Laboratory Medicine Clinical Procedure	
Abbott Panbio COVID-19 Antigen Test	Document Number: PROV-43 Version Number: 12 Approved Date: July 15, 2021
Approving Authority (Sponsor): Director Quality Safety Logistics – Laboratory Medicine, and provincial Multidisciplinary Clinical Practice Oversight Committee Owner: Laboratory Quality and Regulatory	Next Review Date: July 15, 2022
Contact for Interpretation: POCTLab@saskhealthauthority.ca	
Healthcare providers eligible to perform this function: Trained POCT employees	Document Type: Clinical Procedure, Point of Care Test – Laboratory Medicine
Key words: pandemic coronavirus sars	

1. PURPOSE

This procedure provides instruction for the point of care personnel to use the Abbott Panbio SARS-CoV-2 (COVID-19) Antigen test, a qualitative standalone rapid test. It is intended for the detection of viral antigen of SARS-CoV-2 from patient respiratory specimens.

2. PRINCIPLES

2.1 The Abbott Panbio SARS-CoV-2 (COVID-19) Antigen Test is a rapid diagnostic test that aids in the detection of SARS-CoV-2 from individuals who meet COVID-19 clinical and/or epidemiological risk factors.

2.2 The assay detects antigen from SARS-CoV-2 using antigen capture. The test line on the strip is coated with antibodies that are specific to SARS-CoV-2. Once the virus is captured, conjugate antibody can react with antigen on the surface of SARS-CoV-2 that has been captured, and produces a visible line in the test line area.

2.3 The Abbott Panbio SARS-CoV-2 (COVID-19) Antigen Test is intended for use by trained personnel specifically instructed and trained on use of the product. A Qualified Professional is required to collect the nasopharyngeal swab.

2.4 CV-19 G0113 Abbott Panbio™ or BD Veritor Point of Care Testing Pocket Guide March 2, 2021

3. ROLES AND RESPONSIBILITIES

3.1 **Point of Care User/Tester or Health Care Provider**

- Positively identify the patient: full name, unique identifying number (HSN), noting the date and time of collection, label specimen, maintain Patient ID continuity through testing process.
- Follow procedure to perform the Abbott Panbio antigen test for the SARS-CoV-2 virus.
- Educates patients:

- Explanation of test process (i.e. swab collection, test result)
- Explanation that test is used to monitor for COVID in those not showing symptoms
- Explanation that COVID antigen testing is not retained on personal health records

- Collects the nasal swab, performs the testing with test kits provided and reads test results at 15 minutes
- Provides patient their results along with appropriate counselling
- Documents and submits data by using required logs / forms and applications
- Liaise with POCT Laboratory team

3.2 **Site Lead**

- Responsible to ensure test location is set up appropriately (i.e. screening, testing and information areas)
  - Refer to SHA Test to Protect Playbook for specific details
- Ensure location has the ability to provide data through WebForm and fax

4. SPECIMEN INFORMATION

Specimen Type/Source	• Nasopharyngeal swabs • Nasal swabs (dual) – Health Canada approved Abbott Panbio compatible Nasal swab
Specimen Stability	• The collected sample should be used immediately • If immediate testing is not possible, the swab can be stored in the extraction tube with extraction buffer for up to 2 hours at room temperature.
Unacceptable specimens and follow-up action	• Inadequate specimen collection • Improper sample handling/storage/transport • Improperly labelled specimens • Patient has a previous positive result within past 7 days
Specimen Handling	The collected sample should be used immediately according to the procedure

5. EQUIPMENT & SUPPLIES / REAGENTS / FORMS & LABELS

- Each kit comes with all of the supplies needed to perform 25 tests
- Kits should be stored at room temperature between 15-30° C, away from direct sunlight
- The positive and negative control swabs that come with each kit may be used to train point of care operators. The Quality Control was performed at Roy Romanow Provincial Laboratory (RRPL) prior to distribution of the kit lot numbers.

Equipment & Supplies	Reagents	Forms & Labels

• Nasopharyngeal swabs (If not used for Panbio specimen collection, dispose of in waste)
Or Nasal swabs
• Panbio test kit (includes extraction tube, extraction tube cap, fold-up cardboard
	• Panbio test kit includes:
	  • Antigen Test device
	  • Extraction Buffer (1 bottle per kit)
	  • Positive control (1 swab per kit)
	  • Negative control (1 swab per kit)
		• COVID-19 Pandemic electronic Requisition
		• SHA 0012 Antigen Testing Daily Log
		• SHA 0014 Antigen Test Positive - Public Health Referral form

tube rack, package insert, quick reference guide) • Personal protective equipment (PPE) (eg. gloves, masks, face shield) • Timer • Waste disposal		• COVID-19: ANTIGEN test Supply Sign Out Form

6. SAFETY PRECAUTIONS

6.1 Hazards

- The SARS-CoV-2 virus may cause mild to severe respiratory illness and has spread globally, including Canada.
- The virus is spread during close contact (within a 2 meter distance), contact with high touch surfaces (hand hygiene), and droplet production (wear procedural mask, eye protection, gloves and gown).
- The extraction buffer contains <0.1% Sodium Azide which may be toxic if ingested.

6.2 Safe Work Practices

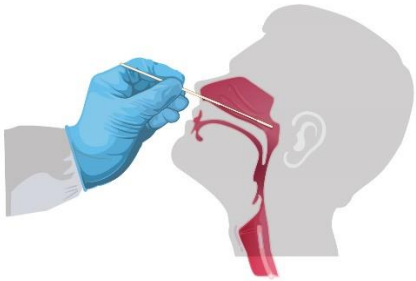
- All Point of Care testing personnel shall don required personal protective equipment, prior to performing the task(s) outlined in this standard operating procedure
- Don gown & gloves, procedure mask with eye or facial protection (face shield or goggles), change gloves between patients.
- Discard the used sample, antigen test cartridge, and extraction tubes into a biohazard waste container when complete. See exception below.

Waste Disposal	
Panbio testing used by	Waste discard
SHA facility (Acute care, LTC, by staff person on duty)	Follow biohazard processes to dispose of waste
Third-party, or business, or by staff in a congregate setting	Biohazard bag/bin if available otherwise general waste
Individual for self-testing off SHA premises (SHA employee, first responder, dentist, pharmacist)	Household waste

7. EQUIPMENT MAINTENANCE

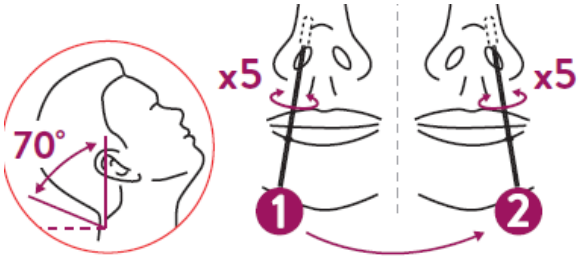
The Abbott Panbio COVID-19 Antigen Test does not require equipment or maintenance
Clean the work area according to routine practices, between each patient.

8. A. SPECIMEN COLLECTION - Nasopharyngeal Swab



Step	Action - Nasopharyngeal Swab
A.1	Use the swabs provided in the test kit.
A.2	To minimize risk of contamination of PPE and swab package during sample collection, it is recommended to widely open the package by pulling from the top down. Carefully remove the swab and perform sample collection.
A.3	When to collect the NP Swab: After setting up extraction tube, as outlined in section 9 of this document.
A.4	How to Collect an NP Swab: Have the patient incline head to 70 degrees. Insert dry swab straight back (not upwards) until slight resistance is felt. The nasal passage runs parallel to the floor, not parallel to the bridge of the nose. The approximate distance to insert the swab is ½ the distance from the nostril to the earlobe. Rotate swab 2-3 times and hold in place for 5 seconds to allow for maximum absorbency. Remove swab from nostril.
A.5	DO NOT USE FORCE while inserting the swab. The swab should travel smoothly with minimal resistance; if resistance is encountered, withdraw the swab a little bit without taking it out of the nostril. Then elevate the back of the swab and move it forward into the nasopharynx.

B. SPECIMEN COLLECTION - NASAL Swab

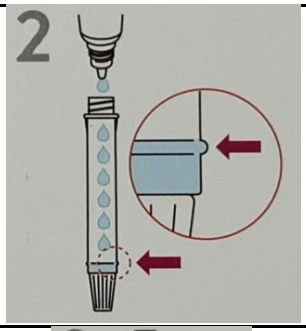
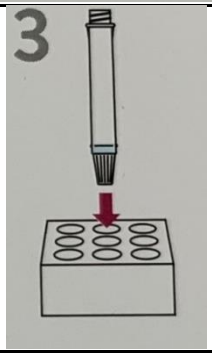
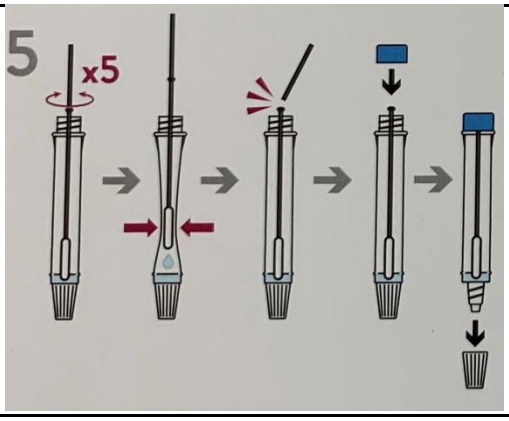


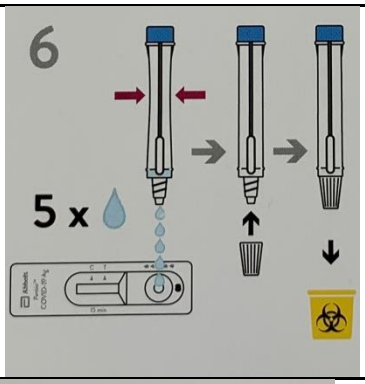
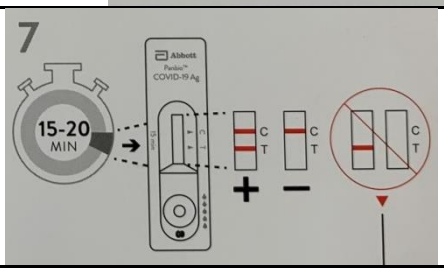
Step	Action – Nasal Swab (dual)
B.1	To minimize risk of contamination of PPE and swab package during sample collection, it is recommended to widely open the package by pulling from the top down. Carefully remove the swab and perform sample collection.
B.2	When to collect the Nasal Swab: After setting up extraction tube, as outlined in section 9 of this document.
B.3	How to Collect an Nasal Swab:

	1. Tilt the patient's head back 70 degrees. While gently rotating the swab, insert swab less than one inch (about 2 cm) into nostril (the soft part of the nose). 2. Rotate the swab five times against the nasal wall then slowly remove from the nostril. 3. Using the same swab repeat the collection procedure with the second nostril. Caution: If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.

9. PROCEDURE

Follow the steps in the table below:

Step	Action	
9.1	Remove the test device from the foil pouch, write patient ID – example Health Services Number (HSN) on the back of the device. Then place on a flat, horizontal, clean surface.	Check expiry date on the back of the test device pouch to ensure in date.
9.2	Label the extraction tube with patient HSN. 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 (approximately 300 µl).	
9.3	Place the extraction tube in the tube rack.	
9.4	Collect the swab (i.e. nasopharyngeal or nasal) from the patient using standard technique – see section 8 of this document.	
9.5	**Sample Extraction**	
9.5.1	Insert the swab into the extraction tube.	
9.5.2	Swirl the swab tip in the buffer fluid inside the extraction tube, pushing into the wall of the extraction tube at least five times.	
9.5.3	Squeeze out the swab by squeezing the extraction tube with your fingers.	
9.5.4	Break the swab at the breakpoint, then place and close the cap of extraction tube.	

9.6	**Loading specimen onto Antigen Test**	
9.6.1	Open the dropping nozzle cap at the bottom of the extraction tube.	
9.6.2	Dispense 5 drops of extracted specimen vertically into the specimen well on the device.	
9.6.3	Re-secure the dropping nozzle cap, then wait until the result appears, discard extraction tube into biohazard waste	
9.7	Set a timer and read results after 15-20 minutes. See Section 10 of this document for result interpretation	

10. INTERPRETATION OF RESULTS, DOCUMENTING AND DATA REPORTING

Result Interpretation	Panbio Device	Action	
Positive (presumptive)		• Confirmatory testing required	
		Confirmatory Testing	
		Does your location have a qualified person to collect a nasopharyngeal (NP) swab AND is the location is Licensed to collect NP swabs?	
		If • Yes	Then • Collect NP swab for referral • Complete COVID-19 electronic Requisition
		• No	• Select one of the options below: • Contact Test Assessment site and make appointment for person **OR** • Instruct person to call 811 (HealthLine) **OR** • Instruct person to attend Drive Thru test location
Negative (presumptive)		If • Patient verbally screened positive	Then • Confirmatory testing required
		Confirmatory Testing	

<table>
<tr><td></td><td></td><td colspan="2">Does your location have a qualified person to collect a nasopharyngeal (NP) swab AND is the location is Licensed to collect NP swabs?</td></tr>
<tr><td></td><td></td><td>If
• Yes

• No</td><td>Then
• Collect NP swab for referral
• Complete COVID-19 electronic Requisition

• Select one of the options below:
• Contact Test Assessment site and make appointment for person
OR
• Instruct person to call 811 (HealthLine)
OR
• Instruct person to attend Drive Thru test location</td></tr>
<tr><td>Invalid</td><td> 

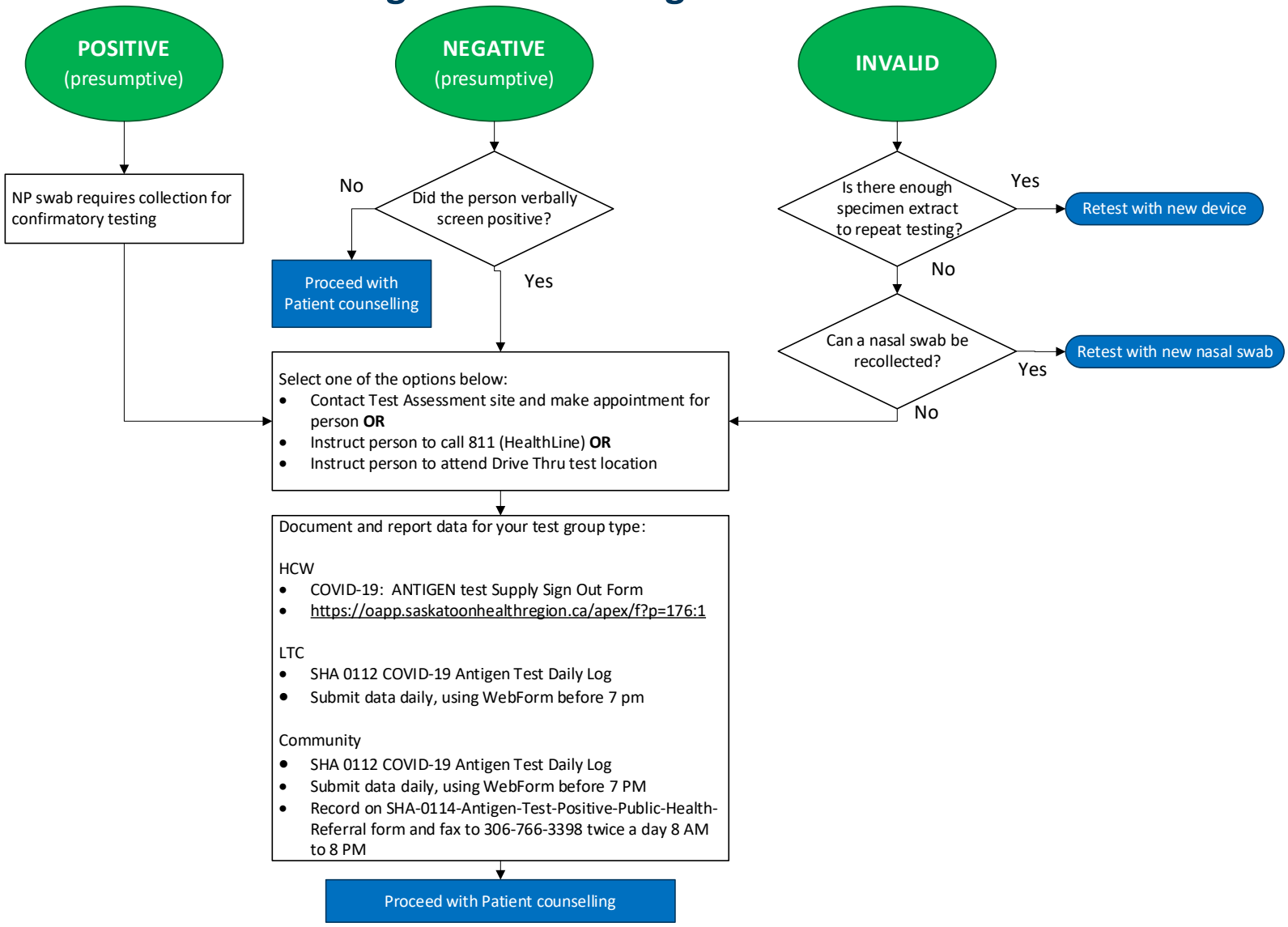
no line at C</td><td colspan="2">• Retesting required

Retest by collecting new swab
OR
If enough sample in extraction tube retest with new test device/cartridge
OR
If your location has a qualified person to collect a nasopharyngeal (NP) swab AND is the location is Licensed to collect NP swabs then :
• Collect the NP swab
Complete the COVID-19 electronic Requisition</td></tr>
</table>

Documenting and Data Reporting
*It is recommended that these logs be confidential retained for a period of time. Discard must be done in in a confidential manner if they contain personal health information.
*Refer to SHA Work Standard Web App for Panbio POC Antigen Test Tracking for specifics related to data entry on WebForm.

	Log / Form	Action
Health Care Worker at Home Testing	• COVID-19: ANTIGEN test Supply Sign Out Form	• Submit daily tally to https://oapp.saskatoonhealthregion.ca/apex/f?p=176:1
Long Term/Continuing Care and Community	• SHA 0112 COVID-19 Antigen Test Daily Log	• Submit before 7 pm daily, all testing tallies from SHA-0112 COVID-19 Antigen Test Daily log, daily, using WebForm • Total tests performed today • Total number of positives today • Total number of staff tested today • Total number of staff tested positive today • Total number of clients/students tested today • Total number of clients/ students tested positive today • Total numbers of COVID-19 tests performed • Total number of positive COVID-19 tests identified
Positive Results	• SHA-0114 Antigen Test Positive – Public Health Referral Form	• Fax this Antigen Test Positive Public Health Referral form to 306-766-3398, twice a day between 8 AM to 8 PM for **all** positive antigen results only

Handling COVID-19 Antigen Test Results



11. POINT OF CARE TEST RESULT COUNSELLING (Test to Protect Toolkit)

a. Test to Protect Testing Negative Script
b. Test to Protect Testing Positive Script
c. Test to Protect Information Sheet for Patients, Residents, Clients and Families
d. Test to Protect Testing Negative Patient Handout
e. Test to Protect Testing Positive Patient Handout

12. CONFIRMATORY TESTING

Confirmatory Testing is required for:

- All antigen positives
- Unresolved invalid tests where insufficient sample extraction or recollection of nasal swab was not available for retesting
- Patients with negative antigen result but who verbally screen positive or where patient is suspected of COVID-19 infection

Collect a New Nasopharyngeal swab, place in viral transport media, and refer to SHA Laboratory for confirmatory testing.

Enter POCT Antigen test result into the COVID-19 electronic Requisition, print and send with the confirmatory specimen.

(NP swab and viral transport media should be obtained through the SHA Materials Management supply chain.)

13. ELECTRONIC COVID-19 REQUISITION – When referring a confirmatory nasopharyngeal swab to the SHA Laboratory, Positive Test results must be entered into the COVID-19 electronic Requisition, then print off the requisition.

The printed requisition will accompany the NP swab to the SHA Laboratory for confirmatory testing. Ensure the eREQ has been fully completed, identifying Medical Health Officer as the Ordering Physician.

Digital Health will provide each individual access to the electronic Requisition:

- SHA users login using the SHA network account unique USER NAME and PASSWORD
- Non-SHA users will need to go through eHealth to obtain a MYSASKHEALTHRECORD account, so there is a secure way to access the network.

Refer to Pandemic eRequisition for details or contact the SHA Ereq Support ereqsupport@saskhealthauthority.ca for further information.

The designated trained staff will need to perform the NP swab and test. However, administrative support may be utilized for data entry into the electronic requisition.

In accordance with the requirement for a downtime procedure, a Paper Copy of the electronic requisition is located on the SHA COVID website. This paper copy is only to be used during downtime.

Refer to: Pandemic eRequisition (eReq) Downtime Process

14. METHOD LIMITATIONS

14.1 Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target sequences.

14.2 Specimens other than the provided nasopharyngeal swabs may provide incorrect results and should not be used.

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

14.4 False-negative results may arise from:

- Improper sample collection
- Improper sample handling (delayed testing, improper extraction)
- Specimen collection after virus can no longer be found in the specimen matrix
- Failure to follow instructions for use

14.5 False-positive results may arise from:

- Cross contamination during specimen handling or preparation
- Specimen mix-up

14.6 Negative results do not preclude infection with SARS-CoV-2 virus, and should not be the sole basis of a patient management decision.

14.7 Positive results do not rule out co-infection with other bacteria or viruses.

14.8 This test is not intended to detect defective (non-infectious) virus during the later stages of viral shedding that might be detected by PCR molecular tests.

14.9 Trouble shooting concerns contact the POCT Medical Laboratory staff
POCTLab@saskhealthauthority.ca or Email: canproductsupport@abbott.com
Abbott Technical Support Phone: 1-877-441-7440

15. MATERIALS MANAGEMENT

Community to fill in Antigen Testing Request Supply Form and email to antigentestingintake@saskhealthauthority.ca to reorder supplies POCT COVID supplies.
SHA facilities can order via materials management.

Product Description	SHA Order Number	Manufacturer Number
Panbio NP Test Kits	308571	41FK10
Panbio Nasal Test Kits	308579	41FK11
Nasal Swabs	308655	

16. SUPPORT

- For testing related assistance POCTLab@saskhealthauthority.ca
- For process related assistance Antigentestingintake@saskhealthauthority.ca
- For Health Care worker assistance healthcareworkerintake@saskhealthauthority.ca
- For Electronic Requisition assistance ereqsupport@saskhealthauthority.ca

17. PROCEDURE MANAGEMENT

The management of this procedure including procedure communication, education, implementation, evaluation and audit is the responsibility of Lab Quality and Regulatory Manager, Regina Area. Renewal and amendment is the responsibility of the Lab Quality and Regulatory Manager, Regina Area and Dr. Jessica Minion, Medical Microbiologist.

18. APPLICABILITY

Compliance with this procedure is required by all Saskatchewan Health Authority employees, practitioner staff, students, and any other persons acting on behalf of the SHA, including contracted services. Non-compliance with this procedure may result in disciplinary action, up to and including termination of employment and/or privileges.

19. REFERENCES

18.1 Abbott Panbio COVID-19 Ag Rapid Test Device (Nasopharyngeal) IFU (41FK10-07-A0; date issued 2020.08)
18.2 Abbott Panbio COVID-19 Ag Nasal IFU (41FK11-07-A0, date Issued : 2020.11)

20. SUPPORTING DOCUMENTS

19.1 Reporting Templates:

- SHA 0012 Antigen Testing Daily Log
- SHA 0014 Antigen Test Positive - Public Health Referral form