TITLE: PPR-R-MB-0001 Procedure - Amplification - Coronavirus RT-PCR Abbott: ID NOW COVID-19 Point Of Care Test	**Doc #:** PPR-R-MB-0001
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Purpose

The Abbott ID NOW is a molecular rapid point-of-care test for the detection of SARS-CoV-2 (the causative agent of COVID-19). It is less sensitive than traditional PCR performed in the laboratory, but it can be performed with minimal training and at the point of sample collection. The test also provides a faster turn around time allowing the result to result to be acted on more quickly. It is to be used in limited settings as approved by Microbiology at Nova Scotia Health, IWK Health Centre, and the Covid Network.

Abbreviations and Definitions

Term, abbreviation, acronym, etc.	Definition
ºC	Degrees Celsius
ID	Identification
N/A	Not Applicable
NP	Nasopharyngeal
PCR	Polymerase Chain Reaction
PPE	Personal Protective Equipment
QC	Quality Control
SOP	Standard Operating Procedure
SARS-CoV-2	Severe Acute Respiratory Syndrome - Coronavirus-2
COVID-19	Coronavirus Infectious Disease, 2019
SPC	Sample Processing Control
POC	Point of Care
VTM or UTM	Viral transport medium or Universal Transport medium (pink liquid)

Safety Precautions

Hazards

SARS-CoV-2 is an enveloped, single-stranded RNA virus that can cause mild to severe respiratory illness and has spread globally, including Canada. For the purposes of this procedure, the virus is spread during close contact (within a 2 meter distance), contact with contaminated surfaces, and droplet production.

Safe Work Practices

- All Point of Care (POC) testing personnel shall don required personal protective equipment, as per routine practices and standard precautions, 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 and sanitize hands between patients.
- Discard used swab, and reagent cartridges in hazardous waste receptacle.
- If the machine becomes contaminated with a droplet, wipe dry using a lint-free towel and then decontaminate the area with an isopropyl or ethanol-moistened (70%) towel/wipe or 10% bleach.

Materials

Reagents:

- Test Bases: Orange plastic components containing two reaction tubes of lyophilized/powdered reagents for the targeted amplification of SARS-CoV-2 viral RNA and an internal control.
- Sample Receivers: Blue plastic components (sealed) containing 2.5 mL of elution buffer.
- Transfer Cartridges: White plastic components used to transfer 2 x 100 µL of sample extract from the Sample Receiver to the Test Base; DO NOT touch the white tips that protrude from the bottom

Equipment & Supplies

- Nasopharyngeal swabs are NOT provided in test kits
- Positive Control Swab: The positive control swab is coated with inactivated influenza A & B viruses. The positive control swab ensures sample elution/lysis and workflow were performed correctly but does not confirm amplification of the SARS-CoV-2 target (RdRp gene).
- Universal Printer Order Number: 55115
- Barcode Scanner Order Number: OPR2001ZWU1-201
- ID NOW™ USB Drive Order Number: EQ004001

Sample

Specimen Type/Source	Direct nasopharyngeal swab (Nasal and Oropharyngeal/nares swabs acceptable by the manufacturer, but are not preferred for our use)
Acceptable Collection Containers	Dry collection tube (dry and empty)
Specimen Stability	Up to 1 hour prior to testing
Storage Requirements	15 - 30˚C (room temperature)
Unacceptable specimens and follow-up action	• All other types of specimens (including gargles)

	• Swabs placed in universal transport media (UTM) • Improper sample handling/storage/transport • Improperly labelled specimens
Specimen Handling	ID NOW COVID-19 is intended for testing a swab directly without elution in viral transport media as dilution will result in decreased detection of low positive samples that are near the limit of detection of the test.

Maintenance

The ID NOW Instrument is maintenance-free and has no serviceable parts.	In the case of instrument failure or damage, contact Abbott Technical Support.
The ID NOW Instrument can be cleaned using 70% ethanol or 10% bleach solution, on a damp, lint free cloth. (Ensure no excess liquid is used when cleaning as it may damage the instrument.) 70% Ethanol and 70% Isopropanol wipes are acceptable for the ID NOW™.	Abbott recommends that the exterior instrument surfaces and the surfaces visible under the open lid be cleaned daily.
To avoid contamination of the work area with previous positive samples, which may cause false positive results.	Clean instrument and surrounding areas immediately after possible patient sample contamination, and daily.
Software updates	Following a software upgrade, the user is required to run both a positive and a negative successful QC test before patient testing is allowed.
ID Now software will hold up to 999 patient results	When the instrument notifies the User that it has reached the storage limit, the patient results will be overwritten.

Quality Control

New testing kits will undergo a lot release process prior to being shipped from the QEII Microbiology Laboratory.

Quality Control Schedule	Regular ongoing QC: Run the vendor supplied Positive and Negative QC specimen after moving the ID NOW instrument or with the opening of a new box of reagents. Record ongoing QC data in the ID Now SARS-CoV-2 Quality Control Log.

	Verification and Lot release: New lots or after instrument service will be verified using previous residual specimens positive and negative by NAAT testing centrally at the QEII.
Location of QC ranges	N/A
Control criteria	Positive, Negative, Invalid - See 13. Interpretation of Results
Documentation of QC Data	ID NOW SARS-CoV-2 Quality Control Log
Alternate QC Measures	Internal QC, and External QC
Storage of QC Data	QC Log Binders - 2 years or as per Laboratory Retention

- ID NOW COVID-19 has built-in internal procedural controls. The result of the Procedural Control is displayed on the screen and is automatically stored in the instrument with each test result. This can be reviewed later by selecting Review Memory on the instrument.
- In positive samples where target amplification is strong, the internal control is ignored and the target amplification serves as the 'control' to confirm that the clinical sample was not inhibitory and that assay reagent performance was robust.
- At a very low frequency, clinical samples can contain inhibitors that may generate invalid results.
- Procedural Control Valid displayed on the instrument screen indicates that the assay reagents maintained their functional integrity and the sample did not significantly inhibit assay performance.

External Positive and Negative Controls:
For new lots, prior to their release, the QEII will verify performance using residual specimens that have previously tested positive and negative by NAAT.

Regular ongoing QC samples:
ID NOW COVID-19 kits contain a Positive Control Swab and Sterile Swabs that can be used as a Negative Control Swab. These swabs will monitor the entire assay. The QC test is run in the same manner as a Direct Nasal/Throat/Nasopharyngeal Swab Patient Test.

- Negative Control: use a new unused swab.
- Positive Control: supplied from Abbott. Record the Lot number and expiry date. Open at the right end. The QC swab sits in a tray. Slide out the tray and pick up the swab and use when prompted. Discard the used swab and packaging in biohazard bucket. Change gloves.

Perform QC:
On the Home Screen, select "Run QC Test"
Select "COVID-19"
Select either "Positive QC Test" or "Negative QC Test" (use the appropriate swab)
Follow the test procedure as you would for a patient sample.
The instrument will report as a QC Pass or QC Fail.
Record the QC on the provided document.

Note: If the QC fails, record the results and repeat. If QC fails again, notify a unit manager and POC testing representative
If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Technical Support during normal business hours before testing patient specimens.

Procedure

1. Nasopharyngeal Swab

Step	Action - Nasopharyngeal Swab (method preferred for current use)
1.1	Use flocked flexible-shaft NP swabs to collect a nasopharyngeal sample as per institution policy, in accordance with IPAC guidelines and use of PPE.
1.2	How to Collect an NP Swab: "Remember the 4 Ds" Direction: 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. Depth: The approximate distance to insert the swab is 1/2-2/3 the distance from the nostril to the earlobe. Duration: Hold in place for 5 seconds to allow for maximum absorbency. Dialing: Rotate swab 2-3 times and remove swab from nostril.
1.3	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. If resistance persists try the other nostril
1.4	DO NOT PLACE in the UTM liquid. Place the swab in a labelled dry, sterile tube to transport to the instrument. Testing should occur as soon as possible after collection.

2. Throat/Nares Swab

Step	Action - Throat/Nares Swab (acceptable specimen but not preferred)
2.1	For optimal test performance, use the throat/nares swab provided in the test kit.
2.2	Collect patient specimen by swabbing the posterior oropharynx, tonsils, nares and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.
2.3	DO NOT PLACE in the UTM liquid. Place the swab in a labelled dry, sterile tube to transport to the instrument. Testing should occur as soon as possible after collection.

3. INSTRUMENT START UP

Step	Action - INSTRUMENT START UP
3.1	Start - press and hold the Power Button on the right side of the instrument.

	NOTE: Power save - If the unit is unattended for one hour, the instrument will switch to power save mode, and the screen will go black. Touch the screen to return the unit to active display operation.
3.2	Enter User ID and Password.

4. Perform a Test

Step	Action **Perform a Test**
4.1	Before testing with ID NOW COVID-19: · Put on a clean pair of gloves. · Verify that there is a reagent pellet at the bottom of the reaction tubes in the ORANGE Test Base. Do not use the Test Base if a pellet is not visible at the bottom of each reaction tube. · DO NOT open the seal on the BLUE Sample Receiver. You will be directed to open at the appropriate time. · DO NOT touch the white tips that protrude from the bottom of the white cartridge.
4.2	Select 'Run Test'
4.3	Select 'COVID-19 Test'
4.4	Scan patient barcode (account number) - using on screen keyboard, Touch √.
4.5	Verify that the account number was entered correctly, then Touch √ to confirm entry.
4.6	**All of the instructions will be prompted on the screen.** The Lid remains open until you are directed to close the Lid. Once the testing has begun, each step must be completed within a timely manner. The times will countdown on the screen. If a step times out, the test must be discarded.
4.7	When prompted, open Package 1 and visually inspect the orange cartridge to ensure dry, white powder is visible in each protruding tube, and that one tube contains a metal ball-bearing.
4.8	Open the Lid and set **Orange Test Base** into Orange Test Base holder.
4.9	Confirm that the COVID-19 test is displayed on the screen. Select 'OK' to proceed.
4.10	Set **Blue Sample Receiver** into the Blue Sample Receiver holder. *Caution: Once the Sample Receiver has been placed in the holder, the user will have 10 minutes to start the test. If the test is not started within 10 minutes, the instrument will time out and all test pieces (Test Base and Sample Receiver) must be removed and discarded.*
4.11	The Blue Sample Receiver needs to Warm Up. A timer will begin a countdown of 3 min.

	Caution: Do not remove the Sample Receiver from the instrument once Warm Up begins.
4.12	When prompted, remove the foil seal from the Blue Sample Receiver. *Caution: To ensure that the Sample Receiver remains in the instrument while removing the foil seal, place two fingers along the outer edge of the Sample Receiver to hold it in place.* *Caution: If the Sample Receiver spills after warm up, cancel the test by pressing the Home button. Remove and discard the test pieces (Sample Receiver and Test Base) and clean the instrument. Press Run Test to start a new test using a new Test Base and Sample Receiver.*
4.13	As directed, insert the **Patient Swab** into the liquid in the **BLUE Sample Receiver**. Mix the swab in the liquid for a count of 10 seconds. (Mixing helps remove the sample from the swab.)
4.14	Lift the swab out of the liquid and press the swab head against the side of the Sample Receiver to remove excess liquid. Discard the swab into a leak-proof biohazardous waste container (like a sharps container). If gloves become wet or contaminated, remove, perform hand hygiene, and don fresh gloves.
4.15	**Once the swab is removed, touch 'OK' to proceed.**
4.16	**Watch the screen for instructions on when to do the next steps.** **It is important that the steps are done at the correct times when prompted.**
4.17	The instrument will now direct you to press the **White Transfer Cartridge** into the **Blue Sample Receiver**. Listen for a **click**. Ensure the orange indicator on the top of the Transfer Cartridge **popped up**. Leave the cartridge in place. Watch the screen for instructions. *Caution: When the Transfer Cartridge is properly attached to the Sample Receiver, the orange indicator on the Transfer Cartridge will rise. If the orange indicator does not rise, continue pushing onto the Sample Receiver until it does.* *Caution: The orange indicator should be observed closely. If the orange indicator does not fully rise, the Transfer Cartridge may not collect enough sample.*
4.18	The instrument will next direct you to lift the **White Transfer Cartridge** and move it directly to the **Orange Test Base**. Press down (may need two hands) on the Transfer Cartridge and listen for a **series of clicks**. The orange indicator on the Transfer Cartridge will **descend**. *Caution: If the orange indicator does not descend, continue pushing onto the Test Base until it does. If the orange indicator does not fully descend, not enough*

	sample will be dispensed. This may potentially result in invalid or false test results.
4.19	The instrument will now direct you to **Close the Lid**. The timer will display 10 min as a countdown until test results are available. *Caution: This screen will be displayed for up to 30 seconds once the Transfer Cartridge is detected. If the instrument does not detect that the lid has been closed by then, it will time out and all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. The instrument will proceed to the Home screen.* *Caution: DO NOT OPEN THE LID until the Test Complete message appears on the screen.* *Note: The test will be cancelled if the lid is opened.*
4.20	The results may become available sooner if the sample is a strong positive or if the test fails. *When amplification and detection is complete, the instrument will automatically save the data before advancing to the results screen.* *Caution: The test is not saved until the completed result is displayed. Do not open the lid until the results are displayed.*
4.21	The Test Results screen displays either a **Negative** or **Positive** result for a successfully completed test. If a test error occurs, the display will read '**Invalid**'.
4.22	If a printer is connected, Press Print to print test results. Peel result label and stick into patient chart, double-checking patient identifier, and documenting your name, the date and time, and result. Sign the report and place it in the patient chart
4.23	The instrument will prompt to open the lid and discard the used test pieces. Follow these directions: Remove test pieces by lifting the **White Transfer Cartridge**/attached to the **Orange Test Base**, and clicking it into the **Blue Sample Receiver**, by pressing into the Sample Receiver. *Caution: Do not try to remove the Sample Receiver by any other method as there is a risk of spilling the patient sample.* Discard connected pieces in hazardous waste receptacle. Close the lid. Remove and dispose of gloves. Perform hand hygiene.
4.24	Press **New Test** to run another test. Press **Home** to return to the Home screen.
4.25	The instrument will then run a **Self-Test** before showing the Home screen or Enter Patient ID screen, depending on the previous selection.

Result Interpretations

Interpretation of Results:	
Result	**Specific Instruction**
COVID-19 Positive	• Notify MRHCP to determine next steps • Notify IPAC and microbiology lab immediately • Isolate patient and initiate case management • Obtain physician order to collect a New NP-swab for confirmatory in-lab PCR testing (should be expedited, with "STAT Gene Xpert – POS POCT, DO NOT POOL" written clearly on the requisition and on the outside of the specimen bag)
COVID-19 Negative	• If patient is suspected of COVID-19, collect a New NP swab for confirmatory in-lab PCR testing
Invalid - The presence or absence of COVID-19 Viral RNAs cannot be determined.	• Collect a new NP swab for repeat testing using a new ID NOW kit **OR** • Collect a New NP swab for confirmatory in-lab PCR testing

CONFIRMATORY TESTING

- Confirmatory testing must be performed on all Positives, unresolved Invalid tests, and Negatives where patient is suspected of COVID-19 infection.
- Obtain physician order to collect a New NP swab, place in viral transport media, and refer to the Microbiology Laboratory for confirmatory testing. Use Nova Scotia Health requisition, and indicate "STAT Gene Xpert – POS (or INV) POCT, DO NOT POOL"

Procedural Notes

ID NOW Cleaning:

- The ID NOW™ is maintenance-free and has no serviceable parts.
- The ID NOW™ can be cleaned using 70% ethanol, 70% isopropanol, or 10% bleach solution, on a damp, lint free cloth. 70% ethanol and isopropanol wipes are acceptable for use on the ID NOW™.
- **Do not spray** or pour solution directly onto instrument when cleaning.
- Ensure no excess liquid is used when cleaning as it may damage the instrument.
- Abbott recommends that the exterior instrument surfaces and the surfaces visible under the open lid be cleaned daily.
- Clean the surrounding bench area.
- Clean instrument and surrounding areas immediately after possible patient sample contamination.
- Do not disassemble the instrument for cleaning
- Do not immerse in water or cleaning solutions
- Do not clean with soap or other solutions

Principle

- The Abbott: ID NOW platform uses single-use disposable cartridges that contain reagents required for the extraction (RNA purification), nucleic acid amplification, and real-time detection of a target gene utilizing an isothermal nucleic acid amplification technology for the qualitative detection of nucleic acid from the SARS-CoV-2 virus. Fluorescently-labeled molecular beacons are used to specifically identify each of the amplified RNA targets. Internal controls are included in each reaction to monitor specimen processing and reaction inhibition, and to ensure proper functioning of the equipment.
- Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and repeat testing with laboratory based NAAT assays will be necessary to confirm patient infection status.
- Negative results should be interpreted in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. If there is concern that the patient has COVID 19 infection, repeat testing using laboratory based NAAT assays will be necessary.
- The ID NOW COVID-19 test is intended for use by trained operators who are competent in performing tests using the ID NOW Instrument in point of care settings.

Clinical Utility

METHOD LIMITATIONS

- False negative results may occur if a specimen is improperly collected, transported or handled.
- False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate levels of viruses are present in the specimen.
- Positive or Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
- As with any molecular test, mutations within the target regions of the Abbott ID NOW COVID-19 test could affect primer and/or probe binding resulting in failure to detect the presence of the virus.
- The test cannot rule out diseases caused by other bacterial or viral pathogens.
- ID NOW COVID-19 is intended for testing a swab directly without elution in viral transport media, as dilution will result in decreased detection of low positive samples that are near the limit of detection of the test.
- Swab samples eluted in UTM are NOT appropriate for use in this test.
- For optimal test performance, use the swabs provided in the test kit.
- Contact Abbott Canada Technical Support Email: canproductsupport@abbott.com or Abbott Technical Support Phone: 1-800-818-8335

Related Documents

- An instruction booklet comes with the instrument to demonstrate how to connect the printer, etc.
- A quick reference guide comes with the COVID-19 kit as the instrument is capable of performing other tests such as Influenza.

Document Name	Document #	Location
QEII Job Aid – Abbott ID NOW	PPR-J-MB-0001	OP3/HUB
QC Log – COVID ID NOW	PPR-F-MB-0002	OP3/HUB
POCT Order Log COVID ID NOW	PPR-F-MB-0001	OP3/HUB
ID NOW Pilot Result Log	PPR-F-MB-0003	OP3/HUB
Peri-op algorithm	PPR-J-MB-0002	OP3/HUB

Authorship

This document was adapted from a document prepared by Carrie Phillips for Jason LeBlanc. The Saskatchewan Health Authority document was copied with some minor changes (not procedural).

Reference

This procedure was copied from the Abbott: ID NOW COVID-19 Test procedure used by Saskatchewan Health Authority. Document Number PROV-46 Version 5. Effective Jan 18, 2021.
ID NOW COVID-19 Product Insert, 2020/09/29
ID NOW™ COVID-19 Quick Reference Instructions 2020/09/17
ID NOW Instrument User Manual 2019/07/02