Queensland Health

COVID-19

Laboratory testing for SARS-CoV-2: Information and FAQs

29 June 2020

The capacity to identify and isolate cases of COVID-19 is critical to limit the spread of the virus, protect vulnerable persons in the community and ensure healthcare systems maintain the capacity to deliver quality healthcare.

Laboratory testing for SARS-CoV-2 has evolved over the course of the pandemic and continues to advance as more is known about the virus and testing capability is enhanced.

Testing for SARS-CoV-2 should be done in conjunction with assessment and testing for other potential causes of the person's presentation, as deemed appropriate by the treating clinician and in line with local protocols.

What types of tests are available for SARS-CoV-2?

Testing can be broadly grouped into:

- SARS-CoV-2 specific testing (testing directly for the virus), done by nucleic acid testing AND
- Serology (testing for antibody response).

Nucleic acid testing (NAT)

NAT is performed by real time polymerase chain reaction (PCR). This method involves amplification of RNA of the SARS-CoV-2 virus. PCR is the appropriate test for diagnosis of acute COVID-19 infection.

PCR is most commonly performed on upper respiratory tract specimens. For best results from upper respiratory tract sampling, both deep nasal and throat swabs should be collected. Both sites can be sampled using the same swab.

PCR can also be performed on lower respiratory tract specimens including sputum, bronchoalveolar lavage and tracheal aspirate. Lower respiratory tract specimens contain higher viral loads in SARS-CoV-2, and therefore should be tested wherever appropriate.

PCR is occasionally performed on faecal and tissue specimens in special circumstances. Testing of faeces or tissue is only available by special request on the advice of a microbiologist, infectious diseases physician or public health physician.

Serology

Serology tests are performed on serum to look for antibodies that are produced by the person against SARS-CoV-2. They do not detect the virus itself.

A validated SARS-CoV-2 serology assay is now available at Queensland Health Forensic and Scientific Services (QHFSS). The assay detects both IgM and IgG antibodies in serum from patients who have been infected with the virus. Serology assays are currently being assessed by other laboratories in Queensland and will likely become available soon.

Serology is not recommended for diagnosis of acute infection. Acute and convalescent specimens collected 10–14 days apart can assist in diagnosis of COVID-19 in persons with negative PCR tests where there remains a high suspicion of COVID-19, or in persons suspected to have recovered from COVID-19 who did not undergo PCR at the time they were unwell.

Serology testing is currently limited in Queensland and must be prioritised for epidemiological investigations where the results will be used to provide information relating to current community transmission. Examples of this include:

- an active outbreak or cluster investigation, or
- investigation of potential upstream contacts of a confirmed case of COVID-19 where the case has no apparent epidemiological links (i.e. contact with other known cases or travel to an area where there is known community transmission of the virus).

Serology test requests via QHFSS must be discussed with the local public health unit and approved by the QHFSS microbiologist.

Point of care (POC) serology tests

Point of care (POC) serology tests, or finger-prick tests, are yet to be validated. The accuracy and clinical utility of these tests is unknown and therefore they are not endorsed for use by Queensland Health outside of the research setting.

Please refer to the following Chief Health Officer direction in relation to the use of POC serology tests in Queensland, effective from 23 April 2020, available at https://www.health.qld.gov.au/system-governance/legislation/cho-public-health-directions-under-expanded-public-health-act-powers/point-of-care-serology-tests

Is there a possibility of false negative or false positive PCR results?

There are no pathology tests that are completely accurate, however the accuracy of PCR assays used to detect SARS-CoV-2 in diagnostic laboratories in Queensland perform very well.

Factors that can influence the accuracy of PCR testing and correct classification of cases include:

- a variable presence of virus in different body sites at different phases of illness
- the quality of the sampling (how well the swab is taken)
- technical factors specific to the assay
- specimen handling and processing.

If the results of testing do not fit with the clinical and epidemiological context of the person being evaluated, this should be discussed with a microbiologist, infectious diseases physician or public health physician and consideration given to repeat testing.

Despite more than 250 000 tests for SARS-CoV-2 having been performed in Queensland to date, fewer than 10 have been identified as false positive reports. For further information on false positive PCR tests, refer to the "Public Health Laboratory Network Statement on Nucleic Acid Test False Positive Results for SARS-CoV-2", available at: https://www1.health.gov.au/internet/main/publishing.nsf/Content/2FCDB8DA4EB40BA9CA257BF000211F2A/$File/Nucleic-Acid-Test-False-Positive-Results-SARS-CoV-2-PHLN.pdf

What platforms are available for PCR?

There are a variety of platforms in use for PCR testing across different laboratories. These platforms are continually being evaluated and enhanced as new information on the virus and testing methods becomes available.

PCR is principally performed using high throughput instruments, processing specimens in large batches. These tests take approximately six hours to process once they are loaded onto the instrument in the laboratory.

In regional sites and some hospitals across Queensland, there are also GeneXpert instruments available. GeneXpert can process a small number of specimens with a quicker processing time than high throughput instruments.

The availability of testing kits for GeneXpert are currently very limited worldwide, and therefore their use in Queensland must be prioritised for investigation of suspected cases of COVID-19 where the confirmation of a positive or negative result would prompt:

- a rapid public health response, or
- a significant change to immediate clinical management.

The use of GeneXpert tests require approval from a clinical microbiologist, infectious diseases physician, public health physician or executive director of medical services (EDMS), depending on processes in place at your facility.

GeneXpert are sometimes referred to as 'point of care' PCR tests. Specimens being evaluated for SARS-CoV-2 using the GeneXpert must still be processed in a laboratory or clinic environment with adequate safety precautions in place to protect the operator of these tests from contracting COVID-19 from the specimens they are handling.

Can a serology test prove that a person is immune to COVID-19?

The presence of antibodies detected on serology testing demonstrates recent or past COVID-19 infection. They cannot be used to demonstrate immunity to the virus. Some people may never make antibodies to the virus, particularly if they are immunosuppressed.

It is currently not known how long antibodies remain in the body, and there is a possibility that they wane over time.

Serology results are not used to shorten a person's period of quarantine.

Can test results be fast-tracked?

Laboratory turn-around times are very good for SARS-CoV-2 testing and continue to improve. Laboratories in Queensland operate extended hours, seven days per week. Queensland currently tests around 5000 people per day.

If the testing processes were interrupted in order to fast-track one or more specimens, this would slow down the turn-around time for results for all the other specimens being processed on that run. Therefore, prioritisation of testing is not done.

Is there a shortage of SARS-CoV-2 tests?

There are worldwide shortages of some of the reagents used for SARS-CoV-2 testing. Diagnostic laboratories in Queensland have responded to these shortages by diversifying their testing platforms and by using innovative processes within the laboratory to ensure there is enough testing capacity to respond to the COVID-19 pandemic.

Testing should continue to be requested for persons who have symptoms of COVID-19 infection in accordance with state and national guidelines.

Should I test asymptomatic people for SARS-CoV-2?

Testing asymptomatic persons should only occur in specific circumstances, for example, under the guidance of your public health unit during investigation of an outbreak or prior to organ donation. Although asymptomatic and pre-symptomatic shedding of SARS-COV-2 is described, as the current prevalence of COVID-19 in Australia is so low, the predictive value of testing asymptomatic persons without epidemiological risk factors is significantly limited. Increased testing of asymptomatic persons in a low prevalence setting can lead to an increased proportion of false positive tests results.

Where can I find further information about SARS-CoV-2 testing?

- PHLN guidance on laboratory testing for SARS-CoV-2, https://www.health.gov.au/sites/default/files/documents/2020/05/phln-guidance-on-laboratory-testing-for-sars-cov-2-the-virus-that-causes-covid-19_1.pdf
- Queensland Health public health alerts, https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/novel-coronavirus-qld-clinicians/public-health-alerts
- Coronavirus Disease 2019 (COVID-19) - CDNA National guidelines for public health units, https://www1.health.gov.au/internet/main/publishing.nsf/Content/cdna-song-novel-coronavirus.htm
- Australian Health Protection Principal Committee (AHPPC) coronavirus (COVID-19) statements on 14 May 2020, https://www.health.gov.au/news/australian-health-protection-principal-committee-ahppc-coronavirus-covid-19-statements-on-14-may-2020