Point of Care Testing (POCT)

Asymptomatic Screening for Continuing Care Panbio COVID-19 Ag Rapid Test Learning Module
Course Instructions

This course is for initial training and annual competency.
Objectives

- Competency Requirements
- Test Kit Components
- Quality Controls
- Testing
- Results and Interpretation
- Limitations
Competency Requirements

Initial Training:
• Written Education Quiz - successful achievement of a minimum 80% score or
• Practical - demonstrate competency
• Education Checklist - Successful completion of all elements outlined

Annual Competency:
Annual competency is each health care professional’s responsibility
Panbio COVID-19 Ag Rapid Test

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 nasal swab specimens from individuals who meet COVID-19 testing criteria.
Panbio COVID-19 Ag Rapid Test Device Kits

Panbio COVID-19 Ag Rapid Test Device kits contain the components shown in the image to the left.

Each kit contains materials to perform up to 25 tests.
Panbio COVID-19 Ag Rapid Test Device Kits

Storage and Stability:

• Store the test kit and all components between 2 and 30°C

• All components are stable until expiry date printed on each pouch when stored correctly

• Keep out of direct sunlight

Kit lot number and expiry date are located on the side of the box
Components – Test Device

Test Device in Foil Pouch

- Lot Number
- Expiry Date:
  - Always check the expiry date on the pouch and ensure the pouch is not damaged.

Test Device

- Control test line
- Patient test line
- Specimen well
Other Components

**Buffer** – lot number and expiry are located on the side of the bottle

**Nasal Swab** – individually packaged with the lot number and expiry on it

**Tube Rack** – made of cardboard and will need to be built by the end user

**Extraction Tube and Cap**
Quality Control – Internal Control

Controls ensure the reagents are working and that the test is performed correctly.

Internal Control:
The test device has a control line that will indicate the reagents and test device are working correctly. If the control line does not appear when a test is performed, the result is invalid.
Quality Control – External Control

**External Quality Control** testing is required:

- When a new box of Panbio COVID-19 Ag Rapid Test Device kits is opened

Always check the expiry date on the back of the foil pouch and ensure the pouch is not damaged.
Clinical Indications

Asymptomatic healthcare providers
– to be used as a screening tool Continuing Care facilities
Sample Collection Guidelines

• Perform hand hygiene as per AHS Hand Hygiene Policy PS-02-01
• Refer to the AHS Donning and Doffing PPE posters for details on careful removal and disposal of gloves

Clearly label the extraction tube and test device with information about the person being screened:
  • Healthcare provider’s full name
  • Healthcare provider’s identification number
  • Date and Time of Collection
Sample Requirements

Use swab included in the Panbio kit to collect one nasal swab for the Panbio COVID-19 Ag Rapid Test

Sample Type: Nasal Swab

Storage and Stability:
- Samples must be collected and tested immediately
- If required, samples may be stored up to 2 hours prior to testing when placed in an extraction tube filled with buffer at room temperature (15-30°C)
Nasal Swab Collection

<table>
<thead>
<tr>
<th>Step</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Remove any mucous from the patient’s nose with a tissue or cotton tipped swab prior to collecting the nasal swab.</td>
</tr>
<tr>
<td>2</td>
<td>Open the nasal swab.</td>
</tr>
<tr>
<td>3</td>
<td>Insert the swab into one nostril of the patient. The swab tip should be inserted up to 2.5cm (1 inch) from the edge of the nostril.</td>
</tr>
<tr>
<td>4</td>
<td>Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.</td>
</tr>
<tr>
<td>5</td>
<td>Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.</td>
</tr>
<tr>
<td>6</td>
<td>The swab is ready for testing.</td>
</tr>
</tbody>
</table>
Patient Testing

- Perform hand hygiene and don appropriate PPE.
- Record healthcare provider information of the person receiving the screening test, testing date and certified users full name on the Staff Signature Log.
- Label extraction tube and test device with name and identification number of the healthcare provider receiving the test. Holding the buffer bottle vertical, fill the extraction tube to the Fill-line.
- Place extraction tube in rack.
- Collect nasal swab specimens.
Patient Testing - Continued

• Immediately insert the patient swab specimen into the extraction tube. Ensure the swab tip is immersed completely into buffer.

• Extract sample by gently swirling the swab tip in the buffer fluid by pushing into the extraction tube wall at least 5 times.

• “Ring out” then squeeze out the swab by squeezing the extraction tube with your fingers.

• Break the swab at the breakpoint, remove and dispose of the broken top piece of the swab into an appropriate biohazard container.

• Remove bottom dropping nozzle cap.
Patient Testing - Continued

• Dispense **5 drops** of the extracted specimen onto the test device well (S) by gently squeezing the extraction tube.

• Start the timer and wait 15 minutes before reading the results. **Do not** report after 20 minutes.

• Document results as per result and interpretation guide (following slides).

• After results are reported, dispose of test device/extractor tube as per AHS IP&C Protocols.

• Doff PPE and perform hand hygiene.
Testing Procedure Video

Results - 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.

Reporting & Follow-up

- Document positive result on the Panbio COVID-19 Ag Rapid Test – Result Log Sheet.
- Ensure healthcare provider does not continue working. Instruct them to follow AHS and Alberta Health guidelines for isolation. Tell them this result is a SCREEN and must be confirmed.
- Direct them to book confirmatory testing through the AHS portal.
- Document positive result on the Rapid Antigen Screening Positive and False Positive Tracking Record.
Results - Negative

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

Reporting & Follow-up

- Document negative result on the Panbio COVID-19 Ag Rapid Test – Result Log Sheet.
- No further action/follow-up is required.
Results - Invalid

If the control line (C) is not visible within the result window after performing the test, the result is considered invalid.

Reporting & Follow-up

• Document invalid result on the Panbio COVID-19 Ag Rapid Test – Result Log Sheet.
• Repeat testing.
• If results continue to be invalid, follow process for screen positive result (do not continue to work, isolate and book confirmatory testing).
Limitations

• The contents of this kit are to be used for the professional and qualitative detection of SARS-CoV-2 antigen from nasal swab. Other specimen types may lead to incorrect results and must not be used.

• Failure to follow the instructions for test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.

• A negative test result may occur if the specimen was collected, extracted or transported improperly. A negative test result does not eliminate the possibility of SARS-CoV-2 infection and should be confirmed by viral culture or a molecular assay.

• Positive test results do not rule out co-infections with other pathogens.

• Test results must be evaluated in conjunction with other clinical data available to the physician.

• Reading the test results earlier than 15 minutes or later than 20 minutes may give incorrect results.

• Panbio™ COVID-19 Ag Rapid Test Device is not intended to detect from defective (non-infectious) virus during the later stages of viral shedding that might be detected by PCR molecular tests.

• Positive results may occur in cases of infection with SARS-CoV.
Important Notes To Remember

• Always follow the Standard Operating Procedures (SOPs),
• Prepare all test components before specimen collection
• Test devices are single use only
• Do not mix components of the test kits with other test kits.
Quiz

All device users must complete the quiz and pass with a minimum of 80%.

Checklist

All device users must have the training checklist completed by an educational designate/super-user.