Abbott Panbio™ COVID-19 Ag Rapid Test

Operator Handbook

COMMERCIAL

SA PATHOLOGY

Contents

PUB-0785 v1
Published 9/11/21

Symbols and meanings

WARNING – Failure to follow these instructions may adversely effect patient results, your health or damage the equipment.

CAUTION – Failure to follow these instructions may damage equipment over time or require the test to be repeated.

WEAR GLOVES and any other appropriate PPE

WASH HANDS

CORRECT – the preferred way to do something

INCORRECT – do not do this

DOCUMENT your actions

CONTACT

INFORMATION – an operational hint or tip

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Foreword

SA Pathology has been at the forefront of COVID-19 testing in Australia, establishing a rapid, robust and scalable testing capability to support the state's early detection and containment response.

Within days of the SARS-CoV-2 genome sequence being published online, SA Pathology's scientists had designed primers to ensure an in-house multiplex nucleic acid amplification (NAT) was running by 28 January. In the critical early stages of the pandemic in March-April 2020, South Australia had one of the highest testing rates both nationally and internationally and remains among the highest per capita worldwide.

Through COVID-19, SA Pathology transformed its collection centre model; introducing Australia's first drive-through testing service, as well as a domiciliary service and drive-through testing stations at South Australian border sites.

In 2021, following the release of the vaccination program, increased movement across state and international borders, and low prevalence of COVID-19 in South Australia, the challenge has been to maintain testing vigilance and rapidly identify potential outbreaks.

SA Pathology continues to deliver innovative testing solutions, including the introduction of Rapid Antigen Testing. SA Pathology Rapid Antigen Tests produce a result within 15 minutes, enabling faster containment action for positive cases and providing greater reassurance to the South Australian community.

SA Pathology offers a seamless end-to-end Rapid Antigen Testing regime, including:

- Expert clinical and scientific oversight
- Comprehensive training and support
- Direct data feed to the Communicable Diseases Control Branch (CDCB)
- Comprehensive 24/7 support
- User-friendly software for fast resulting via SMS

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What is Rapid Antigen Testing?

The Panbio™ Ag Rapid Test is a Point of Care Testing (PoCT) device capable of detecting the presence of COVID-19 in human samples within a 20-minute window. PoCT is complementary to any relevant testing performed in your local SA Pathology laboratory and is designed to assist with decision making when a rapid result is required.

Results can be recorded and managed through SA Pathology's Covid Screening software.

Point of Care tests must only be performed by appropriately trained and certified users.

The operator of this kit is ultimately responsible for any test results produced, and for any results they have interpreted.

Aims

The aim of this handbook is to ensure that operators can use the Rapid Antigen Test (RAT) with confidence and competence. Once trained, operators must maintain aptitude through ongoing competency checks, as well as following the standard procedures and participating in Quality Control (QC) testing.

This handbook identifies the procedures and competencies that must be demonstrated before this test can be performed.

Objectives

The operator must:

- ✓ Understand the procedures outlined in this handbook
- ✓ Understand the operation of this kit and sample requirements
- ✓ Understand the limitations of this test and results produced
- ✓ Demonstrate competency in sample collection, data entry, performing the test and result entry
- ✓ Identify and troubleshoot common problems
- ✓ Understand the procedures involved for positive and invalid results
- ✓ Know who to contact for support

Training Summary

Training is a train the trainer model with SA Pathology providing initial training opportunities.

It is required that you observe and participate in the performance of a test under the guidance and observation of a trainer.

Before commencement of testing, *all* trained staff must complete and email the following training documents **TRD-5609 RAT Training Record** and **TRD-5610 Questionnaire** to Health.SAPathologyRapidCOVIDTesting@sa.gov.au

Competency should be assessed on a 12-monthly basis.

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Use and Limitations

The Panbio™ COVID-19 Ag Rapid Test Device is an in vitro diagnostic rapid test for the qualitative detection of SARS-CoV-2 antigen (Ag) in human nasopharyngeal and nasal swab specimens from individuals who meet COVID-19 clinical and/or epidemiological criteria.

This test produces preliminary test results. Negative results do not exclude SARS-CoV-2 infection and cannot be used as the sole basis for treatment or other management decisions. Positive results are presumptive in nature (that is, they should be confirmed by another validated assay). All results must be combined with clinical observation, patient history, and epidemiological information. This test is not intended for use as a donor screening test for SARS-CoV-2.

Failure to follow instructions for the test procedure and interpretation of results may produce invalid results. The control line (C) is used for procedural control, and will appear if the test is performed properly and test reagents are working.

Immunoassay may produce a 'hook effect' where high levels of the virus can produce false negative results. The manufacturer has not detected a hook effect at a concentration of $1x10^{5.8}$ $TCID_{50}$/ml of SARS-CoV-2. The manufacturer has detected cross-reactivity with Human-SARS-coronavirus Nucleoprotein, as SARS-CoV has high homology with SARS-CoV-2.

Kit Components

- Test device (cassette) (x25)
- Swabs (x25)
- Buffer solution (9ml bottle) (x1)
- Extraction tubes (x25)
- Extraction tube caps (x25)
- Positive control swab (x1)
- Negative control swab (x1)
- Tube rack (x1)
- Instruction leaflet

Required Materials (not supplied)

- Personal Protective Equipment (PPE) including a level 3 (P2 or N95) fitted surgical mask, lab gown, face shield, gloves and enclosed footwear
- Appropriate disinfectant. 70% ethanol is appropriate for the virus.
- Container and bags for biohazardous waste (sharps disposal container is also acceptable)
- Timers (recommended model is Oracle code 15002605)
- Permanent markers and pens
- A min/max thermometer for temperature monitoring

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Ordering kits

To order COVID-19 Ag Rapid Test kits, complete form **FOR-5743 Order form** and email to Health.SAPathologyRapidCOVIDorders@sa.gov.au. SA Pathology will arrange delivery to your designated site.

On receipt, complete form **FOR-5713 Consumables Order and Transport** to confirm the quantity of goods received and check that they are within the acceptable temperature range (2-30°C). Ensure that all kits received appear to be in good condition.

Email the completed form to Health.SAPathologyRapidCOVIDorders@sa.gov.au and return any eskies and ice packs received.

Perform Quality Control (QC) testing on every batch received.

Storage and Handling

Store kits at room temperature (2-30°C) and have a monitoring system in place to ensure temperature remains within this range. Monitor and record temperatures using form **FOR-1232 Min-Max Temperature Check Record**. All kit components are stable up to the expiry date. If refrigerated, allow 30 minutes for components to equilibrate to room temperature prior to use. Do not freeze. Do not leave test kits in direct sunlight.

The buffer bottle has a cap with a dripping nozzle. Ensure the cap is firmly sealed in storage.

Do not remove the test cassette from its foil pouch until performing the test.

Do not use the kit if it has passed the expiration date. The expiration date can be seen on the kit box and on the foil pouch around every cassette.

Do not use any components that appear damaged or any foil pouches with a broken seal.

Direct swab specimens should be tested as soon as practicable after collection. A swab can be kept in an extraction tube with buffer at room temperature (15-30°C) for up to two hours before use. Any collected swab left in buffer for more than two hours should not be tested.

Precautions

Appropriate understanding and application of PPE and hand hygiene are requirements for testing.

This test does not inactivate any biohazardous material. Decontaminate and dispose of all specimens, test kits and contaminated material into a biohazard container as they are potentially infectious.

Be cautious of possible aerosol formation and spillage while collecting and testing specimens.

Components are not suitable for reuse. Do not mix or interchange different specimens. Do not mix reagents from different lots. Do not dilute the provided extraction buffer with any other solution.

The buffer contains <0.1% sodium azide as a preservative which may be toxic if ingested. If disposed of through a sink, flush with a large volume of water.

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Quality Control

The test cassette has a test line (T) and a control line (C). Neither should be visible before testing. The control line will appear if performed properly and the reagents are working.

Each kit comes with a positive control and negative control swab to ensure that reagents are working and that the test is being properly performed.

External quality control (QC) should be performed upon receipt of every new delivery (batch). If a kit is repeatedly producing invalid results, QC testing should be performed. Refer to the QC procedure on page 15.

QC testing is automatically recorded if the Covid Screening software is used. For offline testing, results must be recorded and archived. Paper copies should be kept on site and a copy emailed to Health.SAPathologyRapidCOVIDTesting@sa.gov.au

Infection control

As this test involves working with potentially infectious material, relevant Work Health and Safety (WHS) and infection control measures must be in place. All samples should be treated as if they are infectious.

Appropriate Personal Protective Equipment (PPE) must be worn at all stages of testing. This includes a gown, protective gloves, level 3 (P2/N95) fitted face mask and a face shield. Make sure enclosed shoes are worn. Long hair must be tied back.

Specimen collection involves a risk of aerosol production, and transmission-based precautions are required.

Gloves and any visibly contaminated PPE should be discarded between collections and hand hygiene performed.

Donning and doffing of PPE should be performed as per established procedures. A poster depicting donning/doffing should be displayed for easy reference for staff.

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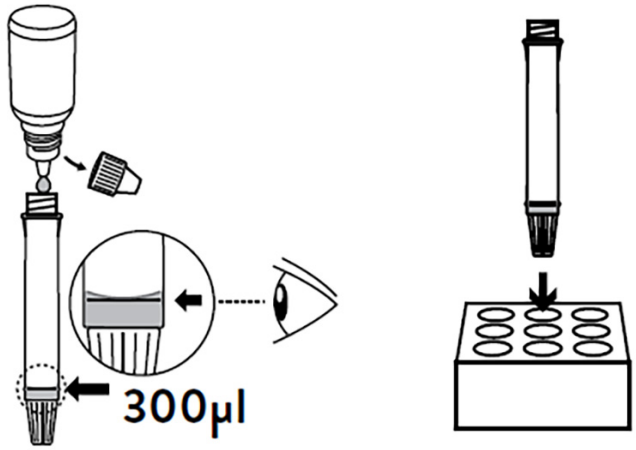
Using the Ag Rapid Test

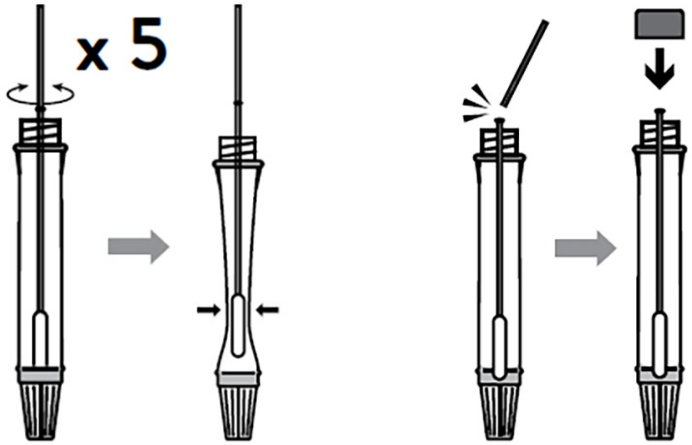
Preparation

1. Take an extraction tube and check that the white nozzle cap is firmly closed.
2. Ensure the nozzle cap remains firmly fixed until the testing stage.
3. Hold the buffer bottle vertically and fill an extraction tube up to the fill-line marked on the tube (approx. 0.3ml). The buffer may form a ‘meniscus’, where the top of the liquid forms a concave shape (curves downward). The base of this meniscus should be level with the fill-line.
4. Close a cap firmly on the extraction tube and place into a rack.
5. Collect the specimen as soon as practicable after pre-filling.



Collection

1. Using a test swab, conduct a nose/throat collection as per established procedure.
2. Insert the swab into a pre-filled extraction tube.
3. Swirl the swab tip in the buffer, pushing against the wall of the tube at least 5 times.
4. Squeeze out the swab through the tube using your fingers.
   Make sure you feel the tip of the swab through the tube.
5. Break the swab at the breakpoint and close the cap on the tube.



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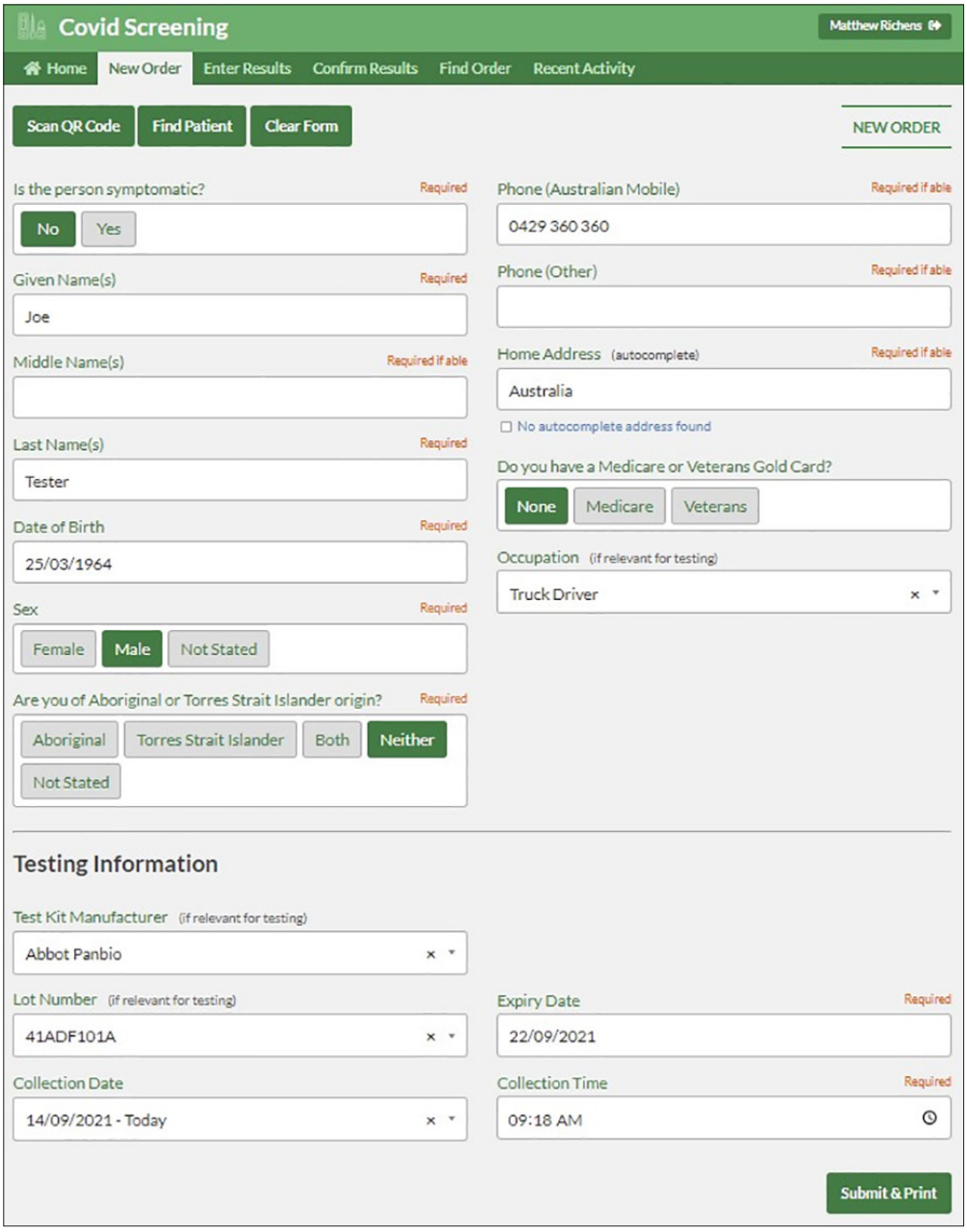
Data Entry

Covid Screening software http://covidscreening.sapathology.sa.gov.au

1. Open ‘New Order’ on the Covid Screening app.
2. Ask for the patient’s name, date of birth, home address, mobile number, Medicare details, and occupation.
   Once recorded, obtain verbal confirmation of these details.
3. Kit details are also required: manufacturer, lot number, expiry, and time and date of testing.
4. Hit ‘Submit & Print’ to print the request form.



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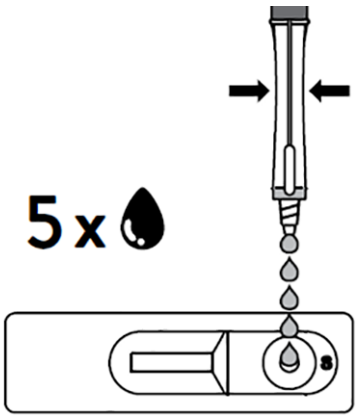
Testing

1. Remove a cassette from its pouch and place on a clean, flat surface.
2. Place labels onto the cassette, request form and collected swab ensuring that the labels match.
3. Open the dripping nozzle cap at the bottom of the tube.
4. Dispense 5 drops of specimen into the specimen well on the cassette.
5. Close the nozzle and dispose of the tube into a biohazard container.
6. Record this time on the request form – this is recorded as the ‘extraction time’ on result entry.
7. Set a timer for 15 minutes.
8. Read results after 15 minutes and before 20 minutes. Any result after 20 minutes must be considered invalid.
9. Dispose of the used cassette into a biohazard container.



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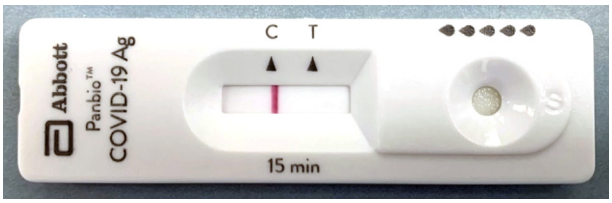
Interpretation

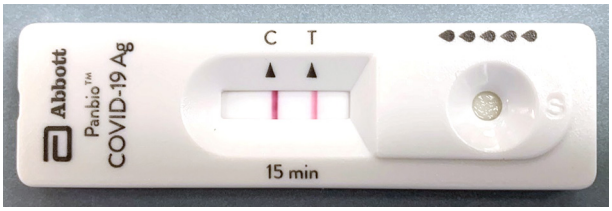
Note the presence of the control line (C) and test line (T).

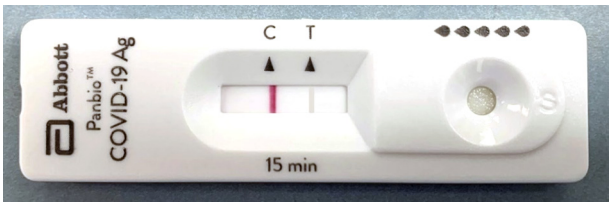
A **NEGATIVE** result is indicated by a control line (C) only.



A **POSITIVE** result is indicated by both control line (C) and test line (T).

Even a weak test line is considered positive.

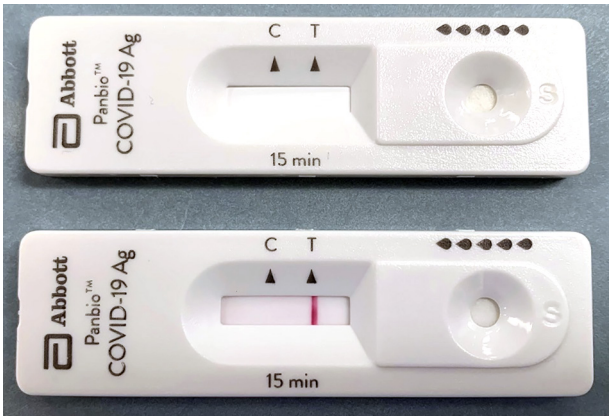




A weak positive may look like this. Remember any intensity is considered positive.

An **INVALID** result occurs with the absence of a control line (C).

The test line (T) may or may not be present.



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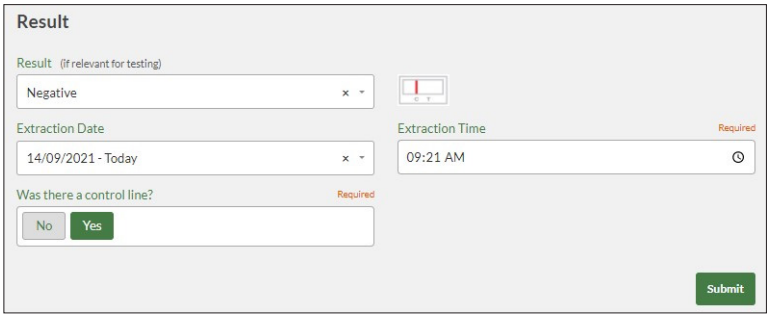
Result Entry

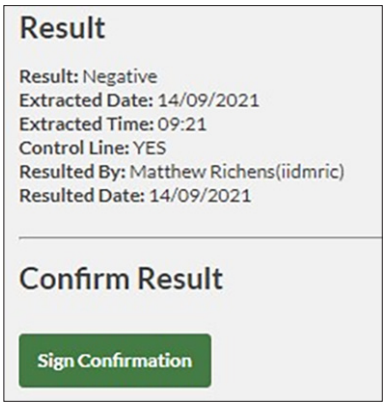
Covid Screening software http://covidscreening.sapathology.sa.gov.au

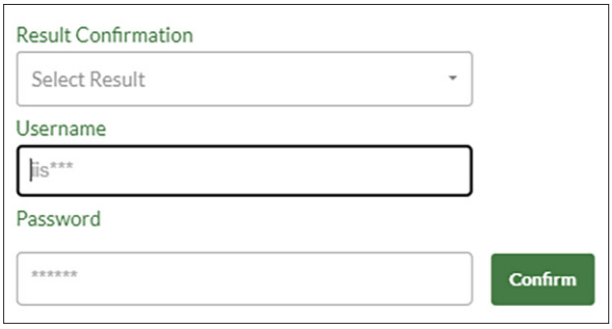
1. On the Covid Screening app, hit ‘Enter Results’ and find your patient.
2. Enter ‘positive’, ‘negative’ or ‘invalid’ as required. You may also cancel the test if any errors have occurred.
3. Make sure to transcribe the extraction time, which was recorded on the request form at the testing stage. Presence of a control line must be confirmed.
4. Hit ‘Submit’.



The result must be validated by a second operator.

5. Sight the cassette before 5 minutes has elapsed and check against the transcribed result.
6. Hit ‘Sign Confirmation’ and enter user details. Discrepant results will be flagged by the system.
7. Once confirmed, hit ‘Submit & Print’.





Please note that patient results are confidential and should only be disclosed to appropriate medical staff.

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Positive Results

Due to the significance of a positive COVID-19 diagnosis, standardised workflows must be in place to manage any non-negative results.

1. Notify the CDCB doctor on 1300 232 272
2. If recording results manually (without the software) you must email the positive result and patient details to:

   Health.CDCBCOVIDLiaison@sa.gov.au and

   DL.HealthSAPathologyMicro&IDMedicalOfficersAll@sa.gov.au and

   DL.HealthSAPathologyMicro&IDRapidCOVIDTesting@sa.gov.au

   If recording results in the Covid Screening software, these emails will send automatically.
3. The CDCB will provide directions for patient management.

Invalid results also require further investigation, which will depend on the nature of the result itself. If no control or test band has appeared, the RAT should simply be repeated. If the test band only appears, the specimen should be dealt with as if it were a positive result.

Spills

A spill kit must be in a readily accessible location in the event of a spillage.

If you spill on yourself, cease work immediately, then:

1. Remove PPE in the following order. Perform hand hygiene with an alcohol-based hand gel between each step:
   - gloves
   - face shield
   - face mask
   - gown
2. Discard into biohazard waste.
3. Any affected skin areas should be cleaned thoroughly with an appropriate disinfectant and water.

Cleaning up spills

Wear full PPE

1. Cover any spills with an absorbent material wetted with an appropriate disinfectant and leave for at least 10 minutes.
2. Collect materials into a waste bag.
3. Starting from the outside and working in, wipe over the spillage from outside the visible boundary with fresh disinfectant. Leave for 10 minutes.
4. Wipe over the surface to remove any remaining disinfectant.
5. Discard all waste into a biohazard bin and seal off.
6. Remove PPE as described above and wash hands.

Report incidents to Health.SAPathologyRapidCOVIDTesting@sa.gov.au

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Quality Control procedure

Perform on receipt of every new batch.

1. Scan control ‘patient’ QR code for positive control and submit details. Scan control ‘patient’ QR code for negative control and submit details. If performing offline, manually transcribe positive and negative control details onto a paper document.
2. Remove two cassettes from foil and place on a clean, flat surface.
3. Label a cassette and tube for positive control. Label a cassette and tube for negative control.
4. Fill two extraction tubes with buffer to the fill-line (approx. 0.3ml). Place tubes into a tube rack.
5. Remove the positive control (red) swab from foil, insert into a pre-filled tube and soak for 1 minute. Swirl the swab in buffer fluid, pushing against the tube wall at least 5 times. Squeeze out the swab through the tube using your fingers. Remove the swab and dispose in biohazardous waste. Close the cap on the tube.
6. Repeat step 5. for the negative control (green) swab.
7. Open the dripping nozzle at the bottom of the tube. Dispense 5 drops of specimen into the specimen well of a cassette. Close the nozzle and dispose tube into biohazardous waste. Perform for both positive and negative controls.
8. Set a timer for 15 minutes. Read results after 15 minutes and before 20 minutes. Any result after 20 minutes must be considered invalid.
9. Record results ‘positive’, ‘negative’ or ‘invalid’ as appropriate. Note that a kit that has not passed QC cannot be used for testing.
10. Dispose of the used cassettes into biohazardous waste.
11. If performed offline, ensure results are kept as detailed in the ‘Quality Control’ section.

In the event of QC failure, repeat on another kit from the same batch.

If repeat QC fails, cease all testing on relevant kits and contact Health.SAPathologyRapidCOVIDTesting@sa.gov.au

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Troubleshooting

There are many sources of error which can occur throughout the performance of a test. These may be pre-analytical (errors that occur before testing), analytical (errors while performing the test) or post-analytical (errors after a result is produced).

Pre-analytical errors may include:

- The client refuses to undertake sample collection
- The swab breaks while collecting, or the swab is dropped before secured in the extraction tube. The client will have to give consent for another collection, or the test will have to be cancelled.
- Patient details are entered incorrectly, and the request is submitted. If this occurs, amend the printed request form with a pen. Details can be altered on result entry. The second operator must check any amended details as well as the test result.

Analytical errors may include:

- Too much or too little specimen is added to the test cassette.
- The extraction tube is underfilled on preparation and there is insufficient specimen for testing. The test will have to be cancelled in this instance. Ensure the buffer is at the fill-line prior to collection to prevent this.
- Bubbles or blockages might form in the extraction tube and interfere with dripping. Gently agitate the tube to remove any blockage until you can see free drop formation.

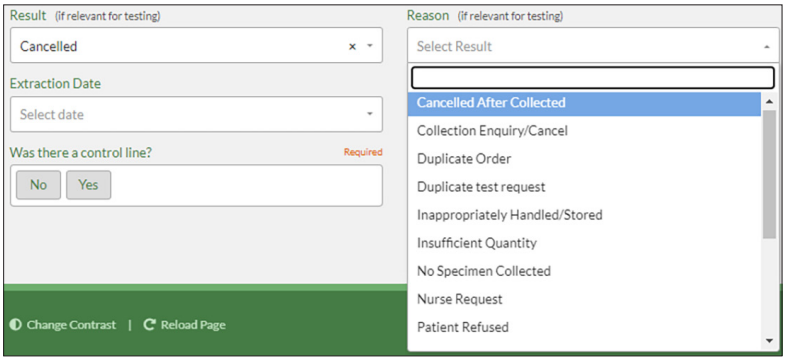
Post-analytical errors may include:

- Incorrect transcription of the test result. The secondary check is in place to account for this.
- More than 5 minutes has elapsed before verifying the result. These must be reported as invalid.

If the secondary checker enters a different test result than the first operator (the result is discrepant), you will not be able to submit the result. The patient will have to be data entered and resulted again – make sure the collection and extraction times are recorded and accurately transcribed.

If a system outage prevents the reporting of a result, retain the request form and scribe the result by hand. This should be signed by the operator and secondary checker. Record the time resulted. This form will likely be contaminated and so it should be sealed in a transparent plastic bag. When the system is restored, a text box is available for tracking the outage and recording the actual time of result entry.

If a test needs to be cancelled, there is an option to do so in result interpretation. This will provide a selection of possible reasons for the cancellation.



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Support and Contacts

Send completed training documents and delivery forms to:
Health.SAPathologyRapidCOVIDTesting@sa.gov.au

Result notification and Point of Care testing support
DL.HealthSAPathologyMicro&IDRapidCOVIDTesting@sa.gov.au

Microbiology & Infectious Diseases Medical Officer
DL.HealthSAPathologyMicro&IDMedicalOfficersAll@sa.gov.au
T 8222 3123 (External)

SA Pathology clinical microbiologist – Dr Morgyn Warner
Morgyn.Warner@sa.gov.au

Communicable Disease Control Branch (CDCB)
T 1300 232 272
Health.CDCBCOVIDLiaison@sa.gov.au

SA Health Service Desk (IT support)
T 1300 138 913

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Abbott Panbio™ Covid-19 Rapid Test Device Training Record

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Name: _____

HAD ID (if applicable): _____

Mobile number (may be required for login):_____

email address (work): _____

Trainer:_____

Task	Trainee Sign / Date	Trainer Sign / Date
Work Health & Safety		
• PPE		
• Hand hygiene		
• Infection control risks		
• Spills protocol		
• Reporting incidents to PoCT supervisor		
Preparation and Maintenance		
• Cleaning and arrangement of work/bench space		
• Storage and handling of kits, temperature		
Quality Control		
• Why QC is performed		
• When QC is required		
• QC failure protocol		
• Quality assurance & ongoing competency		
Preparation and collection		
• Obtaining details & secondary check		
• Patient confidentiality		
• Significance of errors/mismatch		
• Sample collection		

Abbott Panbio™ Covid-19 Rapid Test Device Training Record

Running Test		
• Labelling form, tube & cartridge, checking details		
• Rotating swab in buffer & squeezing		
• Waste disposal		
Resulting		
• Interpretation of results		
• Recording & supervisor check		
• Negative & invalid result workflow		
• Positive result workflow & notification		
Troubleshooting		
• Sources of error		
• System outage workflow		
Support		
• Contacts for clinical advice, problems with test		
• Ordering of kits		

Final Sign-off:

	Name	**Date**	**Sign**
Trainee			
Trainer			

Please scan this form with a completed questionnaire and send to:

Health.SAPathologyRapidCOVIDTesting@sa.gov.au

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Abbott Panbio™ Covid-19 Ag Rapid Test Device: Questionnaire

1. What temperature range must the kits remain within:
    a. While in storage?

    b. While testing?

2. Once a swab has been collected and placed into the extraction buffer, how long can it be left before testing? What do you do if it is left longer than this time?

3. When your cassette is ready to read and interpret, how long can it be left for? What do you do if it is left longer than this time?

4. Quality Control (QC) testing must be performed:

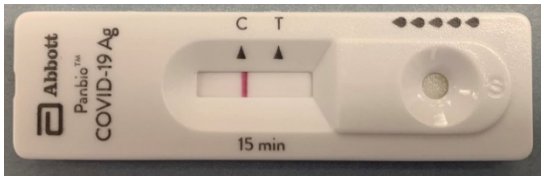
    a. For every new batch received
    b. Every day
    c. For every new lot number, as well as once a week

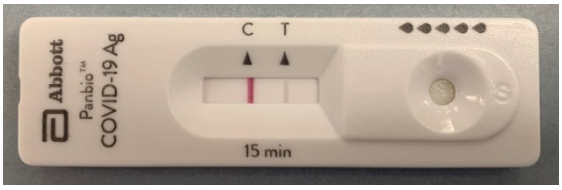
5. Why is QC testing so important?

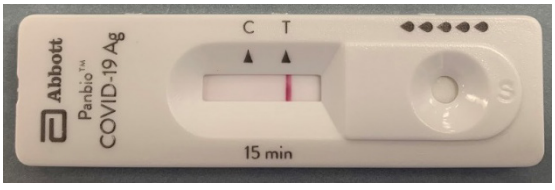
6. You have completed your test order and printed the form, and you have noticed that the patient's first name is misspelled. What do you do?

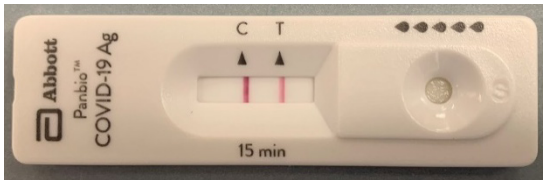
7. Testing involves labelling the extraction tube, cassette and request form with a pre-printed label. Why does this need to be done?

8. Describe the results below as 'positive', 'negative' or 'invalid'.









9. Every result must be checked by a second operator. Why is this so important?

10. Through the procedure you will record a collection time, extraction time and a resulting time.

a. What is happening at the extraction time?

b. Which two times must be within 20 minutes of each other?

11. Describe three examples where you might have to cancel the test.

Please scan this form with a completed checklist and send to:

Health.SAPathologyRapidCOVIDTesting@sa.gov.au

Point of Care Testing
Consumables Order and Transport

SA PATHOLOGY

Requested By:

Organisation	
Delivery Address	
Contact Name	
Contact Phone #	

Goods Ordered/Received:

Your Order		SA Pathology Packed Lot No.	Goods Received Qty
Item	**Qty Ordered**		
Abbott Panbio™ Covid-19 Ag Rapid Test Device			

Delivery No. _____

SA Pathology Dispatch Checklist:

1. Kit QC □ Yes □ No
2. Packed to maintain 2°C to 30°C □ Yes □ No
3. Include this form □ Yes □ No

Recipient:

1. Kits have arrived within temperature range □ Yes □ No
2. Condition of kits □ Good □ Damaged
   Qty of damaged kits: _____
3. QC performed □ Yes □ No
4. QC passed □ Yes □ No
5. Complete this form, scan and email to:
   Health.SAPathologyRapidCOVIDorders@sa.gov.au

Minimum / Maximum Temperature Check Record.

SA PATHOLOGY

Directorate/Section: .... Department/Site: .... Months / Year: ....

Instrument Description: .... Asset Number: .... Location: ....

Measuring Device (ie thermometer) ID or Asset No. .... Acceptable Temperature Range: ....

Other monitored conditions: Condition .... Acceptable condition(s) Range: ....

NOTE: **Record** the reading(s); **check** readings are within the acceptable range(s); clear the max/min (if the device has this feature) so a new max/min is obtained during the next record cycle;
action & record actions if reading(s) are not within acceptable ranges.
If there are any temperature / condition adjustments, record adjustments in comments/problems area below.

Month	Cond.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
	Max																															
	Min																															
	init																															
	Max																															
	Min																															
	init																															
	Max																															
	Min																															
	init																															

For our patients and our population

Minimum / Maximum Temperature Check Record.

SA PATHOLOGY

Directorate/Section: ..... Department/Site: ..... Months / Year: .....

Instrument Description: ..... Asset Number: ..... Location: .....

Comments / Problems	Date / Initial	Actions taken	Date / Initial	Reviewed by / Date

For our patients and our population

ORDER FORM
COVID-19 Ag Rapid Test Device

SA PATHOLOGY

To order Abbott Panbio™ COVID-19 Ag Rapid Test Device kits, please complete this form and email to Health.SAPathologyrapidCOVIDorders@sa.gov.au

Reset Form Save As

Client Details

Client name	
Contact name	
Phone number	
Email	
Delivery location	
Delivery address	

Ordering Details

QTY of Kits required	

Invoicing Details

Contact name	
Invoice address	
Email	

Please note:
Orders will be dispatched within 2 business days of order receipt.

OFFICE USE ONLY

Current stock levels	
Current Batch and Expiry	