Testing for COVID-19 (SARS-CoV-2) in Pathology Queensland

All Public and Private Pathology laboratories in Australia and Queensland are testing SARS-CoV-2 to the Australian National standard. Further, the Series of National Guidelines define how COVID-19 is diagnosed. PCR Testing is one of several methods used by medical practitioners in the diagnosis of COVID-19.
PCR testing is highly specific, and a positive result indicates with a very high degree of confidence the presence of the SARS-CoV-2 virus. Diagnoses of COVID-19 and a decision about infectivity are made by physicians, informed by PCR results and many other pieces of information.

Queensland was one of the first health jurisdictions in the world to have a reliable and accurate testing regime in place for COVID-19. It's very uncommon for these tests to return an incorrect result, but it's important to remember that issues can occur in all types of testing. To account for this, if there are doubts about the accuracy of a test result, a doctor may ask for a test to be repeated or new specimen re-tested.

To monitor how effective and safe the tests are, the Therapeutic Goods Administration [10]are receiving evidence regularly from people using the tests.

The table below indicates the appropriate test and specimen to use according the clinical situation

Clinical Situation	Test	Specimen
Acute COVID-19 infection	Nucleic acid testing	Respiratory tract sample
Past infection	SARS-CoV-2 serology	Acute and convalescent sera
Public health investigations	Whole Genome Sequencing	Respiratory tract sample or virus isolates
Sero-epidemiology	SARS-CoV-2 serology	Serum
Specialised investigations	Virus isolation	Respiratory tract sample

Identification of acute SARS-CoV-2 (COVID-19) infection is made by Nucleic Acid Testing (NAT) on respiratory tract sampling. The sensitivity of testing depends on the stage of disease, nature of the swab used, quality of sample collected and assay performance.

Self-collection of nose and throat swabs can be used for respiratory virus NAT. The validity of self-swabbing for influenza has been reviewed and suggests reasonable

sensitivity (pooled estimate 87%) compared to swabs taken by healthcare workers (HCWs). This approach was suggested for use in influenza research, and surveillance and studies. Throat washes, saliva samples and gargles have also been used for the diagnosis of SARS-CoV-2 with reasonable efficacy.

This includes monitoring hospitalised patients already known to be NAT positive, and for influenza and respiratory tract bacteria. Self -collection of respiratory tract swabs has been used in the current SARS-CoV-2 outbreak, particularly in busy screening clinics, or in the context of reduced availability of personal protective equipment (PPE). Laboratory validation of self-collected samples for the identification of SARS-CoV-2 is limited but shows reasonable concordance with HCW swabbing.

Without care and training, self -collection in the home environment may pose issues of contamination of collection material and transport packaging.

Nucleic acid testing for SARS-CoV-2

The diagnostic test of choice for acute symptomatic COVID-19 disease is nucleic acid testing (NAT) performed on an appropriately collected upper or lower respiratory tract sample. NAT is performed using either in-house real-time polymerase chain reaction (RT-PCR) with SARS-CoV-2 specific probes, or commercial assays. In-house RT-PCR assays were used in the early stages of COVID-19 outbreak in Australia, but increasingly commercial assays have become available.

In Queensland NAT using real time polymerase chain reaction (RT-PCR) is still the method of choice to detect SARS-CoV-2 during the acute illness. The PHLN (Public Health Laboratory Network) describes specific diagnostic test approaches for SARS-CoV-2 below in broad terms. There is significant variation in PCR assays employed by different PHLN member laboratories and non-PHLN laboratories. Commercial NAT assays have been available for SARS-CoV-2 testing in Australia since March 2020.

In the early phases of the pandemic, before commercial assays were available, the PHLN member laboratories and Pathology Queensland designed their own specific RT-PCR primer sets or implemented primer sets.

Leading international coronavirus reference laboratories recommended these primer sets to the World Health Organization (WHO) to detect SARS-CoV-2. Well pedigreed PCR primer sets, probes and protocols are available from the WHO/ European Viral Archive (Eva). During this stage, NAT was generally done as a twostep process with an initial screening, followed by a confirmatory test.

Complementary DNA (cDNA) synthesized from the VIDRL SARS-CoV-2 is now available to all PHLN member laboratories as a test positive control. Synthetic positive control material in the form of nucleic acid templates is also available through WHO.

Most diagnostic laboratories in Pathology Queensland now employ mainly commercial developed assays for testing. The turnaround times are less than 24 hours after the laboratory receives a specimen. Faster turnaround times can be achieved when using rapid, but low throughput, RT-assays.

To minimise the risks of false positive results in low prevalence settings, confirming positive results is done with either:

- RT-PCR assays detecting a different target gene (particularly for assays with a single target); or
- sequencing (see below).

Find further PHLN guidance on NAT result interpretation at PHLN guidance on nucleic acid test result interpretation for SARS-CoV-2.

The RCPAQAP, with Australian Government support, offers a SARS-CoV-2 specific NAT QAP. This proficiency testing program (PTP) supplements previous SARS-CoV, MERS-CoV and other coronaviruses PTP.

There are different types of nucleic acid tests that can be used to detect SARS-CoV-2 viral RNA, including reverse transcriptase (RT) polymerase chain reaction (PCR) and isothermal nucleic acid amplification tests (e.g., loop-mediated isothermal amplification (LAMP) tests). PCR tests are generally considered better at detecting the presence of the SARS-CoV-2 virus and are currently the gold standard for diagnosis of COVID-19.

PCR assays typically take several hours (including specimen processing time) to generate results and require complex laboratory equipment and trained technicians. There are now some near patient SARS-CoV-2 PCR instruments available that can be used outside of a laboratory. These systems can provide quicker results but cannot do as many tests at once.

Consecutive negative PCR tests in a previously positive individual are currently being used as criteria when considering release from isolation in certain cases. However, this may change with increasing knowledge around SARS-CoV-2. National guidelines for public health units can be found on the Department of Health's website(link is external).

The Peter Doherty Institute for Infection and Immunity has completed a validation study of the Beijing Genomics Institute SARS-CoV-2 Real time PCR test kit and associated instrumentation and reagents(link is external).

The general public may find the following website really useful; it provides advice about testing for coronavirus (COVID-19) in Queensland. It is aptly titled *Everything you ever wanted to know about testing for coronavirus (COVID-19) in Queensland,* found here.

The PCR Sensitivity/cycle thresholds vary depending on the commercial or IVD assay used. Please refer to each of the commercial assays listed in 3b.

The cycle threshold (CT) is an important metric in understanding the PCR test for detection of the virus which causes COVID 19 . The more virus present, the lower the CT. The upper limit of a CT value which is considered a positive test is specified by the manufacturers of commercial PCR tests and the exact value can vary slightly. Where tests are developed in house, a careful evaluation is conducted before the test is used for patient diagnosis.

Most patients with the recent onset of symptoms have a low cycle threshold with little doubt regarding the validity of the test.
High CT values may reflect early infection, late infection or sometimes a false positive result. Clinicians look at the whole picture (history and examination of the patient, epidemiology, antibody response) in order to establish what is the likely scenario. High CT values at the limit of detection of the test are not common.

All testing is performed within the approved Pathology Queensland Laboratory Information System (LIS) within Queensland Health in line with Queensland Health and Queensland Government guidelines. Access to information is controlled as per https://www.health.qld.gov.au/__data/assets/pdf_file/0027/439164/doh-privacy-plan.pdf

https://www.health.gov.au/resources/publications/phln-guidance-on-laboratory-testing-for-sars-cov-2-the-virus-that-causes-covid-19

There is a different testing protocol depending on the testing method as listed below.

All testing protocols are performed to the manufactures requires as per TGA and Australian NATA Requirements for Accreditation.

What is the current cycle threshold used in our PCR testing?

The PCR sensitivity/cycle thresholds vary depending on the commercial or in vitro diagnostic device (IVD) assay used. The commercial assays used by Pathology Queensland for SAR-CoV-2 testing are listed below. Specific information about each assay can be found on the manufacturer's webpage.

Manufacturer	Australian sponsor	Name of test	Date approved for supply
Cepheid (USA)	Cepheid Holding Pty Ltd	Xpert®Xpress SARS-CoV-2	22/03/20
Roche Molecular Systems Inc (USA)	Roche Diagnostics Australia Pty Ltd	cobas® SARS-CoV-2	20/03/20
Hologic Inc (United States of America)	Hologic (Australia & New Zealand) Pty Ltd	Aptima® SARS-CoV-2	29/06/20
Hologic Inc (United States of America)	Hologic (Australia & New Zealand) Pty Ltd	Panther Fusion® SARS-CoV-2	20/03/20
BGI Europe A/S (Denmark)	BGI Health (AU) Company Pty Ltd	Real-time fluorescent RT-PCR kit for detecting SARS-CoV-2	10/04/20
Abbott Molecular Inc (United States of America)	Abbott Australasia Pty Ltd Molecular Division	Alinity m SARS-CoV-2 AMP Kit	27/08/20

Where is the scientific evidence that states that PCR is an effective "diagnostic" tool given that the higher the cycle the more false positives are registered?

Please be assured that testing for SARS-CoV-2 in all Australian states and territories, including Queensland, is consistent with the expert advice of the Public Health Laboratory Network (PHLN) and Communicable Diseases Network Australia (CDNA). This advice is based on analysis of all of the available scientific evidence and is continually updated as further information about the virus emerges over the course of the pandemic.

Further information about these expert advisory groups and their publications about SARS-CoV-2 testing and management can be found at the following links

Department of Health | Overview of the Public Health Laboratory Network (PHLN)

Department of Health | Communicable Diseases Network Australia (CDNA)

Their advice is consistent with World Health Organisation (WHO) advice and is regularly updated. For example, the WHO link provided in your email relates to the issue of potential false negative and false positive test outcomes when using reverse transcriptase polymerase chain reaction (RC-PCR) testing. The PHLN's publication *Public Health Laboratory Network Guidance on Nucleic Acid Test Result Interpretation for SARS-CoV-2* provides a comprehensive summary of this issue, and is available for your review at:

https://www.health.gov.au/resources/publications/phln-guidance-on-nucleic-acid-test-result-interpretation-for-sars-cov-2

Overview of diagnostic testing for SARS-CoV-2

Diagnostic testing for SARS-CoV-2 (the virus that causes COVID-19) is vital to containing the COVID-19 pandemic in Australia. Nucleic acid tests (NAT), predominantly reverse transcriptase polymerase chain reaction (RT-PCR), are the primary methods used to detect SARS-CoV-2 in Australia. It is also the benchmark for acute diagnosis of COVID-19 infection. There is a range of NAT used in Australian laboratories, including:

- In-house and commercial assays;
- Assays targeting different parts of the SARS-CoV-2 genome, including the N gene, E gene, S gene, RdRp gene and Orf-1ab gene;
- Single gene target assays, or assays that detect multiple SARS-CoV genes in one test.

SARS-CoV-2 NAT Reporting

Due to the range of commercial and in-house RT-PCR tests available and the different viral genome targets for each, several reporting outcomes from a RT-PCR test for SARS-CoV-2 test are possible.

- Positive or detected:
  - the detection of SARS-CoV-2-specific target
- Negative or not detected:
  - no detection of SARS-CoV-2-specific target
- Presumptive positive:
  - Several commercial and in-house RT-PCR tests for SARS-CoV-2 include both Sarbeco subgenus and SARS-CoV-2-specific targets.
  - The Sarbeco subgenus includes SARS-CoV-2, SARS-CoV-1 and several bat-derived SARS-like viruses.
  - Several commercial assays report the combination of a Sarbeco target detection with a negative SARS-CoV-2-specific target as a presumptive positive.
  - As it is extremely unlikely SARS-CoV-1 or other SARS-like bat viruses are circulating in the human population, a presumptive positive report most likely indicates SARS-CoV-2 detection.
  - Sarbeco subgenus only detections are most commonly found when the amount of SARS-CoV-2target is near the lower limit of detection for the assay.
- Indeterminate or equivocal:
  - Testing has produced discrepant results that cannot be resolved as either a negative or positive despite repeat or further testing of the sample (e.g. testing using a different RT-PCR assay or genetic sequencing).
  - In this situation, the sample may be sent to a reference laboratory for further testing and a repeat sample collection is recommended.
- Invalid:

- There has been a failure of one or more test's internal controls, such as inhibition of the PCR reaction.
  - In this situation, a repeat sample collection is recommended.

Test performance of SARS-CoV-2 RT-PCR

PCR assays are extraordinarily high-fidelity assays which are designed for maximal sensitivity and minimal off-target reactivity that benefit from a design process. This includes accurate in silico design of PCR primers and probes and use of extensive databases to identify high-fidelity target sequences with minimal potential off-target interactions. The formats used for PCR enhance fidelity, such as the use of nested, or hemi-nested PCR formats, or formats that include binding of a target-specific probe, potentially boosts specificity. The use of multiple gene targets within the same test, or reflex testing of positives samples with a second PCR test using a different gene target also increases specificity. Cumulatively, all these factors contribute to high specificity and make PCR assays the highest fidelity assays used in infectious disease diagnostics. Although PCR tests are the most accurate tests for detection of SARS-CoV-2, no test has 100% sensitivity or specificity in all clinical circumstances. Australian laboratories performing NAT are required to:

- implement the National Pathology Accreditation Advisory Council's (NPAAC) Requirements for Medical Testing of Microbial Nucleic Acids quality framework. This includes procedures to minimise the risk of false positive and false negative tests,
- document procedures for reviewing suspected incorrect results, and
- retain records documenting contamination including the identified source of contamination (if known), and measures taken to reduce the risk of such events in the future.

Analytical accuracy of the PCR is therefore very high but clinical accuracy of the PCR is a function of the prevalence of SARS-CoV-2 in the population being tested. A higher prevalence of SARS-COV-2 in the population, increases the pretest probability and the likelihood for detecting SARS-COV-2 RNA. This is reflected in a higher positive predictive value for the test. Conversely, even a very specific test will have a reduced positive predictive value if the population being tested has a very low prevalence of SARS-CoV-2. For example, if a test with a specificity of 99% is used to test symptomatic passengers on a cruise ship where the likelihood of infection is 50%, the positive predictive value is 99% (i.e. for every 100 people with a positive test result, 99 people will have SARS-CoV-2 infection but 1 person without infection will have a false positive result). However, using the same test, if a low risk asymptomatic population is tested where the likelihood of infection is 5 in 10,000 (i.e. 0.05%), the positive predictive value is 4.3% (i.e. for every 100 people with a positive test result, four to five will have SARS-CoV-2 infection but 95-96 people without infection will have a false positive result).
The SARS-CoV-2 RT-PCR tests used in Australia have very high specificities and the strategy of using a second and/or third SARS-CoV-2 PCR assay with different gene targets increases the specificity of the PCR even further. The combined SARS-CoV-2

PCR testing experience of the PHLN laboratories is that the false positive rate is extremely low.
Test performance can be measured by:

- Analytical sensitivity (the ability of the test to detect a pathogen when it is present).
- Analytical specificity (the ability of a test to be negative when a pathogen is not present).
- Clinical sensitivity (the proportion of people with infection who will have a positive test).
- Clinical specificity (the proportion of people without the infection who will have a negative test).

Clinical sensitivity

All PCR tests have a lower limit of detection for SARS-CoV-2, below which they will return a negative result. The amount of virus in a SARS-CoV-2 infected patient's upper respiratory tract increases over several days before symptom onset to peak around the time of COVID-19 illness onset, and then reduce through the first week of illness. Upper respiratory tract specimens often become PCR negative toward the end of the first week of COVID-19 illness, but some remain PCR positive for several more weeks and a few remain PCR positive, usually with high cycle threshold (Ct) values, for several months. Therefore, a SARS-CoV-2 PCR test can be negative despite a person being symptomatic with COVID-19 and the longer into the illness, the more likely the SARS-CoV-2 PCR will be negative. Also, when the amount of virus in the sample is near the limit of detection for the SARS-CoV-2 RT-PCR test, the result is very dependent on the sampling site and technique. Therefore, either a positive, presumptive positive, indeterminate or negative result can be recorded for the sample, or differing PCR results can be found between different samples.

False negative and false positive SARS-CoV-2 RT-PCR results

PHLN emphasises the likelihood of false positive and false negative results occurring is very low. Within the laboratory, false positive and false negative results may not always be easily identified, and laboratory staff, clinicians and/or public health physicians should remain vigilant. Indicators of false positive and false negative results include:

- discrepant clinic-epidemiological findings;
- unexpected laboratory results (such as when an entire batch of or consecutive samples test positive);
- erroneous results from external quality assurance programs;
- warnings from diagnostic companies about potential contaminated assays or reagents; or
- when supplemental NATs or other diagnostics tests such as genomic sequencing or serology do not concur with the initial NAT result.

Sensitivity data from package inserts for

1. **Cobas 6800** 2. **Panther EUA/TMA and 3. GeneXpert**

- **cobas® SARS-CoV-2** – see below copied from package insert i.e. sections on analytical sensitivity and clinical evaluation.

Analytical sensitivity using cultured virus serially diluted to determine limit of detection - see below (TCID=tissue culture infectious dose)

As shown in Table 10, the concentration level with observed hit rates greater than or equal to 95% were 0.009 and 0.003 $TCID_{50}$/mL for SARS-CoV-2 (Target 1) and pan-Sarbecovirus (Target 2), respectively. As shown in Table 11, th Probit predicted 95% hit rates were 0.007 and 0.004 $TCID_{50}$/mL for SARS-CoV-2 (Target 1) and pan-Sarbecovirus (Target 2), respectively.

Clinical evaluation
"100 individual negative clinical samples and 50 contrived positive clinical samples"

Performance against the expected results are:
Positive Percent Agreement 50/50 = 100% (95% CI: 86.7% - 100%)
Negative Percent Agreement 100/100 = 100% (95% CI: 96.3% - 100%)

- **SARS-CoV-2 Assay (Panther Fusion® System)**

Panther Fusion SARS-CoV-2 Assay Performance

Analytical Sensitivity

The analytical sensitivity (limit of detection or LoD) of the Panther Fusion SARS-CoV-2 Assay was determined by testing serial dilutions of pooled negative clinical nasopharyngeal swab specimens spiked with inactivated cultured SARS-CoV-2 virus (USA-WA1/2020; BEI Resources; NR-52281). Ten replicates of each serial dilution were evaluated using two assay reagent lots across two Panther Fusion systems. The LoD was determined to be $1x10^{-2}$ $TCID_{50}$/mL and verified by testing an additional 20 replicates with one assay reagent lot.

Clinical Performance
The clinical performance of the Panther Fusion SARS-CoV-2 Assay was evaluated in comparison to a panel of contrived specimens. For the study, a panel of 178 remnant clinical
nasopharyngeal specimens was tested using two Panther Fusion SARS-CoV-2 Assay reagent
lots. All specimens were collected from US patients with signs and symptoms of respiratory
infection. The panel consisted of 69 SARS-CoV-2 positive and 109 SARS-CoV-2 negative

specimens. Of the 69 positive specimens, 45 were at concentrations 1-2x LoD and 24 were at
concentrations 3-5x LoD using inactivated cultured SARS-CoV-2 virus (USA-WA1/2020; BEI
Resources; NR-52281) as the target.

Table 4: Panther Fusion SARS-CoV-2 Performance Relative to Expected Results

		Contrived Specimen Expected Result	
		Positive	Negative
Panther Fusion SARS-CoV-2 Assay	Positive	69	0
	Negative	0	109

Positive Percent Agreement: 100% (94.7% – 100%)
Negative Percent Agreement: 100% (96.6% – 100%)
Overall Agreement: 100% (96.6% – 100%)

- **Aptima SARS-CoV-2 Assay (Panther System)**

Panther SARS-CoV-2 Assay Performance

Analytical Sensitivity

The analytical sensitivity (limit of detection or LoD) of the Aptima SARS-CoV-2 assay was determined by testing serial dilutions of pooled negative clinical nasopharyngeal swab specimens spiked with inactivated cultured SARS-CoV-2 virus (USA-WA1/2020; BEI Resources; NR-52281). Ten replicates of each serial dilution were evaluated using each of two assay reagent lots across two Panther systems. The LoD was determined to be 0.01 $TCID_{50}$/mL and verified by testing an additional 20 replicates with one assay reagent lot. The LoD was also confirmed using saline, Liquid Amies and specimen transport medium (STM) swab collection media.

Clinical Performance

The clinical performance of the Aptima SARS-CoV-2 assay was evaluated in comparison to the Panther Fusion SARS-CoV-2 assay (Hologic, Inc.) using a panel of remnant clinical specimens. For the study, 105 remnant clinical nasopharyngeal specimens were collected from US patients with signs and symptoms of respiratory infection. One replicate from 55 negative and 50 positive specimens for SARS-CoV-2 were tested with both the Aptima and Panther Fusion assays.

The Positive Percent Agreement (PPA) and Negative Percent Agreement (NPA) was calculated in relation to the Panther Fusion assay as the reference result, as shown in Table 3. The Aptima SARS-CoV-2 assay showed positive and negative agreements of 100% and 98.2%, respectively.

Table 3: Aptima SARS-CoV-2 Clinical Agreement

		Panther Fusion SARS-CoV-2 Assay	
		Positive	Negative
Aptima SARS-CoV-2 Assay	Positive	50	1
	Negative	0	54

Positive Percent Agreement: (95% CI): 100% (92.9% – 100%)
Negative Percent Agreement: (95% CI): 98.2% (90.4% – 99.7%)
Overall Agreement: (95% CI): 99.0% (94.8% – 99.8%)

- **Cepheid Xpert Xpress SARS-CoV-2 – GeneXpert**

Published : https://jcm.asm.org/content/jcm/early/2020/04/17/JCM.00772-20.full.pdf

Note that where the abstract refers to “lowest limit of detection” this refers to be able to detect the lowest viral load. i.e. ‘the Xpert Xpress had the lowest limit of detection (100% detection at 100 copies/mL), followed by 26 the ePlex (100% detection at 1,000 copies/mL), and the ID NOW (20,000 copies/mL)’

Results include following

Clinical performance
Clinical testing was performed on 108 retrospective and prospective clinical specimens and was compared to the reference standard. The Xpert Xpress demonstrated a PPA of 98.3%, followed by the
ePlex at 91.4% and the ID NOW at 87.9%. NPA was also calculated and was 100% for each platform evaluated (Table 2). One sample was invalid on the ID NOW and was not included in the calculations for this platform. When distribution of positive results was further evaluated across all three platforms, the Xpert Xpress detected a total of 57 positive results, followed by the ePlex at 53 and the ID NOW at 50. The ePlex also detected 3 positive results that were not detected by the ID NOW and the ID NOW detected 1 positive result that was not detected by the ePlex, but all 4 of these positive results were detected by the Xpert Xpress, as well as 4 additional positive results that were only detected by the Xpert Xpress. The ePlex and the ID NOW did not detect any additional results that were not detected by the Xpert Xpress. One specimen that was positive on Panther fusion was not detected on all 3 platforms.
A total of eight discordant samples were found among the three sample-to-answer platforms evaluated, with ID NOW having the most discordant results (n=7), followed by the ePlex (n=5), and the Xpert Xpress (n=1). All discordant results were negative results as compared to a positive result from the reference method. When evaluating cycle threshold (Ct) values obtained from the reference method, A-24, which was the only discordant specimen by the Xpert Xpress assay, had a Ct value of 38.5, which would be considered a low viral load positive specimen. The ePlex exhibited negative

results with specimens that had Ct values ranging from 33.1- 38.5, while the ID now ranged 32- 38.5 (Table 3).

- **Abbreviations and definitions**
- COVID-19: Coronavirus disease 2019. The name of the disease caused by the virus SARS-CoV-2, as agreed by the World Health Organization, the World Organisation for Animal Health and the Food and Agriculture Organization of the United Nations. For more information, refer to the World Health Organization Director-General's remarks: (https://www.who.int/dg/speeches/detail/who-director-general-s-remarks-at-the-media-briefing-on-2019-ncov-on-11-february-2020)
- SARS-CoV-2: Severe acute respiratory syndrome coronavirus 2. The formal name of the coronavirus that causes COVID-19, as determined by the International Committee on Taxonomy of Viruses. Previously, this coronavirus was commonly known as 'novel coronavirus 2019 (2019-nCoV)'. For more information, refer to the Consensus Statement of the Coronaviridae Study Group of the International Committee on Taxonomy of Viruses.

Definition

Confirmed case

A confirmed case requires laboratory definitive evidence.

Laboratory definitive evidence:

1. Detection of SARS-CoV-2 by nucleic acid testing[1];

   OR

2. Isolation of SARS-CoV-2 in cell culture, with confirmation using a nucleic acid test;

   OR

3. SARS-CoV-2 IgG seroconversion or a significant increase in SARS-CoV-2 neutralising or IgG antibody level (e.g. four-fold or greater rise in titre)[2].

Saliva Background

Saliva sampling for COVID-19 NAT(nucleic acid testing)has been considered by the Public Health Laboratory Network (PHLN), noting its advantages and disadvantages. Saliva testing for SARS-CoV-2 has been technically validated in numerous studies. Patients in saliva sample validation studies are often known positive inpatients hospitalised for COVID-19, and data on mild or asymptomatic cases is uncertain. Evaluation of saliva sample use has two components: •Validating NAT on saliva samples across multiple platforms. •Validating the sampling methods for saliva, including in-laboratory processing with VTM (viral transport medium) or other diluents. The techniques for saliva sample collection may vary across the studies but a consistent, uniform process has been established in Pathology QLD. Analysis Collection of saliva may be problematic in some groups such as young children or frail elderly, but possibly less so than nasal and oral swabs. Saliva sample positive test rates are 13-15 per cent less than matched swab samples. These data are derived from studies accessing known positive patients often with high viral load. This means that 13-15 per cent of infected patients are not detected by saliva sampling alone. The impact of this detection concern has not been addressed in cases with a low viral load.

At the current time, rates of infection remain low in QLD, which means the impact of false negatives missing infrequent new positive cases is an important consideration. This therefore supports higher frequency of testing using this less sensitive diagnostic methodology. Therefore, the general principle would be to use less sensitive diagnostic methodologies more frequently to remedy rate of false negatives. When saliva and swab samples are obtained from a patient, and NAT performed, the saliva samples demonstrate significantly higher Ct values. This is indicative of lower viral load in saliva samples compared with matched nasal and oral swab samples. As a result, the amount of diagnostic material is less in saliva compared with nasal and oral swab samples. The significance of higher salivary Ct values in cases with low viral load has not been examined but would raise concern that false negative rates may be even higher. Saliva sample methodology for assays has not been NATA accredited and scope of accreditation has not yet been extended to any laboratories. NSWHP is however undertaking steps to comply with new NATA accreditation requirements. Performing testing of two different sample types (saliva and nasal/oral) will have impact upon laboratory workflows.
For example:
• Test codes and reporting criteria may need to be modified for different specimens.
• All these adaptations may complicate and adversely impact laboratory workflows and compromise laboratory turn-around-times (TATs).

The decision about approaches to sampling is underpinned by important considerations of consumer experience and compliance. Sample requirement is but one component for consideration and it is acknowledged that attending a clinic to provide a saliva sample maybe more palatable than “gold standard” upper respiratory tract swabbing.

Saliva Recommendation

Pathology Queensland recommends cautious acceptance of saliva sampling for COVID-19 testing ONLY in public health indicated circumstances.

Quarantine Testing and Antigen Testing

- We have moved to daily testing for our quarantine staff on saliva as daily NPA testing is unacceptable
- Weekly NPAs are still done
- Saliva is a less sensitive sample compared to an NPA
- We accept some loss of sensitivity for saliva as repeated testing increases sensitivity
- PCR testing of both saliva and NPA samples for quarantine staff is being done with acceptable TATs under 24 hours and is logistically manageable for the state
- PCR is the gold standard currently in use on NPA and saliva samples for quarantine staff
- There are many different rapid antigen testing kits with various sensitivities, specificities, costs and ease of use
- Rapid antigen tests are currently being validated in Queensland on NPA samples
- Validation will need to be done on saliva if they are to be used on these samples
- Validation studies are hampered by the low number of positives

Rapid Diagnostic test development

- Genxpert Rapid PCR testing platforms can provide a result for COVID within 2 hours
- These platforms test for viral genetic material
- These systems are placed in all public laboratories and many private laboratories in Queensland
- These systems are also in various remote clinics under care of the Kirby Institute in Queensland
- Rapid antigen testing kits are currently being investigated for utility and sensitivity by Pathology Queensland
- These kits test the the presence of the viral particles in samples
- These kits are not yet in use in Queensland
- The sensitivity of these kits is variable and is not at the level of PCR testing
- These kits would have a useful nice role Public Health physicians in outbreak management in a remote or disaster situation and would need confirmation.
- A CHO Directive is currently being developed on the use of such kits

- Pathology Queensland will continue to monitor and test any other new diagnostics as they become available

Rapid Antigen Kits

PHLN Documentation
https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwjVgZSUw_LuAhWkguYKHWxmAaoQFjABegQIBBAD&url=https%3A%2F%2Fwww.rcpa.edu.au%2FLibrary%2FCOVID-19-Updates%2FCOVID-19-Useful-Resources%2FDocs%2FPHLN-Communicable-Diseases-Network-Australia-Joint&usg=AOvVaw0ffgo_U-jbE0zCmuXo1jJS
RCPA Documentation
https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwiBmaTQxvLuAhU2wjgGHRFDBV8QFjACegQIBBAC&url=https%3A%2F%2Fwww.rcpa.edu.au%2FNews-and-Media-Releases%2FMedia-Releases%2FDocs%2FRCPA-advises-against-the-widespread-use-of-COV-(1)&usg=AOvVaw1R3f0oHV3uf2vNL3AB-Sq_

- Several Rapid antigen testing kits are currently being investigated for utility and sensitivity by Pathology Queensland
- This is challenging in the face of very few new SARS-CoV-2 cases
- These kits test for the presence of the viral proteins in respiratory samples
- These kits are not yet in use in Queensland
- The sensitivity of these kits is variable and may not at the level of RT-PCR testing – PCR testing remains the gold standard
- These kits may be appropriate for use in settings where RT-PCR is unavailable, or prolonged turnaround times preclude clinical utility.
- These kits should not be used in settings or populations with low expected prevalence of disease
- Rapid antigen tests may have a role in facilitating a rapid public health response for outbreak management in a remote or disaster situation where/if PCR testing not readily available
- Positive rapid antigen test results may be falsely positive and should be confirmed by a PCR method.
- A CHO Directive is currently being developed on the use of such kits
- We are monitoring for any new diagnostic modalities that are listed on the ARTG as TGA approved for diagnostic use in Australia, especially if they offer some material advance over existing methods. PQ will continue to work with academic collaborators to help develop new diagnostic technologies for SARS-CoV-2 wherever possible.

Evidence Pathology Queensland NATA Accreditations

NATA/RCPA ACCREDITATION NO.: 2639
FACILITY NAME: Pathology Queensland
SITE NO.: 2843
SITE NAME: Townsville Laboratory

Thank you for your submissions received 30 September and 19 October 2020, provided in response to the Desktop Variation commenced on 8 October 2020. All of the nonconformities raised in the report on the Desktop Variation have now been satisfactorily addressed. I am pleased to inform you that the accreditation of your facility has been extended to include the activities of SARS-CoV-2 testing.

Accreditation is for a period as defined in the Sixth schedule of the NATA Rules, being continued in accordance with Regulation R.32. Continuance of accreditation is dependent on adherence to the NATA Rules, and the current NATA General Accreditation Criteria, which include ISO 15189 and the NATA Specific Accreditation Criteria.

Should the Members Portal have been utilised in relation to this activity, please ensure that you have copies of documents lodged in the 'My Jobs' folder for your permanent records. The associated job folder and its contents will be removed in due course.

Scope of Accreditation

Additions

ISO 15189
Human Pathology

Service	Product	Determination	Technique	Procedure
Microbiology - Molecular biology - Detection, characterisation and/or quantitation of microbial nucleic acids (viruses)	Nasopharyngeal swabs	Severe acute respiratory syndrome *coronavirus* 2 (SARS-CoV-2)	Applied Biosystems 7500; QIAGEN OneStep RT kit; QIAGEN QIAgility; QIAGEN Rotor-Gene Q; Roche MagNA Pure 96	Documented in-house procedures using RT-PCR

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Accreditation NO. 2639
SITE NO. 2632
FACILITY NAME: Pathology Queensland
SITE NAME: Central Laboratory - SARS-CoV-2 CCDC Assay

Thank you for your submission, received 11 December 2020, provided in response to the Desktop Variation, at the above facility on 15 November 2020.

Your submission has been reviewed and found to be satisfactory. A recommendation to continue accreditation will now be made by the Accreditation Advisory Committee and formal notification of the outcome provided by separate correspondence.

If you have any queries, please do not hesitate to contact me.

Yours sincerely

NATA/RCPA Accreditation No.: 2639
Facility Name: Pathology Queensland

Thank you for your final submission(s), received on 24 November 2020, provided in support of your application to extend your scope of accreditation. I am pleased to inform you that the accreditation of your facility has been extended as outlined below.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) at the following sites (site number in brackets):

- Central Laboratory (Site No: 2632)
- Bundaberg Hospital Laboratory (Site No: 14632)
- Caboolture Laboratory (Site No: 13037)
- Cairns Laboratory (Site No: 3053)
- Charleville Laboratory (Site No: 12544)
- Dalby Laboratory (Site No: 9840)
- Emerald Hospital Laboratory (Site No: 14635)
- Gold Coast University Hospital Laboratory (Site No: 5277)
- Gladstone Hospital Laboratory (Site No: 9444)
- Gympie District Laboratory (Site No: 9559)
- Hervey Bay Hospital Laboratory (Site No: 14631)
- Ipswich Hospital Laboratory (Site No: 2460)
- Kingaroy Hospital (Site No: 14390)
- Logan Hospital Laboratory (Site No: 12634)
- Longreach Hospital Laboratory (Site No: 12543)
- Mackay Base Hospital Laboratory (Site No: 9905)
- Mt Isa Laboratory (Site No: 9891)
- Nambour Laboratory (Site No: 5485)

NATA/RCPA Accreditation No.: 2639
Facility Name: Pathology Queensland
Site No.: 2632
Site Name: Central Laboratory

Thank you for your final submission, received 10 December 2020, provided in support of your application to extend your serology scope of accreditation to include severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) using the Roche Cobas 6800. I am pleased to inform you that the accreditation of your facility has been extended.

Accreditation is for a period as defined in the Sixth schedule of the NATA Rules, being continued in accordance with Regulation R.32. Continuance of accreditation is dependent on adherence to the NATA Rules, and the current NATA General Accreditation Criteria, which include ISO 15189 and the NATA Specific Accreditation Criteria.

Accreditation NO. 2639
SITE NO. 2843
FACILITY NAME: Pathology Queensland
SITE NAME: Townsville Laboratory

Thank you for your submission, received 19 October 2020, provided in response to the Desktop Variation, at the above facility on 08 October 2020 - 08 October 2020.

Your submission has been reviewed and found to be satisfactory. A recommendation to extend your scope of accreditation will now be made by the Accreditation Advisory Committee and formal notification of the outcome provided by separate correspondence.

If you have any queries, please do not hesitate to contact me.

ACCREDITATION NO. 2639
SITE NO. 2632
FACILITY NAME: Pathology Queensland
SITE NAME: Central Laboratory, DTV for COVID Testing

Your submission has been reviewed and found to be satisfactory. A recommendation to grant accreditation will now be made by the Accreditation Advisory Committee and formal notification of the outcome provided by separate correspondence.

18 December 2020

Ms Mary Hardwick
Quality Manager
Pathology Queensland
Level 4, Block 7
Herston Road
ROYAL BRISBANE HOSPITAL QLD 4029
AUSTRALIA

Mary.Hardwick@health.qld.gov.au

Dear Ms Hardwick

NATA/RCPA Accreditation No.: 2639
Facility Name: Pathology Queensland

Thank you for your final submission(s), received on 24 November 2020, provided in support of your application to extend your scope of accreditation. I am pleased to inform you that the accreditation of your facility has been extended as outlined below.

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) at the following sites (site number in brackets):

- Central Laboratory (Site No: 2632)
- Bundaberg Hospital Laboratory (Site No: 14632)
- Caboolture Laboratory (Site No: 13037)
- Cairns Laboratory (Site No: 3053)
- Charleville Laboratory (Site No: 12544)
- Dalby Laboratory (Site No: 9840)
- Emerald Hospital Laboratory (Site No: 14635)
- Gold Coast University Hospital Laboratory (Site No: 5277)
- Gladstone Hospital Laboratory (Site No: 9444)
- Gympie District Laboratory (Site No: 9559)
- Hervey Bay Hospital Laboratory (Site No: 14631)
- Ipswich Hospital Laboratory (Site No: 2460)
- Kingaroy Hospital (Site No: 14390)
- Logan Hospital Laboratory (Site No: 12634)
- Longreach Hospital Laboratory (Site No: 12543)
- Mackay Base Hospital Laboratory (Site No: 9905)
- Mt Isa Laboratory (Site No: 9891)
- Nambour Laboratory (Site No: 5485)

NEW SOUTH WALES & ACT
7 Leeds St
Rhodes NSW 2138
P O Box 7507
Silverwater NSW 2128
Tel: 02 9736 8222

VICTORIA & TASMANIA
2-6 Railway Parade
Camberwell
VIC 3124
Tel: 03 9274 8200

QUEENSLAND
628 Ipswich Road
Annerley Qld 4103
P O Box 1122
Archerfield BC QLD 4108
Tel: 07 3721 7300

SOUTH AUSTRALIA & NT
Level 1,
203 Fullarton Road
Eastwood 5063
Tel: 08 8179 3400
Fax: 08 8179 3498

WESTERN AUSTRALIA
Business Centre
Suite 7
2A Brodie Hall Drive
Bentley WA 6102
Tel: 08 9486 2800

Freecall: 1800 621 666

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- Princess Alexandra Laboratory (Site No: 2325)
- Queensland Children's Hospital Laboratory (Site No: 22632)
- QE II Hospital Laboratory (Site No: 14634)
- Redcliffe Laboratory (Site No: 13036)
- Redland Hospital Laboratory (Site No: 14629)
- Robina Laboratory (Site No: 15037)
- Rockhampton Base Hospital Laboratory (Site No: 2658)
- Roma Laboratory (Site No: 12542)
- Sunshine Coast Laboratory (Site No: 23958)
- Thursday Island Hospital Laboratory (Site No: 12644)
- Toowoomba Laboratory (Site No: 2406)
- Townsville Laboratory (Site No: 2843)
- The Prince Charles Hospital Laboratory (Site No: 2570)
- Warwick Laboratory (Site No: 10798)

Testing for *Influenza A virus*, *Influenza B virus* and *Respiratory syncytial virus* (RSV) by Cepheid GeneXpert Xpress at the following sites only:

- Dalby Laboratory (Site No: 9840)
- Nambour Laboratory (Site No: 5485)
- Roma Laboratory (Site No: 12542)

Accreditation is for a period as defined in the Sixth schedule of the NATA Rules, being continued in accordance with Regulation R.32. Continuance of accreditation is dependent on adherence to the NATA Rules, and the current NATA General Accreditation Criteria, which include ISO 15189 and the NATA Specific Accreditation Criteria.

Should the Members Portal have been utilised in relation to this activity, please ensure that you have copies of documents lodged in the 'My Jobs' folder for your permanent records. The associated job folder and its contents will be removed in due course.

Membership fees

Due to the scope extension at the Roma, Dalby and Nambour Laboratories your annual fee charges have been amended to increase by 0.25 units per site. All other sites have a sufficient microbiology scope of accreditation to absorb the ongoing assessment effort required to reassess this extension to scope.

A pro rata invoice will be forwarded to cover the additional charges shortly.

NPAAC Category

There is no change to the NPAAC category.

Scope of Accreditation

The following has been added to the scope of accreditation of the Central Laboratory and all of the laboratories listed above:

Service	Product	Determination	Technique	Procedure
Microbiology - Molecular biology - Detection, characterisation and/or quantitation of microbial nucleic acids (viruses)	Nasal swabs; Nasopharyngeal swabs	Severe acute respiratory syndrome *Coronavirus* 2 (SARS-CoV-2)	Cepheid GeneXpert Xpress	Manufacturer's published procedures

The following has also been added to the scope of accreditation of the Dalby, Nambour and Roma Laboratories only:

Service	Product	Determination	Technique	Procedure
Microbiology - Molecular biology - Detection, characterisation and/or quantitation of microbial nucleic acids (viruses)	Nasal swabs; Nasopharyngeal swabs	*Influenza A virus*; *Influenza B virus*; *Respiratory syncytial virus* (RSV)	Cepheid GeneXpert Xpress	Manufacturer's published procedures

Each scope of accreditation will be available on the NATA website within one business day of this letter.

Please note that as previously advised and as outlined in the NATA Fee Schedule, the facility will be charged for this activity required to review the application for RSV and Flu at Dalby, Roma and Nambour. Invoices can be identified by the job number 78493.

The application for SARS-CoV-2 at all sites listed above has been conducted as a non-chargeable activity.

Next Visit Type

The Central Laboratory is next scheduled for a surveillance in February 2022, in line with the agreed Corporate Surveillance Plan for Pathology Queensland.

Endorsement of Reports

We continue to encourage you to apply the NATA endorsement to your reports whenever possible. This will enhance the standing of your facility with your clients and help to

promote increased recognition of accreditation and NATA throughout the community. If you have any queries about the most appropriate means of reproducing the NATA endorsement or material for advertising your NATA accreditation, please contact NATA Communications on 1800 621 666.

Reports issued by your facility may also include the Accredited CAB Combined ILAC MRA Mark. To apply for the Mark, please contact NATA's Quality Manager in our Melbourne office.

The correct use of the NATA/RCPA endorsement is included in the current edition of NATA's *Rules* which are available on the NATA website.

Authorised Representative

Your rights and responsibilities as your facility's Authorised Representative are stated in the Association's Rules. Copies of these and other appropriate publications, e.g. the Charter of Service and *NATA General Accreditation Criteria: Responsibilities of Authorised Representatives* are available from the NATA website www.nata.com.au.

At this time I take the opportunity to remind you that you are our point of contact with your organisation and hence our source of formal advice regarding your organisation. I therefore ask you to advise the Association within 14 days if:

- the name or ownership of the laboratory changes;
- changes in duties or departures of key staff occur; or
- significant changes occur to the functions or accommodation of the laboratory.

I also remind you that on behalf of the accredited facility, you are responsible for ensuring that all NATA's Accreditation Criteria continue to be met including:

- NATA's requirements for the content and endorsement of report documents;
- that the NATA emblem is not misused;
- all fees and charges are promptly paid.

NATA also enters into agreements with other parties. Where NATA has an agreement with or from the Commonwealth or a State Government or where the Association is engaged in accreditation in conjunction with or on behalf of one or more other Stakeholders, NATA may pass information otherwise privileged under the NATA Rules, to the party concerned. Additionally, agreements may contain other obligations/undertakings of NATA which may have an impact on your facility. The following are given as examples of such agreements.

Agreement	Party/ies	Scope
Memorandum of Understanding	State of Tasmania	Facilities accredited by NATA, public or private, and conducting testing, measurement, inspection or related activities for the State of Tasmania.
Memorandum of Understanding	State of Victoria	Facilities accredited by NATA, public or private, and conducting testing, measurement, inspection or related activities, Reference Material Producers, Proficiency Testing Scheme Providers for the State of Victoria.
Memorandum of Understanding	Dept of Industry, Innovation, Climate Change, Science, Research and Tertiary Education	Concerns raised by the Commonwealth agencies with regard to facilities accredited by NATA or NATA's MRA Partners.

A full listing of agreements and the obligations/undertakings placed on NATA by the agreement in question can be viewed on the NATA website by clicking on the *About Us tab/Structure/Formal* Agreements. You should be aware that the contents of one or more of these agreements may be relevant to your accreditation(s).

On behalf of NATA, may I take this opportunity to thank you and your staff for the cooperation and hospitality during the recent visit to your facility. If you have any queries with the information contained in this letter please contact your client coordinator s.47(3)(b) s.47(3)(b) at our Sydney office.

Yours sincerely

s.47(3)(b)

for
Jennifer Evans
CHIEF EXECUTIVE OFFICER

National Association of Testing Authorities, Australia

15 December 2020

Ms Mary Hardwick
Quality Manager
Pathology Queensland
Level 4, Block 7
Herston Road
ROYAL BRISBANE HOSPITAL QLD 4029
AUSTRALIA

Mary.Hardwick@health.qld.gov.au

Dear Ms Hardwick

NATA/RCPA Accreditation No.: 2639
Facility Name: Pathology Queensland
Site No.: 2632
Site Name: Central Laboratory

Thank you for your final submission, received 10 December 2020, provided in support of your application to extend your serology scope of accreditation to include severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) using the Roche Cobas 6800. I am pleased to inform you that the accreditation of your facility has been extended.

Accreditation is for a period as defined in the Sixth schedule of the NATA Rules, being continued in accordance with Regulation R.32. Continuance of accreditation is dependent on adherence to the NATA Rules, and the current NATA General Accreditation Criteria, which include ISO 15189 and the NATA Specific Accreditation Criteria.

Should the Members Portal have been utilised in relation to this activity, please ensure that you have copies of documents lodged in the 'My Jobs' folder for your permanent records. The associated job folder and its contents will be removed in due course.

Membership fees

There is no change to your annual membership fees as a result of this activity.

NPAAC Category

There is no change to the NPAAC category.

NEW SOUTH WALES & ACT
7 Leeds St
Rhodes NSW 2138
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Silverwater NSW 2128
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VICTORIA & TASMANIA
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VIC 3124
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QUEENSLAND
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Annerley Qld 4103
P O Box 1122
Archerfield BC QLD 4108
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SOUTH AUSTRALIA & NT
Level 1,
203 Fullarton Road
Eastwood 5063
Tel: 08 8179 3400
Fax: 08 8179 3498

WESTERN AUSTRALIA
Business Centre
Suite 7
2A Brodie Hall Drive
Bentley WA 6102
Tel: 08 9486 2800

Freecall: 1800 621 666

www.nata.com.au

Scope of Accreditation

The following has been added to your scope of accreditation:

Service	Product	Determination	Technique	Procedure
Microbiology - Serology of infection - Microbial antibody and/or antigen detection and/or quantitation	Nasopharyngeal swabs; Oropharyngeal swabs	Severe acute respiratory syndrome *Coronavirus* 2 (SARS-CoV-2)	Roche Cobas 6800; Roche Cobas SARS-CoV-2	Manufacturer's published procedures

Your scope of accreditation will be available on the NATA website within one business day of this letter.

Next Visit Type

This testing will be reviewed at the next routine assessment of your laboratory, in line with the agreed Corporate Surveillance Plan for Pathology Queensland.

Endorsement of Reports

We continue to encourage you to apply the NATA endorsement to your reports whenever possible. This will enhance the standing of your facility with your clients and help to promote increased recognition of accreditation and NATA throughout the community. If you have any queries about the most appropriate means of reproducing the NATA endorsement or material for advertising your NATA accreditation, please contact NATA Communications on 1800 621 666.

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Memorandum of Understanding	State of Victoria	Facilities accredited by NATA, public or private, and conducting testing, measurement, inspection or related activities, Reference Material Producers, Proficiency Testing Scheme Providers for the State of Victoria.
Memorandum of Understanding	Dept of Industry, Innovation, Climate Change, Science,	Concerns raised by the Commonwealth agencies with regard to facilities

	Research and Tertiary Education	accredited by NATA or NATA's MRA Partners.

A full listing of agreements and the obligations/undertakings placed on NATA by the agreement in question can be viewed on the NATA website by clicking on the *About Us tab/Structure/Formal* Agreements. You should be aware that the contents of one or more of these agreements may be relevant to your accreditation(s).

On behalf of NATA, may I take this opportunity to thank you and your staff for the cooperation and hospitality during the recent visit to your facility. If you have any queries with the information contained in this letter please contact your client coordinator s.47(3)(b) s.47(3)(b) at our Sydney office.

Yours sincerely

s.47(3)(b)

for
Jennifer Evans
CHIEF EXECUTIVE OFFICER