Rapid Antigen Testing for COVID-19 – Dialysis

Western Health

COVID - 19

Be Safe – Be Smart – Be Kind

Purpose:

This document describes how to use the Abbot Panbio COVID-19 Antigen Rapid Test Device.

The test is an immunochromatographic membrane assay 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 SCOVID

All positive results will need to be validated by a COVID PCR test, and some negative results will also need to be further validated by a COVID PCR test.

Overview:

The Panbio 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 Panbio COVID-19 Rapid Test will be undertaken in the Dialysis Departments.

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

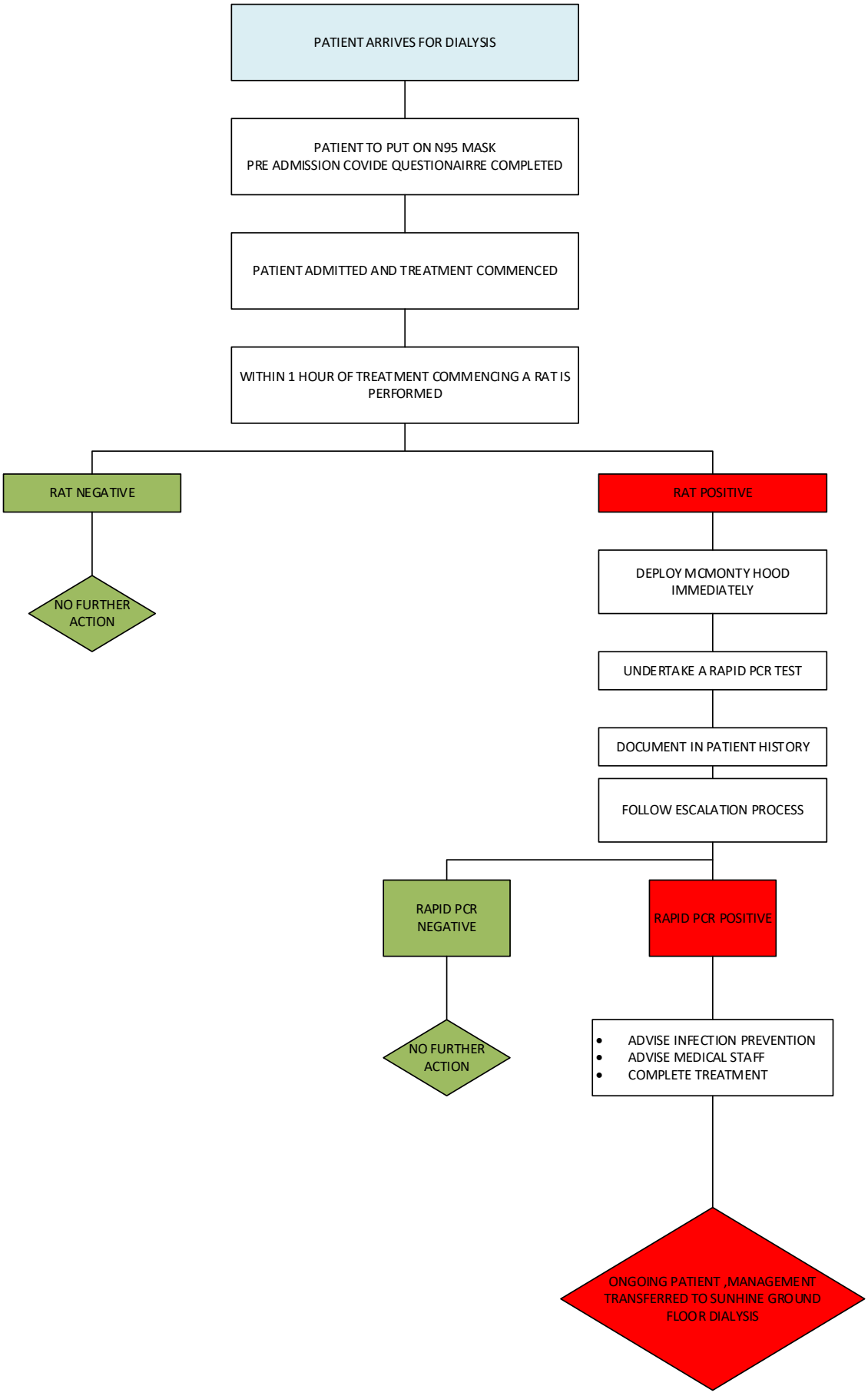
Rapid Antigen Testing in the Dialysis Departments

Rapid Antigen Testing is one step in the COVID initial screening and testing processes of the Dialysis Departments.

Rapid Antigen Testing should be completed on all patients after they are allocated to a dialysis treatment space of a clinical point of care. The test should be completed in conjunction with the Initial COVID EMR screening tool. The results of the tool, and the test should inform the decision to complete a COVID PCR test.

The Rapid Antigen Test process in the Dialysis Departments is described in Figure 1

Figure 1: Western Health Dialysis Unit COVID Screening and Testing

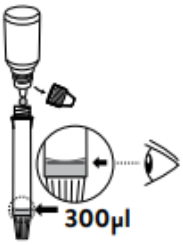

PATIENT ARRIVES FOR DIALYSIS
PATIENT TO PUT ON N95 MASK
PRE ADMISSION COVIDE QUESTIONAIRRE COMPLETED
PATIENT ADMITTED AND TREATMENT COMMENCED
WITHIN 1 HOUR OF TREATMENT COMMENCING A RAT IS PERFORMED
RAT NEGATIVE
NO FURTHER ACTION
RAT POSITIVE
DEPLOY MCMONTY HOOD IMMEDIATELY
UNDERTAKE A RAPID PCR TEST
DOCUMENT IN PATIENT HISTORY
FOLLOW ESCALATION PROCESS
RAPID PCR NEGATIVE
NO FURTHER ACTION
RAPID PCR POSITIVE
ADVISE INFECTION PREVENTION
ADVISE MEDICAL STAFF
COMPLETE TREATMENT
ONGOING PATIENT ,MANAGEMENT TRANSFERRED TO SUNHINE GROUND FLOOR DIALYSIS

Administering the Test:

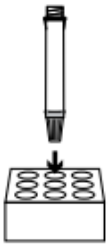
TEST PROCEDURE

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.

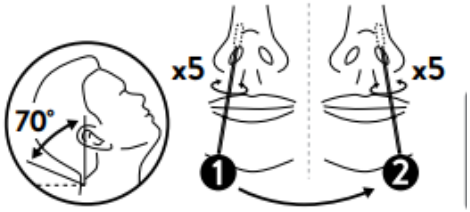


2 Place the extraction tube in the tube rack.



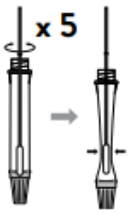
3 Tilt the patient's head back 70 degrees. While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril (until resistance is met at the turbinates). Rotate the swab five times against the nasal wall. Using the same swab repeat the collection procedure with the second nostril.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

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

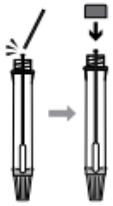


TEST PROCEDURE

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.



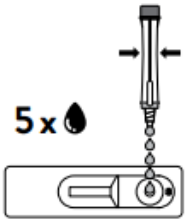
5 Break the swab at the breakpoint and close the cap of extraction tube.



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

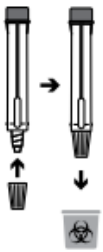
7 Dispense 5 drops of extracted specimens vertically into the specimen well (S) on the device. Do not handle or move the test device until the test is complete and ready for reading.

⚠ **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.



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.

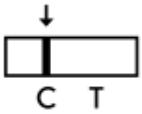
Reporting Results

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

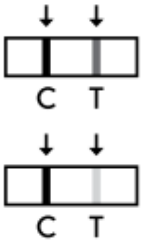
The presence of only the control line (C) and no test line (T) within the result window indicates a negative result.



POSITIVE

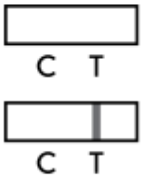
The presence of the test line (T) and the control line (C) within the result window, regardless of which line appears first, indicates a positive result.

⚠ **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 Dialysis Department:

- If the result is negative the patient continues dialysis as planned no further action required
- If a High-Risk patient gets a negative result they should still have a COVID PCR test
- If the result is positive:
    - Notify the Nurse In Charge or the NUM in the area immediately
    - All COVID positive patients will be dialysed under the McMonty Hood with an N95 mask on immediately & complete treatment
    - Further rapid PCR test to confirm result
- If patient is asymptomatic for discharge home and to continue isolation dialysis treatments in the Ground Floor Dialysis Unit

Documenting the results:

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

1. The clinical dialysis treatment record

2. The initial EMR COVID screening tool in the designated section for Rapid Antigen Results.

3. Positive results only: notify via email the treating medical team, infection control, WPHU, WH-COVID contact tracing, Dialysis CNC and RACDR using the email template COVID positive dialysis pts email template

Pathology Ordering and Rapid Antigen Testing

The result of a Rapid Antigen Test should be included in the clinical notes section of a pathology order for a COVID PCR swab. This allows the laboratory to validate the type of PCR test that has been requested.

Limitations

1. A negative result does not exclude infection with SARS-CoV-2.

2. Positive results should be confirmed by SARS-CoV-2 PCR