Evidence table

Rapid testing for COVID-19

14 July 2022

This is the final version of the living evidence table on COVID-19 rapid testing. This evidence table was last updated in June 2022. The information in this table is no longer monitored on a regular basis.

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 gold standard for diagnosing COVID-19.

Rapid 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.

The Royal College of Pathologists of Australasia highlights that rapid antigen tests should be deployed principally for surveillance of asymptomatic individuals to preserve PCR testing capacity for diagnosis.

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. Some rapid diagnostic tests may lead to high rates of false negatives and false positives.

Limitations

Different testing protocols are used throughout the literature, as well as differing definitions of what constitutes a rapid test. Some publications do not include in their results how long a test takes. 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.

Sensitivity and specificity rates were taken from Cochrane reviews where available, otherwise recent systematic reviews, and do not represent a full range as reported throughout the literature. In regards to rapid molecular tests, only tests evaluated in the published Cochrane review are included in this table.

Table one - Test types

	NAAT (RT-PCR)	Rapid antigen tests	Rapid molecular tests	Rapid antibody tests
Definition	Detect SARS-CoV-2 viral (Ribonucleic acid) RNA	Identify virus proteins, often using disposable single-use devices	Detect the virus's genetic material, using small portable or table-top devices	Detect human antibodies produced in the days and weeks after a person is infected
Sensitivity	99.91 - 99.98% False negative rates that subsequently turn positive cases, in symptomatic patients early in the disease, have been estimated to be as high as 20% to 30%	72% (symptomatic) 58% (asymptomatic) Results are better early in disease.	73%* (ID NOW) 100%* (Xpert Xpress) *Insufficient data to investigate the effect of symptom status or time after symptom onset	The combination of IgG/IgM: 30% (for 1 to 7 days) 72% (for 8 to 14 days) 91% (for 15 to 21 days)
Specificity	97.4 - 99.1% At times where infections are rare, population prevalence surveys have shown false positive rate of RT-PCR of less than 0.077%	99.6% (overall summary specificity in symptomatic and asymptomatic patients)	99.7%* (ID NOW) 97.2%* (Xpert Xpress) *Insufficient data to investigate the effect of symptom status or time after symptom onset	98%
Specimen type	Nasal, Nasopharyngeal, Oropharyngeal, Sputum, Saliva	Mostly Nasal, Nasopharyngeal Some studies have used oropharyngeal and saliva	Mostly Nasal, Nasopharyngeal Some studies have used oropharyngeal and saliva, not all instruments TGA registered or validated for saliva.	Blood test (serology)
Time to perform the test	Generally less than 24 hours after the laboratory receives specimen.	Most range from 15 minutes–30 minutes	Approximately 15 minutes (ID NOW) Approximately 60 minutes (Xpert Xpress)	Up to two hours

	NAAT (RT-PCR)	Rapid antigen tests	Rapid molecular tests	Rapid antibody tests
			Time varies depending on assay and device type	
Processing modality	Individual specimen May use pooled samples depending on disease incidence and samples	Individual specimen Each rapid antigen test is a single test on a single individual	Individual specimen This is dependent on what rapid system is used and how it is used	Individual specimen
Applications	Gold standard for diagnosis Pooled sample testing can be considered for individuals/where prevalence is low.	For screening, many publications recommend a twostep screening strategy: rapid antigen testing as a first diagnostic method followed by RT-qPCR to distinguish false from true positives. Repeated mass antigen testing can temporarily reduce the number of new infections. For lasting effects, re-testing at regular intervals would likely be necessary. The benefits of testing tend to be small in low-prevalence settings.	For screening, many publications recommend a twostep screening strategy: rapid antigen testing as a first diagnostic method followed by RT-qPCR to distinguish false from true positives.	In Australia, the Public Health Laboratory Network (PHLN) only recommends laboratory based serology testing in specific cases where this kind of testing may be requested as part of the assessment by a treating medical practitioner to inform a patient's clinical pathway e.g. immunocompromised patients. In the US, CDC recommends that antibody testing should not replace virologic testing and should not be used to establish the presence or absence of acute SARS-CoV-2 infection.

Table two - Test samples

	Saliva	Respiratory specimens	Serum
Collection method	Different collections methods reported including: • Swab on tongue • Swab that looks like a small honey dipper • Drooled into jar	Nasopharyngeal, oropharyngeal and nasal swabs	Fingerpick blood test
Self-collection	The sensitivity of a self-saliva sample was inferior by 9.5% compared to a healthcare work swab. Sensitivities up to 95% reported.	Sensitivity for detecting SARS-CoV-2 in patient collected (compared to professionally collected) tongue, nasal, and mid-turbinate samples was 89.8%, 94.0% and 96.2% respectively.	High percentage (97-99%) able to self-collect an adequate sample
Sensitivity	85%	97% (nasal and throat swab) 86% (nasal swab) 68% (throat swab) Sensitivity depends upon the collection methods and device. Combining a throat and nasal swab can increase sensitivity.^ There is emerging evidence suggesting sensitivity for detecting Omicron is highly variable between rapid tests.^	The combination of IgG/IgM: 30% (for 1 to 7 days) 72% (for 8 to 14 days) 91% (for 15 to 21 days)
Specificity	99%	99% (nasal and throat swab) 99% (nasal swab) 97% (throat swab) Specificity depends upon the collection methods and device.	98%
Test mechanism	RT-PCR	RT-PCR	Antibody tests

	Saliva	Respiratory specimens	Serum
	Isothermal nucleic acid amplification tests e.g. LAMP Infrared light technology Lateral flow Rapid antigen tests Rapid molecular tests	Isothermal nucleic acid amplification tests e.g. LAMP Lateral flow Rapid antigen tests Rapid molecular tests	Lateral flow immunoassay technology

Table three - Policy and evidence

	NSW	Australia	NZ	UK	USA	Canada	Evidence
Preadmission hospital or surgery	NSW does not recommend routine COVID-19 testing prior to surgery. Testing can be considered where patient screening reports symptoms, recent overseas travel, or close/casual contact.	Testing may be recommended by individual states or territories depending on local rates of community transmission.	Routine preoperative testing is not recommended in patients with no risk factors.	NHS advises that individuals may need to get tested if they are due to have surgery or a procedure.	The CDC recommends pre-procedure or pre-admission testing be at the discretion of the facility. Some facilities require all patients scheduled for surgery be tested for COVID-19 prior to admission.	Providers should use their clinical judgement in determining whether pre-operative testing is required. Some facilities require all patients to be tested for COVID-19 prior to admission.	Observational studies have found that rapid antigen testing in the emergency department and in hospital settings can improve the identification of COVID-19 infected patients (especially when the pre-test probability of infection is high); and assist with patient management.
Routine testing population	The NSW government recommends rapid testing for anyone who: • has COVID-19 symptoms • is at higher risk of severe illness and has been recently exposed to someone with COVID-19, or • is a household contact or has	The Australian government recommends a PCR or rapid antigen test for anyone who: • has COVID-19 symptoms, • is a close contact of someone who has tested positive, or • has been advised to get tested by a	Rapid antigen tests (RATs) are currently the primary testing tool for people with COVID-19 symptoms or household contacts. RATs are free online for those feeling unwell or are a household contact.	Most people in England , Scotland and Wales are no longer advised to get tested. Free testing is provided to people who: • have a health condition which makes them eligible for COVID-19 treatments • are going into hospital for	Testing is recommended for anyone with signs or symptoms of COVID-19, and close contacts The CDC recommends screening for asymptomatic individuals where community levels of COVID-19 is high.	Testing is recommended by the Canadian government for anyone who has • symptoms • has been exposed to a person with COVID-19 Some provinces have programs in place that distribute free COVID-19 rapid test kits and	A systematic review identified six categories of rapid testing initiatives: mass screening; targeted screening; healthcare entry testing; at-home testing; surveillance; and prevalence survey.^ A Cochrane review on rapid antigen tests identified virtually no evidence for mass screening of asymptomatic individuals using rapid antigen tests in people with no known exposure, and no

	NSW	Australia	NZ	UK	USA	Canada	Evidence
	had a high or moderate risk exposure to someone with COVID-19 PCR testing is recommended for individuals with a high risk of severe illness. Each positive rapid antigen test must be registered within 24 hours of getting the results and every time there is a positive result.	health professional. The TGA has approved rapid antigen tests for home use. Anyone with an eligible Commonwealth concession card can access up to 20 free rapid antigen tests over a five month period, but no more than five tests in a month.		• surgery or a procedure • work in the NHS or in adult social care		others have extensive testing programs.	evidence of test accuracy in at-risk asymptomatic groups. Rapid antigen tests have been implemented across a variety of settings including: frontline screening at emergency departments, mass gathering live music event, hospital admission, schools, universities, screening test for travellers, points of entry, targeted testing to release individuals from unnecessary quarantine, and targeted testing in outbreak settings. Evidence suggests the benefits of screening with rapid antigen testing is greater when there is a higher prevalence of COVID-19 in the community. A French study found that population testing was associated with a

	NSW	Australia	NZ	UK	USA	Canada	Evidence
							significantly lower hospital mortality rate. In schools, evidence suggests rapid tests have a low diagnostic sensitivity in children. The test-to-stay strategy can reduce transmission in schools.
Routine testing staff	Routine rapid antigen testing is not required in NSW and is not routinely recommended. Some businesses may choose to implement workplace screening using rapid antigen tests based on an individual risk assessment.	The Communicable Diseases Network Australia recommends considering routine testing of close contacts, staff working in quarantine and isolation settings. Rapid antigen test kits were made available to residential aged care, home care, short-term restorative care, and services delivered through the Commonwealth Home Support Program.	Businesses can use RATs as part of managing the health and safety of their workers in their response to COVID-19.	It is no longer required for workplaces to consider COVID-19 in their risk assessment or to have specific testing measures in place.	Screening testing of asymptomatic healthcare workers is required in nursing homes and could be considered in other settings. Fully vaccinated workers may be exempt from screening testing.	The Canadian government is providing rapid tests to some eligible organisations for workplace screening.	An Italian observational study found systematic surveillance of asymptomatic vaccinated healthcare workers uncovers more breakthrough infections than symptom-based testing. Asymptomatic staff at a hospital in Singapore were required to self-administer a rapid antigen test twice weekly to mitigate transmission to patients during a period of high community transmission. Studies suggest regular use of rapid antigen tests in the workplace is effective at diagnosing asymptomatic SARS-CoV-2 infections, and has low rates of false positives.

	NSW	Australia	NZ	UK	USA	Canada	Evidence
Pre-entry testing for travellers	NSW no longer requires travellers to take a COVID-19 test on arrival.	Inbound passengers to Australia are not required to provide a negative test prior to departure. Testing requirements may differ by state and territory.	Inbound passengers to NZ are not required to undertake a pre-departure test. Most passengers still need to undertake two rapid antigen tests after arriving.	It is not necessary to take a COVID-19 test before travelling to England, Wales, Scotland or Northern Ireland.	CDC no longer requires proof of a negative COVID-19 test before their board their flight.	Pre-entry tests are not required for fully vaccinated inbound travellers. Unvaccinated travellers are required to provide a negative pre-entry test or proof of recent infection	A study found rapid antigen testing no earlier than the fifth day after arrival was a reliable method for detecting infectious travellers.

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