Rapid Antigen Testing for COVID-19 in MAC & Birthing

Western Health

COVID - 19

Be Safe -- Be Smart -- Be Kind

VERSION 2: LAST UPDATED 16/11/2021

Purpose:

This document describes how to use the Abbot Pan Bio COVID-19 Antigen Rapid Test Device prior to patients attending the Maternity Assessment Centre (MAC) and Birthing to aid the early identification of asymptomatic patients and reduce the numbers of staff and patients 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 patients into COVID zones:

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

All positive results will need to be validated by a COVID PCR test, and negative results in patients who have a high risk on the COVID screening tool will need to be further 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 of patients 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 patients prior to attending the Maternity Assessment Centre (MAC) and Birthing.

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

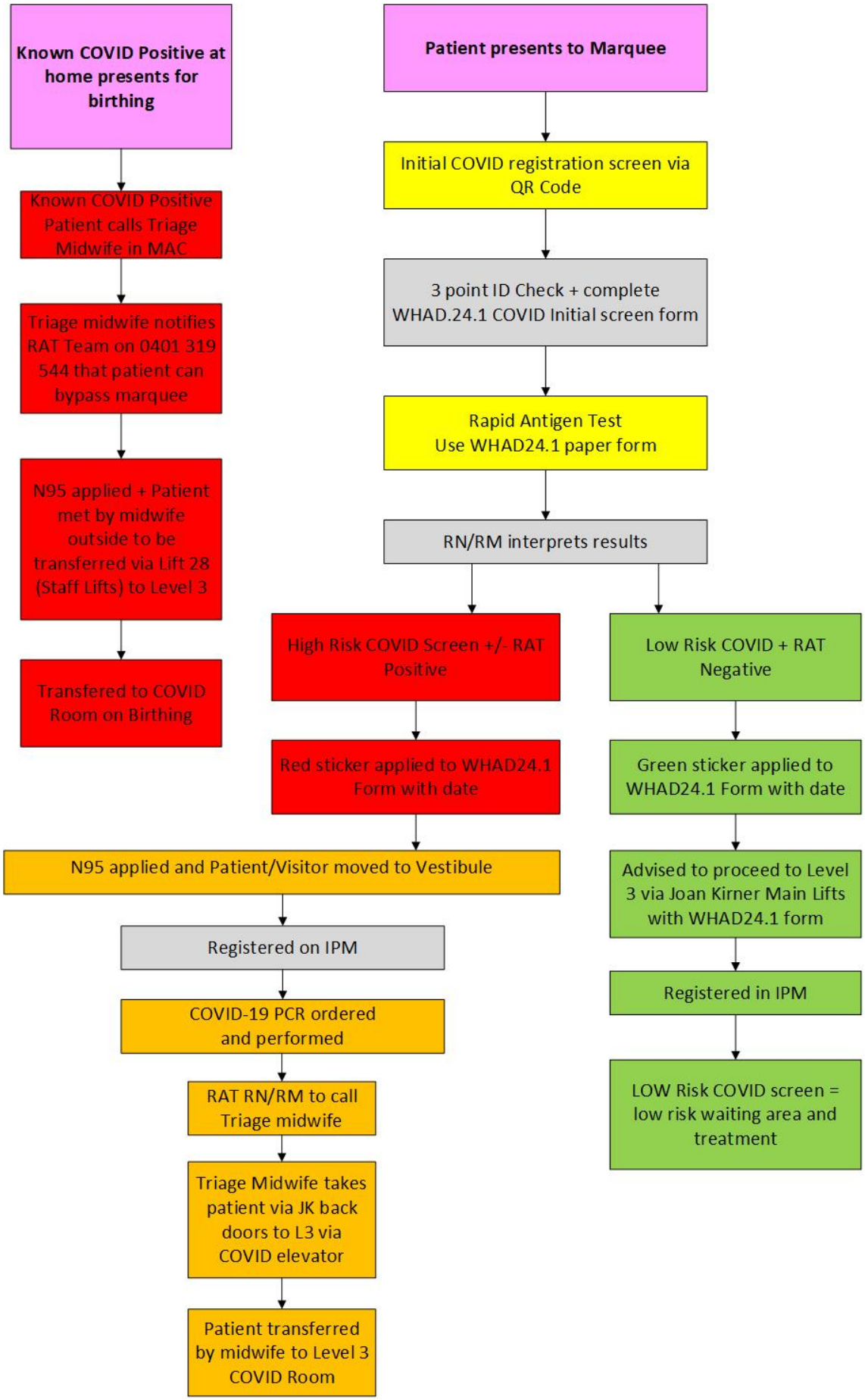
Rapid Antigen Testing in the Maternity Assessment Centre (MAC) and Birthing

Rapid Antigen Testing is one step in the COVID initial screening and testing processes of the Maternity Assessment Centre (MAC) and Birthing.

Rapid Antigen Testing should be completed on all patients who present to the Maternity assessment Centre before they attend Level 3 and are allocated to a clinical point of care. The test should be completed in conjunction with the Initial COVID EMR 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 Maternity Assessment Centre (MAC) and Birthing is described in **Figure 1.**

Figure 1: Maternity Assessment Centre (MAC) and Birthing COVID Screening and Testing



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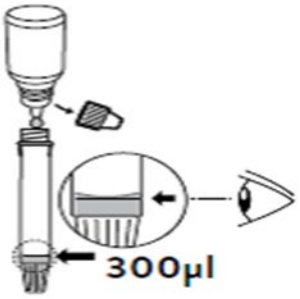
Administering the Test:

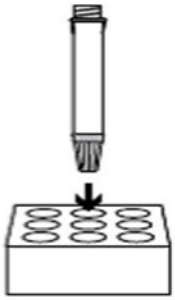
TEST PROCEDURE

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 (300µl).

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

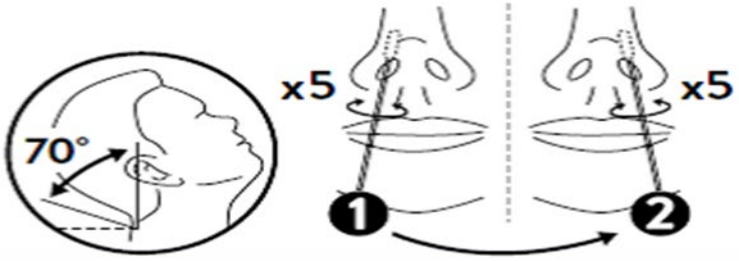


2 Place the extraction tube in the tube rack.



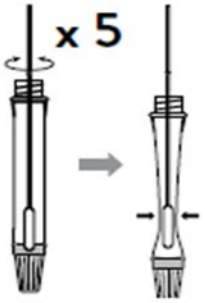
3 Tilt the patient's head back 70 degrees. While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril (until resistance is met at the turbinates). Rotate the swab five times against the nasal wall. Using the same swab repeat the collection procedure with the second nostril.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

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



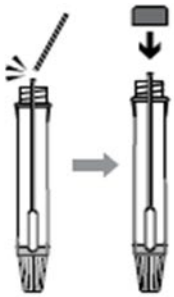
TEST PROCEDURE

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.



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

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

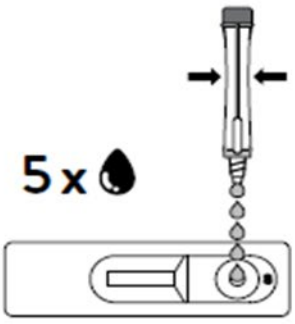


Important: please be careful to snap the swab at the designated breakpoint during **Step 5** – so the swab can fit in the extraction tube.

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

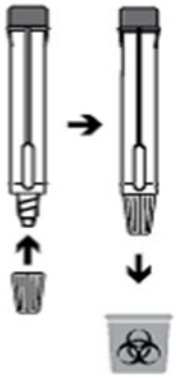
7 Dispense 5 drops of extracted specimens vertically into the specimen well (S) on the device. Do not handle or move the test device until the test is complete and ready for reading.

⚠ **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.



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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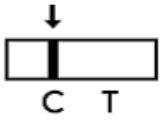
Reporting Results

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

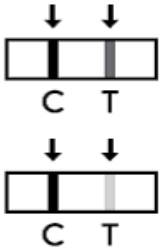
The presence of only the control line (C) and no test line (T) within the result window indicates a negative result.



POSITIVE

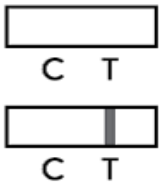
The presence of the test line (T) and the control line (C) within the result window, regardless of which line appears first, indicates a positive result.

⚠ **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 in the Maternity Assessment Centre (MAC) and Birthing:

- If the COVID screen is low risk and the rapid antigen test result is negative the patient can proceed to Level 3 and wait in the low risk MAC waiting area.

  Notify the Triage Midwife:
- All patients who screen high risk or have a positive RAT will be asked to swap their surgical mask for an N95 mask prior to admission into the JK Building
- If the rapid antigen test result is positive the patient is upgraded a risk level i.e.:
  - Low-Risk upgraded to High-Risk
  - High-Risk upgraded to COVID positive
- If a High-Risk patient has a negative rapid antigen result they should still have a COVID PCR test and be allocated to a SCOVID room via the COVID-19 transit pathway
- All COVID positive patients without evidence of a positive test should have a COVID PCR test and be allocated to a COVID room via the COVID-19 transit pathway.
- Known Maternity HITH COVID positive patients with results in the Western Health medical record do not require a rapid antigen test, they should be allocated to a COVID room via the COVID-19 transit pathway.

Documenting the results:

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

1. On the WHAD 24.1 paper form in the Marquee, this form should be given to the treating clinician to be filed on the patient record .
2. The initial EMR COVID screening tool in the designated section for Rapid Antigen Results

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 2.0	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 A Pearce, Acting CSD, W&C M Kainer, ID Physician A Tramontana, ID Physician K Cranwell, WPHU G, Veliz, DD – CSSC W Renwick, CSD, CSSC J Ferraro, DEDO S Crowe, EDONM	