

Rapid Antigen Testing for COVID-19 for visitors to Newborn Services



Western Health

COVID - 19

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VERSION 1: LAST UPDATED 16/11/2021

Purpose:

This document describes how to use the Abbot Pan Bio COVID-19 Antigen Rapid Test Device in visitors to Newborn Services to aid the early identification of asymptomatic visitors and minimise the number of vulnerable newborns exposed to COVID-19.

The test is designed to detect SARS-CoV-2 nucleocapsid soluble antigen from nasal swabs.

The test is to be used as a screening tool, to support the streaming of visitors into COVID zones:

- High-Risk COVID (SCOVID),
- Low-Risk COVID.

All positive Rapid Antigen Test results will need to be validated by a COVID PCR test.

Overview:

The Pan Bio COVID-19 Rapid Tests are an aid in the diagnosis of SARS-CoV-2 infection enabling quick screening in particular settings. Only clinical staff who have been appropriately trained are to perform the test. A local process for ensuring competency will be implemented in each area that is using Rapid Antigen Testing.

The Pan Bio COVID-19 Rapid Test will be undertaken in visitors prior to attending Newborn Services.

Results are preliminary, positive results must be confirmed by COVID PCR and negative results do not exclude SARS-CoV-2 infection.

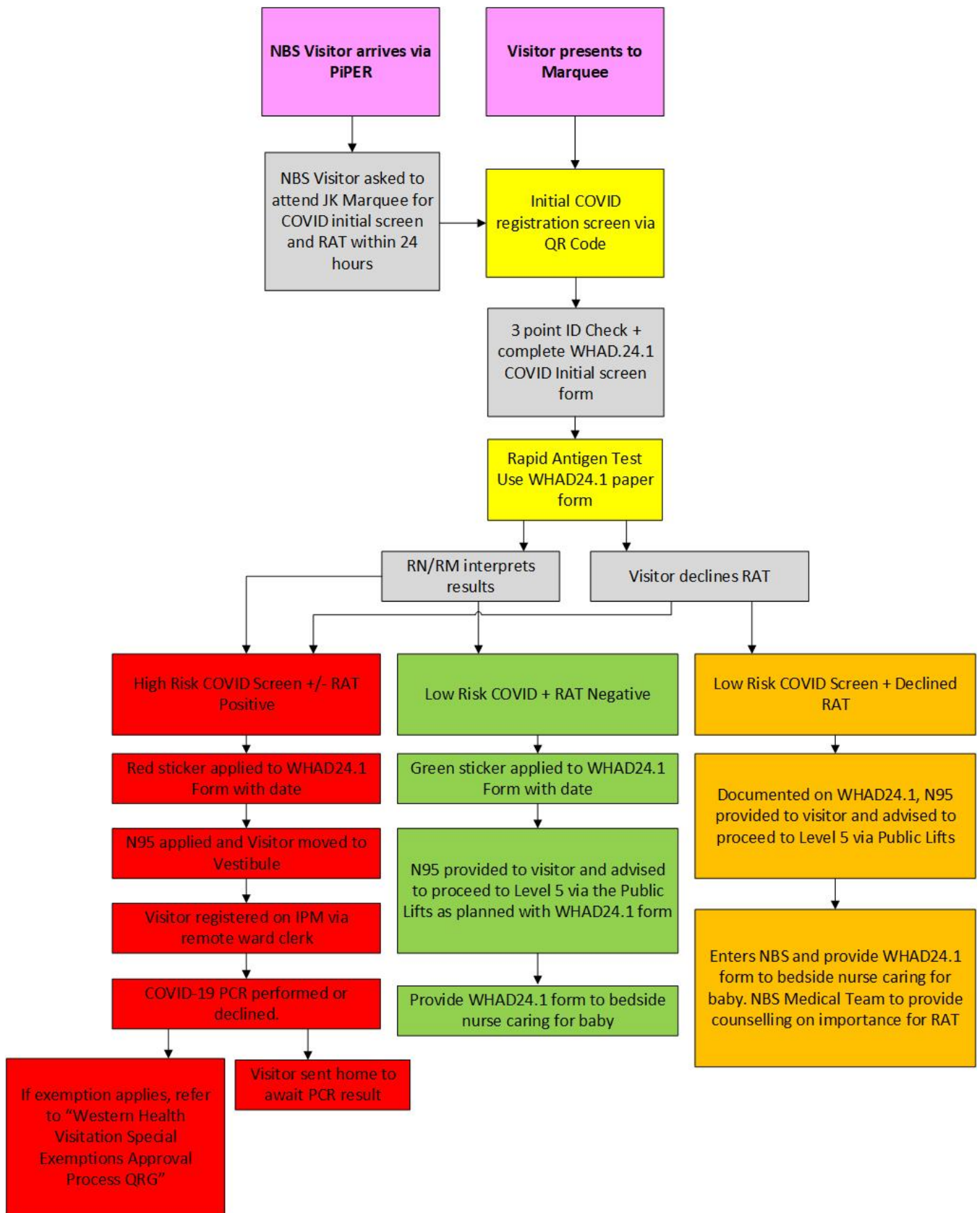
Rapid Antigen Testing in the Newborn Services Setting

Rapid Antigen Testing is one step in the COVID initial screening processes of the Newborn services setting.

Rapid Antigen Testing should be completed daily on all visitors to Newborn Services before they attend Level 5 clinical care area. The test should be completed in conjunction with the initial COVID visitor screening tool. The results of the screening tool, and the test should inform the decision to complete a COVID PCR test.

The Rapid Antigen Test process in the Newborn services visitors is described in **Figure 1**.

Figure 1: Newborn Services Visitor COVID-19 Screening and Rapid Antigen Testing



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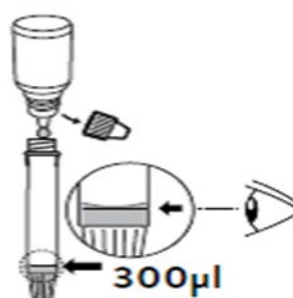
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Administering the Test:

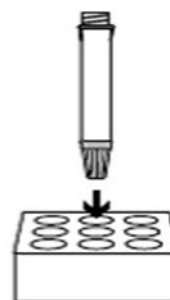
TEST PROCEDURE

- 1 Hold the buffer bottle vertically and fill the extraction tube with buffer fluid until it flows up to the Fill-line of the extraction tube (300 μ l).

⚠ Caution: If the amount of buffer is excessive or insufficient, an improper test result may occur.

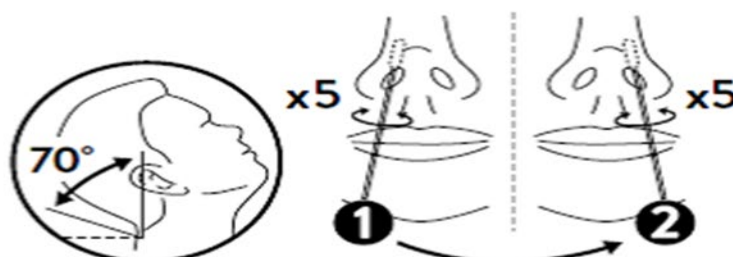


- 2 Place the extraction tube in the tube rack.



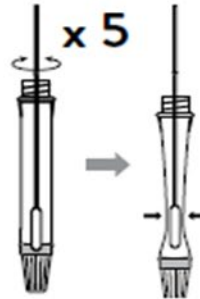
- 3 Tilt the patient's head back 70 degrees. While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril (until resistance is met at the turbinates). Rotate the swab five times against the nasal wall. Using the same swab repeat the collection procedure with the second nostril. Slowly remove swab from the nostril.

⚠ Caution: If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.

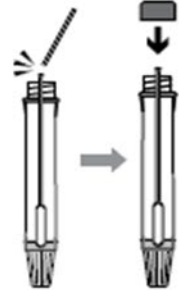


TEST PROCEDURE

- 4** Insert the swab specimen in the extraction tube. Swirl the swab tip in the buffer fluid inside the extraction tube, pushing into the wall of the extraction tube at least five times and then squeeze out the swab by squeezing the extraction tube with your fingers.



- 5** Break the swab at the breakpoint and close the cap of extraction tube.

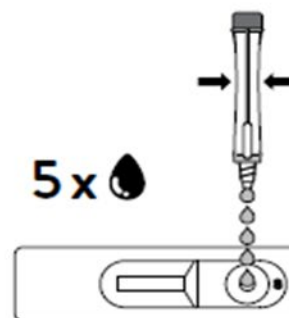


- 6** Open the dropping nozzle cap at the bottom of the extraction tube.



- 7** Dispense 5 drops of extracted specimens vertically into the specimen well (S) on the device. Do not handle or move the test device until the test is complete and ready for reading.

⚠ Caution: Bubbles that occur in the extraction tube can lead to inaccurate results. If you are unable to create sufficient drops, this may be caused by clogging in the dispensing nozzle. Shake the tube gently to release the blockage until you observe free drop formation.

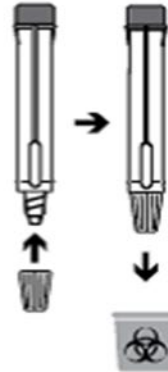


Important: please note the importance of squeezing the extraction tube during **Step 4**

Important: please be careful to snap the swab at the designated breakpoint during **Step 5** – so the swab can fit in the extraction tube.

TEST PROCEDURE

- 8** Close the nozzle and dispose of the extraction tube containing the used swab according to your local regulations and biohazard waste disposal protocol.



- 9** Start timer. Read result at 15 minutes. Do not read results after 20 minutes.



- 10** Dispose of the used device according to your local regulations and biohazard waste disposal protocol.



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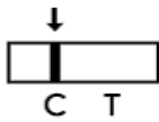
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Reporting Results

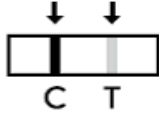
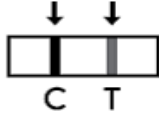
For a test to be valid, a single pink to purple coloured line must appear in the Control Line area (left hand side of the test window).

TEST INTERPRETATION



NEGATIVE
The presence of only the control line (C) and no test line (T) within the result window indicates a negative result.



POSITIVE
The presence of the test line (T) and the control line (C) within the result window, regardless of which line appears first, indicates a positive result.
⚠ **Caution:** The presence of any test line (T), no matter how faint, indicates a positive result.



INVALID
If the control line (C) is not visible within the result window after performing the test, the result is considered invalid. Instructions may not have been followed correctly. It is recommended to read the IFU again before re-testing the specimen with a new test device.



A **negative specimen** will give a single pink-to-purple coloured Control Line on the left-hand side of the window, indicating a presumptive negative result. This Control Line means that the detection part of the test was done correctly, and the patient sample is negative.

A **positive specimen** will give two pink-to-purple coloured lines, one being the Control Line and the other the Sample Line. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. **Any visible line is positive, regardless of which line appears first.**

If no lines are seen, or if just the Sample Line is seen (right hand side of the test window), **the assay is invalid**. Invalid tests should be repeated. If the problem persists, contact your supervisor.

Actioning results on visitors to Newborn Services:

- All visitors to Newborn Services will be asked to swap their surgical mask for an N95 mask
- If the COVID visitor screen is low risk and the rapid antigen test result is negative the visitor can proceed to Level 5 as per WH visitor guidelines.
- If a visitor answers YES to ANY of the screening questions, OR a red screen is presented the visitor should NOT be permitted entry.
- If the COVID visitor screen is low risk and the rapid antigen test is declined, the visitor should have this documented on the WHAD24.1 form with a request to the NBS medical team caring for the baby to provide counselling on the reasons for the test prior to entry to the unit. The NBS bedside nurse can request this.
- If a NBS parent arrives via PIPER, they should be asked to attend the JK marquee to have a COVID visitor screen and the rapid antigen test performed as soon as practical and documented on the WHAD24.1 form within 24hrs of arrival.
- If the COVID visitor screen is low risk and the rapid antigen test result is positive the visitor is upgraded to High-Risk and should have a COVID PCR test.
- COVID PCR tests will be conducted in the JK marquee using the JK Respiratory Assessment Clinic location to create an encounter in the EMR to complete the COVID-19 PCR orderset
- If the visitor requests an exemption to visitation rules, clarify whether the visitor has a visitation exemption granted and what the exemptions are. This information may have already been provided by the ward, however if not, contact the Nurse in Charge of Newborn Services on 9055 3055 to seek clarification
- Any visitors with an exemption provided should be referred to Level 5 via the COVID-19 designated lift located in the staff lifts of Joan Kirner Women's and Children's.

Documenting the results:

The results of each Rapid Antigen Test should be documented in the following area:

1. In visitors with a negative RAT, on the WHAD24.1 paper form by the staff member administering the test in the JK Marquee, this form should be given to the visitor to give to the NBS nurse caring for the newborn on Level 5 for collection
2. In visitors who require a PCR; document in the initial EMR COVID screening tool in the designated section for Rapid Antigen Results and in the COVID orderset by the staff member administering the test in the JK marquee

Limitations

1. A negative result does not exclude infection with SARS-CoV-2.
2. Positive results should be confirmed by SARS-CoV-2 PCR

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Document Control, Revision History and Approvals

Version & Revision History				
Version	Version Date	Authors	Approved	Approval Date
Version 1.0	16.11.2021	H Sinnott, DONM SH/W&C M Pink, Paediatric Ambulatory Service, W&C B Van Ooi, Operations Manager EMA	W Watson, DD W&C C Collins, HOU, NBS A Tramontana, ID Physician M Kainer, ID Physician Kate Cranwell, DD, WPHU G, Veliz, DD – CSSC W Renwick, CSD, CSSC J Ferraro, DEDO S Crowe, EDONM M Dodsworth, NUM NBS	