigen test alone is not recommended for an initial COVID-19 diagnosis because of its low sensitivity.

Low performance of rapid antigen detection test as frontline testing for COVID-19 diagnosis Scohy et al. 2020 (4)	• Performance evaluation of a rapid immunochromatographic test for the detection of COVID-19 antigen, in comparison to RT-qPCR, using 148 nasopharyngeal swabs collected between 6 April and 21 April 2020. • Belgium. • Coris COVID-19 Ag Respi-Strip test (Coris BioConcept, Gembloux, Belgium). • Approximately 15 minutes for detection. • Amongst the 106 positive samples, the COVID-19 Ag Respi-Strip detected 32 samples. The overall sensitivity is 30.2%. All the samples detected positive with the antigen rapid test were also positive with RT-qPCR. • Concludes that the overall poor sensitivity of the COVID-19 Ag Respi-Strip does not allow using it alone as the frontline testing for COVID-19 diagnosis.
Evaluation of a novel antigen-based rapid detection test for the diagnosis of SARS-CoV-2 in respiratory samples Porte et al. 2020 (17)	• Performance evaluation of fluorescence immunochromatographic antigen test, for detection of COVID-19 antigen, in comparison to RT-qPCR, using 127 nasopharyngeal and oropharyngeal from suspected COVID-19 cases, between 6 April and 21 April 2020. • Chile. • Fluorescence Antigen Rapid Test Kit (Bioeasy Biotechnology Co., Shenzhen, China). • Approximately 10 minutes for detection. • Sensitivity and specificity were 93.9% (95% CI: 86.5% - 97.4%) and 100% (95% CI: 92.1% - 100%), respectively, with a diagnostic accuracy of 96.1% and Kappa coefficient of 0.9. Sensitivity was significantly higher in samples with high viral loads. • Concludes the testing method has the potential to become an important tool for early diagnosis of COVID-19.
Comparison of automated SARS-CoV-2 antigen test for COVID-19 infection with quantitative RT-PCR using 313 nasopharyngeal swabs, including from seven serially followed patients Hirotus et al. 2020 (18)	• Performance evaluation of a rapid antigen test, for detection of COVID-19 antigen, in comparison to RT-qPCR, using 313 nasopharyngeal swabs from infected and non-infected individuals. • Japan. • LUMIPULSE SARS-CoV-2 Ag kit (Fujirebio) based on chemiluminescence enzyme immunoassay (CLEIA). • Approximately 30 minutes. • The antigen test exhibited 55.2% sensitivity and 99.6% specificity with a 91.4% overall agreement rate (286/313). • Concludes the test can identify individuals infected with COVID-19 with moderate to high viral loads and may be helpful for monitoring viral clearance in hospital settings.
Implementation of rapid SARS-CoV-2 antigenic	• Prospective study compared the negative results obtained with the COVID-19 Ag Respi-Strip kit with

testing in a laboratory without access to molecular methods: Experiences of a general hospital Blairon et al. 2020 (19)	those obtained from qRT-PCR, with 714 samples collected between 5 April and 4 May 2020. • Belgium (hospital setting). • Of 774 patients tested, 714 negative samples were sent for confirmation, and 159 were found to be positive by qRT-PCR. • Concludes using the immunochromatographic assay as a triage test did not significantly reduce the number of samples outsourced for COVID-19 confirmation by qRT-PCR and it was not suitable for large volumes of routine samples.
Accuracy of a nucleocapsid protein antigen rapid test in the diagnosis of SARS-CoV-2 infection Diao et al. 2020 (20)	• Prospective study to assess diagnostic accuracy of a fluorescence immunochromatographic (FIC) assay to detect COVID-19 NP antigen, using samples from 251 patients, collected between 10 and 15 February 2020 (RT-PCR was performed simultaneously). • China (patients were hospitalised with suspected COVID-19 symptoms). • TaqMan One-Step RT-PCR Kit (Da An Gene Co Ltd, Guangzhou, China). • Approximately 10 minutes for detection. • 201 participants (80.1%) had a Ct value ≤40. With Ct value 40 as the cut-off of NA testing, the sensitivity, specificity and percent agreement of the FIC assay was 75.6% (95% CI: 69.0% -81.3%), 100% (95% CI: 91.1% - 100%) and 80.5% (95% CI: 75.1% - 84.9%), respectively. • Concludes that NP antigen testing by FIC assay shows high specificity and relative high sensitivity in SARS-CoV-2 diagnosis in the early phase of infection.
Field Evaluation of the Performance of a SARS-CoV-2 Antigen Rapid Diagnostic Test in Uganda using Nasopharyngeal Samples Nalumansi et al. 2020 (21)	• Cross-sectional, prospective performance evaluation of a rapid antigen diagnostic test, in comparison to qRT-PCR, using 262 samples including 90 qRT-PCR positives. • Uganda. • STANDARD Q COVID-19 Ag Test (SD Biosensor, Gyeonggi-do, 16690, Korea). • Approximately four to six hours for detection. • Sensitivity and specificity of the antigen test were 70.0% (95% CI: 60.0% - 79%) and 92% (95% CI: 87% - 96%) respectively; diagnostic accuracy was 84% (95% CI: 79.0% - 88.0%). The antigen test was more likely to be positive in samples with qRT-PCR Ct values ≤29 reaching a sensitivity of 92%. • Concludes the STANDARD Q COVID-19 Ag test had a less than optimal performance.
Clinical evaluation of BD Veritor SARS-CoV-2 point-of-care test	• Two studies performed; firstly, nasal specimens and either nasopharyngeal or oropharyngeal specimens from 251 participants with COVID-19 symptoms were utilised

performance compared to PCR-based testing and versus the Sofia 2 SARS Antigen point-of-care test Young, et al. 2020 (22)	to compare Veritor with the Lyra® SARS-CoV-2 PCR Assay (Lyra) and then nasal specimens from 361 participants with COVID-19 symptoms (≤5 days from symptom onset (DSO) were utilised to compare performance of Veritor to that of the Sofia® 2 SARS Antigen FIA test (Sofia 2). • Rapid test name: BD Veritor™ System – antigen test • 15-minute run time. • USA. • In the first study, PPA for Veritor, compared to Lyra, ranged from 81.8% - 87.5% for 0-1 through 0-6 DSO ranges. In the second study, Veritor had a positive, negative, and overall percent agreement of 97.4%, 98.1%, and 98.1%, respectively. • In study two, Sofia 2, discordant analysis showed one Lyra positive missed by Veritor and five Lyra positives missed by Sofia 2; one Veritor positive result was negative by Lyra. • The Veritor test allows for more rapid COVID-19 testing utilising easy-to-collect nasal swabs but demonstrated less than 100% positive percent agreement compared to PCR.
Diagnostic accuracy of the FebriDx host response point-of-care test in patients hospitalised with suspected COVID-19 Clark, et al. 2020 (5)	• Diagnostic accuracy study of FebriDx in hospitalised patients during the first wave of the pandemic. • FebriDx detects two host response proteins, Myxovirus resistance protein A (MxA – a marker of interferon-induced antiviral host response) and C reactive protein (CRP), in finger prick blood samples. • UK. • FebriDx was performed on 251 patients and gave a valid result in 248. • Results available after 10 minutes. • 118 of 248 (48%) were PCR positive for COVID-19. FebriDx results were available after 10 minutes compared with 1.7 (1.6 - 2.1) hours with point-of-care PCR testing and 23.4 (17.2 - 31.1) hours with laboratory PCR testing. • Sensitivity of FebriDx for the identification of COVID-19 was 93% (110 of 118; 95% CI: 87% - 97%) and specificity was 86% (112 of 130; 95% CI: 79% - 92%). Positive and negative likelihood ratios were 6.73% (95% CI: 4.37% - 10.37%) and 0.08% (95% CI: 0.04% - 0.15%) respectively. • Conclusion: FebriDx had high accuracy for the identification of COVID-19 in hospitalised adults and could be deployed as a front-door triage tool.
Utility of the FebriDx point-of-care test for rapid triage and identification of	• An observational, prospective, single-centre study evaluating the utility of a triage strategy including a point-of-care blood test in patients with suspected COVID-19

possible coronavirus disease 2019 (COVID-19) Karim, et al. 2020 (6)	presenting at a hospital between March and April 2020. Valid results available in 47 patients. • England (an acute care hospital). • FebriDx, a finger-stick blood test that differentiates viral from bacterial acute respiratory infection through detection of Myxovirus-resistance protein A (MxA) and C-reactive protein (CRP), to rapidly isolate viral cases requiring confirmatory testing. • 10 minutes. • By reference standard, 35 had viral infections (34 of 35 COVID-19; 1 of 35 non-COVID-19; overall FebriDx viral sensitivity 97.1% (95% CI: 83.3% - 99.9%)). Of the COVID-19 cases, 34 of 34 were FebriDx viral positive (sensitivity 100%; 95% CI: 87.4% - 100%); 29 of 34 had an initial SARS-CoV-2 positive molecular test (sensitivity 85.3%; 95% CI: 68.2% - 94.5%). FebriDx was viral negative when the diagnosis was not COVID-19 and SARS-Cov-2 molecular test was negative (negative predictive value (NPV) 100% (13 of 13; 95% CI: 71.7% - 100%)) exceeding initial SARS-CoV-2 molecular test NPV 72.2% (13 of 19; 95% CI: 46.4% - 89.3%). The diagnostic specificity of FebriDx and initial SARS-CoV-2 molecular test was 100% (13 of 13; 95% CI: 70% - 100% and 13 of 13; 95% CI: 85.4% - 100%, respectively). • Concludes that FebriDx could be deployed as part of a reliable triage strategy for identifying symptomatic cases as possible COVID-19 in the pandemic.
Urgent need of rapid tests for SARS CoV-2 antigen detection: Evaluation of the SD-Biosensor antigen test for SARS-CoV-2 Cerutti, et al. 2020 (23)	• The STANDARD Q COVID-19 Ag (R-Ag) was applied to 330 patients of two different admitted to the emergency department. • Italy. • STANDARD Q COVID-19 Ag (SD-Biosensor, RELAB, I). • Results were manually read after 15-30 minutes. • Detection rates of SARS CoV-2 by R-Ag and RT-PCR were 23.3% (77 of 330 patients) and 33% (109 of 330 patients), respectively; no false positive with R-Ag were observed. • R-Ag sensitivity, specificity, negative and positive predictive values were 70.6%, 100%, 87.4% and 100%, respectively, compared with RT-PCR. • Concordance between the two techniques was 90.3% (Cohen's k = 0.76, 95% CI: 0.69% - 0.84%).
Rapid chromatographic immunoassay-based evaluation of COVID-19: A cross-sectional, diagnostic test accuracy study & its implications for COVID-	• A cross-sectional, single-blinded study was conducted at a tertiary care teaching hospital in north India. • A rapid chromatographic immunoassay-based test (index test) compared with a clinical reference standard (rRT-PCR). • India.

19 management in India Gupta, et al. 2020 (24) *Abstract only available*	• Of 330 participants, 77 were rRT-PCR positive for SARS-CoV-2. Of these participants, 64 were also tested positive for SARS-CoV-2 by rapid diagnostic test. • The overall sensitivity and specificity were 81.8% and 99.6%, respectively.
Panbio antigen rapid test is reliable to diagnose SARS-CoV-2 infection in the first 7 days after the onset of symptoms Linares, et al. 2020 (25)	• Clinical data and nasopharyngeal samples collected during September 2020 from patients who attended the emergency department of a secondary hospital and two primary healthcare centres in Madrid. • There were 255 nasopharyngeal swabs, including 150 from the emergency department and 105 from primary healthcare centres. • Panbio™ COVID-19 AG Rapid Test Device. • Among the 60 positive RT-qPCR samples, 40 were detected by the rapid antigen test, given an overall sensitivity of 73.3%. • All the samples detected positive with the rapid antigen test were also positive with RT-qPCR.

COVID-19 rapid diagnostic test could contain transmission in low- and middle-income countries
 	
Olalekan, et al. 2020 (26)
	• A scoping review to document the performance characteristics of 18 COVID-19 rapid diagnostic tests to understand their public health utility in the ongoing pandemic. Literature was searched up to 22 April 2020, irrespective of geographical location.
	• Tests produced in eight countries:
	  ○ Antigen detection based rapid diagnostic testing kits (n=4)
	  ○ Antibody based (total immunoglobulin) rapid diagnostic testing kits (n=9)
	  ○ Antibody based (IgG) or/and (IgM) separated rapid diagnostic testing kit (n=5).
	• The testing time for all the identified kits ranged from two to 30 minutes with an average testing time of 13.5 minutes (95% confidence interval = 10.8 minutes - 16.1 minutes).
	• Reported sensitivity ranged from 18.4% - 100% (average was 84.7%), whereas specificity ranged from 90.6% - 100% (average was 95.6%). The testing time ranged from two minutes to 30 minutes. Of the 12 validated rapid diagnostic tests, the IgM/IgG duo kit with non-colloidal gold labelling system was reported to elicit the highest sensitivity (98% - 100%) and specificity (98% - 99% for IgG and 96% - 99% for IgM).
	• Literature reports high sensitivity and specificity among the developed rapid diagnostic tests that could complement RT-PCR for the detection of SARS-CoV-2 antibodies. Concludes that it is necessary to validate these kits locally.

Note: Febridx detects two host response proteins, Myxovirus resistance protein A (MxA – a marker of interferon -induced antiviral host response) and C reactive protein (CRP) and has been included in the Antigen section.

Table 3: Molecular tests

Source	Summary
Peer reviewed sources	
PCR / molecular	
The diagnostic accuracy of isothermal nucleic acid point-of-care tests for human coronaviruses: A systematic review and meta-analysis Subsoontorn, et al. 2020	• Systematic review and meta-analysis including 81 studies from 65 research articles on POCTs of SARS, MERS and COVID-19. • PubMed, BioRxiv and MedRxiv were searched up to 28 September 2020. • Diagnostic specificities were high (> 0.95) for included studies while sensitivities varied depending on type of assays and sample used. • Most studies used reverse transcription loop-mediated isothermal amplification (RT-LAMP) for diagnosis. • RT-LAMP of RNA purified from COVID-19 patient samples had pooled sensitivity at 0.94% (95% CI: 0.90% - 0.96%). • RT-LAMP of crude samples had substantially lower sensitivity at 0.78% (95% CI: 0.65% - 0.87%). Abbott ID Now performance was similar too RT-LAMP of crude samples. • Diagnostic performances by CRISPR and RT-LAMP on purified RNA were similar. • Other diagnostic platforms including RT- recombinase assisted amplification (RT-RAA) and SAMBA-II also offered high sensitivity (> 0.95).
Performance of Abbott ID Now COVID-19 Rapid Nucleic Acid Amplification Test Using Nasopharyngeal Swabs Transported in Viral Transport Media and Dry Nasal Swabs in a New York City Academic Institution	• Performance evaluation of rapid nucleic acid amplification test for detection of COVID-19, in comparison to two RT-PCR platforms, using nasopharyngeal swabs (transported in viral media and dry). • USA (in an emergency department setting). • ID Now COVID-19 (Abbott Diagnostics Scarborough, Inc., Scarborough, ME) is a rapid test that qualitatively detects SARS-CoV-2 viral nucleic acids from nasal, nasopharyngeal and throat swabs. • Approximately five minutes for detection.

Basu et al. 2020 (27)	• Regardless of method of collection and sample type, Abbott ID Now COVID-19 had negative results in a third of the samples that tested positive by Cepheid Xpert Xpress (one of the real-time reverse transcription-PCR platforms) when using nasopharyngeal swabs in viral transport media and 45% when using dry nasal swabs. • Concludes that ID Now is not recommended for its use as a singular rule-out test, especially in the setting of samples with lower viral loads.
Multicenter Evaluation of the Cepheid Xpert Xpress SARS-CoV-2 Test Loeffelholz et al. 2020 (8)	• Performance evaluation of an automated molecular test to detect COVID-19 and other coronaviruses, using 482 upper- and lower-respiratory-tract specimens, collected between 1 March and 2 April 2020, and previously analysed by standard-of-care (PCR nucleic acid amplification tests). • Settings across USA, UK, France and Italy (patients were referred for COVID-19 testing at seven sites). • The Xpert Xpress SARS-CoV-2 (Xpert) test (Cepheid, Sunnyvale, CA, USA). • Approximately 45 minutes for detection. • Compared to standard-of-care, the positive agreement of the Xpert test was 219 of 220 (99.5%), and the negative agreement was 250 of 261 (95.8%). • Concludes that Xpert test provided sensitive and accurate detection of SARS-CoV-2 in a variety of upper- and lower-respiratory-tract specimens.
Multi-center evaluation of cepheid xpert® xpress SARS-CoV-2 point-of-care test during the SARS-CoV-2 pandemic Wolters et al. 2020 (7)	• Performance evaluation of Xpert Xpress point-of-care test for COVID-19 detection, in comparison to routine real-time RT-PCR assays, using upper respiratory tract samples of patients tested for SARS-CoV-2 between January 2020 and March 2020. • Samples were primarily taken by nasopharyngeal or mid-turbinate and oropharyngeal swabs. • The Netherlands. • Approximately 50 minutes for detection (limited to two to three minutes of hands on time). • Cepheid Xpert Xpress SARS-CoV-2 point of care test showed equal performance compared to routine in-house testing with a limit of detection (LOD) of 8.26 copies/mL. • Concludes Xpert Xpress is suitable for molecular point-of-care testing that is highly specific to and sensitive for the detection of COVID-19.
Assessing a novel, lab-free, point-of-care test for SARS-CoV-2 (CovidNudge): a diagnostic accuracy study	• Diagnostic accuracy study, authors obtained 386 paired samples: 280 (73%) from self-referred health-care workers, 15 (4%) from patients in the emergency department, and 91 (23%) hospital inpatient admissions. • UK. • CovidNudge test – a real time RT-PCR test.

Gibani, et al. 2020 (28)	• Run time is less than 90 minutes. • Of the 386 paired samples, 67 tested positive on the CovidNudge point-of-care platform and 71 with standard laboratory RT-PCR. • The overall sensitivity of the point-of-care test compared with laboratory-based testing was 94% (95% CI: 86% - 98%) with an overall specificity of 100% (99% - 100%). • The sensitivity of the test varied by group (self-referred healthcare workers 94% (95% CI: 85% - 98%); patients in the emergency department 100% (48% - 100%); and hospital inpatient admissions 100% (29% - 100%)). • Specificity was consistent between groups (self-referred health-care workers 100% (95% CI: 98% - 100%); patients in the emergency department 100% (69% - 100%); and hospital inpatient admissions 100% (96% - 100%)). • The CovidNudge platform was a sensitive, specific, and rapid point of care test for the presence of SARS-CoV-2 without laboratory handling or sample pre-processing.
Evaluation of the commercially available LightMix® Modular E-gene kit using clinical and proficiency testing specimens for SARS-CoV-2 detection Yip, et al. 2020 (29)	• To evaluate the performance characteristics of the LightMix® E-gene kit in comparison with well-validated in-house developed COVID-19 RT-PCR assays. • China. • A total of 289 clinical specimens from 186 patients with suspected COVID-19 and eight proficiency testing (PT) samples were used to evaluate the diagnostic performance of the LightMix® E-gene kit against in-house developed COVID-19-RdRp/Hel and COVID-19-N RT-PCR assays. • PCR running time of the LightMix® E-gene assay (66 minutes) was slightly shorter than our in-house COVID-19-RdRp/Hel and COVID-19-N assays (72 minutes). • The LightMix® E-gene kit had a limit of detection of 1.8 × 10-1 TCID50/mL, which was one log10 lower than those of the two in-house RT-PCR assays. • The LightMix® E-gene kit (149 of 289 (51.6%)) had similar sensitivity as the in-house assays (144 of 289 (49.8%) for RdRp/Hel and 146 of 289 (50.5%) for N). • All three assays gave correct results for all the PT samples.
SARS-CoV-2 sample-to-answer nucleic acid testing in a tertiary care emergency department: evaluation and utility Jokela, et al. 2020 (9)	• Performance evaluation of two rapid nucleic acid tests, in comparison to a combination reference of three large-scale PCR tests. The utility of one of the tests in tertiary care emergency departments was also assessed. Respiratory samples were analysed between 18 and 31 May 2020. • Helsinki, Finland. • Cepheid Xpert® Xpress SARS-CoV-2 and Mobidiag Novodiag® Covid-19.

	• On average, a test result using Novodiag® was available nearly eight hours earlier than that obtained with the large-scale PCR tests. • Analysis of 90 samples resulted in 100% specificity and sensitivity for Xpert®, whereas analysis of 107 samples resulted in 93.4% sensitivity and 100% specificity for Novodiag®. Rapid SARS-CoV-2 testing with Novodiag® was made available for four tertiary care emergency departments. Altogether 361 respiratory specimens, together with relevant clinical data, were analysed with Novodiag® and reference tests: 355 of 361 specimens were negative with both methods, and 1 of 361 was positive in Novodiag® and negative by the reference method. Of the five remaining specimens, two were negative with Novodiag®, but positive with the reference method with late Ct values. • Concludes that novel sample-to-answer PCR tests may provide timely and reliable results in detection of SARS-CoV-2 and thus facilitate patient management including effective cohorting.
Rapid and sensitive detection of SARS-CoV-2 RNA using the Simplexa™ COVID-19 direct assay Bordi et al. 2020 (30)	• Performance evaluation of a real-time RT-PCR test for COVID-19 detection using viral stock solutions; and 278 consecutive respiratory samples (nasal and nasopharyngeal swabs), collected between 20 February and 24 March 2020 from patients with laboratory confirmed COVID-19. • Italy. • Simplexa™ COVID-19 Direct assay is an all-in-one reagent mix with no separate extraction. • Approximately 60 minutes for detection. • Concordance analysis showed an 'almost perfect' agreement in SARS-CoV-2 RNA detection between the two assays Simplexa™ COVID-19 and routine method being κ = 0.938; SE = 0.021; 95% CI: 0.896% - 0.980%. • Concludes that there is a high sensitivity and specificity for Simplexa™ COVID-19.
Multicenter evaluation of the NeuMoDx™ SARS-CoV-2 Test Mostafa et al. 2020 (31)	• Performance evaluation of the NeuMoDx SARS-CoV-2 assay with 212 samples (106 COVID-19 positive, 106 negative) collected between 1 March and 15 April 2020 using nasopharyngeal swabs. • USA (across three testing sites). • NeuMoDx™ SARS-CoV-2 assay, performed on a NeuMoDx molecular system, is a rapid, fully automated, qualitative real-time RT-PCR diagnostic test. • Compared to all standard of care methods combined, the positive agreement of the NeuMoDx SARS-CoV-2 test was 105 of 106 (99%) and the negative agreement was 97 of 106 (91.5%).

	• Concludes that the analytical and clinical performance of the NeuMoDx SARS-CoV-2 test, meets or exceeds that of other assays used at each study site.
Point of Care Nucleic Acid Testing for SARS-CoV-2 in Hospitalized Patients: A Clinical Validation Trial and Implementation Study Collier et al. 2020 (32)	• Prospective clinical validation trial comparing SAMBA (simple amplification-based assay) performance against the standard lab RT-PCR test in 149 suspected COVID-19 cases presenting to hospitals between 2 May and 11 May 2020. • UK. • SAMBA II SARS-CoV-2 test. • Approximately 2.6 hours for detection. • Effective sensitivity of the SAMBA II SARS-CoV-2 test as compared to the standard lab RT-PCR was 96.9% (95% CI: 84.2% - 99.9%), with a specificity of 100% (95% CI: 96.9% - 100%).
Development and Clinical Application of a Rapid and Sensitive Loop-Mediated Isothermal Amplification Test for SARS-CoV-2 Infection Hu et al. 2020 (33)	• Performance evaluation of novel reverse transcription–loop-mediated isothermal amplification (RT-LAMP) assay, in comparison to RT-qPCR, using 481 samples, collected from two prospective cohorts of suspected patients with COVID-19, between 26 January and 8 April 2020. • China. • Approximately 60 minutes for detection. • RT-LAMP assay was validated to be accurate (overall sensitivity and specificity of 88.89% and 99.00%, respectively) and diagnostically useful (positive and negative likelihood ratios of 88.89% and 0.11%, respectively). • Concludes that RT-LAMP assay was a simple, rapid, and sensitive approach and can facilitate COVID-19 diagnosis, especially in resource-poor settings.
Diagnostic Performance of a Rapid Point-of-care Test for SARS-CoV-2 in an Urban Emergency Department Setting McDonald, et al. 2020 (10)	• Retrospective analysis of data for prospectively collected specimens from symptomatic ED patients in the United States (n=585). • All subjects had dry nasal swab (NS) testing with the Abbott COVID-19 assay on the ID Now platform (IDNOW, Abbott Diagnostics, Scarborough ME) paired with nasopharyngeal swab (NPS) collected in viral transport medium (VTM). • IDNOW capable of delivering results in five to 13 minutes. Six observations were removed due to an invalid result on the ID NOW or no corroborating m2000 result leaving a total of 579 samples. • The prevalence of COVID-19 was 5.7%. (95% CI: 4.0% - 7.9%). There was a total of seven false-negative tests (7 of 33 true positives) using the ID NOW with agreement of 78.8% (95% CI: 61.0% - 91.0%). The negative predictive value was 98.7% (95% CI 97.4% - 99.5%).

Comparison of the Accula SARS-CoV-2 Test with a Laboratory-Developed Assay for Detection of SARS-CoV-2 RNA in Clinical Nasopharyngeal Specimens Hogan, et al. 2020 (11)	• Study to assess the test performance of this point of care test (n=100 NPS swab samples). • USA. • Accula (Mesa Biotech). Nucleic acid amplification test – molecular). • Requires only 30 minutes from sample to answer. • Overall percent agreement between the assays was 84.0% (95% CI: 75.3% - 90.6%), PPA was 68.0% (95% CI: 53.3% - 80.5%), and the kappa coefficient was 0.68 (95% CI: 0.54% - 0.82%). • Sixteen specimens detected by the SHC-LDT were not detected by the Accula test and showed low viral load burden, with a median cycle threshold value of 37.7. • NPA was 100% (95% CI: 94.2% - 100%). • The false-negative rate of the Accula POC test calls for a more thorough evaluation.
Clinical impact of molecular point-of-care testing for suspected COVID-19 in hospital (COV-19POC): a prospective, interventional, non-randomised, controlled study Brendish, et al. 2020 (12)	• A prospective, interventional, non-randomised, controlled study of molecular point-of-care testing in 499 patients aged 18 years or older presenting with suspected COVID-19 to the emergency department or other acute areas of a hospital, between March 20 and April 29, 2020. • Southampton General Hospital during the first wave of the pandemic in the UK. • QIAstat-Dx Respiratory SARS-CoV-2 Panel (n=499) vs. laboratory PCR (n=555) • Median time to results was 1.7 hours (interquartile range 1.6-1.9 hours) in the point-of-care testing group and 21.3 hours (16.0-27.9 hours) in the control group (difference 19.6 h (19.0-20.3 hours), p<0.0001). • A Cox proportional hazards regression model controlling for age, sex, time of presentation and severity of illness showed that time to results was significantly shorter in the point-of-care testing group than in the control group (hazard ratio 4023 (95% CI: 545-29 696), p<0.0001). • 197 (39%) patients in the point-of-care testing group and 155 (28%) in the control group tested positive for COVID-19 (difference 11.5% (95% CI: 5.8% - 17.2%), p=0.0001). • The QIAstat-Dx Respiratory SARS-CoV-2 Panel returned positive results in 176 of 177 positive cases (sensitivity 99·4% (95% CI: 96·9% - 100%) and negative results in 288 of 292 negative cases (specificity 98·6% (96·5% - 99·6%)), using a composite reference standard of detection by any PCR assay with confirmation by a second assay to determine true positive and negative cases for comparison. • Concludes that point-of-care testing is associated with large reductions in the time it takes to get results and could lead to improvements in infection control

	measures and patient flow compared with centralised laboratory PCR testing.
Sensitivity, Specificity and Predictive Values of Molecular and Serological Tests for COVID-19: A Longitudinal Study in Emergency Room. Bisoffi, et al. 2020 (34)	• A longitudinal study in emergency room assessing the sensitivity, specificity and positive and negative predictive value of molecular and serological tests for the diagnosis of SARS-CoV-2 infection. • Three RT-PCRs including six different gene targets, five serologic rapid diagnostic tests and one ELISA were evaluated using samples from 346 patient who presented to the emergency department. • The final classification of infected or non-infected patients was performed using Latent Class Analysis combined with clinical re-assessment of incongruous cases. • Overall, 24.6% of patients were classified as infected. - The molecular test RQ-SARS-nCoV-2 showed the highest performance with 91.8% sensitivity, 100% specificity, 100.0% positive predictive value (PPV) and 97.4% NPV respectively. - Considering the single gene targets, S and RdRp of RQ-SARS-nCoV-2 had the highest sensitivity (94.1%). - The in-house RdRp presented the lowest sensitivity (62.4%). The specificity ranged from 99.2% for in-house RdRp and N2 to 95.0% for E. - The PPV ranged from 97.1% of N2 to 85.4% of E and the negative predictive value (NPV) from 98.1% of S to 89.0% of in-house RdRp. - All serological tests had < 50% sensitivity and low PPV and NPV. VivaDiag IgM (RDT) had 98.5% specificity, with 84.0% PPV, but 24.7% sensitivity. • Molecular tests for SARS-CoV-2 infection showed excellent specificity, but significant differences in sensitivity. Serological tests have limited utility in a clinical context.

Appendix 1

Table 4: Selected rapid tests for COVID-19

Developer	Test	Description	Status
Abbott	BinaxNOW COVID-19 Ag Card POC SARS-CoV-2 test	Fifteen-minute LFA antigen test and accompanying app that provides a temporary digital pass to users who test negative	FDA EUA granted for use in care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance or Certificate of Accreditation
Access Bio	CareStart COVID-19 Antigen Test	A 10-minute LFA	EUA, CE Mark granted
ArcDia (Turku, Finland)	mariPOC COVID-19 antigen test	A 20-minute POC test for primary care centres; available as a single test or as part of a multianalyte panel of respiratory viruses; samples are processed and analysed on a benchtop device	CE mark granted
Becton Dickinson	BD Veritor System	A 15-minute POC chromatographic antigen immunoassay read on a desktop analyser	EUA granted
Celltrion Healthcare (Incheon, South Korea)	Sampinute COVID-19 antigen MIA	A 10-minute electrochemical sandwich immunoassay for use in labs CLIA-certified to perform high- or medium-complexity tests; requires desktop analyser	EUA granted
Cue Health	Cue COVID-19	A 20-minute lab or POC PCR test employing LAMP of viral nucleic acid; single-use cartridges are analysed in a compact device and results are transmitted by an app	EUA granted
Ellume	COVID-19 antigen test	A 15-minute digital fluorescent immunoassay; different single-use cartridges are in development for POC or lab settings and for home use in conjunction with a Bluetooth-connected analyser for transmission of results and issuance of	RADx funded

		a digital certificate through the user's phone	
Luminostics	Clip COVID Rapid Antigen Test	Immunoassay employing luminescent nanomaterials and smartphone-based readout; for POC use initially, to be followed by an at-home test	RADx funded; fourth-quarter 2020 launch planned
LumiraDx (London)	SARS-CoV-2 Ag Test	A12-minute POC microfluidic immunofluorescence antigen test	EUA, CE mark granted
Maxim Biomedical	Maxim SARS-CoV-2 Rapid Antigen Diagnostic Test	A 15-minute single-tube LFA	RADx funded
MicroGEM	COVID-19 saliva test	Fifteen-minute PCR-based POC and at-home test that identifies SARS-CoV-2 and influenza A and B nucleic acids	RADx funded
Quidel	Sofia 2 SARS Antigen Fluorescent Immunoassay	LFA	EUA granted
SD Biosensor	STANDARD Q COVID-19 Ag Test	Chromatographic immunoassay that delivers results in 15-30 minutes	Eligible for global procurement under WHO Emergency Use Listing procedure
Ubiquitome (Auckland, New Zealand)	Liberty16 mobile PCR test	Battery-operated mobile PCR device suitable for remote hospitals; it delivers results in 40 minutes and reports data through an iPhone app	RADx funded
Visby Medical	COVID-19 Personal PCR test	Disposable 30-minute PCR test	RADx funded; EUA granted for moderate-complexity labs

POC, point of care; MIA, magnetic force-assisted electrochemical sandwich immunoassay. Sources: company websites, WHO, FDA, NIBIB.

Source: Sheridan C. Coronavirus testing finally gathers speed. Nature biotechnology. 2020. (14)

Appendix 2

PubMed search terms

((((2019-nCoV[title/abstract] or nCoV*[title/abstract] or covid-19[title/abstract] or covid19[title/abstract] OR "covid 19"[title/abstract] OR "coronavirus"[MeSH Terms] OR "coronavirus"[title/abstract] OR sars-cov-2[title/abstract] OR "severe acute respiratory syndrome coronavirus 2"[Supplementary Concept])) AND ("rapid"[title/abstract] OR "point-of-care"[title/abstract] OR "point of care"[title/abstract])) AND ((Diagnostic Tests, Routine[MeSH Terms]) OR (test*[title]))) AND (2020/05/25:2020/12/31[pdat])

Inclusion and exclusion criteria

Inclusion	Exclusion
• Rapid point-of-care tests to diagnose COVID-19 Study type: • Study reports empirical data (e.g. diagnostic accuracy study, observational study) • Systematic reviews or meta-analysis (or evidence review with documented methods including search terms and inclusion criteria).	• Non-systematic reviews • Animal studies • Letters • Changes to laboratory protocols for RNA extraction • Studies investigating different methods of serum pooling • Studies not in English language.

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