

Document History:

Title: Abbott ID NOW™ COVID-19
Procedure Manual for POCT

Site(s): POCT Sites that Test for
COVID-19 using the Abbott
ID NOW™ Instrument

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Details of Recent Revision

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Abbott ID NOW™ COVID-19 Procedure Manual

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Abbott ID NOW™ COVID-19 Procedure Manual

1.0 Principle

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

ID NOW™ COVID-19 is a rapid (13 minutes or less), instrument-based isothermal test for the qualitative detection and diagnosis of SARS-CoV-2 from nasal or nasopharyngeal swabs.

ID NOW™ COVID-19 is an automated assay that utilizes isothermal nucleic acid amplification technology for the qualitative detection of SARS-CoV-2 viral nucleic acids. It is comprised of a Sample Receiver, containing elution/lysis buffer, a Test Base, comprising two sealed reaction tubes, each containing a lyophilized pellet, a Transfer Cartridge for transfer of the eluted sample to the Test Base, and the ID NOW™ Instrument.

The reaction tubes in the Test Base contain the reagents required for amplification of SARS-CoV-2, as well as an internal control. The templates (similar to primers) designed to target SARS-CoV-2 RNA amplify a unique region of the RdRp segment. Fluorescently-labeled molecular beacons are used to specifically identify each of the amplified RNA targets.

To perform the assay, the Sample Receiver and Test Base are inserted into the ID NOW™ Instrument. The sample is added to the Sample Receiver and transferred via the Transfer Cartridge to the Test Base, initiating target amplification. Heating, mixing and detection are provided by the instrument.

2.0 Specimen

Nasal, nasopharyngeal swab

3.0 Reagents and Materials

Materials Provided:

ID NOW™ Instrument

- Test Bases **BASE**: Orange plastic components containing two reaction tubes of lyophilized reagents for the targeted amplification of SARS-CoV-2 viral RNA and an internal control.
- Sample Receivers **RCVR**: Blue plastic components containing 2.5 mL of elution buffer.
- Transfer Cartridges **CARTRDG**: White plastic components used to transfer 2x100 μ L of sample extract from the Sample Receiver to the Test Base.
- Patient Swabs: 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 and workflow were performed correctly but does not confirm amplification of the SARS-CoV-2 target (RdRp gene).
- Package Insert
- Quick Reference Instructions

Materials Required but not Provided

- Nasopharyngeal Swabs

4.0 Storage and Stability

Store kit at 2-30°C. The ID NOW™ COVID-19 kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use.

5.0 Quality Control

ID NOW™ COVID-19 has built-in 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.

Procedural Controls:

ID NOW™ COVID-19 contains an internal control that has been designed to control for sample inhibition and assay reagent function. 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:

Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. 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. Test these swabs with each new shipment, lot number or untrained operator.

6.0 Specimen Collection and Handling

Use freshly collected specimens for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) <https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

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.

Follow Standard Precautions when handling clinical specimens, all of which may contain potentially infectious materials. Standard Precautions include hand hygiene and the use of personal protective equipment (PPE), such as laboratory coats or gowns, gloves, and eye protection.

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. Swabs can be carefully placed back in the swab package labeled with the patient information (Full name and PHIN or equivalent) and then placed in a specimen bag for transportation to the lab. Do not label the outer plastic bag with the patient information.

Nasal Swab

For optimal test performance, use the swabs provided in the test kit. Alternatively, rayon, foam, HydraFlock® Flocked swab (standard tip), HydraFlock® Flocked swab (mini tip), Copan Mini Tip Flocked Swab, or Copan Standard Flocked swabs can be used to collect nasal swab samples.

Puritan PurFlock Standard Tip Ultra Flocked Swabs, Puritan PurFlock Mini Tip Ultra Flocked Swabs and Copan Standard Rayon Tip Swabs are not suitable for use in this assay.

To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab several times against the nasal wall then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril.

Nasopharyngeal Swab

Use sterile rayon, foam, polyester or flocked flexible-shaft NP swabs to collect a nasopharyngeal sample.

To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Pass the swab directly backwards without tipping the swab head up or down. The nasal passage runs parallel to the floor, not parallel to the bridge of the nose. Using gentle rotation, insert the swab into the anterior nare parallel to the palate advancing the swab into the nasopharynx, leave in place for a few seconds, and then slowly rotate the swab as it is being withdrawn.

To ensure proper collection, the swab should be passed a distance that is halfway of that from the nose to the tip of the ear. This is about half the length of the swab. 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.

Biosafety Responsibilities and Precautions

It is the responsibility of all personnel trained to handle and test clinical specimens suspected of containing SARS-CoV-2 to be familiar and in compliance with the procedures outlined in this document.

***Other pathogens may be present in clinical specimens. As such, precautions outlined in this document will protect the user against potential risks inherent to clinical specimens.

It is the responsibility of personnel using the Abbott ID NOW™ system to report all accidents or incidents involving potential biohazardous materials to their supervisor, charge or biosafety officer.

Accidents or incidents associated with risk of infection include spills and exposure during swab collection. The main sources of risk identified with the ID NOW™ test procedure include (but are not limited to);

1. Dropping a patient sample swab once the specimen is collected.
2. Splashing or spilling liquid from the Sample Receiver during swab mixing.
3. Spilling the test components during assembly for disposal.
4. Incomplete or insufficient clean-up procedures.

It is the responsibility of each user, in conversation with site support and in keeping with Provincial, Territorial and Institutional biosafety requirements and guidelines, to abide by the following precautions to mitigate risk of infection:

1. Patient specimens (swabs) should only be opened for testing in a space dedicated for SARS-CoV-2 testing, such as a clinical laboratory.
 - a. Access to the space should be restricted to authorized personnel, i.e., laboratory staff.
2. It is recommended that absorbent material be used on the work surface to absorb any spills.
3. Only one sample and components of one test will be prepared and opened for testing at a time.
4. Test operators should receive proper training in thorough clean-up procedures
5. **Test operators are to wear appropriate Personal Protective Equipment (PPE) when working with suspect SARS-CoV-2 specimens; for example:**
 - a. Laboratory coat
 - b. Gloves (change gloves between each patient sample)
 - c. Eye protection
 - d. Respiratory protection/procedural mask

****For SARS-CoV-2, respiratory and ocular protection is mandatory, as both are known sites of infection****

Sample Preparation and Handling

1. Direct nasal or nasopharyngeal swabs can be used for the ID NOW™ COVID-19 assay, and for best performance, should be tested as soon as possible after collection.
 - a. If immediate testing is not possible, swabs can be placed back in swab package or in a capped, clean, unused tube, labeled with patient information, and stored at room temperature (15-30°C) for up to one (1) hour prior to testing. This remains the preferred storage conditions for samples to be analysed by the ID NOW™ COVID-19 test.
 - b. If workflow does not permit the use of the sample within this period, Health Canada has also reviewed sufficient evidence supporting the stability of a sample that is stored in a capped, clean, unused tube at 2-8°C for no more than 24 hours (March 5, 2021). If the sample will be shipped during this period, the same storage condition and temperature range needs to be respected.
 - c. If greater than 24 hour delay occurs, dispose of sample and collect a new sample unless indicated otherwise by your local health authority.

***The swab **must not** be placed into transport media.

****Proper swab collection and storage are critical. A trained healthcare professional must collect the swab sample****

7.0 Procedure

Please refer to the ID NOW™ Instrument User Manual for full instructions.

Before testing with ID NOW™ COVID-19:

- Put on a clean pair of gloves for each patient test.
- Allow all samples to reach room temperature.
- Allow all test pieces to reach room temperature.
- 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.

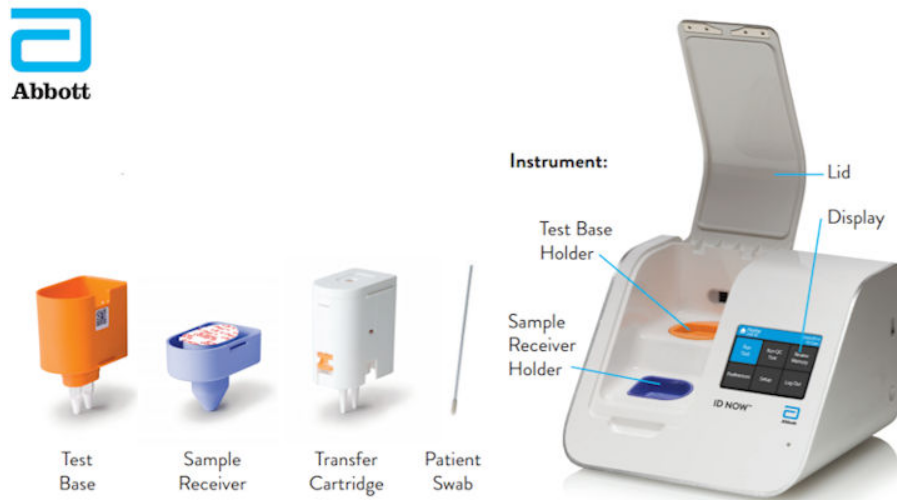
7.1. Prepare the Abbott ID NOW™ Instrument

1. Turn on the ID NOW™ instrument using the switch located at front of the instrument.
2. Turn on the printer using the switch located at the back left of the printer
3. Enter your login information
4. The instrument will run a “Self Test” and the display will tell you to wait.
5. Once the Self Test is complete, the display will show the Instrument Home Menu Options which include:
 - a. **Run Test**
 - Touch ‘**Run Test**’ – this will begin the test process.
 - Touch ‘**COVID-19 Test**’ – this starts a COVID-19 test.
 - Select Swab Sample Type (if prompted) – If the sample type has already been specified by the Admin, the instrument will automatically advance to the next step.
Caution: VTM Samples are not an appropriate sample type for the ID NOW™ COVID-19 test.
 - Enter Patient ID using on screen keyboard or barcode scanner – Touch ‘✓’ – Verify that the ID was entered correctly, then touch ‘✓’ to confirm entry.
 - b. **Run QC Test**
 - Initially completed by the NML-trained staff prior to sending out each ID NOW™ instrument
 - The QC test should be repeated with each new shipment, lot number or untrained operators.
 - c. **Review Memory**
 - Capacity to store memory for up to 999 tests.
 - To export results and log files.
 - d. **Preferences**
 - e. **Setup**
 - f. **Log Out**
6. To perform a test:
 - a. Select the **Run Test** icon
 - b. Select the assay that you want to perform (i.e., COVID-19)
 - c. Enter the patient ID either manually or by scanning the patient code using the scanner
 - d. Confirm patient ID

7.2. Prepare the Work Area

1. Put on appropriate PPE (listed on page 5).
2. Disinfect the work area before and after use with an approved disinfectant (as determined by your local safety authority).
3. Set up the work area with the following:
 - a. Absorbent paper/pad on level working surface
 - b. Biohazard bag in rack or biohazard container
 - c. Single-use disinfectant wipes, or paper towel and liquid disinfectant for cleaning
See Appendix B for information on approved disinfectants

- d. One of each package #1 (Test Base) and package #2 (Sample Receiver and the Transfer Cartridge) – Ensure packages have no signs of damage or leaks
- e. One patient sample swab



7.3. Run the Test

Working in the prepared work area and wearing PPE, open the ID NOW™ instrument lid, following the display prompts.

1. Insert the Orange Test Base into the Orange Test Base Holder and Select **OK**. Confirm the correct test is displayed on the screen. Touch **OK** to proceed.

Caution: Once the Test Base has been placed in the holder, the user will have 10 minutes to confirm the test. If the test is not confirmed within 10 minutes, the instrument will time out and the Test Base must be removed and discarded.

If the incorrect Test Base has been inserted, remove and dispose of the incorrect Test Base. Close the lid. The instrument will then run a self-test before proceeding to the Home screen. Press Run Test and restart the test using the correct Test Base.

2. Place the Blue Sample Receiver in the Blue sample receiver holder and wait for the instrument to warm up (3 minutes).
 - a. **Do not** remove the foil on the Sample Receiver until prompted by the instrument. It will prohibit the Elution Buffer from reaching the appropriate temperature and may impact test performance.

Caution: DO NOT REMOVE THE FOIL SEAL UNTIL PROMPTED BY THE INSTRUMENT. DO NOT close the lid or insert the sample until prompted by the instrument.

Caution: Do not apply excessive force. Excessive force could damage the instrument.

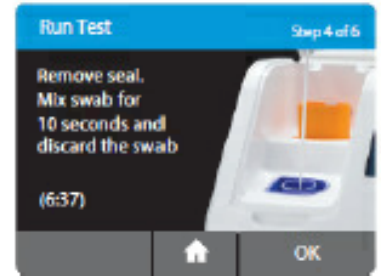
Caution: Once the Sample Receiver has been placed in the holder, the user will have 10 minutes to start the test (Steps 3 through 5). If the test is not started within 10 minutes, the instrument will time out and all test pieces (Test Base and Sample Receiver) must be removed and discarded. The instrument will proceed to the Home screen. Press Run Test and restart the test using a new Test Base and Sample Receiver.



- b. If the Sample Receiver is spilled while opening, clean the instrument per instructions provided in the Instrument User Manual and cancel the test. Repeat test with a new Sample Receiver.
 - c. The Sample Receiver contains an acidic buffer with detergent, which, in combination with heat, is reported to inactivate the virus.
3. When prompted, remove the seal (ensure the sample receiver remains in place) from the Sample Receiver and mix the patient swab in the Receiver liquid for 10 seconds then select **OK**.

- a. Avoid creating excessive bubbles when mixing which can interfere with the assay
- b. Gently squeeze the swab against the side of the Sample Receiver to expel excess liquid from the swab
- c. Discard swab in biohazard bag or biohazard container.

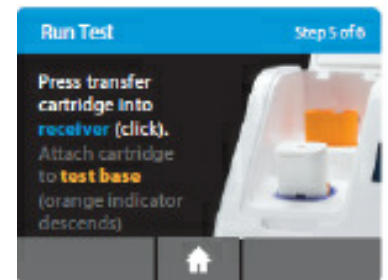
Caution: To ensure that the Sample Receiver remains in the instrument while removing the foil seal, place two fingers along the outer edge of the Sample Receiver to hold it in place. If the Sample Receiver spills after warm up, cancel the test by pressing the Home button. Remove and discard the test 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.



4. Press the White Transfer cartridge into the Blue Sample Receiver.
 - a. Press the White Transfer Cartridge into the Blue Sample Receiver until a click is heard. This may require a small amount of effort to achieve the “click”.

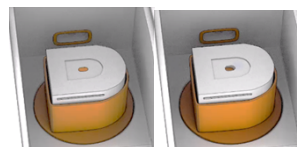
Note: When the Transfer Cartridge is properly attached to the Sample Receiver, the Orange Indicator on top of the Transfer Cartridge will rise. If it does not rise, continue pressing on the Sample Receiver until it does.

Caution: The orange indicator should be observed closely. If the orange indicator does not fully rise, the Transfer Cartridge may not collect enough sample.



5. Lift and then connect the Transfer Cartridge to the Test Base, taking care not to spill liquid into the ID NOW™ Device. In the event of a spill, see Appendix C.
6. Attach the Transfer Cartridge to the Test Base.
 - a. To properly expel all of the liquid sample into the Test Base, make sure to listen for several “clicks” and watch that the orange indicator circle descends

Caution: If the orange indicator does not fully descend, not enough sample will be dispensed. This may potentially result in invalid or false test results.



7. Close the lid to start the test.
8. **Do not** open the lid until the **Test Complete** message appears on the display panel as well as the result of the test. The test result is not saved until this message appears.

Note: The test will be cancelled if the lid is opened.

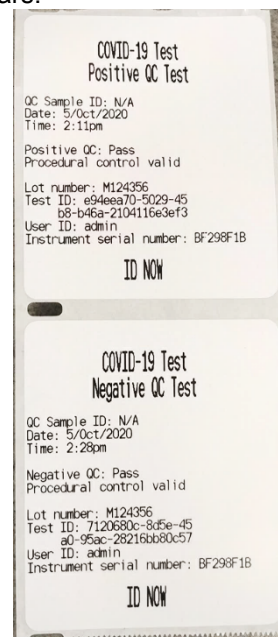
Caution: This screen will be displayed for up to 30 seconds once the **Transfer Cartridge** is detected. If the instrument does not detect that the lid has been closed by then, it will time out and all test pieces (**Sample Receiver, Test Base, and Transfer Cartridge**) must be removed and discarded. The instrument will proceed to the **Home** screen. Collect a new sample from the patient. Press **Run Test** and restart the test using a new **Test Base** and **Sample Receiver**.

Caution: **DO NOT OPEN THE LID.** The test will be cancelled and all test pieces (**Sample Receiver, Test Base, and Transfer Cartridge**) must be removed and discarded. A test result will not be reported or saved in the instrument memory.

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.

9. The assay will provide a result (Positive, Negative or Invalid) in 15 minutes or less.
 - a. Result interpretations and follow-up guidelines can be found in Appendix A.
 - b. The result will appear on the ID NOW™ display screen and can be printed by selecting the **Print** icon in the bottom right hand of the screen.
 - c. To run another test, select the **Home** icon to return to the Home screen.



7.4. Dispose of the Test Components and Disinfect the ID NOW™ Instrument

1. After printing or if a **New Test** or the **Home** icons are selected, the instrument will prompt you to open the lid and discard the test components.
 - a. Remove test components by lifting the Transfer Cartridge attached to the Test Base and pressing into the Sample Receiver until it clicks.

***Pieces **must not** be separated once they are assembled as there is risk of spilling the patient sample.
 - b. All test pieces must be disposed of as biohazard waste.
 - c. Test pieces do not contain significant amounts of hazardous chemicals to warrant inclusion in chemical waste disposal.
2. Close the lid. The instrument will then run a **Self-Test** before showing either the **Home** screen or **Enter Patient ID** screen (dependent upon which was previously selected).
3. When finished with the ID NOW™ instrument, using a single-use disinfectant wipe or paper towel moistened with disinfectant. Wipe clean the outer surface of the instrument.
4. The used wipes/paper towels are disposed of in a biohazard waste bag.
5. When cleaning is complete, remove gloves and dispose of in biohazard waste bag. Wash your hands.

7.5. Export the Test Results

1. An Excel file report can be generated for the patient samples.
2. To export results and log files, insert a USB drive into the USB port of the instrument then select the **Review Memory** icon on the **Home** screen.
3. Scroll down to the **Export Results** section and select the **OK** icon. Follow the prompts.

7.6. Quality Control Swab Test Procedure

For QC testing, select Run QC Test on the Home screen, and follow the displayed instructions. Refer to Running a QC Test in the ID NOW™ Instrument User Manual for further details.

1. Touch 'Run QC Test'
2. Touch 'COVID-19'
3. Select the QC Test to be Run
4. 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.

The user has the option to enter an ID for the QC Sample being run.

Note: The QC test is run in the same manner as a Direct Nasal/Nasopharyngeal Swab Patient Test. See the To Perform a Test section above for step by step instructions for direct nasal/nasopharyngeal swab samples.

8.0 Limitations

- The performance of the ID NOW™ COVID-19 was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
- Negative results should be treated as presumptive for symptomatic patients and tested with an alternative authorized molecular assay, if necessary for clinical management, including infection control.
- Negative results are definitive for asymptomatic pre-surgical patients within 24 hours of surgery.
- 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.
- 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 VTM are not appropriate for use in this test.
- The additional recommended swab types have not been validated in the ID NOW™ COVID-19 test. The recommendation for use is based on data generated with other, similar ID NOW™ assays. For optimal test performance, use the swabs provided in the test kit.

9.0 Precautions

1. For in vitro diagnostic use.
2. To be used in conjunction with the ID NOW™ Instrument.
3. **Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.**
4. Proper sample collection, storage and transport are essential for correct results.
5. Leave test pieces sealed in their foil pouches until just before use.
6. Do not tamper with test pieces prior to or after use.
7. Do not use kit past its expiration date.
8. Do not mix components from different kit lots or from other ID NOW™ assays.
9. Solutions used to make the positive control swab are inactivated using standard methods. However, patient samples, controls, and test pieces should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
10. Wear clean personal protection equipment and gloves when running each test. **Change gloves between the handling of specimens suspected of COVID-19.**
11. If any assay components are dropped, cracked, found to be damaged or opened when received, DO NOT USE and discard. Do not use scissors or sharp objects to open foil pouches as damage to test pieces can occur.

12. Do not open the Sample Receiver before placing in the instrument. It will prohibit the Elution Buffer from reaching temperature and may impact test performance.
13. If the Sample Receiver is spilled while opening, clean the instrument per instructions provided in the instrument User Manual and cancel test. Repeat test with a new Sample Receiver.
14. All test pieces must be removed from the instrument according to removal instructions displayed on the instrument and disposed of according to country and local requirements. Pieces must not be separated once they are assembled.
15. All test pieces are single use items. Do not use with multiple specimens.
16. Once reacted, the Test Base contains large amounts of amplified target (Amplicon). Do not disassemble the Test Base and Transfer Cartridge. In the case of a positive sample, this could lead to amplicon leakage and potential ID NOW™ COVID-19 false positive test results.
17. At a low frequency, clinical samples can contain inhibitors that may generate invalid results. Site to site invalid rates may vary.

10.0 References

ID NOW™ COVID-19 Product Insert, IN191000CAN Rev.1 2020/09

Testing Procedures for the Abbott ID NOW™ and the ID NOW™ COVID-19 Assay-National Microbiology Laboratory, Winnipeg, Canada v1.0 2020

ID NOW™ COVID-19 Instructions for Use (IFU), package insert, October 2020

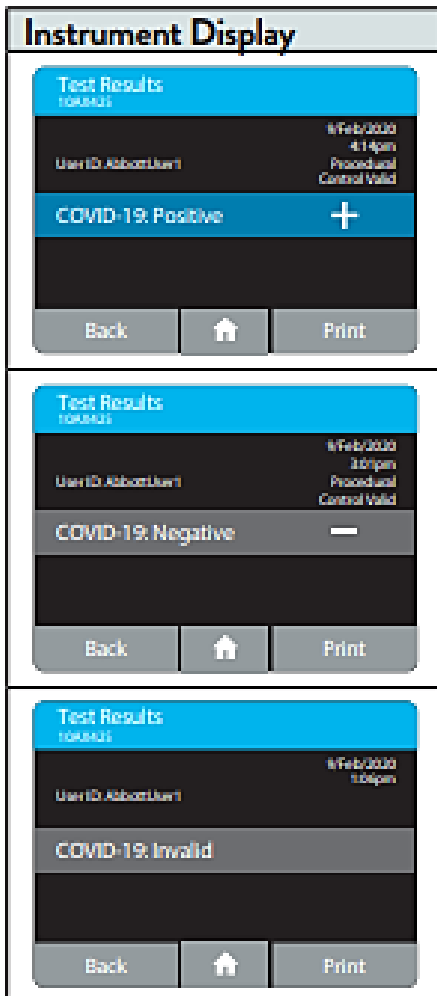
ID NOW™ System User Manual

Abbot training video modules:

<https://www.globalpointofcare.abbott/en/support/product-installation-training/id-now-training-videos.html>

Appendix A Results Outputs, Interpretations & Follow-up Actions

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



COVID-19 positive:

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

COVID-19 negative:

Negative results should be treated as presumptive for symptomatic patients and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with an alternative molecular assay. Negative results do not rule out bacterial infection or co-infection with other viruses.

Negative results are definitive for asymptomatic pre-surgical patients within 24 hours of surgery.

COVID-19 Invalid:

The presence or absence of COVID-19 Viral RNA cannot be determined.

Repeat testing of the sample using new test components. If upon repeat testing, another invalid result is obtained, results should be confirmed with another method prior to reporting.

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.

Appendix B Waste Disposal

Health Canada: Hard-surface disinfectants and hand sanitizers (COVID-19) – List of disinfectants effective against COVID-19 - <https://www.canada.ca/en/health-canada/services/drugs-health-products/disinfectants/covid-19/list.html>

Commonly used disinfectants for use with the ID NOW™ include:

- 70% Isopropanol
- 70% Ethanol
- 1 in 10 dilution of household Bleach (*prepared fresh daily*)

Use site/facility approved disinfectant.

Facility Approved Disinfectants: <https://sharedhealthmb.ca/files/facility-approved-disinfectants.pdf>

All consumables that have potentially come into contact with or have been used to handle specimens suspected of containing SARS-CoV-2 must be disposed of as biohazard waste. This includes:

1. Used test components
2. Used specimen swabs
3. Gloves and masks
4. Single-use disinfectant wipes, absorbent pad, and other paper products used

All items in the work area must be surfaced decontaminated prior to removing them for storage or disposal using an approved disinfectant. These items include the following:

- Waste bag holder
- Paper products used for cleaning may go directly into a biohazard waste bag for disposal

Biohazard waste bags may now be treated according to your own site's protocol for safe disposal of infectious material (i.e., Stericycle, Daniels, autoclave or incineration).

Appendix C Handling a Spill

All personnel handling potential SARS-CoV-2 specimens should be knowledgeable in their site's biological spill clean-up protocol for infectious respiratory samples.

The cleaning and reporting of spills are to follow instructions provided by the designated Biosafety Oversight for your facility.

Each site should have a well-stocked Spill Kit stored in the room.

Key considerations for dropped test components

***Following completion of the ID NOW™ COVID-19 assay, the temperature of the assay combined with the pH and detergents of the sample buffer are reported to inactivate the SARS CoV-2, thus reducing the risk of exposure to the user. However, spills may provide a molecular contamination of the site and must be cleaned appropriately before continuing with testing.

Dropping attached test components is unlikely to cause the components to separate. However, in the event that the test pieces do separate and the test liquid spills, follow the cleaning and reporting instructions outlined by the designated Biosafety Oversight for your site.