



Title: SARS-CoV-2 Abbott ID NOW, Nasopharyngeal, Throat, Nasal Swabs		SOP #:
Effective Date:	Supersedes:	Author:
Accreditation Standard:	Review Date:	Date Discontinued:
Laboratory Director Signature:		Date approved by LD:

POLICY

The Abbott ID NOW SARS-CoV-2 test is to be performed using Nasopharyngeal or Throat or Direct Nasal Swab specimens collected from individuals who meet CDC clinical and/or epidemiological criteria for COVID-19 testing. In addition, laboratories are required to report all POSITIVE results to the appropriate Public Health authorities.

PURPOSE

The purpose of this procedure is to provide step-by-step instructions to the laboratory staff performing this test by following strict guidelines set by the CDC due to the virus classified as highly contagious when not utilizing the appropriate personal protective equipment and a physical barrier.

PRINCIPLE

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, nasopharyngeal and throat swabs. The ID NOW™ Instrument has a small footprint and easy to use graphical user interface for convenience within a busy hospital or near patient testing environments. The ID NOW™ COVID-19 kit contains all components required to carry out an assay for SARS-CoV-2 on the ID NOW™ Instrument.

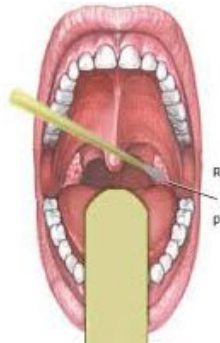
ID NOW COVID-19 is an automated assay that utilizes isothermal nucleic acid amplification technology for the qualitative detection of SARS-CoV-2 viral nucleic acids. It is comprised of a Sample Receiver, containing elution/lysis buffer, a Test Base, comprising two sealed reaction tubes, each containing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

SPECIMEN COLLECTION

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

CAUTION – VTM samples are not an appropriate sample type for the ID NOW COVID-19 test.

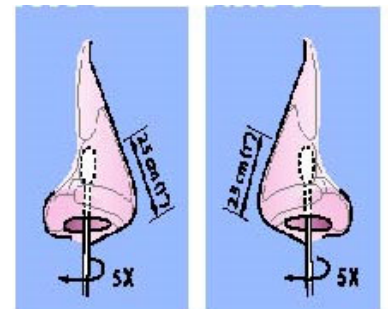
Throat Swab – Included in Test Kit



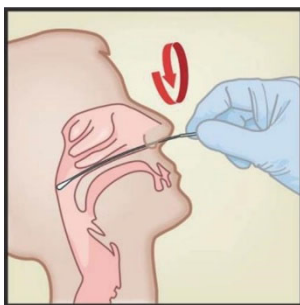
For optimal test performance, use the swabs provided in the test kit. Alternatively foam, polyester, HydraFlock® and nylon flocked throat swabs can be used to collect throat swab samples. Rayon swabs are not suitable for use in this assay. Collect patient specimen by swabbing the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.³

Nasal Swab – Included in Test Kit

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 – Preferred Method by CDC – Not included in Test Kit



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 nares 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.

SPECIMEN TRANSPORT AND STORAGE

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. Direct nasal, throat or nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, the nasal, throat or nasopharyngeal swab can be held in its original package at room temperature (15-30°C) for up to two (2) hours prior to testing. If a direct throat or nasopharyngeal swab specimen will be held longer than two (2) hours, it must be refrigerated at 2-8°C and tested within 24 hours from the time of sample collection. If the transport of nasal, throat or nasopharyngeal swab samples is required, the transport media listed below were tested and are acceptable for use in ID NOW COVID-19.

Transport Media:

Amie's Media

Dulbecco's Modified Eagles' Medium (D-MEM)

Hank's Balanced Salt Solution

M4 Media

M4-RT Media

M5 Media

M6 Media

Phosphate Buffered Saline

Saline

Stuart's Media

Universal Transport Media

Starplex Multitrans

It has been determined that Tryptose Phosphate Broth, Brain Heart Infusion Broth, Veal Infusion Broth, and Wako's E-MEM transport media are NOT suitable for use with this test.

WARNINGS AND PRECAUTIONS**General**

- Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. Because it is often impossible to know which might be infectious. All biological specimens should be treated with standard precautions. **POSITIVE SPECIMENS ARE HIGHLY CONTAGIOUS!**
- For procedures with a high likelihood to generate aerosols or droplets, use either a certified Class II Biological Safety Cabinet (BSC) or additional precautions to provide a barrier between the specimen and personnel, such as surgical mask or face shield, or a splash shield; centrifuge safety cups and sealed centrifuge rotors to reduce the risk of exposure to laboratory personnel. *The CDC recommends placing the Cepheid analyzer inside the BSC or as close as possible to the BSC.*
- Wear clean lab coats and gloves. Change gloves between the handling of each specimen.
- Change gloves before leaving work area and upon entry into work area.
- CHANGE GLOVES if they come in contact with specimen or appear to be wet to avoid contaminating other specimens.
- In the event of a spill of specimens or controls, wear gloves and absorb the spill with paper towels and discard into a biohazardous waste receptacle. Then, thoroughly clean the contaminated area with a 10% freshly prepared household chlorine bleach. Allow a minimum

Laboratory Name

of two minutes of contact time. Ensure the work area is dry before using the 70% denatured ethanol to remove bleach residue. Allow surface to dry completely before proceeding. For equipment, follow the manufacturer’s recommendations for decontamination of equipment.

- Proper sample collection, storage and transport are essential for correct results.
- Leave test pieces sealed in their foil pouches until just before use. Do not tamper with test pieces prior to or after use.
- Do not mix components from different kit lots or from other ID NOW assays.
- **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.**
- 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.
- 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.
- 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.**
- All test pieces are single use items. Do not use with multiple specimens.
- 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.
- At a low frequency, clinical samples can contain inhibitors that may generate invalid results. Site to site invalid rates may vary.
- **Due to the high sensitivity of the assays run on the instrument, contamination of the work area with previous positive samples may cause false positive results.** Handle samples according to standard laboratory practices. Clean instruments and surrounding surfaces according to instructions provided in the cleaning section of the instrument User Manual. Refer to Section 1.6, Maintenance & Cleaning, for further information.

TEST KIT CONTENTS – EACH KIT CONTAINS 24 TESTS

- **Test Bases:** 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:** Blue plastic components 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.
- **Patient Swabs:** Sterile swabs (foam) for use with the ID NOW COVID-19 Test.
- **Positive Control Swab:** The positive control swab ensures sample elution/lysis and workflow were performed correctly.
- **Negative Control Swab:** The negative control swab ensures appropriate negative results are obtained.
- **Plastic Disposable Pipettes capable of delivering 200 µL VTM Sample.**

SUPPLIES	STORAGE	TEMPERATURE
Nasopharyngeal, Nasal and Throat specimens	Rm temp: 2 hours	15-30 ⁰ C
	Ref temp: 24 hours	2-8 ⁰ C

Laboratory Name

	Eluated Swab: 72 hours	2-8 ⁰ C
Test Kit	Stable until Expiration Date	2-30 ⁰ C
UTM-Universal Transport Media	Rm. temperature	15-30 ⁰ C

** Make sure all test components are at room temperature before use.

CALIBRATION

Not applicable. The analyzer performs self-checks.

Before testing with the Abbott ID NOW:

- *Proper PPE is required before testing. See Procedure titled “SARS CoV-2 CDC Guidelines for Testing” for instructions if the laboratory does not have a Biological Safety Cabinet (microbiology hood).*
- Only if needed such as test completion of a positive specimen, disinfect Abbott ID NOW instrument and work area with 70% Ethanol or 10% Bleach Solution on a damp (not dripping), lint free cloth such as Kimwipes or guaze sponges. If using Bleach solution, rinse camera and touch screen with DI H2O dampened Kimwipe. Always, dry the camera lens and touch screen.
- Use appropriate covered biohazard waste receptacle for all testing device and sample disposal.
- 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 each 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.

QUALITY CONTROL

External Positive and Negative Control swabs are provided and should be tested following the Run QC Test instructions on the ID NOW Instrument. 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.

Frequency:

- ✓ Each time a new shipment of reagent kits is received even if it is the same lot previously received.
- ✓ Each time a new operator is performing the test (i.e., operator who has not performed the test recently).
- ✓ When problems (storage, operator, instrument or other) are suspected or identified.
- ✓ If otherwise required by your institution’s standard Quality Control procedures.

External Controls:

Negative Control - Negative Control Swab

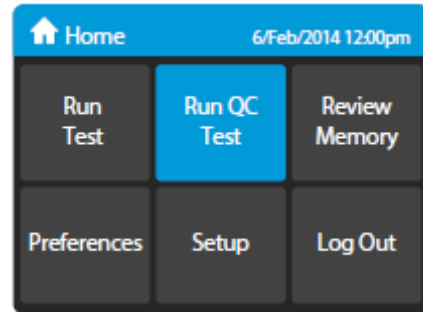
Positive Control - Positive Control Swab

Note: *The ID NOW Instrument reports QC results as Pass or Fail*

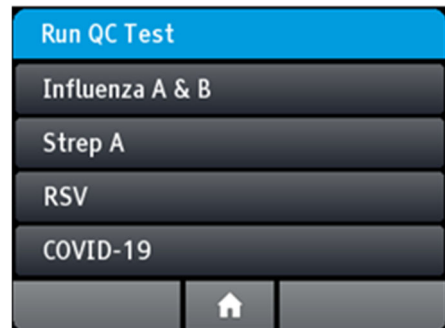
Quality Control Swab Test Procedure

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.

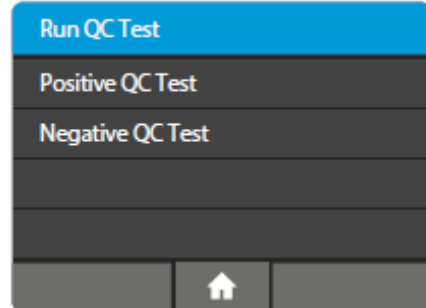
- 1 Touch 'Run QC Test'



- 2 Touch 'COVID-19'



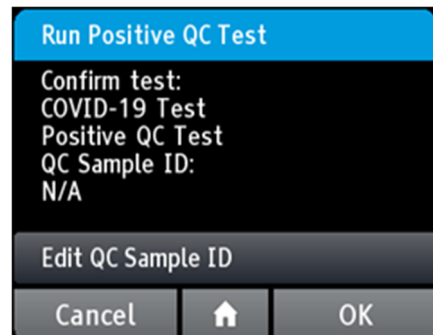
- 3 Select the QC Test to be Run



- 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.

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




Documentation and Troubleshooting:

Laboratory Name

Record QC performed on the appropriate log sheet and any corrective actions taken for failed QC runs. If the correct control results are not obtained, do not perform patient tests or report patient results. Contact the Laboratory Supervisor and Technical Support if problem is not resolved during normal business hours before testing patient specimens. Email customerservice@abbottmolecular.com or call 1-800-553-7042.


PROCEDURE FOR PATIENT TESTING:

STEP 1:

Turn on the ID NOW™ Instrument - press the power button  on the side of the instrument.

Note: If the unit is unattended for one hour, the instrument will go to a black screen power save mode. Touch the screen to return the unit to active display operation.

Enter User ID

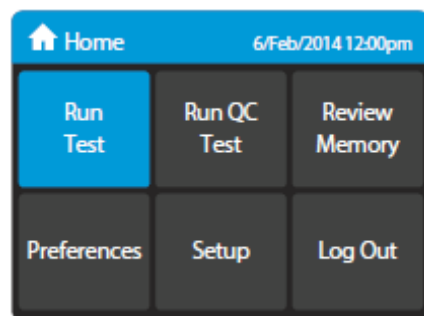
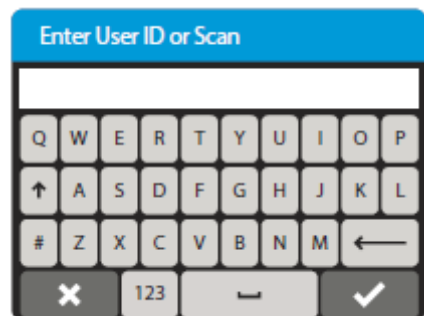
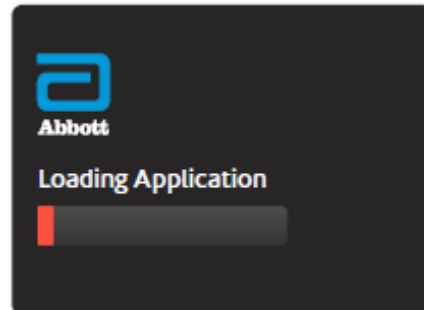
Press  after entry.

Touch 'Run Test'

This will begin the test process.

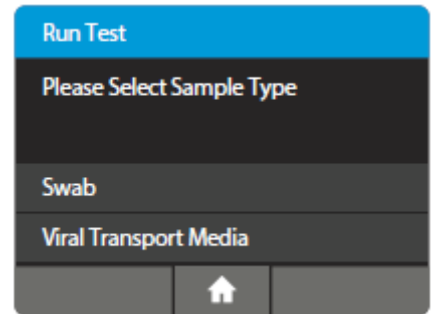
Touch 'COVID-19 Test'

This starts a COVID-19 test.



Select Sample Type (if prompted)

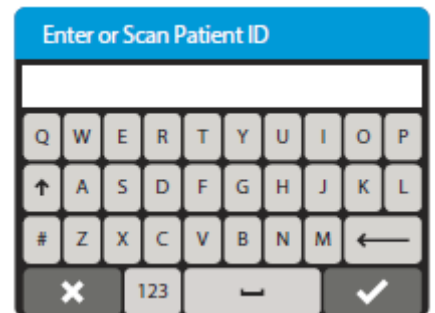
If the sample type has already been specified by the Admin, the instrument will automatically advance to the next step. Swab is the default sample type if not specified.



Enter Patient ID using on screen keyboard or barcode scanner.


Touch .

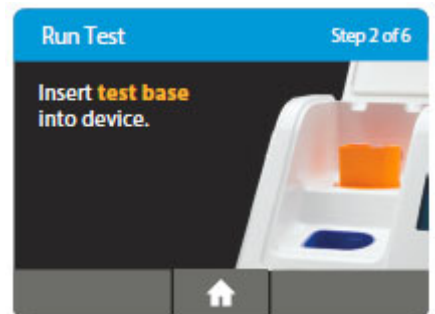
Verify that the ID was entered correctly, then touch  to confirm entry.



STEP 2:


Open the Lid and insert Orange Test Base into Orange Test Base holder.

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

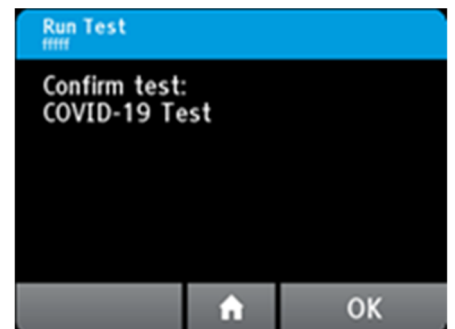


Confirm that the correct test is displayed on the screen.

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.



STEP 3:

Insert Blue Sample Receiver into the Blue Sample Receiver holder.



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



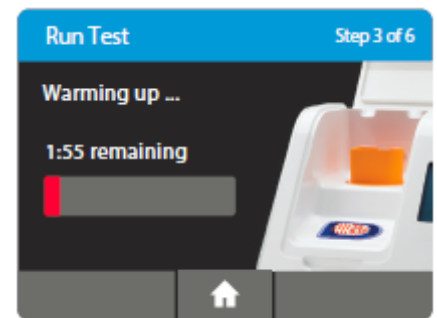
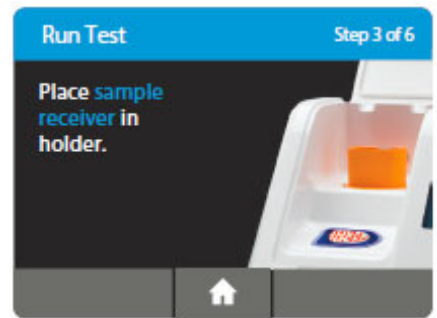
Caution: Once the Sample Receiver has been placed

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.

Wait for the Sample Receiver to Warm Up. Do not remove the Sample Receiver from the instrument once the Warm Up begins.

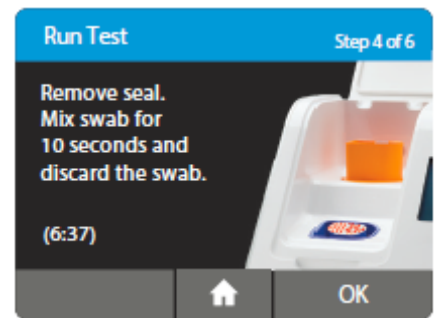


Caution: DO NOT REMOVE THE FOIL SEAL UNTIL PROMPTED BY THE INSTRUMENT. DO NOT close the lid or insert the sample until prompted by the instrument.



STEP 4:

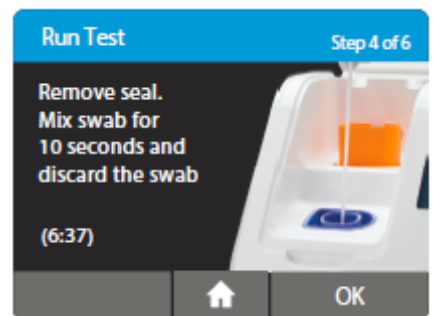
When prompted, remove the foil seal and place the patient swab to be tested into the Sample Receiver.



Vigorously mix the swab in the liquid for 10 seconds. Press the swab head against the side of the Sample Receiver as you mix it. This helps remove the sample from the swab. Once the swab is removed, touch 'OK' to proceed.



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



Laboratory Name

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.

Discard the swab.

Skip to Step 5a.

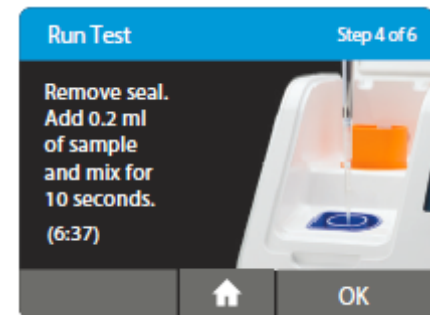
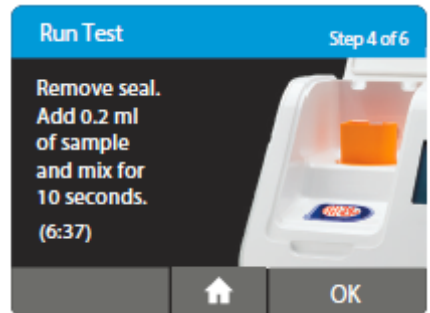
Nasal, Throat or Nasopharyngeal Swab Eluted in Transport Media Test Procedure

When prompted, remove the foil seal and add 0.2 ml of sample to the Sample Receiver using the disposable pipettes provided in the kit.

Vigorously mix the sample in the liquid for 10 seconds. Use the pipette tip to swirl the liquid. Once the sample is mixed and the pipette is removed, immediately touch 'OK' to proceed. Continue to Step 5a.



Caution: To ensure 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.



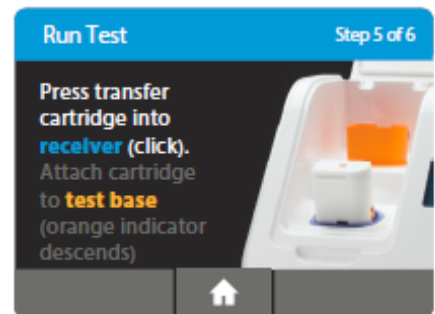
STEP 5a:

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.



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




STEP 5b:

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.



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

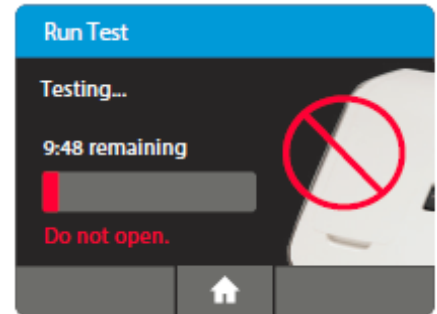
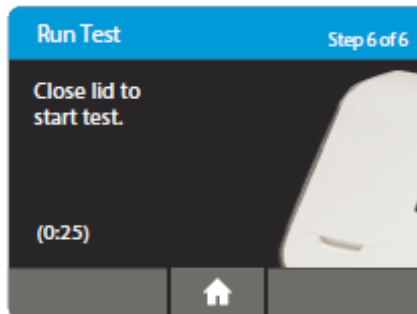



STEP 6:


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. 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.

Laboratory Name

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.

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'. Refer to the Result Interpretation Section for Interpretation of Results.

Press Print to print test results, press New Test to run another test, Press Home to return to the Home screen

After printing, or if New Test or Home are selected, 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.

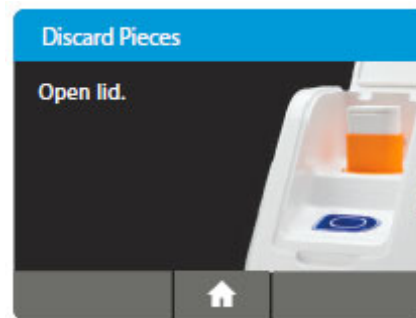
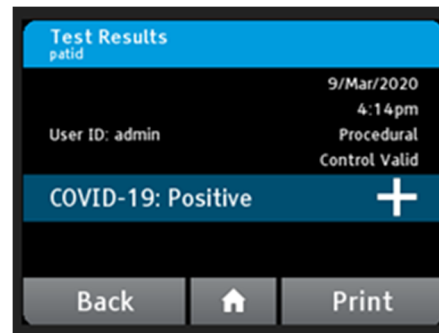
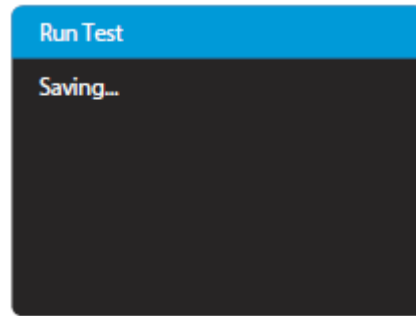


Caution: Do not try to remove the Sample Receiver by any other method as there is a risk of spilling the patient sample.

All test pieces will be connected and can now be removed from the instrument and disposed of according to federal, state and local regulations.

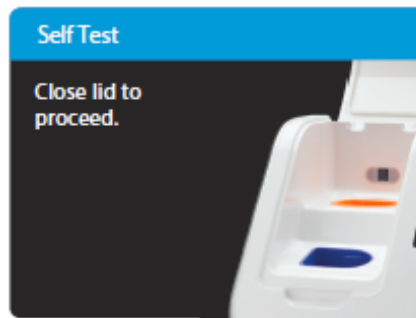


Caution: DO NOT disassemble the Transfer Cartridge and the Test Base before disposal.



Laboratory Name

Close the lid. The instrument will then run a Self-Test before showing the Home screen or Enter Patient ID screen, depending on the previous selection.



Turnaround Time for Tests:

Positive Tests can be reported out within 5 minutes if there is a high viral load. Negative tests will need to process for 13 minutes before the test is completed.

INTERNAL 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.

RESULT INTERPRETATION

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

Result	Explanation	Action
COVID-19 Positive		Report Test Results. Internal Procedural Control is Valid.
COVID-19 Negative	This result does not rule out co-infections with other viruses and bacteria.	Report Test Results. Internal Procedure Control is Valid.
COVID-19: Invalid	If an Invalid result is received, one additional test may be run using the same Sample Receiver.	Repeat Test of the sample using new test components. See Retest Procedure. If repeated invalid results are obtained, send the appropriate specimen to the Reference Laboratory for confirmation testing.

CONDITIONS OF AUTHORIZATION FOR LABORATORY AND PATIENT CARE SETTINGS

The ID NOW COVID-19 Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>

Reference Range: Negative

Alert Value: POSITIVE – Notify the ordering provider and document in the patient’s Electronic Health Record with date/time of notification and tester’s initials. No repeat testing is needed to confirm the result.

Reporting Test Results: Enter test results under the test name created in the RPMS laboratory Menu using EM for manual entries or EA if interfaced through Data Innovations middleware. Follow the laboratory’s procedures on using the RPMS Laboratory Information System. File printed test results. The following will be reported with each test result under interpretation: *“Negative results do not preclude SARSCoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions.”*

Retest Procedure:

1. 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.
2. 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.
3. 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

BACK-UP METHOD WHEN THE TEST IS UNAVAILABLE

Notify the Laboratory Supervisor first for troubleshooting assistance. If troubleshooting fails and there is no additional analyzer to run the test on, then notify the medical staff that the test is unavailable either due to reagent depletion, nonfunctioning equipment or other reason. Send out specimens to the Reference Laboratory until the test system is in operation again.

WASTE DISPOSAL

1. Handle laboratory waste from testing suspected or confirmed COVID-19 patient specimens as all other biohazardous waste in the laboratory. Currently, there is no evidence to suggest that this laboratory waste needs any additional packaging or disinfection procedures.
2. Consult your institution’s environmental waste personnel on proper disposal of used cartridge, which may contain amplified material. This material may exhibit characteristics of federal EPA Resource Conservation and Recovery Act (RCRA) hazardous waste requiring specific disposal requirements. Check state and local regulations as they may differ from federal disposal regulations.

LIMITATIONS

- Swab sample eluted in VTM are not appropriate for use in this test.
- 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.

Laboratory Name

- 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.
- As with any molecular test, if the virus mutates in the target region, COVID-19 may not be detected or may be detected less predictably.
- The test cannot rule out diseases caused by other bacterial or viral pathogens

PERFORMANCE CHARACTERISTICS: Refer to the Manufacturer’s Instructions for Use. ID NOW COVID-19 Test Agreement with the Expected Results by Sample Concentration

TARGET CONCENTRATION	NUMBER CONCORDANT/ NUMBER TESTED	% AGREEMENT [95% CI]
2X LOD	20/20	100% [83.9% - 100%]
5X LOD	10/10	100% [72.3% - 100%]
Negative	30/30	100% [88.7% - 100%]

REFERENCES

Abbott ID NOW COVID-19 Instructions for Use, Revision IN190000 Rev. 1 2020/03; **For Use under an Emergency Use Authorization (EAU) only.**

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html#testing>