

Aboriginal and Torres Strait Islander COVID-19 Point-of-Care Testing Program Guideline

In collaboration with the Australian Government Department of Health, Kirby Institute, UNSW, Sydney and Flinders University International Centre for Point-of-care Testing (ICPOCT)

1 Background

The Program

The Aboriginal and Torres Strait Islander COVID-19 Point-of-Care (POC) Testing Program (the Program) enables on-site testing for COVID-19 to occur in remote health services where laboratory-based pathology testing is limited or where significant delays in time to results exist.

The Program, funded by the Australian Government Department of Health, led by the Kirby Institute and ICPOCT, aims to provide a tool to improve public health responses, reduce transmission and morbidity in these remote communities.

Purpose

To provide Primary Health Care staff with a guideline on the management of POC testing specific to COVID-19 using the Xpert® Xpress SARS-CoV-2 test and utilising the Cepheid GeneXpert platform, including operator training requirements, Quality Management, maintenance and the supply of consumables.

Locations

There will be 19 GeneXpert sites in Queensland that are affiliated with the Program. These sites include hospitals, Primary Health Care Centres (PHCCs) and Aboriginal and Islander Community Controlled Health Services (AICCHSs). In addition, four sites act as 'hubs' and will process specimens from smaller sites ('spokes').

A table of GeneXpert sites are on the following page.

Queensland GeneXpert Locations

Queensland Health HHS	Health Service ('Hub' site)	'Spoke' site
Darling Downs	CRAICCHS (Cherbourg)	
Townsville	Townsville Aboriginal and Islander Health Service	
	Palm Island Hospital	
North West	Doomadgee Hospital	
	Cloncurry Hospital	
	Normanton Hospital	
	Mornington Island Hospital	
Cairns	Gurriny Yealamucka (AICCHS)	
	Wuchopperen (AICCHS)	
Torres and Cape	Pormpuraaw PHCC	
	Lockhart River PHCC	Coen
	Weipa Hospital	Napranum Mapoon
	Bamaga Hospital	
	Cooktown Hospital	Hope Vale Wujal
	Saibai Island PHCC	
	Badu Island PHCC	Mabuiag St Pauls Kubin
	Aurukun PHCC	
	Kowanyama PHCC	
	Boigu Island PHCC	

2 Procedure

2.1 Testing Criteria

Any person living in a First Nations community who meets criteria for COVID-19 testing will receive the test either as conventional polymerase chain reaction (PCR) testing or through POC PCR testing.

Suspect case

In Queensland, the state testing criteria should always be adhered to. These are constantly evolving, and all sites must ensure they have systems in place to ensure they use the most up to date version.

Prior to testing please consult with the health service's Senior Medical Officer (or equivalent).

It is expected that Xpert® Xpress SARS-CoV-2 cartridges will be limited in number and therefore use of cartridges will be prioritised. Consistent with these, it is proposed that the Aboriginal and Torres Strait Islander COVID-19 Point-of-Care (POC) Testing Program will be prioritised for:

- Individuals **meeting the suspect or probable case definition** for COVID-19 as defined in the COVID-19 Series of National Guidelines (SoNG):
 - Noting this includes clinical and epidemiological criteria
- Aboriginal and Torres Strait Islander people who meet the criteria for enhanced testing (e.g. respiratory symptoms, or unexplained fever or history of fever) and where **delays in testing or longer periods of isolation places others at higher risk of transmission** (e.g. due to overcrowded or inadequate housing). Within this category, the following could be considered as priorities:
 - Individuals who are likely to leave the community prior to a result becoming available
 - Individuals who are likely to have or have had multiple contacts e.g. where an individual is intending to attend a mass gathering before a result will be available and would be at risk of not following guidance to isolate
 - Individuals who are likely to have major barriers to **any** kind of isolation (e.g. those who have difficulty following directions due to barriers in understanding)
- **Non-Aboriginal and/or Torres Strait Islander residents and visitors to Aboriginal and/or Torres Strait Islander communities, who meet criteria for enhanced testing and have had** direct contact with community members in the 14 days prior to onset of illness (that may have resulted in disease transmission), or will need to have direct contact with community members as part of their role, where waiting for a conventional PCR test could lead to risk of service failure
- **Asymptomatic close contact** of a confirmed COVID-19 positive case upon endorsement of this approach by the Public Health Physician.
- Requests for individual inpatients or patients in ED for whom a rapid POC test PCR result would **change** clinical management.
- Other situations as deemed necessary by the local Public Health Physician.

If there is any unexpected surge requiring further sub-prioritisation within these priority groups, the site clinician will contact the local Public Health Physician for advice.

Any other person not eligible for POC PCR testing will otherwise have a conventional PCR swab collected and transported for processing at a Pathology Queensland facility.

As stated in the CDNA Interim National Guidance for remote Aboriginal and Torres Strait Islander communities for COVID-19, options for situations where GeneXpert testing is not available include urgently transporting samples through agreed systems such as drivers employed to transport samples across multiple communities on a daily run, or commercial/charter light aircrafts and pilots on standby in each region for picking up swabs on a daily basis aiming for 48 hours between pick up of sample until result availability. RFDS in Queensland also has a specific contract that supports remote communities transporting patients and swabs for COVID-19 to expedite testing and management. These conventional PCR tests should be marked urgent and the on-call pathologist at the receiving laboratory should be phoned to arrange urgent processing.

2.2 Testing a patient

- When a treating clinician identifies that a person meets COVID-19 testing criteria, they should:
 - Discuss the case with the clinic Senior Medical Officer.
 - Provide the patient with a mask.
- If the collection is occurring at a 'spoke' site, complete a pathology request form. The Senior Medical Officer or Director of Nursing (on advice of the Senior Medical Officer) can complete the form.
- A person trained in specimen collection can collect the appropriate specimen from the patient.
 - The person completing the pathology form may also be the designated person collecting the swab.
 - The person collecting the specimen must be wearing appropriate PPE.
- Following the test, advise the patient to isolate whilst awaiting their result.
- The approved point-of-care (POC) Operator processes the PCR test on the GeneXpert platform.
- Results that read as invalid, error, or no result must be repeated using the same sample in a new test cartridge.
- Write the patient's details on the 'Test results sheet' provided by the Program.
- Additional information on GeneXpert platform use can be found in the **Aboriginal and Torres Strait Islander COVID-19 POC Testing Program SOPs** located in the Useful Resource section below.

IMPORTANT DEVIATIONS FROM KIRBY STANDARD OPERATING PROCEDURES

- Health services assessing suspect patients, collecting specimens for COVID-19 testing or conducting testing should adhere to the Queensland Health [Interim infection prevention and control guidelines for the management of COVID-19 in healthcare settings](#).
- Follow the above Queensland Health guidelines (Appendix 5), or local facility procedures, for use of PPE in healthcare
 - Clearly follow the order for putting on and removing PPE.

- **Do not** dispose of any specimens.
 - All specimens must be transferred to **Queensland Forensic and Scientific Services (QFSS)** in Brisbane for storage and/or validation.
 - Clearly adhere a Scientific Services address label to the specimen bag



- **Note:** When sending a batch of specimens to the QFSS for storage, please email QFSS so that they know to expect a delivery of specimens. The contact at QFSS is Fred Moore – email Frederick.Moore@health.qld.gov.au.
- **Do not** use any PrimeStore® **MTM** specimens in Panther Fusion® System machines.

2.3 Result interpretation

Results are to be interpreted as per the Aboriginal and Torres Strait Islander COVID-19 POC Testing Program Guidelines.

Xpert [®] Xpress SARS-CoV-2 test result	Interpretation	Action
NEGATIVE	The COVID-19 virus was not detected in the sample	Follow local guidelines for a NEGATIVE COVID-19 test.
POSITIVE	The COVID-19 virus was detected in the sample	Follow local guidelines including notification process for CONFIRMED COVID-19 infections and send the remaining sample in the viral transport tube to the laboratory for storage, with relevant request form, consistent with good laboratory practice for infectious diseases.
PRESUMPTIVE POSITIVE	The COVID-19 virus may be present in the sample	Repeat the test using the same sample in a new test cartridge. <ul style="list-style-type: none"> • If repeat test is POSITIVE, follow actions above for POSITIVE results. • If repeat test is also PRESUMPTIVE POSITIVE, follow actions above for POSITIVE results. • If repeat test is NEGATIVE, collect a new nasopharyngeal swab from the patient and send both the new viral transport tube and the remaining sample in the original viral transport tube to the laboratory, with relevant request form, for testing and storage.
INVALID	Test was unsuccessful	Repeat the test using the same sample in a new test cartridge.
ERROR	Test was unsuccessful	Repeat the test using the same sample in a new test cartridge.
NO RESULT	Test was unsuccessful	Repeat the test using the same sample in a new test cartridge.

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Careful consideration and confidentiality of results is paramount to ensure a valid result is disseminated and the appropriate response ensues. Point-of-care Operators will receive training and support for actioning positive (or presumptive positive) SARS-CoV-2 GeneXpert POC results. There will be labels attached to the GeneXpert and laptop to prompt the operator to call all positive (or presumptive positive) results. The phone numbers of the on-call senior scientist will be provided on the labels

Negative result – Action

- Place the labelled, tested specimen tube in the specimen bag.
- Clearly adhere a Scientific Services address label to the specimen bag.
- Store the tested specimen in an appropriate refrigerator.
- Bulk send negative specimens to QFSS (Brisbane) for storage. (see Section on *Transfer of Specimens to QFSS* below for further information).
 - **Note:** When sending a batch of specimens to the QFSS for storage, please email QFSS so that they know to expect a delivery of specimens. The contact at QFSS is Fred Moore – email Frederick.Moore@health.qld.gov.au.

Positive or Presumptive Positive Result – Action

24 hours a day, 7 days a week

1. The POC Operator is to call the Program On-Call Senior Scientist **0434 834 269** to notify of 'Positive' or 'Preliminary Positive' POCT and provide the following information:
 - The health service name and the State, name of the operator and contact phone number.
 - Time and date of the specimen tested, the patient ID and sample ID.
 - Name and contact phone number for the responsible **Public Health Physician** for the patient in the remote community.
 - Refer to Section 4 for a list of contacts.

In a low prevalence setting, high CT values (e.g. > 37 for the N2 target), not considered a suspect case, should be interpreted with caution and POC Operator/onsite clinician may be instructed to repeat the point-of-care test on the same specimen. In some circumstances, recollection of another swab specimen may be requested.

2. The POC senior scientist and/or program clinical microbiologist (from the Program) will review the analytical data and then call to discuss the result with the responsible **Public Health Physician** and onsite clinician. This consultative process will be completed in a timely manner, as not to delay public health response and will guide further actions.
 - If there is a high CT value, the local clinical microbiologist will also be involved in the discussion as re-testing would need to occur urgently.
3. The Public Health Physician is to phone COVID-IMT on **07 3181 1173** and email **COVID-19.IMT@health.qld.gov.au** and alert them to a 'Positive' or 'Preliminary positive POCT result'; explain clinical and epidemiological details including specific travel history within the last 14 days.
4. The **Public Health Physician** will then:
 - Notify their relevant Incident Management Team (IMT)/Health Emergency Operations Centre (HEOC) to discuss the response.
 - Notify the onsite clinician with the necessary course of action (if this wasn't already discussed in point 2 above).
5. The **POC Operator** or onsite clinician will then:
 - Follow local escalation pathway as per advice from public health.
 - Inform the patient of the results. Advise them that they are to remain in the clinic (separate room), and they will soon receive a call from Public Health.
 - Arrange transfer of the remaining specimen (and/or recollection) to QFSS (Brisbane) for storage or further testing with a SARS-CoV-2 assay of equal or better sensitivity and with different targets
 - Ensure a pathology request form has been completed for the specimen. In the clinical notes, clearly state: **Positive SARS-CoV-2 POC test: send to reference lab**
6. The **Public Health Physician** will then coordinate a response by their unit and will follow up with the case accordingly.

Transfer of specimens to QFSS

- No specimens are to be discarded; all are to be sent to QFSS for storage/validation.
- Ensure that the specimen is clearly labelled on the tube.
- Adhere a Scientific Services green address label to the specimen bag (see Section 2.2).
- **Note:** When sending a batch of specimens to the QFSS for storage, please email QFSS so that they know to expect a delivery of specimens. The contact at QFSS is Fred Moore – email Frederick.Moore@health.qld.gov.au.

Negative results

- A pathology request form is not required.
- Batch up negative result specimens and send in one package to QFSS
 - Recommend that specimens are batched in groups of eight (8) – as this is the number of specimens that can be listed on the *GeneXpert COVID-19 Patient Test Result Sheet*.
- Include the completed *GeneXpert COVID-19 Patient Test Result Sheet* with the associated package of specimens for transport to QFSS.
- Clearly adhere a Scientific Services green address label to the package.
- Arrange for transport of the package to QFSS.
- **Note:** When sending a batch of specimens to the QFSS for storage, please email QFSS so that they know to expect a delivery of specimens. The contact at QFSS is Fred Moore – email Frederick.Moore@health.qld.gov.au.

Positive results

- Ensure a pathology request form has been completed for the specimen. In the clinical notes, clearly state: **Positive SARS-CoV-2 POC test: send to reference lab.**
- Liaise with Public Health Physician and/or QFSS as to how to prioritise transportation of specimens to QFSS.
- **Note:** When sending a batch of specimens to the QFSS for storage, please email QFSS so that they know to expect a delivery of specimens. The contact at QFSS is Fred Moore – email Frederick.Moore@health.qld.gov.au.

Recording and reporting

It is essential to document COVID-19 POC results (both negative and positive) in a patient's clinical record.

Under the *Public Health Act 2005* (Qld), SARS-CoV-2 is notifiable upon pathology request.

Public Health should be notified of the test, regardless of the result. Notify as per local protocols. The local Public Health Unit is to provide a line list of tested patients to CDIS-NOCS-Support@health.qld.gov.au daily.

The Program is to provide a line list of patients who have undergone testing directly via HealthLink or to CDIS-NOCS-Support@health.qld.gov.au.

When there is a 'positive' or 'presumptive positive' result, staff are to refer to the Section 2.3 *Result Interpretation*.

Assistance

Phone the Help Desk on **08 8201 7555** if you have any problems (Flinders University International Centre for Point-of-Care Testing).

2.4 Testing in an outbreak

In the event of a COVID-19 outbreak in a community, that has access to GeneXpert testing through the Program, the capacity of the GeneXpert® machine and consumables should be considered.

The GeneXpert® machine is not a high-throughput machine with only four specimens able to be tested each hour. There are also limited cartridges in Australia. It does not have the capacity to mass-test an entire community.

During a community outbreak, all symptomatic persons will be treated as a positive case, and managed accordingly by public health, until results are returned.

Use of the GeneXpert® machine should be reserved for when results are urgently required, such as requests for individual inpatients or patients in ED for whom a rapid POC Test PCR result would change clinical management or at the discretion of the local Public Health Physician.

3 Quality, Training and Assurance

This document is to support the practice of GeneXpert testing for rapid molecular detection of COVID-19 infection at/near the point-of-care within pre-determined sites across Queensland. It will guide staff in site requirements, testing criteria, training requirements and quality control measures.

Key processes to be determined and implemented at each participating site prior to commencement of testing are:

3.1 Training and Competency

The use of the GeneXpert platform for COVID-19 POC testing using the Xpert®Xpress SARS-CoV-2 test is restricted to appropriately qualified and competent operators. This is particularly important to ensure the safety of the operator and the reliability of client results obtained.

Theoretical and practical training and competency assessment for the Xpert®Xpress SARS-CoV-2 point-of-care test is provided and coordinated by Flinders University International Centre for Point of Care Testing (ICPOCT) for new and existing GeneXpert operators. Prior to booking training for SARS-CoV-2, pre-requisite safety training including infection control, hand hygiene, personal protective equipment (PPE) and occupational health and safety must be confirmed as completed by the health service manager for each trainee. If the operator successfully completes both written and practical assessments, the ICPOCT will issue a COVID-19 Competency Certificate and an individual Operator ID. Staff performing COVID-19 testing on the GeneXpert at an existing Test, Treat AND Go2 (TTANGO2) sites can maintain their existing operator ID.

In the interest of maintaining the skills and competencies of staff using the GeneXpert and associated policies and procedures, it is advised to perform a minimum of one test per week.

SARS-CoV-2 standard operating procedures (SOPs), reference posters, PowerPoint presentations and other training resources have been developed by the ICPOCT and Kirby Institute team and are available for staff access via the Participants area online at COVID-19 of the Aboriginal and Torres Strait Islander COVID-19 Point-of-Care Testing Program COVID-19 POC Test website:

<https://www.covid19poc.com.au/participants>

3.2 Quality Management

Regular internal quality control (QC) and External Quality Assurance (EQA) testing is required to ensure that the GeneXpert platform is working appropriately and the Xpert® Xpress SARS-CoV-2 assay is providing accurate test results. QC and EQA also ensure that the test process is being performed correctly by competent operators.

Quality checks are integral components of the quality management system.

The table below summarises the QC and EQA required for the Aboriginal and Torres Strait Islander COVID-19 Point-of-Care Testing Program.

Quality Material	Specimen Types	Number of Specimens	Frequency	Expected Result	Result Sheet
COVID-19 QC	Swab	2 / Month	Monthly*	Negative / Positive	Monthly QC Result Sheet
SARS-CoV-2 EQA (CoV-2)	Viral Transport Medium in Tube	2 per Survey	2 Surveys / 6 Months	Unknown at time of testing	EQA Results Sheet

*try to coincide monthly QC training on arrival of a new 'lot number' of cartridges.

The QC and EQA samples will be sent to the services as required and should be stored between 2°C to 8°C in a monitored medication fridge. Training on quality management will be provided by Flinders University International Centre for POC Testing.

Machines should not be moved without consultation with the POC Program first. However, if a machine is moved then QC testing needs to occur when set up at the new destination.

Each participating site must complete a [Quality Testing Enrolment Form](#) and email to covid19PoCT@flinders.edu.au.

3.3 Infection Control

Operator safety is extremely important when dealing with patient specimens which may contain active COVID-19 virus. Risk assessments for the nasopharyngeal specimen collection process and SARS-CoV-2 GeneXpert test process have been completed to identify critical risk steps and develop appropriate mitigation strategies that reduce operator risk to an acceptable level. The required risk mitigation processes (e.g. hazard substitution, defined work area, minimisation of aerosol production, PPE, environmental cleaning and waste disposal) have been integrated in all program material and training resources for the Aboriginal and Torres Strait Islander COVID-19 point-of-care testing program.

Correct stringent use of Personal Protective Equipment (PPE) is mandatory and PPE is provided to enrolled health services with the initial program consumables. Staff are required to follow the departmental procedures for donning and doffing of PPE for COVID-19. Hand hygiene is vital before and after all patient contact, testing and doffing of PPE.

Please refer to local procedures/guidelines or the standardised Queensland Health resources available at <https://www.health.qld.gov.au/clinical-practice/guidelines-procedures/novel-coronavirus-qld-clinicians/public-health,-laboratory-testing-and-infection-control-information>

All waste products should be segregated and disposed of into appropriate general or clinical waste containers as per COVID-19 POC Testing Program and local policy. Refer to COVID-19 POC Testing Program Standard Operating Procedure (SOP) - Infection Control Procedures, SOP #04 available through the participant only section of the COVID 19 POCT website.

Environmental cleaning must occur at intervals in accordance with current Queensland Health recommendations and as described within COVID-19 POC Testing Program SOP# 04.

A supply of PPE will be provided to participating health services for use in this program by the Kirby Institute.

3.4 Routine Maintenance and Cleaning

Cleaning and maintenance tasks are required to be completed on the GeneXpert and surrounding workbench on a regular basis and need to comply with current practices as outlined within the current training and SOPs: SOP # 04 Infection Control Procedures and SOP # 03 Test Process, available through the Participant Only section of the COVID 19 POC website.

DO NOT use bleach to clean up any spills. GeneXpert cartridges and the PrimeStore[®] MTM swabs contain guanidine thiocyanate. Upon mixing with bleach, cyanide gas (a harmful substance) will be released.

4 Useful resources

[Communicable Diseases Network Australia \(CDNA\) National Guidelines for Public Health Units on COVID-19](#)

[Aboriginal and Torres Strait Islander COVID-19 POC Testing Program Guidelines](#)

[Queensland Health Infection Control Guidelines](#)

The Program Standard Operating Procedures (SOPs)

The SOPs are available online at www.covid19poc.com.au

- SOP 01 – COVID-19 POC Testing Recommendations
- SOP 02 – COVID-19 POC Testing Nasopharyngeal Swab Collection
- SOP 03 – COVID-19 POC Testing Process
- SOP 04 – COVID-19 POC Testing Infection Control Procedures
- SOP 05 – COVID-19 POC Testing Quality Control and External Quality Assurance
- SOP 06 – COVID-19 POC Testing Data Management
- SOP 07 – COVID-19 POC Testing Training and Competency
- SOP 08 – COVID-19 Checklists
- SOP 09 – COVID-19 POC Testing Hub and Spoke Model

5 Public Health Physician Contacts

Queensland Health HHS	Health Service	Public Health Unit (PHU)	Public Health Physician
Darling Downs	CRAICCHS (Cherbourg)	Darling Downs	Business Hours: 4699 8240 Ask to speak to a Public Health Physician Afterhours: 3546 1699 Ask to speak to the Public Health Physician on call Fax: 4699 8262
Townsville	Townsville Aboriginal and Islander Health Service Palm Island Hospital	Townsville	All hours: Dr Steven Donohue – 0409 472 036 Dr Julie Mudd – 0475 829 579 Fax: 4433 6901
North West	Doomadgee Hospital Cloncurry Hospital Normanton Hospital Mornington Island Hospital	Townsville	All hours: Dr Steven Donohue – 0409 472 036 Dr Julie Mudd – 0475 829 579 Fax: 4433 6901
Cairns	Gurriny Yealamucka (ACCHS) Wuchopperen (ACCHS)	Tropical	All hours: Dr Richard Gair – 0408 721 092 Fax: 4266 5555
Torres and Cape	Pormpuraaw PHCC Lockhart River PHCC Weipa Hospital Bamaga Hospital Cooktown Hospital Saibai Island PHCC Aurukun PHCC	Tropical	All hours: Dr Richard Gair – 0408 721 092 <i>Please also call Executive Director of Medical Services</i> Dr Tony Brown – 0408 284 078 Fax: 4226 5555

Business hours: 9am – 5pm
After house: 5pm – 9am

6 Definitions

Term	Definition
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.
COVID-19	The clinical disease caused by coronavirus SARS-CoV-2. First recognised in Wuhan, China, in late 2019.
GeneXpert	Cepheid GeneXpert® is a testing instrument used for point-of-care (POC) nucleic acid amplification testing. It can test for SARS-CoV-2
POC Test	Point-of-care test
TTANGO2	Test Treat AND GO (TTANGO2) is a point-of-care testing program for sexually transmitted infections (STIs).
Standard Operating Procedure (SOP)	Written, step-by-step instructions that describe how to perform an activity. Standard operating procedures maintain safety and efficiency. Available via the COVID-19 POCT website, participant login by ensuring each operator performs required tasks using the same method, which incorporates appropriate risk mitigation processes
Negative Test Result	The COVID-19 virus was not detected in the sample.
Positive Test Result	The COVID-19 virus was detected in the sample.
Presumptive Positive Test Result	The COVID-19 virus may be present in the sample.
Inconclusive Test Result	A presumptive positive result has been retested and a negative result has been recorded leading to an inconclusive result.
Invalid/Error/No Result Test Result	Test was unsuccessful. Repeat test.

Document details

Target Audience	All clinical employees trained to use the GeneXpert Platform		
Jurisdiction	Queensland		
Approved by	COVID-19 Response Group and COVID System Leadership Form		
Author	Dr Candice Colbran, Aboriginal and Torres Strait Islander Health Division		
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