From:	Augustine, Kelie
To:	Takenaka, Gavin K
Cc:	Agaran, Tina K; Higa, Stephanie M; Assily, Mahina O; Camacho, Maureen; Menino, Tanyalee; Krueger, Catherine M; Lopez, Jennifer D; Labrador, Landon J; Simeona, Jennifer K
Subject:	[EXTERNAL] Abbott ID NOW COVID-19 Training (2 of 3)
Attachments:	120004872 v04 ID NOW™ Performance Best Practices Dispe.pdf IN190000 v3.0 ID NOW COVID-19 Test Product Insert IN1.pdf 120006456 v06 ID NOW COVID-19 CLSI More Packet.doc

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Hello,

Please join me for a virtual training on the Abbott ID NOW COVID-19 test at the scheduled time. Please attempt to join at least 5 minutes before the start of the training to avoid any delays due to technical difficulties.

Included in this email are some helpful documents that I'll refer to during training.

The attachments include:

* ID NOW COVID-19 Product Insert (electronic copy)
* ID NOW COVID-19 CLSI Document
* ID NOW Performance Best Practices & Troubleshooting Guide

Additional Resources:

* ID NOW Training Video Modules Link: https://www.globalpointofcare.abbott/en/support/product-installation-training/id-now-training-videos.html <https://urldefense.com/v3/__https://www.globalpointofcare.abbott/en/support/product-installation-training/id-now-training-videos.html__;!!LIYSdFfckKA!lXiwtYZEyo3dLV5peaOAZ1b0sFGbvELiC65BOTZtb6KeJAuaZlji1D2eVQFmT0v_d6AMMvIz$>

* ID NOW Technical Service: Phone: 855-731-2288 / Email: ts.scr@abbott.com <mailto:ts.scr@abbott.com>

Our goal is to support you during this critical time to ensure your facility's success with implementing ID NOW COVID-19 patient testing. Thank you for all you're doing for your patients and community.

Best Regards,

Kelie Augustine

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

Meeting number (access code): 146 413 1511

Meeting password: yRDPnVpd332

Join <https://urldefense.com/v3/__https://myabbottmeetings.webex.com/myabbottmeetings/j.php?MTID=me482977d4cbf9d3a740010bfaa47b560__;!!LIYSdFfckKA!lXiwtYZEyo3dLV5peaOAZ1b0sFGbvELiC65BOTZtb6KeJAuaZlji1D2eVQFmT0v_d3HCUXfn$>

Tap to join from a mobile device (attendees only)
+1-408-418-9388,,1464131511## <tel:%2B1-408-418-9388,,*01*1464131511%23%23*01*> United States
+1-855-756-6338,,1464131511## <tel:%2B1-855-756-6338,,*01*1464131511%23%23*01*> United States Toll free

Join by phone
+1-408-418-9388 United States
+1-855-756-6338 United States Toll free
Global call-in numbers <https://urldefense.com/v3/__https://myabbottmeetings.webex.com/myabbottmeetings/globalcallin.php?MTID=m2d572a3064628c2bc3a892e73ee8dd5f__;!!LIYSdFfckKA!lXiwtYZEyo3dLV5peaOAZ1b0sFGbvELiC65BOTZtb6KeJAuaZlji1D2eVQFmT0v_d7zidos8$> | Toll-free calling restrictions
<https://urldefense.com/v3/__https://www.webex.com/pdf/tollfree_restrictions.pdf__;!!LIYSdFfckKA!lXiwtYZEyo3dLV5peaOAZ1b0sFGbvELiC65BOTZtb6KeJAuaZlji1D2eVQFmT0v_d-z2neeD$>

Join from a video system or application
Dial 1464131511@myabbottmeetings.webex.com <sip:1464131511@myabbottmeetings.webex.com>

Need help? Go to http://help.webex.com
<https://urldefense.com/v3/__http://help.webex.com__;!!LIYSdFfckKA!lXiwtYZEyo3dLV5peaOAZ1b0sFGbvELiC65BOTZtb6KeJAuaZlji1D2eVQFmT0v_d3wA3cDY$>

1.1

ID NOW™ Performance Best Practices

Successful testing on ID NOW™ system requires the user adhere to guidelines and recommendations provided within the user manual, assay package inserts, instrument on-screen instructions, and documents contained within assay-specific training folders. To achieve maximum performance of an ID NOW™ assay, this technical memorandum serves to highlight key aspects of the testing process, with particular focus on Step 4, transfer and dispense.

1. **Adopt Good Lab Safety and Disinfection Practices**
   - **a.** Clean gloves should be used for all patient sample handling
   - **b.** Clean instrument and surrounding bench area DAILY with 10% bleach solution or 70% ethyl alcohol. 70 % Ethanol wipes are acceptable for use on the ID NOW™.

2. **Proper Sample Collection**
   - **a.** Due to the sensitive nature of molecular technology, the amount of sample required to perform testing is **less** than that of rapid antigen detection tests. Excessive or aggressive sample collection may compromise test results.
   - **b.** Strictly adhere to guidelines for respective sample collection tech tips documents. Follow the links to Throat Swab Collection, Nasal Swab Collection, and Nasopharyngeal Swab Collection.
   - **c.** It is recommended to return sample swab to its original packaging (this will allow excessive amounts of mucous, saliva, and or other sample matrix material to remain in the wrapper to help minimize risk of inaccurate results)

3. **Proper Test Procedure**
   - **a.** When prompted, remove the foil seal and place the patient swab to be tested into the Sample Receiver.
   - **b.** 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.

4. **Transfer and Dispense** – successful testing requires proper transfer of sample
   - **a.** **Press OK** before proceeding with transfer of sample. Quality assurance measures are in place throughout the entire testing process. Failure to follow prompts as displayed on screen may lead to invalid or false test results.
   - **b.** Press white Transfer Cartridge **FIRMLY** into blue Sample Receiver and observe RISE of orange indicator which indicates sample was successfully pipetted into Transfer Cartridge. **DO NOT BE AFRAID TO PUSH.**
   - **c.** To complete transfer process, lift, connect and firmly press white Transfer Cartridge into orange Test Base. Observe the orange indicator **DESCEND** back into white Transfer Cartridge which indicates sample was successfully transferred into reaction tubes of orange Test Base. **DO NOT BE AFRAID TO PUSH.**
   - **d.** Make sure the test is in progress before walking away. After closing the lid to begin testing, you can ensure no previous prompts were missed by waiting until you see the "Testing" "Do Not Open" screen before walking away.

5. **Dispose** – test components are designed as single use only. **ALWAYS** connect the three test pieces as a single unit for proper disposal. **NEVER** throw pieces away individually and **NEVER** disassemble the pieces once they are connected.

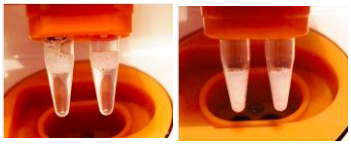
   a. Wrap the assembled test pieces in a glove which provides an added barrier to prevent amplicon contamination and dispose of gloved test in a covered biohazard waste container.

   b. Properly dispose of testing components to minimize risk of amplicon contamination.

ID NOW™ Troubleshooting Tips and Repeating Tests

Main causes of inaccurate results:

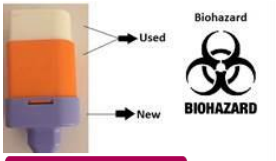
1. **Sample dispense errors**
   a. Visually inspect the orange indicator of the white Transfer Cartridge to verify that it fully descended. If the orange indicator is still visible at the top of the white Transfer Cartridge, the specimen was not transferred into the reaction tubes of the orange Test Base.



   b. Visually inspect the orange Test Base reaction tubes to confirm the liquid levels in both tubes are equal and that all dry (lyophilized) reagents dissolved properly. If the orange indicator was fully descended and the reaction tubes are dry, the sample was never pipetted from the blue Sample Receiver.
2. **Procedural errors**
   a. Confirm test kits are stored at proper temperatures per package insert
   b. Do not remove the foil seal on blue Sample Receiver until prompted by the instrument
   c. Timing is important; follow procedural steps as displayed on the screen
   d. Press OK when prompted
   e. If any test pieces are accidently dropped, do not use any of the pieces for testing
3. **Interfering substances –** Listed in the package insert

Procedure for repeating tests:

1. The used, connected, orange Test Base and white Transfer Cartridge **MUST** be attached to a blue Sample Receiver prior to disposal.
   a. Open a new Specimen Receiver/Transfer Cartridge package (#2)
   b. Remove the blue Sample Receiver from the package and open by removing the foil seal.
   c. Remove the used, connected, orange Test Base and white Transfer Cartridge from the instrument.
   d. Connect the used pieces to the new, **UNUSED**, blue Sample Receiver and dispose.



2. Retain the used, blue Sample Receiver for repeat testing.
   a. Remove the used, blue Sample Receiver carefully from the instrument.
   b. Keep upright to avoid spilling the liquid contents.

3. Repeat test.
   a. Close the lid (of analyzer) to initiate the Self -Test.
   From the Home Screen, begin a new test.
   b. Use a new orange Test Base and white Transfer Cartridge.
   c. Follow the screen prompts; however, when asked to insert the blue Sample Receiver, **reuse the existing blue Sample Receiver from the initial test.**
   d. **DO NOT** re-elute the swab or add additional sample.

If an inaccurate result is obtained using the repeat procedure, do not retest the sample again. The result should be documented according to facility protocol. Additional testing should only be attempted with an alternate method.

If unexplained, invalid, dual positive or false test results continue to be obtained, please contact Technical Support for assistance:

US	+1 855 731 2288	ts.scr@alere.com
Africa, Russia, CIS	+972 8 9429 683	ARCISproductsupport@alere.com
Asia Pacific	+61 7 3363 7711	APproductsupport@alere.com
Canada	+1 800 818 8335	CANproductsupport@alere.com
Europe & Middle East	+44 161 483 9032	EMEproductsupport@alere.com
Latin America	+57 2 6618797	LAproductsupport@alere.com

Abbott

ID NOW™

COVID-19

PRODUCT INSERT

ID NOW™
COVID-19
PRODUCT INSERT

For Use Under an Emergency Use Authorization (EUA) Only
For use with the ID NOW™ Instrument
For use with nasal, throat or nasopharyngeal specimens
For *in vitro* Use Only
℞ Only

INTENDED USE

ID NOW COVID-19 assay performed on the ID NOW Instrument is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology intended for the qualitative detection of nucleic acid from the SARS-CoV-2 viral RNA in direct nasal, nasopharyngeal or throat swabs from individuals who are suspected of COVID-19 by their healthcare provider. Testing is authorized for laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity/high complexity tests. The ID NOW COVID-19 assay is also authorized to be distributed and used in patient care settings outside of the clinical laboratory environment.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2RNA is generally detectable in respiratory samples during the acute phase of infection. 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. Positive results do not rule out bacterial infection or co-infection with other viruses. Testing facilities within the United States and its territories are required to report all positive results to the appropriate public health authorities.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The ID NOW COVID-19 test is intended for use by medical professionals or trained operators who are proficient in performing tests using the ID NOW Instrument. The ID NOW COVID-19 test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY and EXPLANATION of the TEST

An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to WHO on December 31, 2019.[1] Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and in several Southeast Asian countries, Europe and more recently the United States. Cases of severe illness and deaths have been reported. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.[2]

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.

PRINCIPLES of the PROCEDURE

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.

REAGENTS and MATERIALS

Materials Provided

BASE **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.

RCVR **Sample Receivers:** Blue plastic components containing 2.5 mL of elution buffer.

CARTRDG **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.

Package Insert

Quick Reference Instructions

Materials Required but not Provided

ID NOW Instrument

Nasopharyngeal Swabs

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. For use under an Emergency Use Authorization Only.
3. Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
4. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health laboratories.
5. To be used in conjunction with the ID NOW Instrument.
6. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
7. Proper sample collection, storage and transport are essential for correct results.
8. Leave test pieces sealed in their foil pouches until just before use.
9. Do not tamper with test pieces prior to or after use.
10. Do not use kit past its expiration date.
11. Do not mix components from different kit lots or from other ID NOW assays.
12. Solutions used to make the control swabs 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.
13. **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.**
14. 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.
15. 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.
16. 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**.
17. All test pieces are single use items. Do not use with multiple specimens.

18. 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.
19. At a low frequency, clinical samples can contain inhibitors that may generate invalid results. Site to site invalid rates may vary.
20. 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.

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.

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 Positive and Negative Control Swabs. These swabs will monitor the entire assay. Test these swabs once with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab's standard Quality Control procedures.

CONTROL SWAB PROCEDURE

External Positive and Negative Control swabs are provided and should be tested following the Run QC Test instructions on the ID NOW Instrument. Refer to Quality Control Swab Test Procedure or Instrument User Manual for further details.

Note: *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.

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.

Throat Swab

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

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.

SPECIMEN TRANSPORT and STORAGE

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 nasal, 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.

TEST PROCEDURE

Please refer to the ID NOW Instrument User Manual for full instructions.
Before testing with ID NOW COVID-19:

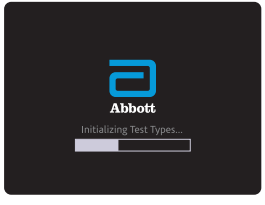
- Allow all samples to reach room temperature.
- Allow all test pieces to reach room temperature.
- Check that a reagent pellet is visible at the bottom of the reaction tubes prior to inserting the Test Base in the ID NOW Instrument. Do not use the Test Base if a pellet is not visible at the bottom of each reaction tube.

To Perform a Test:

Step 1

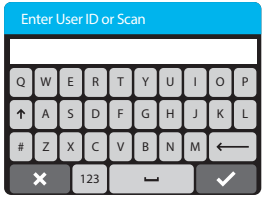
Turn on the ID NOW Instrument - press the power button ⏻ on the side of the instrument.

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.*



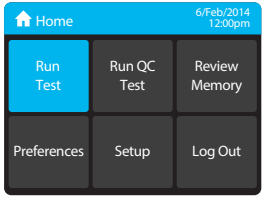
Enter User ID

Press '✔' after entry.



Touch 'Run Test'

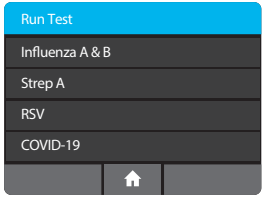
This will begin the test process.



To Perform a Test:

Touch 'COVID-19 Test'

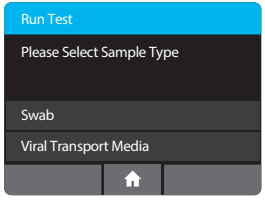
This starts a COVID-19 test.



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.

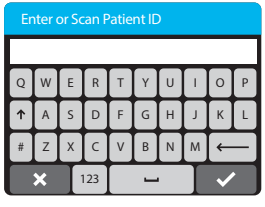
⚠ **Caution: VTM Samples are not an appropriate sample type for the ID NOW COVID-19 test.**



Enter Patient ID using on screen keyboard or barcode scanner.

Touch '✓'.

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



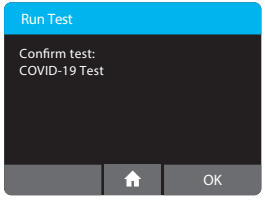
To Perform a Test:

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.

To Perform a Test:

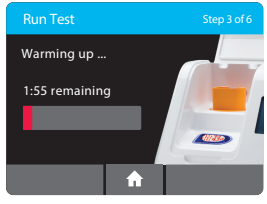
Step 3

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 Warm Up begins.



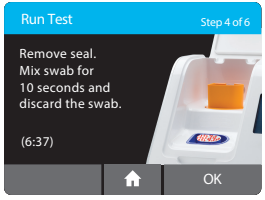
⚠ **Caution: DO NOT REMOVE THE FOIL SEAL UNTIL PROMPTED BY THE INSTRUMENT.**
DO NOT close the lid or insert the sample until prompted by the instrument.

To Perform a Test:

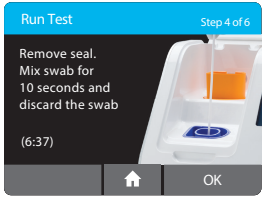
Step 4

Direct Nasal, Throat or Nasopharyngeal Swab Test Procedure

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 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.

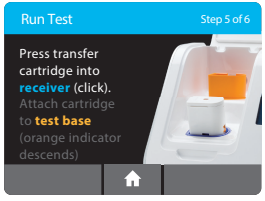
To Perform a Test:

Step 5a

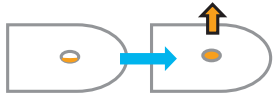
Press the White Transfer Cartridge into the Blue Sample Receiver

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.



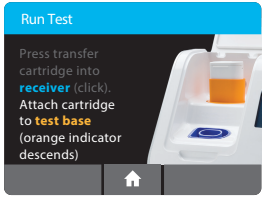
⚠ **Caution: The orange indicator should be observed closely. If the orange indicator does not fully rise, the Transfer Cartridge may not collect enough sample.**



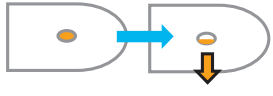
Step 5b

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 test results.**



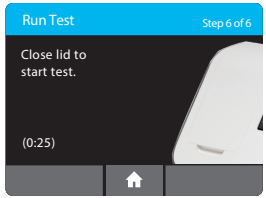
To Perform a Test:

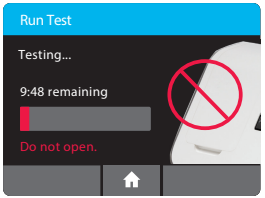
Step 6

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.*

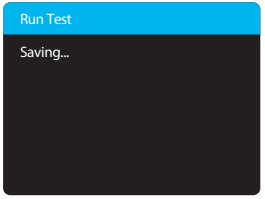




⚠ **Caution: This screen will be displayed for up to 30 seconds once the Transfer Cartridge is detected. If the instrument does not detect that the lid has been closed by then, it will time out and all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. The 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.**

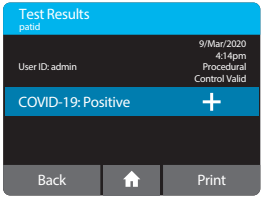
⚠ **Caution: DO NOT OPEN THE LID. The test will be cancelled and all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. A test result will not be reported or saved in the instrument memory.**

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

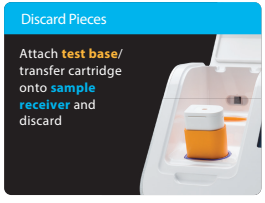
To Perform a Test:

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.



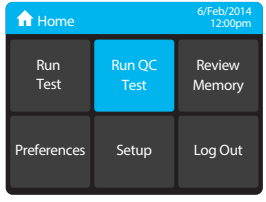
⚠ **Caution: DO NOT disassemble the Transfer Cartridge and the Test Base before disposal.**

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.

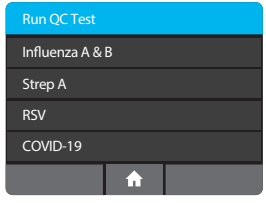
Quality Control Swab Test Procedure

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.

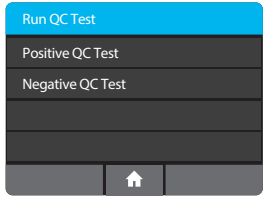
1 Touch 'Run QC Test'



2 Touch 'COVID-19'



3 Select the QC Test to be Run

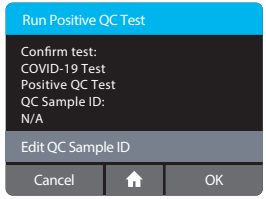


4 Confirm Test

Confirm the test type to match the QC sample intended for testing by touching 'OK' and following the on screen prompts to complete testing.

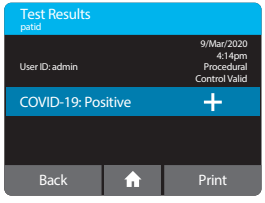
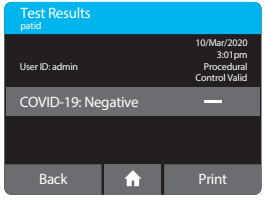
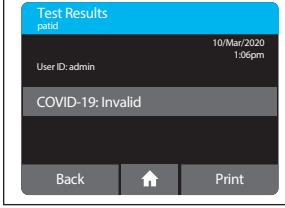
The user has the option to enter an ID for the QC Sample being run.

Note: *The QC test is run in the same manner as a Direct Nasal/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.*



RESULT INTERPRETATION

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

Instrument Display	Interpretation of Results and Follow-up Actions
	**COVID-19 Positive** Positive results do not rule out bacterial infection or co-infection with other viruses.
	**COVID-19 Negative** This result does not rule out co-infections with other pathogens.
	**The presence or absence of COVID-19 Viral RNAs cannot be determined.** Repeat testing of the sample using new test components. If repeated Invalid results are obtained, results should be confirmed by another method prior to reporting the results.

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.

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.
- 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.
- 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.

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/MedicalDevices/Safety/EmergencySituations/ucm161496.htm.

However, to assist clinical laboratories and patient care settings using the ID NOW COVID-19 ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories and patient care settings using your product will include with result reports of your product, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

B. Authorized laboratories and patient care settings using your product will use your product as outlined in the package insert. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

C. Authorized laboratories and patient care settings that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

D. Authorized laboratories and patient care settings using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

E. Authorized laboratories and patient care settings will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Abbott Diagnostics Scarborough, Inc. technical support (via email: ts.scr@abbott.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

F. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

G. You, authorized distributors, and authorized laboratories and patient care settings using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] The letter of authorization refers to, "United States (U. S.) laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high and moderate complexity tests" as "authorized laboratories."

PERFORMANCE CHARACTERISTICS

Clinical Study:

The performance of ID NOW COVID-19 was evaluated using contrived clinical nasopharyngeal (NP) swab specimens obtained from individuals with signs and symptoms of respiratory illness. The samples were prepared by spiking clinical NP swab matrix with purified viral RNA containing target sequences from the SARS-CoV-2 genome at concentrations approximately 2x LOD and 5x LOD. Negative NP swab samples were also tested in this study.

The table below presents ID NOW COVID-19 test agreement with the expected results by sample concentration.

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%]

ANALYTICAL STUDIES:

Analytical Sensitivity (Limit of Detection)

ID NOW COVID-19 limit of detection (LOD) in natural nasopharyngeal swab matrix was determined by evaluating different concentrations of purified viral RNA containing target sequences from the SARS-CoV-2 genome.

Presumed negative natural nasopharyngeal swab specimens were eluted in ID NOW COVID-19 elution buffer. Swab elutes were combined and mixed thoroughly to create a clinical matrix pool to be used as the diluent. Viral RNA was diluted in this natural nasopharyngeal matrix pool to generate virus dilutions for testing.

The LOD was determined as the lowest concentration that was detected ≥ 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive).

The confirmed LOD in natural nasopharyngeal swab matrix is presented in the table below:

Limit of Detection (LOD) Study Results

Virus	Claimed LOD (Genome Equivalents/mL)	Positive/Replicates
SARS-CoV-2 RNA	125	19/20

Analytical Reactivity (Inclusivity)

Due to the limited availability of SARS-CoV-2 isolates for inclusivity testing, an alignment was performed with the oligonucleotide primer and probe sequences of the ID NOW COVID-19 assay with all publicly available nucleic acid sequences for the 2019-nCoV in public databases (NCBI and Genbank) to demonstrate the predicted inclusivity of the ID NOW COVID-19 assay. All of the alignments show 100% identity of the ID NOW COVID-19 to the available SARS-CoV-2 sequences as of March 20, 2020.

Analytical Specificity (Cross Reactivity)

An *in silico* analysis for possible cross-reactions with all the organisms listed in the table below was conducted by mapping primers and probes of the ID NOW COVID-19 target nucleic acid sequence to the sequences download from the NCBI Genbank and GISAID databases.

The ID NOW COVID-19 assay, designed for the specific detection of SARS-CoV-2, showed no significant combined homologies with human genome, other coronaviruses, or human microflora that would predict potential ID NOW COVID-19 false results.

ID NOW™ COVID-19 Analytical Specificity Microorganisms

Microorganisms from the Same Genetic Family	High Priority Organisms
Human coronavirus 229E	Human adenovirus A
Human coronavirus OC43	Human adenovirus B
Human coronavirus HKU1	Human adenovirus B1
Human coronavirus NL63	Human adenovirus C
SARS-coronavirus	Human adenovirus D
MERS-coronavirus	Human adenovirus E
	Human adenovirus F
	Human adenovirus G
	Human adenovirus 7
	Human adenovirus 8
	Human metapneumovirus (hMPV)
	Human parainfluenza virus 1 - 4
	Influenza A
	Influenza B
	Enterovirus A-L
	Human respiratory syncytial virus
	Rhinovirus A - C
	Chlamydia pneumoniae
	Haemophilus influenzae

Microorganisms from the Same Genetic Family	High Priority Organisms
	Legionella pneumophila
	Mycobacterium tuberculosis
	Streptococcus pneumoniae
	Streptococcus pyogenes
	Bordetella pertussis
	Mycoplasma pneumoniae
	Pneumocystis jiroveci (PJP)
	Candida albicans
	Pseudomonas aeruginosa
	Staphylococcus epidermis
	Staphylococcus salivarius (Rhodotorula mucilaginosa)
	Streptococcus salivarius

SYMBOLS

 Fragile, handle with care	BASE Test Base	CARTRDG Transfer Cartridge
RCVR Sample Receiver	℞ Only Prescription Only (Applies to US only)	 Caution, consult accompanying documents.

ORDERING and CONTACT INFORMATION

Reorder numbers:

190-000: ID NOW COVID-19 Test Kit

190-080: ID NOW COVID-19 External Control Kit

US +1 877 441 7440

Technical Support Advice Line

Further information can be obtained by contacting Technical Support on:

US

+1 855 731 2288 ts.scr@abbott.com

REFERENCES

1. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/index.html. Accessed February 9, 2020.
2. bioRxiv. (https://www.biorxiv.org/content/10.1101/2020.02.07.937862v1). Accessed March 3, 2020.
3. Manual of Clinical Microbiology, 11th Edition, Vol. 1, ASM. (2015) pg. 279.

Abbott

Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074 USA
www.abbott.com/poct

IVD

IN190000 Rev.3 2020/04

Abbott
ID NOW
COVID-19

PI

Size:

8.5 in x 5.5 in

Printed Colors

CMYK

Incoming Inspection Colors
(For Reference Only)
Colors below are not used for printing

PMS 2995 U
Primary Blue

PMS 224 U
Magenta-Pink

PMS 303 U
Dark Blue

PN: IN190000
Rev: 3

Date of Last Revision:
3.1 2020/04/15

LABORATORY NAME:	
LABORATORY ADDRESS:	
DATE OF THIS PACKET:	
INSERT REVISION:	IN190000 Rev.6 2020/09

ID NOW™ COVID-19 Part Number # 190-000 24 Test Kit Laboratory Procedure

This procedure is intended to provide a ready outline reference for performance of the assay. These abbreviated directions for use are not intended to replace the complete package insert. **Any modifications to this document are the sole responsibility of the Facility.**

For Use Under an Emergency Use Authorization Only- US only (EUA)
For use with the ID NOW™ Instrument
For use with nasal, throat or nasopharyngeal specimens
For *in vitro* Use Only
Rx Only

1. Intended Use

ID NOW™ COVID-19 assay performed on the ID NOW™ Instrument is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology intended for the qualitative detection of nucleic acid from the SARS-CoV-2 viral RNA in direct nasal, nasopharyngeal or throat swabs from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms. Testing is authorized for laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity/high complexity tests. The ID NOW™ COVID-19 assay is also authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory samples during the acute phase of infection. 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. Positive results do not rule out bacterial infection or co-infection with other viruses. Testing facilities within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with different authorized or cleared molecular tests. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. 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.

The ID NOW™ COVID-19 test is intended for use by medical professionals or trained operators who are proficient in performing tests using the ID NOW™ Instrument. The ID NOW™ COVID-19 test is only for use under the Food and Drug Administration's Emergency Use Authorization.

2. Summary and Explanation of the Test

An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to WHO on December 31, 2019.[1] Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and in several Southeast Asian countries, Europe and more recently the United States. Cases of severe illness and deaths have been reported. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.[2]

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.

3. Principles of the Procedure

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.

4. Specimen Collection and Handling.

A. SPECIMEN	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 the risk of contamination of PPE and swab package during sample collection, it is recommended to widely open the package by pulling from the top down. Carefully remove the swab and perform sample collection.

B. SPECIMEN COLLECTION & HANDLING	**Throat Swab:** 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:** 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.
C. SPECIMEN TRANSPORT & STORAGE	For best performance, direct nasal, throat or nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance, it is highly recommended the nasal, throat or nasopharyngeal swab is placed in a clean, unused tube labeled with patient information, and capped tightly at room temperature (15-30°C) for up to one (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than one (1) hour delay occurs, dispose of sample. A new sample must be collected for testing. If the swab is to be returned to its package for transport, carefully return to allow the swab head to only come into contact with the lower portion of the packaging. Avoid touching the outside of the wrapper with the swab.

5. Reagents and Materials

A. Materials Provided

COMPONENT	CONTENT
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 use of a sterile patient swab ensures appropriate negative results are obtained.
PACKAGE INSERT	
QUICK REFERENCE INSTRUCTIONS	

B. Materials Required but not Provided

ID NOW™ Instrument
Nasopharyngeal Swabs

6. 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.

7. 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 once with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab's standard Quality Control procedures.

8. Control Swab Procedure

Positive and Negative Controls should be tested following the Run QC Test instructions on the ID NOW™ Instrument. A Positive Control Swab is included in the kit. Use a sterile swab provided in the kit as the Negative Control Swab. Refer to Quality Control Swab Test Procedure or Instrument User Manual for further details.

Note: *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.

9. Precautions

1. For *in vitro* diagnostic use.
2. This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. . §263a, to perform moderate complexity/high complexity tests and at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
3. Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
4. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
5. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
6. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health laboratories.
7. To be used in conjunction with the ID NOW™ Instrument.
8. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
9. Proper sample collection, storage and transport are essential for correct results.
10. Leave test pieces sealed in their foil pouches until just before use.
11. Do not tamper with test pieces prior to or after use.
12. Do not use kit past its expiration date.
13. Do not mix components from different kit lots or from other ID NOW™ assays.
14. 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.
15. Wear clean personal protection equipment and gloves when running each test. Change gloves

16. between the handling of specimens suspected of COVID-19.
17. **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.**
18. 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.
19. 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.
20. 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**.
21. All test pieces are single use items. Do not use with multiple specimens.
22. 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.
23. At a low frequency, clinical samples can contain inhibitors that may generate invalid results. Site to site invalid rates may vary.
24. 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.

10. Test 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.**
- 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.

To Perform a Test:

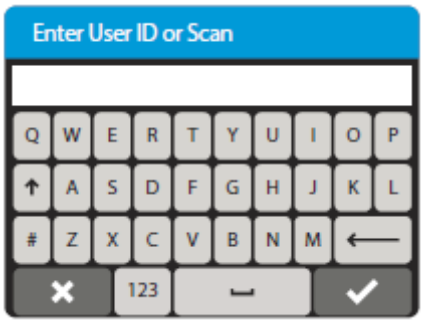
Step 1

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.*

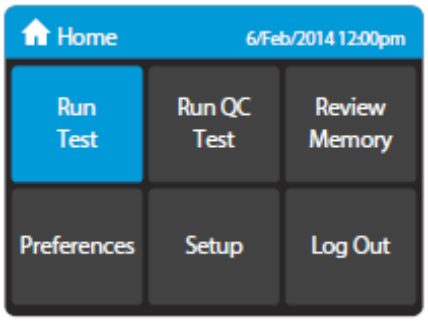
Enter User ID

Press ‘✓’ after entry.



Touch ‘Run Test’

This will begin the test process.

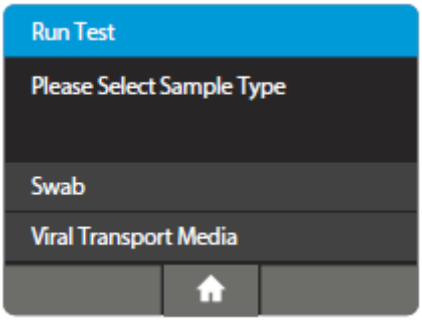


Touch ‘COVID-19 Test’

This starts a COVID-19 test.

Select 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.

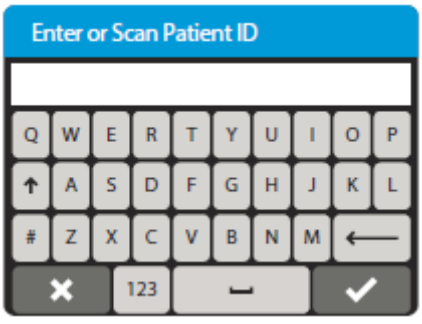


⚠ **Caution: VTM Samples are not an appropriate sample type for the ID NOW™ COVID-19 test.**

Enter Patient ID using on screen keyboard or barcode scanner.

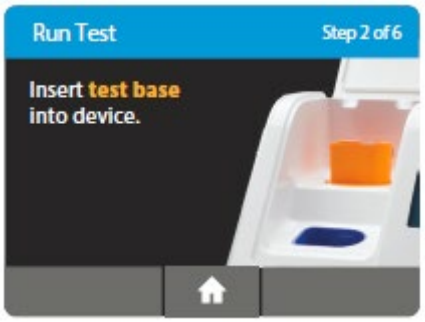
Touch ‘✓’.

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



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.

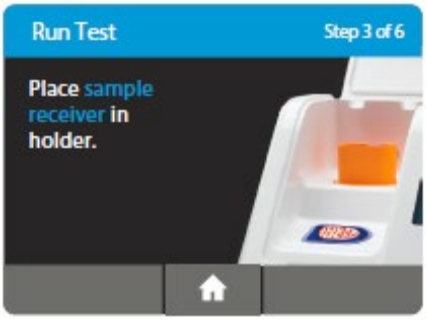
Touch 'OK' to proceed.

⚠ 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

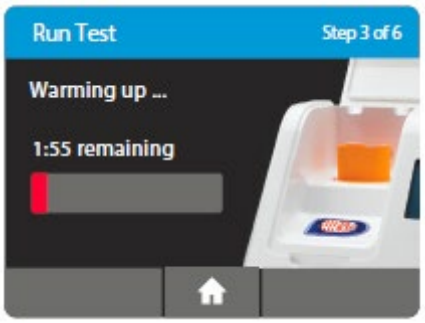
Insert Blue Sample Receiver into the Blue Sample Receiver holder



⚠ 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.

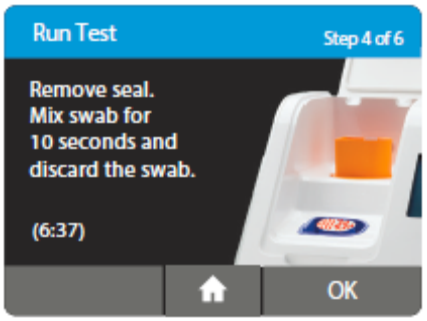


Caution: DO NOT REMOVE THE FOIL SEAL UNTIL PROMPTED BY THE INSTRUMENT. DO NOT close the lid or insert the sample until prompted by the instrument.

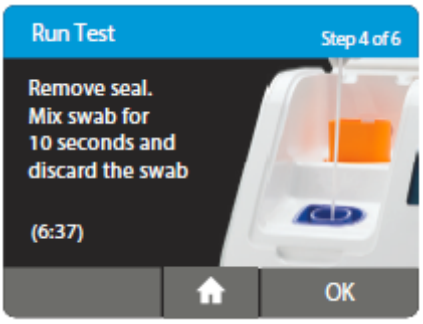
Step 4

Direct Nasal, Throat or Nasopharyngeal Swab Test Procedure

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



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.

Abbott

Step 5a

Press the White Transfer Cartridge into the Blue Sample Receiver

Listen for a click.

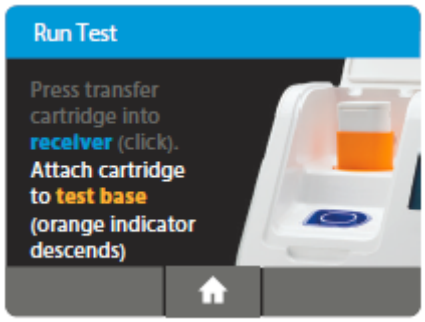
When the Transfer Cartridge is properly attached to the Sample Receiver, the orange indicator on the Transfer Cartridge will rise. If the orange indicator does not rise, continue pushing onto the Sample Receiver until it does.

⚠ **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.



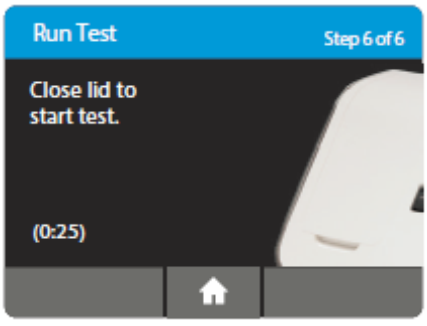
⚠ **Caution: If the orange indicator does not fully descend, not enough sample will be dispensed. This may potentially result in invalid or false test results.**

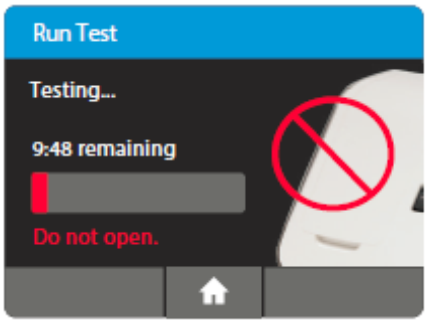
Step 6

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.*

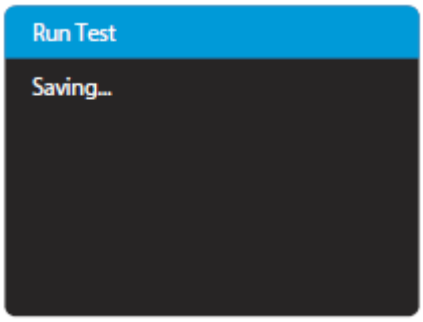




Caution: This screen will be displayed for up to 30 seconds once the Transfer Cartridge is detected. If the instrument does not detect that the lid has been closed by then, it will time out and all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. The instrument 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.

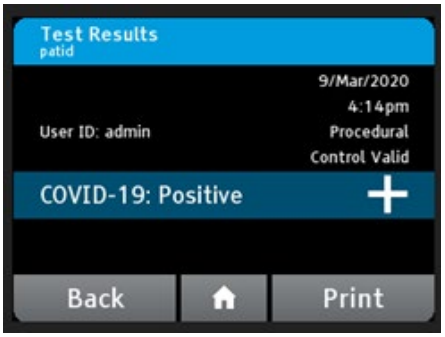
When amplification and detection is complete, the instrument will automatically save the data before advancing to the results screen.



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

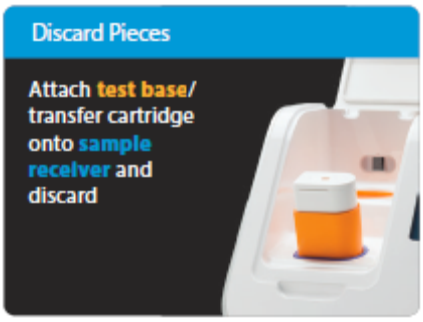


After printing, or if New Test or Home are selected, the instrument will prompt to open the lid and discard the used test pieces.

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.**

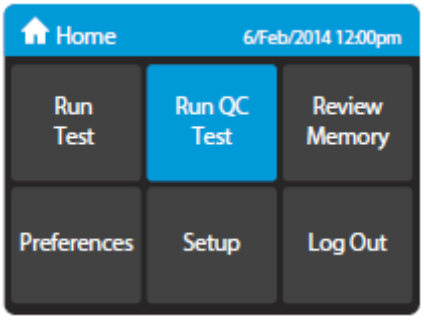
Close the lid. The instrument will then run a Self-Test before showing the Home screen or Enter Patient ID screen, depending on the previous selection.

Remove and dispose of gloves.

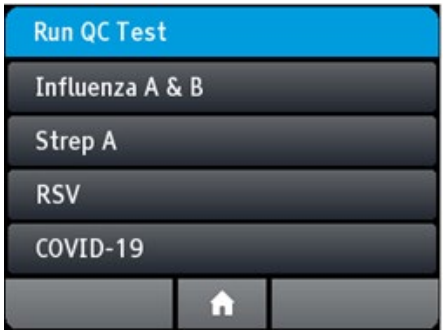
11. Quality Control Swab Test Procedure

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.

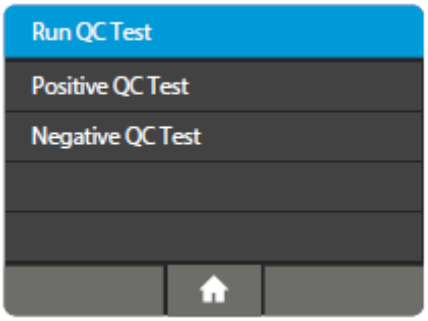
1 Touch 'Run QC Test'



2 Touch 'COVID-19'



3 Select the QC Test to be Run

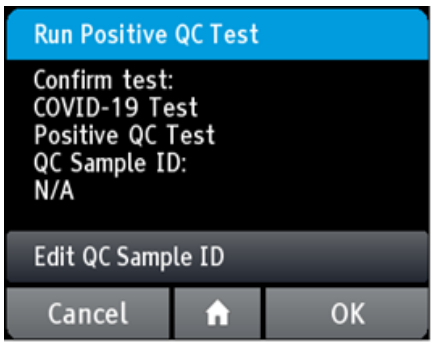


4 Confirm Test

Confirm the test type to match the QC sample intended for testing by touching 'OK' and following the on screen prompts to complete testing.

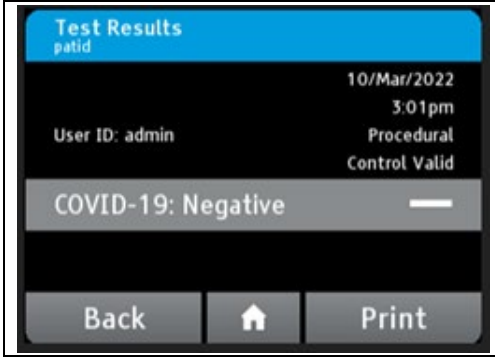
The user has the option to enter an ID for the QC Sample being run.

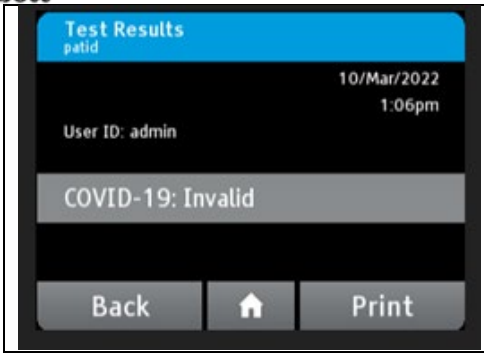
Note: *The QC test is run in the same manner as a Direct Nasal/Throat/Nasopharyngeal Swab Patient Test. See the* ***To Perform a Test*** *section above for step by step instructions for direct nasal/throat/nasopharyngeal swab samples.*



12. Result Interpretation

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

Instrument Display	Interpretation of Results and Follow-up Actions
	**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 and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with an alternative molecular assay. A negative result does not rule out co-infections with other pathogens.



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

Repeat testing of the sample using new test components. If repeated Invalid results are obtained, results should be confirmed by another method prior to reporting the results.

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.

13. Limitations

- The performance of the ID NOW™ COVID-19 test 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 and tested with an alternative FDA authorized molecular assay, if necessary for clinical management, including infection control.
- 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.

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/medical-devices/coronavirus-disease-2019-covid-19-emergency-useauthorizations-medical-devices/vitro-diagnostics-euas.

However, to assist clinical laboratories and patient care settings (authorized laboratories[1]) using the ID NOW™ COVID-19 ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

A. Authorized laboratories using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

B. Authorized laboratories using your product will use your product as outlined in the package insert. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

C. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.

D. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

E. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Abbott Diagnostics Scarborough, Inc. technical support (via email: ts.scr@abbott.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

F. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

G. You, authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

[1] The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests and use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of compliance, or Certificate of Accreditation" as "authorized laboratories."

14. Performance Characteristics

Clinical Study:

The performance of ID NOW™ COVID-19 was evaluated using contrived clinical nasopharyngeal (NP) swab specimens obtained from individuals with signs and symptoms of respiratory illness. The samples were prepared by spiking clinical NP swab matrix with purified viral RNA containing target sequences from the SARS-CoV-2 genome at concentrations approximately 2x LOD and 5x LOD. Negative NP swab samples were also tested in this study.

The table below presents ID NOW™ COVID-19 test agreement with the expected results by sample concentration.

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%]

Analytical Studies:

Analytical Sensitivity (Limit of Detection)
ID NOW™ COVID-19 limit of detection (LOD) in natural nasopharyngeal swab matrix was determined by evaluating different concentrations of purified viral RNA containing target sequences from the SARS-CoV-2 genome.
Presumed negative natural nasopharyngeal swab specimens were eluted in ID NOW™ COVID-19 elution buffer. Swab elutes were combined and mixed thoroughly to create a clinical matrix pool to be used as the diluent. Viral RNA was diluted in this natural nasopharyngeal matrix pool to generate virus dilutions for testing.

The LOD was determined as the lowest concentration that was detected ≥ 95% of the time (i.e., concentration at which at least 19 out of 20 replicates tested positive).

The confirmed LOD in natural nasopharyngeal swab matrix is presented in the table below:

Limit of Detection (LOD) Study Results

VIRUS	CLAIMED LOD (GENOME EQUIVALENTS/mL)	POSITIVE/REPLICATES
SARS-CoV-2 RNA	125	19/20

Analytical Reactivity (Inclusivity)
Due to the limited availability of SARS-CoV-2 isolates for inclusivity testing, an alignment was performed with the oligonucleotide primer and probe sequences of the ID NOW™ COVID-19 assay with all publicly available nucleic acid sequences for the 2019-nCoV in public databases (NCBI and Genbank) to demonstrate the predicted inclusivity of the ID NOW™ COVID-19 assay. All of the alignments show 100% identity of the ID NOW™ COVID-19 to the available SARS-CoV-2 sequences as of March 20, 2020.

Analytical Specificity (Cross Reactivity)
An *in silico* analysis for possible cross-reactions with all the organisms listed in the table below was conducted by mapping primers and probes of the ID NOW™ COVID-19 target nucleic acid sequence to the sequences download from the NCBI Genbank and GISAID databases.

The ID NOW™ COVID-19 assay, designed for the specific detection of SARS-CoV-2, showed no significant combined homologies with human genome, other coronaviruses, or human microflora that would predict potential ID NOW™ COVID-19 false results.

ID NOW™ COVID-19 Analytical Specificity Microorganisms

Microorganisms from the Same Genetic Family	High Priority Organisms
Human coronavirus 229E	Human adenovirus A
Human coronavirus OC43	Human adenovirus B
Human coronavirus HKU1	Human adenovirus B1
Human coronavirus NL63	Human adenovirus C
SARS-coronavirus	Human adenovirus D
MERS-coronavirus	Human adenovirus E
	Human adenovirus F
	Human adenovirus G
	Human adenovirus 7
	Human adenovirus 8
	Human metapneumovirus (hMPV)

Microorganisms from the Same Genetic Family	High Priority Organisms
	Human parainfluenza virus 1 - 4
	Influenza A
	Influenza B
	Enterovirus A-L
	Human respiratory syncytial virus
	Rhinovirus A - C
	Chlamydia pneumoniae
	Haemophilus influenzae
	Legionella pneumophila
	Mycobacterium tuberculosis
	Streptococcus pneumoniae
	Streptococcus pyogenes
	Bordetella pertussis
	Mycoplasma pneumoniae
	Pneumocystis jiroveci (PJP)
	Candida albicans
	Pseudomonas aeruginosa
	Staphylococcus epidermis
	Staphylococcus salivarius (Rhodotorula mucilaginosa)
	Streptococcus salivarius

FDA SARS-CoV-2 Reference Panel Testing

The evaluation of sensitivity and MERS-CoV cross-reactivity was performed using reference material (T1), blinded samples and a standard protocol provided by the FDA. The study included a range finding study and a confirmatory study for LoD. Blinded sample testing was used to establish specificity and to confirm the LoD. The results are summarized in the table below.

Summary of LoD Confirmation Result using the FDA SARS-CoV-2 Reference Panel

Reference Materials Provided by FDA	Specimen Type	Product LoD	Cross-Reactivity
SARS-CoV-2	Nasopharyngeal Swab	3.0x105 NDU/mL	N/A
MERS-CoV		N/A	ND

NDU/mL = RNA NAAT detectable units/mL
N/A: Not applicable
ND: Not detected

15. References:

1. Manual of Clinical Microbiology, 11th Edition, Vol. 1, ASM. (2015) pg. 279.

Symbols

 Fragile, handle with care	BASE Test Base	CARTRDG Transfer Cartridge
 Sample Receiver	Rx Only Prescription Only (Applies to US only)	 Caution, consult accompanying documents.
 CE Mark	IVD *In Vitro* Diagnostics	EUA For Use Under an Emergency Use Authorization Only (Applies to US only)

Ordering and Contact Information

Reorder numbers:

190-000: ID NOW™ COVID-19 Test Kit
190-080: ID NOW™ COVID-19 External Control Kit

US + 1 877 441 7440
OUS +1 321 441 7200

Technical Support Advice Line

Further information can be obtained by contacting Technical Support on:

US
+ 1 855 731 2288 ts.scr@abbott.com
Africa, Russia, CIS
+44 161 483 9032 EMEproductsupport@abbott.com
Asia Pacific
+617 3363 7711 APproductsupport@abbott.com
Canada
+1 800 818 8335 CANproductsupport@abbott.com
Europe & Middle East
+44 161 483 9032 EMEproductsupport@abbott.com
Latin America
+57 (1) 4824033 LAproductsupport@abbott.com

Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, Maine 04074 USA
www.globalpointofcare.abbott

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Test Procedure Approval and Review Sheet

PREPARED BY:	
DATE:	
SUPERVISOR REVIEW:	
DATE:	
LABORATORY DIRECTOR OR DESIGNEE APPROVAL:	
IMPLEMENTATION DATE:	
SUPERSEDES PROCEDURE DATED:	
DATE PROCEDURE RETIRED:	

LABORATORY DIRECTOR OR DESIGNEE	DATE REVIEWED	LABORATORY DIRECTOR OR DESIGNEE	DATE REVIEWED

ID NOW™ COVID-19 Verification Form

ACCOUNT NAME: _____

ADDRESS: _____

_____

TELEPHONE: _____

ID NOW™ COVID-19
LOT #/EXP: _____

DATE: _____

SUPERVISOR SIGNATURE: _____

Record the results from reference samples below.

Record the Sample #, the ID NOW™ COVID-19 results, Tester's Initials, and any comments. After the ID NOW™ RSV results have been recorded (positive or negative) then record the Expected Results (positive or negative).

SAMPLE #	EXPECTED RESULTS	ID NOW™ COVID-19 RESULT	TESTER'S INITIALS	COMMENTS

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ID NOW™ COVID-19 Verification Form (page 2 of 2)

SAMPLE #	EXPECTED RESULTS	ID NOW™ COVID-19 RESULT	TESTER'S INITIALS	COMMENTS

REVIEW: _____ DATE: _____

LABORATORY DIRECTOR REVIEW AND APPROVAL FOR CLINICAL USE: _____

DATE: _____

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ID NOW™ External Quality Control

External QC testing is recommended:

- When a new shipment of kits is received
- When a new untrained operator performs testing
- The first time an assay is run on an instrument
- When required by local, state, and/or federal regulations, accrediting groups, or your lab's Quality Control procedures

DATE	ASSAY (CIRCLE TYPE)	INSTRUMENT SN	ID NOW™ KIT LOT/EXP	POSITIVE CONTROL LOT/EXP	NEGATIVE CONTROL LOT/EXP	POSITIVE CONTROL RESULT	NEGATIVE CONTROL RESULT	TESTER'S INITIALS	COMMENTS
	Flu Strep A RSV COVID-19								
	Flu Strep A RSV COVID-19								
	Flu Strep A RSV COVID-19								
	Flu Strep A RSV COVID-19								

REVIEWED BY: _____ **DATE:**_____

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ID NOW™ COVID-19 Procedural Control Results and Patient Record

LOT NUMBER _____ **EXP. DATE** _____

ID NOW™ INSTRUMENT SERIAL # _____

Abbott recommends that external positive and negative controls be run for once with each new shipment received and once for each untrained operator.

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.
Record the Date, Patient's Name, Patient's ID Number, Patient's Test Result, Procedure Control Results and the Tester's initials.

DATE	PATIENT NAME	PATIENT ID NUMBER	PATIENTCOVIF-19 TEST RESULTS	ARE THE PROCEDURAL CONTROL RESULTS INVALID OR VALID?		COMMENTS	TESTER'S INITIALS
				INVALID	VALID		

REVIEWED BY: _____ **DATE:** _____

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ID NOW™ Cleaning Log

The ID NOW™ is maintenance-free and has no serviceable parts. In the case of instrument failure or damage, contact Abbott Technical Support at 800-257-9525 or ts.scr@abbott.com

The ID NOW™ can be cleaned using 70% ethanol, 70 % isopropanol, or 10% bleach solution, on a damp, lint free cloth. 70% ethanol and isopropanol wipes are acceptable for use on the ID NOW™. Do not spray or pour solution directly onto instrument when cleaning. Ensure no excess liquid is used when cleaning as it may damage the instrument.

Abbott recommends that the exterior instrument surfaces and the surfaces visible under the open lid be cleaned daily. Clean the surrounding bench area. Clean instrument and surrounding areas immediately after possible patient sample contamination.

- Do not disassemble the instrument for cleaning
- Do not immerse in water or cleaning solutions
- Do not clean with soap or other solutions

MONTH_____ **YEAR_____**

SERIAL NUMBER_____ MONTHLY REVIEW DATE _____INITIALS_____

DAY	PERFORMED BY: (INITIALS)	COMMENTS/CORRECTIVE ACTION	DAY	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					

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Quality Assessment Review Form and Checklist

These forms are used for periodical review of the patient testing process. These should be filed with the quality assessment records.

QUALITY ASSESSMENT ACTIVITY	COMMENTS	DATE	INITIALS
Patient test management: evaluate criteria for specimen submission, handling, and rejection; test results requisitions and reporting, accuracy and reliability of reports.			
Quality control: assess control data, errors in reporting results, and corrective actions taken with appropriate documentation records.			
Proficiency testing: review the effectiveness of corrective actions taken for unsatisfactory performance or failures.			
Comparison of test results: review at least semi-annually comparative results for multiple methods, instruments, or site correlations when more than one procedure exists.			
Relationship of patient test information to test results*:* evaluate patient test reports for accuracy of patient information, test results, and normal ranges. Identify and evaluate results inconsistent with patient's age, sex, diagnosis, and other test parameters.			
Personnel: evaluate the effectiveness of policies and procedures for assuring employees' competence of testing and reporting test results.			
Communications: evaluate documented problems and corrective actions that occur between the laboratory and the authorized individual who orders or receives the test result.			
Complaint investigation: evaluate documented complaints and corrective actions.			
Quality assessment reviews with staff: document discussion with staff regarding identified problems and corrective actions during the QA review.			

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Corrective Action Form

PROBLEM/ERROR	CORRECTIVE ACTION

TECHNOLOGIST: _____ **DATE:** _____

SUPERVISOR: _____ **DATE:** _____

LABORATORY DIRECTOR: _____ **DATE:** _____

Temperature Log

EQUIPMENT: _____

NAME OF FACILITY: _____

TO BE RECORDED AT THE BEGINNING OF EACH WORKDAY. TEMPERATURE RANGE: _____

DATE	˚C	INITIALS	ADJUSTMENTS	DATE	˚C	INITIALS	ADJUSTMENTS

ID NOW™ Proficiency Testing Summary

Proficiency Testing Providers require laboratories to test for both Influenza A & B. If a laboratory is using Early Detection on the ID NOW™, see directions below on how to disable Early Detection.

1. **To get results for both Influenza A & B, make sure that Early Detection is disabled.**
2. **To turn off Early Detection, go to Setup, then Assay Preferences, and remove the checkmark from Early Detection.**

College of American Pathologists (CAP):

- **1.800.323.4040**
- www.cap.org

FLU and RSV:

ID2 – (Nucleic acid Amplification, Respiratory) - 1 1.0 mL sample, 2 shipments per year Shipment A has Influenza A challenge and Coronavirus, and Shipment B has an Influenza B challenge and rhinovirus RSV 1 1.0 mL sample, 2 shipments per year

ID3 – (Influenza A, Influenza B and RSV by NAA) – 5 1.0 mL samples, 3 shipments per year designed for molecular multiplex users

IDR – (Influenza A, Influenza B and RSV by NAA) – 5 1.0 mL samples, 3 shipments per year designed for molecular multiplex users

STREP A:

D1 – Throat culture - Presence or absence of Group A *Streptococcus* Throat swabs are compatible with culture or molecular methods – 5 swab specimens with diluents in duplicate, 3 shipments per year

D4 – Limited Bacteriology (contains 2 throat culture specimens, plus other sample challenges) – Throat swabs are compatible with culture or molecular methods - 3 shipments per year

COVID-19 :

COV2 – (SARS-COV-2, MOLECULAR - COV2) - 3 1.5 mL liquid simulated respiratory samples, 2 shipments per year. Whole genome with sequence targets across all assay platform**.**

American Proficiency Institute (API):

- **1.800.333.0958**
- www.api-pt.com

FLU and RSV:

322 – Virology package (includes 1mL Liquid samples for Influenza A or B, RSV, and Adenovirus antigen detection kits and Molecular techniques) – 5 samples, 3 shipments per year

933 – Virology package – waived (includes 1 mL Liquid samples for Influenza A or B, RSV, and Adenovirus antigen detection kits and Molecular techniques) – 2 samples, 2 shipments per year

STREP A:

364 – Strep Pharyngeal (molecular) - Swab - For detection of Group A and Group C/G Strep by molecular methods – 5 samples, 3 shipments per year

COVID-19:
385 - SARS-CoV-2 (COVID-19) using molecular methods. 1.5 mL liquid - Contains the whole genome, providing sequence targets compatible across all assay platforms. 2 samples, 3 shipments per year

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Wisconsin State Lab of Hygiene (WSLHPT):

- **1.800.462.5261**
- www.wslhpt.com

FLU and RSV:
PT06150 – Viral antigens- Limited VA (includes liquid samples for rapid antigen test kits or molecular methods) - 5 samples, 3 shipments per year
PT06170 – Viral antigens- Waived methods VCW (includes liquid samples for waived rapid antigen test kits or molecular methods) - 5 samples, 3 shipments per year

STREP A:
PT05170 – Group A Strep Culture ST (includes samples for culture of Group A Streptococci, compatible with culture and molecular methods – 5 samples, 3 shipments per year
PT05410 – Intended for waived molecular methods only. Group A Strep molecular detection – 3 samples, 2 shipments per year
Notice: These proficiency options are available, but it is the testing facilities responsibility to select the survey that meets their needs. Requirements may vary by state and accreditation agency.

COVID-19:
PTO6270 – SARS-CoV-2 Molecular Swabs with 1.5 mL elution liquid intended for molecular SARS-CoV-2. Whole genome product with 100% genetic sequences of virus. 5 samples, 3 shipments per year
PTO6280 – SARS-CoV-2 Molecular Swabs with 1.5 mL elution liquid intended for molecular SARS-CoV-2. Whole genome product with 100% genetic sequences of virus. 3 samples, 2 shipments per year

If you have any questions or require further assistance, please contact CAP, API, or WSLHPT at the numbers listed above or Abbott Technical Support at: 800-257-9525| ts.scr.@abbott.com

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Tips for Successful PT Performance

- Strictly follow the PT provider's storage or handling requirement ***before testing PT specimens***.
- Analyze PT specimens ***within the time frame*** provided by the PT provider.
- Contact the PT provider ***promptly*** when specimens are received damaged. You may be able to receive a replacement immediately.
- Avoid clerical error when filling out PT answer sheets. Be sure to ***enter the correct result next to the correct analyte*** on the answer form.
- Remember to identify the instrument or method you are using to perform your PT so you are ***graded among your peer group***.
- Make copies of all answer forms ***before submitting them*** to your PT provider.
- Please contact Technical Support at 800-257-9525 or ts.scr@abbott.com for further information on proficiency providers.

ID NOW™ AND ASSAY TIPS

TOP 10 TIPS

1. Place the ID NOW Instrument on a flat, level, stable surface away from direct sunlight. Allow enough room for air flow behind the instrument.

2. External Quality Control: Test QC swabs with each new shipment, each new untrained operator, and with software updates. QC swabs must be performed as a neg/pos pair. Additional controls may be tested in order to conform to local, state and/or federal regulations, accrediting groups, or your lab's standard Quality Control procedures.

3. Do not remove the blue Sample Receiver from the instrument once warm-up has started. Do not remove the foil seal from the blue Sample Receiver until prompted to do so. Place two fingers along the outer edge of the blue Sample Receiver when removing the foil seal to keep the blue Sample Receiver in place.

4. The orange indicator should **rise** to the top of the white Transfer Cartridge when pressed into the blue Sample Receiver. The orange indicator should **descend** back down when the white Transfer Cartridge is pressed into the orange Test Base. Always visually check this when running the procedure, do not rely on listening for clicks.

5. Test components are designed as single use only. Components should be clicked together and must be removed from the instrument according to removal instructions displayed on the screen. Components must not be separated once they are clicked together after test completion.

6. Daily cleaning of the ID NOW Instrument is recommended. Clean exterior surfaces and surfaces visible under the open lid, as well as the surrounding bench area, using a lint free cloth dampened with 70% Ethanol or 10% Bleach. 70 % Ethanol wipes are acceptable for the ID NOW™.

7. 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.

8. For disposal of all used test components, follow the laboratory's safety protocol that documents the safe handling, storage, and disposal of all hazardous waste. Include information on appropriate hazardous spill clean-up procedures.

9. If any test component is dropped, cracked, found to be damaged, or open when received, it should not be used and should be discarded.

10. Refer to package insert for appropriate kit component storage. Leave test components in sealed pouches until just prior to use. Ensure all test components are at room temperature before using. Do not use sharp objects or scissors to open foil pouches.

Product support: Call 1.800.257.9525

ts.scr@abbott.com

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ID NOW™ Training Checklist

FACILITY/LABORATORY:_____

USER NAME:_____ **USER ID:** _____

ITEM DETAILS		
ID NOW™ - INSTRUMENT OVERVIEW	**USER'S INITIALS**	**DATE**
The user acknowledges being shown and understands the purpose of the following components: • Operator's manual and Quick Start guide • Analyzer on/off power button, temperature indicator, touch screen • Power cord and power port • USB connectors and purpose • Printer (if applicable) with power cords, connectors and paper • Barcode Reader if applicable • Touch screen (Run Test, QC, Review Memory, Logout, Preferences, Setup) • Serial number location and Technical Support contact # • Proper cleaning and maintenance		
ID NOW™ - REAGENT OVERVIEW	**USER'S INITIALS**	**DATE**
The user acknowledges being shown reagent package insert(s), and understands storage conditions, kit components, warm up times, lot #, expiry dates, and early detection for the reagent test kits (as applicable below): • Collection Swabs, original swab packaging, and unused screw top tubes • Orange Test Base –Package #1 • Blue Sample Receiver and White Transfer Cartridge - Package #2 • Quality control swabs (Positive & Negative) • Plastic transfer pipette (Flu and RSV only) • The user has reviewed the "Precautions" listed in the package insert e.g. Handling of used test cartridges and prevention of amplicon. Wears clean personal protection equipment and gloves when running each test. Changes gloves between the handling of specimens suspected of COVID-19. **FLU A/B 2 427-000___ Strep A 2 734-000___ RSV 435-000___** **COVID-19 190-000___ (check all that apply)**		
ID NOW™ - SAMPLE REQUIREMENTS	**USER'S INITIALS**	**DATE**
• User has been provided appropriate sample collection support documents and training resources. • User has reviewed package insert(s) for ACCEPTABLE swabs/ transport media types, correct technique to return swab to its package, and sample storage conditions. **FLU A/B 2 427-000___ Strep A 2 734-000___ RSV 435-000___** **COVID-19 190-000___** **(Check all that apply)**		

ID NOW™ - QC AND PATIENT TESTING	USER'S INITIALS	DATE
For Quality Control / Patient Test 1. The user follows universal precautions (uses gloves) to handle reagents, QC, Patient swabs/VTM. 2. Demonstrates how to successfully log in to the ID NOW™**.** 3. The user demonstrates understanding of the "self- test". 4. The user demonstrates how to initiate **Quality control** or **Patient test** from the main menu. 5. The user selects the correct reagent set (package #1 and package #2) for the assay to be performed. 6. The user correctly opens each packet, handles and places reagent components as directed per the user interface displayed on the touchscreen. 7. The user utilizes the quality control swab for the corresponding assay and QC level. OR for patient testing, utilizes correct patient sample type and correctly enters sample identification into the analyzer. 8. The user follows correct timing for the introduction of the sample and 10 second swab rotation in Sample receiver or for VTM, addition of 200 µL. 9. The user demonstrates the initiation of the test by pressing the "OK" key prior to sample transfer. 10. The user OBSERVES the proper positioning of the Transfer Cartridge plunger during the sample transfer.		
11. The user completes the Quality control /Patient test process from start to result. 12. User demonstrates understanding of result and procedural control. 13. User demonstrates connecting all reagent pieces for safe and proper disposal.		
ID NOW™ - TEST RESULT INTERPRETATION AND INVALID RESULTS	**USER'S INITIALS**	**DATE**
• User has been provided support document(s) for handling an invalid test result. • User demonstrates how to find and interpret QC/PATIENT results on the screen or printout. • The user has been instructed what to do if the QC, patient or procedural control are displayed as invalid or have failed. • The user acknowledges instruction on the main causes of an invalid result and how to repeat an invalid test.		
ID NOW™ COVID-19 EUA RESULT REPORTING RESPONSIBILITY	**USER'S INITIALS**	**DATE**
• The user acknowledges the responsibilities of reporting results as outlined in the **Limitations** EUA section.		

USER SIGNATURE_____ **DATE**_____

TRAINER SIGNATURE_____ **DATE** _____

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ID NOW™ TRAINING GRID				
	ID NOW™ Influenza A & B 2	**ID NOW™ Strep A 2**	**ID NOW™ RSV**	**ID NOW™ COVID-19**
PRODUCT PN	427-000	734-000	435-000	190-000
CONTROL KIT PN	425-080	734-080	435-080	190-080
CPT CODE	Refer customers to https://www.codemap.com/abbottpoc/			
TESTING TIME	Results in 13 minutes or less Early positive detection in as little as 5 minutes	Results in 6 minutes or less Early positive detection in as little as 2 minutes	Less than 13 minutes	Positive results in as little as 5 minutes Negative results in 13 minutes
SAMPLE TYPES	Direct nasal/nasopharyngeal (NP) swab or NP swab in Viral Transport Media (VTM)	Throat swab with or without Transport Media (TM)	NP swab with or without VTM	Direct throat, nasal, or nasopharyngeal (NP), swab.
DIRECT SAMPLE STORAGE	**Direct Nasal swab/NP swab:** Room Temp: 2 hrs. 2-8 °C: up to 24 hrs.	**Direct Throat swab:** Room Temp or 2-8° C: up to 72 hrs.	**Direct NP swab:** Room Temp: 2 hrs. 2-8 °C: up to 24 hrs.	**Direct nasal, nasopharyngeal (NP), or throat swab:** Room Temp: for up to 1 hr. prior to testing
TRANSPORT MEDIA SAMPLE STORAGE	**NP swab in VTM:** Room Temp: 8 hrs. 2-8° C: up to 72 hrs.	**Throat swab in BBL™ CultureSwab™ Liquid Amies transport media system** Room Temp or 2-8° C: up to 6 hrs.	**NP swab in VTM:** Room Temp: 8 hrs. 2-8° C: up to 24 hrs.	NA
BOX CONFIGURATION	24 tests/box 1 (+) control/box test swabs disposable pipettes for VTM	24 tests/box 1 (+) control/box test swabs	24 tests/box 1 (+) control/box test swabs disposable pipettes for VTM	24 tests/box 1 (+) control/box test swabs
PATIENT RESULTS MEMORY CAPACITY	999 tests	999 tests	999 tests	999 tests

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ID NOW™ Training Certificate

FLU A/B 2____ Strep A 2____ RSV____ COVID-19____ (Check all that apply)

SYSTEM OVERVIEW	☐ User manual
	☐ Serial number location
	☐ Package Insert (PI)
SET-UP AND CONFIGURATION	☐ Instrument cleaning/maintenance
	☐ Menu settings
	☐ Date & time requirements
SELF-TEST	☐ Review functions of test
	☐ Frequency of test
QUALITY CONTROL	☐ Storage & handling of control material
	☐ Frequency of QC testing
	☐ Logging results
TEST SAMPLE PROCEDURE	☐ Storage & handling of test material
	☐ Sample requirements & storage
	☐ Sample collection
	☐ Running a test
TROUBLESHOOTING	☐ User manual
	☐ Abbott product support: 800-257-9525

PRINT NAME OF TRAINER	SIGNATURE OF TRAINER	DATE
PRINT NAME OF TRAINEE	**SIGNATURE OF TRAINEE**	**DATE**

NAME OF INSTITUTION/FACILITY

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ID NOW™ Certification of Training

FLU A/B 2____ Strep A 2____ RSV____ COVID-19____ (Check all that apply)

This is to verify that personnel responsible for running the ID NOW™ at _____ have been thoroughly in-serviced on the test and the test procedure. This has included:

- **Review of the package insert**
- **Demonstration of the product assay**
- **Successful performance of the ID NOW™ assays and interpretation of results**

Names of the personnel who have been trained with the ID NOW™ and are responsible for reporting patient results:

PRINT NAME	SIGNATURE	DATE

Signature of Laboratory Director(s) responsible for personnel and testing:

_____ _____
SIGNATURE DATE

_____ _____
SIGNATURE DATE

_____ _____
TRAINER DATE

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Testing Personnel Training Assessment

TEST METHOD: ID NOW™ COVID-19

PROCEDURE	SATISFACTORY	UNSATISFACTORY	NOT APPLICABLE	COMMENTS/CORRECTIVE ACTIONS
OBSERVATION OF TEST PERFORMANCE:				
Patient sample preparation (if applicable)				
Specimen handling/processing				
Testing				
Recording/reporting results				
Assessment of test performance using known samples				
REVIEW OF RECORDS:				
Patient/quality control log sheet records				
Proficiency testing records				
Assessment of problem solving skills				

(attach all supporting documents)

EVALUATOR:_____ **DATE:**_____

EMPLOYEE:_____

ID NOW™ Quiz

FLU A/B 2____ Strep A 2____ RSV____COVID-19____

NAME:_____

DATE:_____ **SCORE:**_____

Circle T (True) or F (False) for each Question:

1. Flu A/B 2, Strep A 2, RSV and COVID-19 can be stored at 2-30°C, but ensure all test components are at room temperature before use. T F
2. To transfer the sample, you should press the white Transfer Cartridge into the blue Sample Receiver until a click is heard. The orange indicator needs to rise to the top of the Transfer Cartridge. T F
3. The white Transfer Cartridge is firmly attached to the orange Test Base by pressing down until the orange indicator descends back down to its starting position. T F
4. Test components can be separated once they are assembled. T F
5. It is acceptable to mix components from different kit lot numbers. T F
6. If the instrument was transported or moved, a performance check using ID NOW™ positive and negative controls is recommended to ensure proper functionality. T F
7. If any assay components are dropped cracked, found to be damaged, or opened when received, they should not be used and should be discarded. T F
8. After a test is completed, discard the components by removing the connected orange Test Base and white Transfer Cartridge and connecting them to the blue Sample Receiver in the ID NOW™ Instrument. Discard the three (3) connected components according to federal, state, and local regulations. T F
9. External positive and negative controls, which are included in the kit, should be tested when an assay is run on the instrument for the first time, once with each new shipment and once for each untrained operator, following a software upgrade, or in order to conform to local, state and/or federal regulations, accrediting groups, or your lab's standard Quality Control procedures. T F
10. Clean the ID NOW™ Instrument daily by spraying with 70% ethanol or 10% bleach. T F

ID NOW™ Influenza A&B 2 Quiz

1. Swab specimens should be tested as soon as possible after collection. If immediate testing is not possible, the nasal swab can be held in its original package at room temperature for up to two (2) hours prior to testing. T F
2. If the swab 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. T F
3. Both nasopharyngeal and nasal swab specimens are approved for use with the ID NOW™ Influenza A & B 2 Test, but only nasal swabs tested directly are CLIA waived. T F
4. I can use any swab with the ID NOW™ Influenza A & B 2 Test. T F
5. Control swabs are supplied with the kit. T F

6. Patient collection swabs are supplied with the kit. T F

ID NOW™ RSV Quiz

1. Nasopharyngeal swabs may be eluted in saline or approved viral transport media for testing with the ID NOW™ RSV assay. T F

2. Nasopharyngeal swab specimens can be stored at room temperature up to 2 hours prior to testing, or refrigerated at 2-8°C up to 24 hours from time of collection. T F

3. Nasopharyngeal swabs eluted in viral transport media can be stored at room temperature up to 8 hours prior to testing, or refrigerated at 2-8°C up to 24 hours from time of collection. T F

4. Only the nasopharyngeal swabs provided in the kit can be used to collect specimens. T F

ID NOW™ Strep A 2 Quiz

1. The throat swabs that are included in the kit are the only swabs that may be used. T F

2. Swab specimens can be stored at room temperature up to 24 hours prior to testing, or refrigerated at 2-8°C up to 5 days from time of collection. T F

3. The following transport media are acceptable for use: ESwab™ Collection Kit, Liquid Amies, BBL™ CultureSwab™ Liquid Amies, and BBL™ CultureSwab™ Liquid Stuart. T F

4. Swab specimens may be taken from the throat, tonsils, tongue, cheek or teeth. T F

ID NOW™ COVID-19 Quiz

1. Direct Throat, Nasal, and Nasopharyngeal specimens should be tested as soon as possible after collection. If immediate testing is not possible, the nasal swab can be held in its original package at room temperature for up to two (2) hours prior to testing. T F

2. If the direct throat, nasal and nasopharyngeal swabs are held longer than one (1) hour, it must be refrigerated at 2-8°C and tested within 24 hours from the time of sample collection. T F

3. Direct throat, nasal and nasopharyngeal swab specimens are approved for use with the ID NOW™ COVID-19. T F

4. I can use any swab with the ID NOW™ COVID-19 Test. T F

5. Control swabs are supplied with the kit. T F

6. Throat/nasal collection swabs are supplied with the kit. T F

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ID NOW™ Quiz Answer Key

	ANSWER KEY	EXPLANATION
1.	T	Flu A/B 2, Strep A 2, RSV, and COVID-19 can be stored at 2-30°C, but ensure all test components are at room temperature before use.
2.	T	The orange indicator should be observed closely. If the orange indicator does not fully rise, the Transfer Cartridge may not collect enough sample.
3.	T	Visually check the indicator to see that it has descended. If the orange indicator does not fully descend, not enough sample will be dispensed. This may potentially result in invalid or false negative results.
4.	F	Test components must not be separated once they are locked together. To do so may risk amplicon leakage.
5.	F	Do not mix components from different kit lots.
6.	T	The ID NOW™ Instrument is factory calibrated and does not require any further calibration and verification. However, if the instrument was transported or moved, a performance check using ID NOW™ positive and negative controls is recommended to ensure proper functionality.
7.	T	If any assay components are dropped, cracked, found to be damaged, or open when received they should not be used and should be discarded.
8.	T	The blue Sample Receiver will protect the used reaction tubes from accidental breakage.
9.	T	Additional controls may be tested in order to conform with local, state, and/or federal regulations, accrediting groups, or your lab's standard QC procedures.
10.	F	Clean exterior surfaces and surfaces visible under the open lid, as well as the surrounding bench area, using a lint free cloth dampened with 70% Ethanol, 70% Isopropanol, or 10% Bleach. 70% Ethanol or 70% Isopropanol wipes are acceptable for 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.

ID NOW™ Influenza A&B 2 Quiz Answer Key

	ANSWER KEY	EXPLANATION
1.	T	Swab specimens should be tested as soon as possible after collection. If immediate testing is not possible, the nasal swab can be held in its original package at room temperature for up to two (2) hours prior to testing.
2.	T	If the swab 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.
3.	F	Both nasopharyngeal and nasal swab specimens are approved for CLIA waived use with the ID NOW™ Influenza A & B 2 Test.

4. F **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.

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

5. T Control swabs are supplied with the kit.

6. T Patient collection swabs are supplied with the kit.

ID NOW™ RSV Quiz Answer Key

	ANSWER KEY	EXPLANATION
1.	T	Elute swabs in 0.5 to 3.0 mL of saline or approved VTM within 1 hour of sample collection.
2.	T	Direct nasopharyngeal swab specimens can be stored in its original package at room temperature up to 2 hours prior to testing, or refrigerated at 2-8°C up to 24 hours from time of collection.
3.	T	Viral transport media specimens can be stored at room temperature up to 8 hours, or refrigerated at 2-8°C up to 24 hours from time of collection.
4.	F	For optimal performance, use the swab provided in the test kit. Alternatively, sterile rayon, foam, or flocked flexible-shaft NP swabs can be used to collect nasopharyngeal samples.

ID NOW™ Strep A 2 Quiz Answer Key

	ANSWER KEY	EXPLANATION
1.	F	For optimal 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. The BBL™ CultureSwab™ Liquid Amies transport media system has been tested and is also acceptable. Rayon swabs and the BBL™ CultureSwab™ Liquid Stuart transport media system are not suitable for use in this assay.
2.	F	Swab specimens should be tested as soon as possible after collection. If immediate testing is not possible, the throat swab can be held in its original package or a clean, dry plastic tube or sleeve at room temperature (approximately 22°C) or refrigerated at 2-8°C for up to seventy-two (72) hours prior to testing. The collection swab is to be tested following the step-by-step instructions shown on the instrument screen. If immediate testing is not possible, the transport media system can be held at room temperature (approximately 22°C) or refrigerated at 2-8°C for up to six (6) hours prior to testing.
3.	F	The following transport media is acceptable for use: BBL™ CultureSwab™ Liquid Amies transport media system.

BBL™ CultureSwab™ Liquid Stuart transport media system is not suitable for use in this assay.

4. F Collect patient specimen by swabbing the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.

ID NOW™ COVID-19 Quiz Answer Key

	ANSWER KEY	EXPLANATION
1.	F	Direct throat, nasal, and nasopharyngeal specimens should be tested as soon as possible after collection. If immediate testing is not possible, the nasal swab can be held in its original package at room temperature for up to one (1) hour prior to testing.
2.	F	The nasal, throat or nasopharyngeal swab is placed in a clean, unused tube labeled with patient information, and capped tightly at room temperature (15-30°C) for up to one (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than one (1) hour delay occurs, dispose of sample. A new sample must be collected for testing.
3.	T	Direct throat, nasal and nasopharyngeal swab specimens are approved for use with the ID NOW™ COVID-19 Test.
4.	F	**Throat Swab** 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. **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. **Nasopharyngeal Swab** Use sterile rayon, foam, polyester or flocked flexible-shaft NP swabs to collect a nasopharyngeal sample.
5.	T	Control swabs are supplied with the kit.
6.	T	Throat/nasal collection swabs are supplied with the kit.

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