ABBOTT ID NOW COVID-19 TEST - CLINICAL PROCEDURE FOR SYMPTOMATIC TESTING

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1. Purpose

This procedure provides instruction for trained point of care personnel in Yukon to use the Abbott: ID NOW analyzer to conduct symptomatic testing for clients in approved settings such as rural communities and mines. YCDC and/or Yukon's Medical Officers of Health may also consider the use of the ID NOW as part of an Outbreak or Cluster Response and in other situations as deemed appropriate. The use of the ID NOW outside of these settings is at the discretion and approval by Yukon's Medical Officers of Health.

2. Principles

2.1 ID NOW Instrument is a rapid molecular diagnostic test utilizing nucleic acid amplification technology (NAAT) intended for the detection of genetic material from the SARS-CoV-2 virus in a nares swab from individuals.

2.2 Yukon's use of the ID NOW instrument will include the testing of symptomatic persons within the first 7 days of symptom onset. After this timeframe, routine PCR testing (NP or gargle as appropriate) should be collected.

2.3 The clinical sensitivity and specificity of the ID NOW system approaches that of a traditional PCR when used within the first 7 days of symptom onset, and when Ct values are <30.

2.4 There is no patient minimum or cut-off age for use of the ID NOW instrument

2.5 Each new ID NOW instrument is clinically validated. The first 10 tests per instrument will have a traditional PCR collected/run in addition to a nasal swab. This can be by gargle or NP. In addition, each 10th sample collected should have a PCR test completed.

2.6 The Abbott ID NOW platform uses single-use disposable cartridges that contain reagents required for the extraction (RNA purification), PCR amplification, and real-time detection of two target genes (called N2 and E) associated with the SARS-CoV-2 virus' genetic material. Controls are included in each cartridge to monitor specimen processing and to ensure proper functioning of the equipment.

2.7 Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Negative results do not rule out bacterial infection or co-infection with other viruses.

2.8 Negative results for **symptomatic individuals** should be treated as presumptive and should be considered in the context of a patient's recent exposures, history and the presence of types of clinical signs and symptoms consistent with COVID-19 and other reasons for test (i.e. contact to a case).

2.9 Negative results **should not be used** as a reason to end isolation for a person who would be under isolation based on routine public health practice as outlined in the COVID-19 Interim public health management of cases and contacts.

2.10 The Abbott ID NOW COVID-19 test is intended for use by trained and certified health care professionals who are proficient in performing tests using the ID NOW Instrument in laboratory and point of care settings.

3. Roles and Responsibilities

2.11 Point of Care User

- Positively identify the patient: full legal name, health care number, birthdate, noting the date and time of collection, label specimen, maintain Patient ID continuity through testing process,
- Follow procedure to perform the Abbott ID NOW test for the SARS-CoV-2 virus,
- Complete the ID NOW Assessment Form,
- Maintain competency on the Abbott ID NOW POCT COVID-19 test system,
- Follow accreditation requirements for patient identification, testing and reporting.

2.12 Super User

- Train Users, completes training checklists and provides to immediate to supervisor file accordingly,
- Distribute and receive completed Training Quiz and provide certificates, provides to immediate supervisor to file accordingly ,
- Provide leadership answering questions, offering consistent solutions for Users,
- Liaise with POCT project manager,
- Review and sign off performance of Quality Control and Proficiency Testing results,
- Ensure all Users meet competency and accreditation requirements.

3. Specimen Information

Specimen Type/Source	Fresh direct nares swab
Acceptable Collection	Vulcan tube (dry and empty)
Minimum Requirements	1 ml of sample extract
Specimen Stability	Up to 1 hour prior to testing
Storage Requirements	15 to 30°C
Unacceptable specimens and follow-up action	• All other types of specimens • Dry swabs • Swabs placed in transport media • Inadequate specimen collection or Insufficient volume • Improper sample handling/storage/transport • Improperly labelled specimens • Patient has a previous positive result within past 7 days • >7 days after symptom onset
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 samples with a low amount of virus that are near the limit of detection of the test.

4. Equipment and Supplies / Reagents / Forms and Labels

Equipment & Supplies	Reagents	Forms & Labels
• Nasal Swab: Sterile swabs (foam) for use with the ID NOW COVID-19 test • Positive Control Swab: The positive control swab is coated with inactivated influenza A & B viruses. The positive control swab ensures sample elution / lysis (exposing the genetic material of the virus) and workflow were performed correctly but does not confirm amplification of the SARS-CoV-2 target (RdRp gene). • Universal Printer • Barcode Scanner • ID NOW™ USB Drive	• Test Bases: Orange plastic components containing two reaction tubes of freeze-dried reagents for the targeted amplification of SARS-CoV-2 viral RNA and an internal control. • Sample Receivers: Blue plastic components containing 2.5 mL of elution solvent. • Transfer Cartridges: White plastic components used to transfer 2 x 100 µL (microliters) of sample extract from the Sample Receiver to the Test Base	• Electronic COVID-19 Requisition • Quality Control Log • ID NOW Cleaning Log • ID NOW Error Log • ID NOW Defective Cartridge Form • RT Temperature Storage Chart

5. Safety Precautions

5.1 Hazards

Coronaviruses are a large family of viruses, which can cause illness in animals or humans. SARS-CoV-2 is an enveloped, single-stranded RNA virus of the ß (beta) genus. The virus can cause mild to severe respiratory illness and death, and has spread globally, including Canada.

For the purposes of running this test, the 2019-nCoV virus is spread during close contact (within a 2-meter distance), contact with high touch surfaces (precaution: hand hygiene), and droplet production (precaution: wear procedural mask and eye protection).

SPECIAL CONSIDERATIONS:

- For PPE when *collecting a clinical sample AND running the test* – see section 12,
- For PPE when *running the test ONLY* – see section 13.

5.2 Safe Work Practices

- All Point of Care 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 including all quality control testing.
- Don gown & gloves, procedure mask with eye or facial protection (face shield or goggles), change gloves between patients.
- Discard used samples and reagent cartridge connected pieces in hazardous waste receptacle.

All staff using this test must be familiar with the following guidance documents to support safe operation for the public and health care worker alike.

- Recommended practices and personal protective equipment for allied health facilities, interim guidance
- Putting on (donning) Personal Protective Equipment (PPE)
- Taking off (doffing) Personal Protective Equipment (PPE)

6. Quality Control

Quality Control Schedule	Run a Positive QC specimen: • When the machine is first set up • After the machine is moved to a new space • When training a new user • When opening a new box of cartridges with a new lot number • Every 7 days At present clinical validation is also required. See Abbott ID NOW – Training Procedure for Screening Programs section 9.0 Quality control.
Clinical Validation	At this time, as the Abbott ID NOW is not intended to replace traditional, 'gold standard' PCR testing. This is a new program within YT and Canada, as such, additional clinical validation is required. As more evidence for such symptomatic testing grows, these requirements will be adapted. However, at present this includes: Validation of new machines: The first 10 specimens collected for nasal specimens per ID NOW instrument also need a PCR test, collected at the same visit, for validation of the Abbott ID clinical result. The site may either be nasopharyngeal or saline gargle. Ongoing clinical validation: Every subsequent 10th test run per ID NOW instrument will also need a PCR test collected at the same visit, for validation of the Abbott ID clinical result. The site may either be nasopharyngeal or saline gargle.
Preparation and Handling of QC Material	See Appendix B: ID NOW SARS-CoV-2 Quality Control (QC) Requirements
Levels of QC to use	Positive for SARS-CoV-2, Negative for Sars-COV-2
Location of QC ranges	N/A
Control criteria	Positive, Negative, Invalid - See 14. Interpretation of Results
Troubleshooting Guidelines	Appendix E: ID NOW Error Log Appendix F: ID NOW Defective Cartridge Form
Documentation of QC Data	Appendix C: 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 Records Retention

8. Equipment 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 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	Abbott recommends that the exterior instrument surfaces and the surfaces visible under the open lid be cleaned daily. The ID NOW should be wiped down after any positive test to avoid sample contamination and result errors.
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 patients results will need to be archived.

9. ID NOW Assessment Form (Appendix H)

Complete the ID NOW Assessment form for each individual's COVID-19 point of care test. Once testing is completed, file or store assessment forms according to unit policy. In case of Positive ID NOW Result, include a copy of the ID NOW assessment form with the requisition and sample for confirmatory testing. The ID NOW assessment form will be provided to YCDC for entry into Panorama as per routine reporting process of reporting of COVID-19 testing.

10. Considerations for Clinic Setup

The clinical area for client assessment as well as the area of the Abbott ID NOW machine will vary depending on the setting and in some cases the machine may be in the assessment space itself.

Regardless of the setting, all testing and assessment areas should be informed by the 2020 Novel Coronavirus (COVID-19) Interim Guidance for Mass Clinics during the COVID-19 Pandemic.

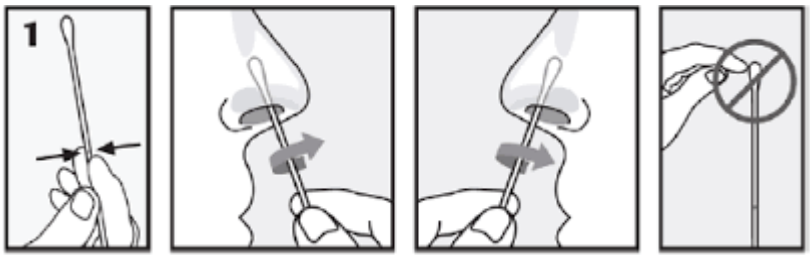
11. Instrument Start Up

Follow the steps in the table below:

Step	Action

1	Start - press and hold the Power Button on the right side of the instrument.
2	Turn Off – shut down by pressing and holding the Power Button for 3 seconds or longer.
3	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.
4	Creating the Admin ID – the User name will be: ADMIN, Passwords must be 2-20 characters. The Admin ID and password has been set up by the POC QA Lead, and available on the front of the analyzer.
5	The ADMIN will set up the User ID's, must be 2 to 20 characters and alphanumeric. User IDs are not case sensitive. Passwords are not required.

12. Specimen Collection – Nasal swab



Step	Action
1	For optimal test performance, use the swab provided in the test kit.
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.
3	How to Collect a Nasal Swab: •Don PPE as per routine process for contact and droplet precautions[1] •Have the patient incline head to 70 degrees. While gently rotating the swab, insert it less than one inch (2cm) into nostril parallel to the palate until resistance is met at turbinates. Rotate the swab at least 4 times for a total of 15 seconds against the nasal wall. Remove swab, insert the same swab into the other nostril and repeat the process. •Complete client care and doff PPE as per routine process for contact and droplet precautions[1].

[1] See PPE direction for donning and doffing, located here
SPECIAL CONSIDERATION: If the POCT user who collects the clinical sample is also running the test, doffing PPE is not required prior to running the test.

13. ID NOW Instrument

Read all steps prior to clinical care. Follow all steps in the table below:

Step	Perform a Test
1	Before testing with ID NOW COVID-19: • Put on a clean pair of gloves if running samples ONLY • If already wearing PPE for clinical sample collection, changing is not required. • Ensure all test pieces and clinical samples are at room temperature before inserting them into the machine.
2	Touch 'Run Test'
3	Touch 'COVID-19 Test'
4	Select Swab Sample Type (if prompted). If the Admin has already specified the sample type, the instrument will automatically advance to the next step.
5	Enter Patient ID - Health Care Number (HCN) using on screen keyboard, Touch √. (If the patient does not have a HCN, use the electronic Requisition ID Number.)
6	Verify that the HCN was entered correctly, and then Touch √ to confirm entry.
7	Open the Lid and Insert Orange Test Base into Orange Test Base holder. Do not apply excessive force. Excessive force could damage the instrument.
8	Confirm that the correct test is displayed on the screen. Touch 'OK' to proceed.
9	Check that a reagent pellet is visible at the bottom of the reaction tubes prior to inserting the Test Base in the ID NOW Instrument. Do not use the Test Base if a pellet is not visible at the bottom of each reaction tube.
10	Insert Blue Sample Receiver into the Blue Sample Receiver holder. Do not apply excessive force. Excessive force could damage the instrument. 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. The instrument will proceed to the Home screen. Press Run Test and restart the test using a new Test Base and Sample Receiver.
11	Wait for the Blue Sample Receiver to Warm Up. DO NOT remove the Sample Receiver from the instrument once Warm Up begins. DO NOT REMOVE THE FOIL SEAL UNTIL PROMPTED BY THE INSTRUMENT.

12	When prompted, remove the foil seal and place the patient swab to be tested into the Sample Receiver (brace the cartridge with one hand and remove the seal with the other). Mix the swab in the liquid for 10 seconds. This helps remove the sample from the swab. Lift the swab out of the liquid and press the swab head against the side of the Sample Receiver to remove excess liquid. Once the swab is removed, touch 'OK' to proceed. Discard the swab into a biohazard waste container. 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. 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.
13	Press the White Transfer Cartridge into the Blue Sample Receiver. Listen for a click. 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. The orange indicator should be observed closely. If the orange indicator does not fully rise, the transfer cartridge may have not collected enough sample.
14	Lift and then connect the Transfer Cartridge to the Test Base. When the Transfer Cartridge is properly attached to the Test Base, the orange indicator on the Transfer Cartridge will descend. 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
15	Close the Lid. 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. 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. 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.

17	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'. Press Print to print test results, press New Test to run another test, Press Home to return to the Home screen.
18	The instrument will prompt to open the lid and discard the used test pieces. Remove test pieces by lifting the Transfer Cartridge attached to the Test Base, and clicking it into the 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.
19	The instrument will then run a Self-Test before showing the Home screen or Enter Patient ID screen, depending on the previous selection.

14. Interpretation of Results and Expected Values

When the test is complete, the results are clearly displayed on the instrument screen.

Interpretation of Results:	
Result	Specific Instruction
COVID-19 Positive	• Direct and provide education to patient to isolate, provide How to isolate (handout) • Call Yukon Communicable Disease Control at 867-667-5080 or 1-800-661-0404 ext. 8323 or email YCDCSurveillance@yukon.ca AND YukonMOHs@yukon.ca • If after hours call the MOH on call at 867-332-6922 • Collect an NP-swab for confirmatory in-lab PCR testing
COVID-19 Negative	• Enter result on to the ID NOW assessment form • If patient is suspected of COVID-19, collect an NP swab for confirmatory in-lab PCR testing
Invalid - The presence or absence of COVID-19 Viral RNAs cannot be determined.	• Enter result on the ID NOW Screening form • Repeat test using current Sample Receiver and ID NOW kit OR • Collect an NP swab or gargle for confirmatory in-lab PCR testing

If an Invalid result is received, **one** additional test may be run using the same Sample Receiver.
The instructions below should be followed:

- Remove the connected Test Base and Transfer Cartridge from the instrument and connect the Test Base portion to an open, UNUSED Sample Receiver. The connected Test Base and Transfer Cartridge MUST be attached to a Sample Receiver prior to disposal. The Sample Receiver from a new Transfer Cartridge package may be used for this.
- Remove the blue Sample Receiver separately and carefully from the instrument. The Sample Receiver should be retained and kept upright to avoid spilling the liquid contents.
- From the Home Screen, start a new test. Follow the screen prompts; however, when asked to insert the Sample Receiver, reuse the Sample Receiver and DO NOT re-elute the swab.

15. Confirmatory Testing

Confirmatory testing **must be performed on all Positives, unresolved Invalid tests, and Negatives where patient is suspected of COVID-19 infection.**

Collect an NP swab, place in viral transport media, complete requisition and submit to Whitehorse General Lab for confirmatory testing (NP swab and viral transport media should be obtained through WGH Materials Management). Ensure a copy of the ID NOW assessment form is included with the confirmatory test requisition.

16. Result Reporting

16.1	**Use of Abbott ID NOW to test symptomatic clients who are within the first 7 days of symptom onset:** • Once testing is completed, enter the result on the ID NOW assessment form **If Negative**: • A patient who has a preliminary negative POC test does not need confirmatory testing, unless there is a high degree of clinical suspicion for COVID-19. • Negative results with ID NOW, just like lab-based PRC testing, should be interpreted within the context of the patient's exposures, history, and signs and symptoms. • The patient must continue to isolate if they are symptomatic, or have been told to isolate for any other reason. A negative POC test should not be used to end self-isolation **If Positive**: • Direct and provide education to patient to isolate, provide handout on how to isolate • Call Yukon Communicable Disease Control at867-667-5080 or 1-800-661-0404 ext. 8323 or email YCDCSurveillance@yukon.ca AND YukonMOHs@yukon.ca • If after hours call the MOH on call at 867-332-6922 • Collect an NP-swab for confirmatory in-lab PCR testing

17. Method Limitations

17.1 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. 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.

17.2 As with any molecular test, mutations within the genetic targets 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.

17.3 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 samples with low amounts of virus that are near the limit of detection of the test.

17.4 Swab samples eluted in VTM are not appropriate for use in this test.

17.5 For optimal test performance, use the swabs provided in the test kit.

17.6 Contact Abbott Canada Technical Support Email: canproductsupport@abbott.com or Abbott Technical Support Phone: 1-800-818-8335

18. Materials Management

Contact your Whitehorse General Hospital Materials Management Inventory, though your routine process, for POCT COVID supplies.

19. Procedure Management

The management of this procedure including procedure communication, education, implementation, evaluation and audit is the responsibility of the facility/unit manager

20. Applicability

Compliance with this procedure is required by all trained healthcare professionals who are proficient in performing tests using the ID NOW Instrument in laboratory and point of care settings.

21. References

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

22. Supporting Documents

Appendix A: Definitions
Appendix B: Quality Control (QC) Requirements
Appendix C: Quality Control Log
Appendix D: ID NOW Cleaning Log
Appendix E: ID NOW Error Log
Appendix F: ID NOW Defective Cartridge – Form
Appendix G: Room Temperature Storage Chart
Appendix H ID NOW COVID-19 Assessment Form

Appendix A: Definitions

For the purposes of this document, the following definitions apply:

Term, abbreviation, acronym, etc.	Definition
ºC	Degrees Celsius
ID	Identification
mL	Milliliter
N/A	Not Applicable
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
µL	Microliter
VTM	Viral transport medium
WGH	Whitehorse General Hospital
YCDC	Yukon Communicable Disease Control

Appendix B: ID NOW SARS-CoV-2 Quality Control (QC) Requirements

External Quality control check should be run when the analyzer is moved, or with every new shipment lot number of cartridges, or after a repair/maintenance event on the ID NOW instrument, as directed by a supervisor, or weekly otherwise.

- Treat the positive and negative control as a specimen (i.e. process as per Procedures A and B)
- Expected result will be Positive for SARS-COV- 2 for the positive control material
- Expected result will be Negative for SARS-COV-2 for the negative control material
- Record results on the ID NOW Quality Control Log – Form and store in the QC binder

Quality Control

A. 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.

B. External Positive and Negative Controls:
   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 Swab Patient Test.

Quality Control Swab Test Procedure

For QC testing, select Run QC Test on the Home screen, and follow the displayed instructions.

1. Don PPE (clean gloves)
2. Touch 'Run QC Test'
3. Touch 'COVID-19'
4. Select the QC Test to be Run
5. Confirm Test - Confirm the test type to match the QC sample intended for testing by touching 'OK' and following the on screen prompts to complete testing.
6. The user has the option to enter an ID for the QC Sample being run.
7. The ID NOW Instrument reports QC results as Pass or Fail.

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.

Appendix C: ID NOW COVID-19 External Quality Control Log

Follow ID NOW Appendix B: SARS-CoV-2 Quality Control (QC) Requirements for detailed instructions on quality control performance.

External Quality control check should be run:

- run a positive QC specimen after changing locations
- with every new shipment or lot number of cartridges (Completed at RRPL) or
- after a repair/maintenance event on the ID NOW instrument or
- when directed by a Supervisory staff

SITE:_____YEAR: _____

DATE	ASSAY	MACHINE SN	ID NOW KIT LOT/EXP	POSITIVE CONTROL LOT/EXP	NEGATIVE CONTROL LOT/EXP	POSITIVE CONTROL RESULT	NEGATIVE CONTROL RESULT	TESTER INITIAL	COMMENTS
	COVID - 19								

If QC results do not match the expected results:

- Repeat test
- Inform Supervisor
- Contact Abbott Canada Technical Support Email: canproductsupport@abbott.com or Abbott Technical Support Phone: 1-800-818-8335

Reviewed By:_____ Date: _____

Appendix D: ID NOW Cleaning Log

The ID NOW™ is maintenance-free and has no serviceable parts.

The ID NOW™ can be cleaned using 70% ethanol or 70% isopropanol, 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 if the machine has been used. 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

MONTH_____YEAR_____

SERIAL NUMBER_____MONTHLY REVIEW DATE_____INITIALS_____

DATE	PERFORMED BY: (Initials)	COMMENTS / CORRECTIVE ACTION	DATE	PERFORMED BY: (Initials)	COMMENTS/ CORRECTIVE ACTION
1			17		
2			18		
3			19		
4			20		
5			21		
6			22		
7			23		
8			24		
9			25		
10			26		
11			27		
12			28		
13			29		
14			30		
15			31		
16					

In the case of instrument failure or damage, contact Canada Abbott Technical Support Email: canproductsupport@abbott.com or Abbott Technical Support

Phone: 1-800-818-8335

Appendix E: ID NOW Error Log

Instrument Serial Number _____

Indicate if technical support was contacted

Date	Error Code	Description of Problem	Steps for Resolution	Technical Support

Appendix F: ID NOW Defective Cartridge – Form

As per manufacturer's standards up to 2% of cartridges may be defective

The Manufacturer may replace cartridges when problems occur

Date	POCT Tester	Cartridge				Description
		Name	Lot Number	Expiry Date	Error Code	
		COVID-19				

When 10 cartridges have failed, contact Abbott Technical Support Email: canproductsupport@abbott.com or Abbott Technical Support Phone: 1-800-818-8335

Appendix G: POCT Room Temperature Chart

POCT Room Temperature Chart

MONTH: **YEAR:** **LOCATION:**

(Acceptable Range 15 - 30° C)

DAILY (Digital Display)																														
TEMP (°C)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
34																															
32																															
30																															
28																															
26																															
24																															
22																															
20																															
18																															
16																															
14																															
12																															
Initials:																															

DAILY

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
TEMP (°C)																															
Digital HI:																															
Digital LOW:																															
Reset (√)																															
Initials:																															

COMMENTS:

REVIEWED BY :

Yukon

Peel and stick addressograph here

Appendix H: Abbott ID NOW COVID-19 POCT Assessment Form for COVID-19- Symptomatic testing

Testing Date (YYYY/MM/DD)	Testing Location	Testing Provider
Last Name	First Name	DOB (YYYY/MM/DD)
Health Card #	Primary Phone	Alternate Phone

Physical Address _____

Exposure Risks (Travel, Employment, Contacts, etc.)

_____

_____

Relevant PMHx, Medications, Psychosocial Hx.

_____

_____

Symptoms

□ Fever / Chills Temperature (°C)_____
□ Cough
□ SOB
□ Dysgeusia / Anosmia
□ Chest pain / tightness
□ Runny nose
□ Sore throat
□ Headache
□ Conjunctivitis

Onset (YYYY/MM/DD) _____

□ Fatigue
□ Anorexia
□ Nausea / Vomiting
□ Diarrhea
□ Myalgias
□ Dizziness / Confusion
□ Abdominal pain
□ Dermatological changes_____
□ Other_____

Result

□ Positive □ Negative □ Invalid (x1 or x2)

PCR sent? □ Yes (include requisition) □ No
If yes: □ Nasopharyngeal □ Saline Gargle
(For positives, <u>two</u> invalids, initial validation, q10 validation)

Peel and stick result here

Plan

□ Self-**isolating**, education done and contact #s sheet given
□ Isolation support contacted at (867) 332-4587
□ Phone call to YCDC / CMOH
□ Other follow-up_____

_____