Table of Contents

Summary and Explanation of The Test

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

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 (like 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.

Analyzer Maintenance

General Procedures for Maintenance and Servicing

The Abbott Analyzer requires little maintenance from the user to provide reliable performance. Any maintenance or repair not described in this section should be performed by v representatives only.

WARNING

All maintenance and repair other than the procedures described in this section must be performed by qualified service personnel. non-compliance with this warning may result in personal injury or instrument malfunction.

Cleaning

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.

The ID NOW™ can be cleaned using 70% ethanol or 10% bleach solution, on a damp, lint free cloth. 70 % Ethanol 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. After each day of use and when the cleaning is completed, document the task on the ID NOW cleaning log attached to this policy.

Servicing

There are no user serviceable components in the unit. For technical issues or questions, please contact your local Abbott representative.

Transportation and Storage

The Analyzer and optional modules should be transported in the original packaging at -20–65 °C for up to 2 days, -20–45 °C for up to 14 days, up to 85% RH, non-condensing. Abbott recommends the original packing materials be retained for this purpose. Follow local transportation regulations for shipping equipment containing a Li-ion secondary battery.

Reagents

The following components are included in the Abbott ID Now System for Rapid Detection of SARS-CoV-2 kit.

Materials Provided:

- 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
-

Materials Required but not provided:

- ID NOW Instrument
- Nasopharyngeal Swabs
- tube rack for specimens
- any necessary personal protective equipment

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

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 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 to conform with local, state and/or federal regulations, accrediting groups, or your lab's standard Quality Control procedures.

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.

Specimen Collection and Handling
ID NOW COVID-19 is intended for testing a swab directly without elution in viral transport media as dilution will result in decreased detection of low positive samples that are near the limit of detection of the test.

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

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

Specimen Transport and Storage

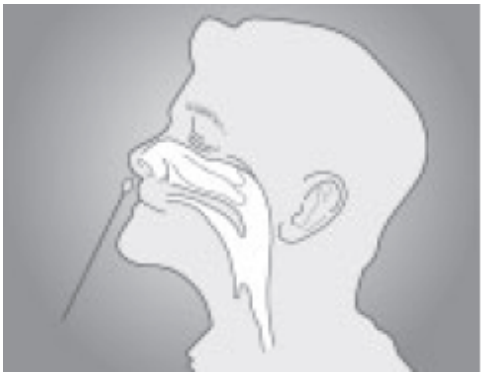
For best performance, direct nasal, throat, or nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, and to maintain best performance, it is highly recommended the nasal, throat or nasopharyngeal swab is placed in a clean, unused tube labeled 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 encounter the lower portion of the packaging. Avoid touching the outside of the wrapper with the swab.

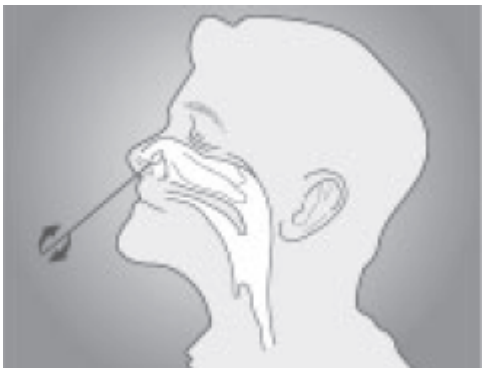
Nasal Swab Specimen Collection

The Abbott ID Now System Kit includes swabs for nasal specimen collection.

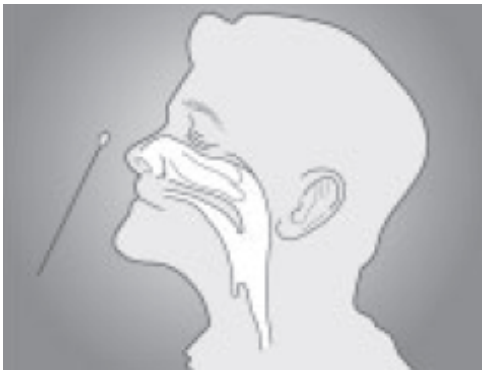
1. Insert the swab into one nostril of the patient. The swab tip should be inserted up to cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.



2. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.



3. Withdraw the swab from the nasal cavity. The sample is now ready for processing using the Abbott ID Now System SARS-CoV-2 kit.



DOs and DON'Ts of Sample Collection

- Do collect sample as soon as possible after onset of symptoms.
- Do test sample immediately.
- Use only swabs provided with the kit.
- Refer to: Interim Guidelines for Collecting, Handling and Testing Clinical Specimens from persons for COVID-19 at https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html

Test Procedure

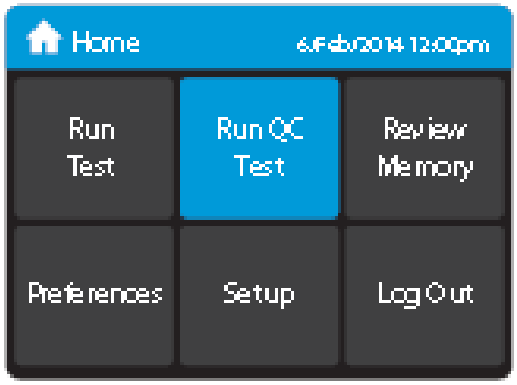
Before testing with ID NOW COVID-19:

- 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.

Freshly collected specimens should be processed within 1 hour.

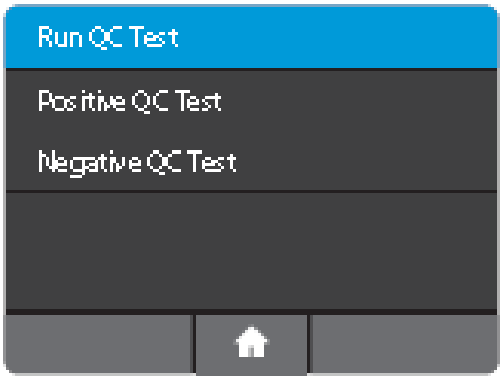
Procedure for Control swabs:

1. Document on the Maintenance sheet if the QC being performed is for a new lot or new operator.
2. Document the test lot # and the expiration date
3. Select **Run QC Test** on the Home screen and follow the displayed instructions.

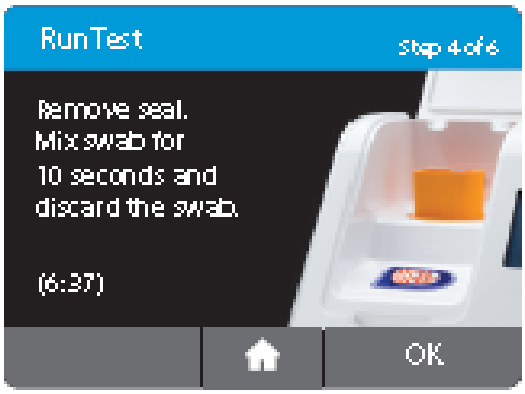


4. Touch **COVID-19**

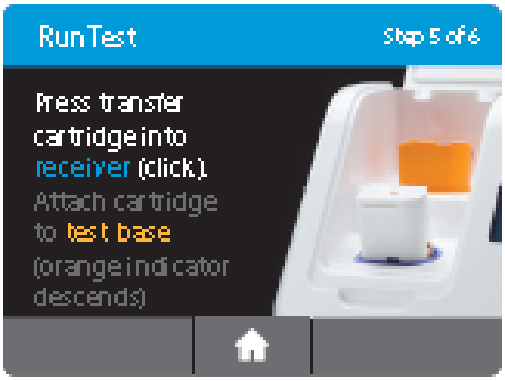
5. Select **Positive QC Test**



6. Remove the foil seal from the sample receiver. Using a sterile swab provided in the kit as a negative control, mix the swab in the liquid for 10 seconds.



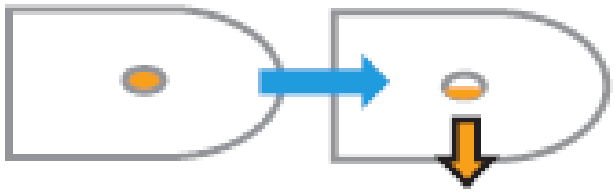
7. Press the swab against the side of the sample receiver and remove the swab. Discard swab into a biohazard waste container.
8. Touch **OK**.
9. Press the white transfer cartridge into the blue sample receiver until you hear a click.



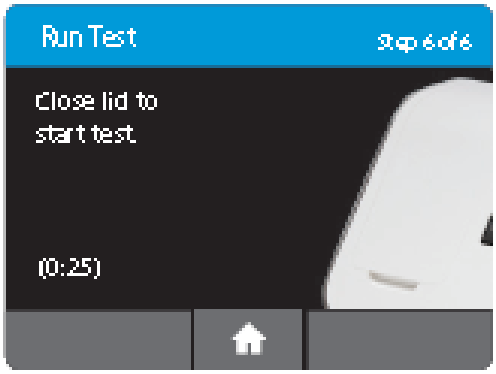
10. Look for the orange indicator on the transfer cartridge to fully rise.

11. Lift and connect the transfer cartridge to the test base.

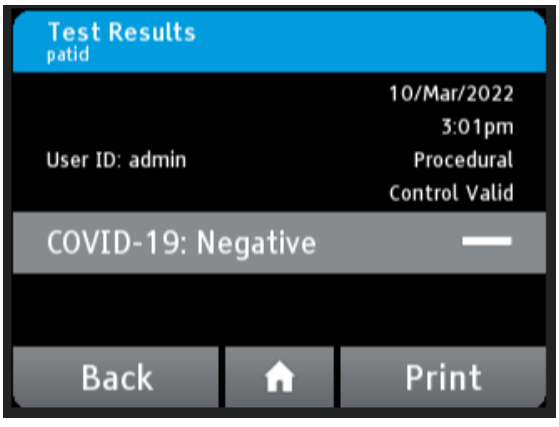
12. Look for the orange indicator on the transfer cartridge to fully descend.



13. Close the lid to start the test. **DO NOT OPEN THE LID UNTIL THE TEST COMPLETE MESSAGE APPEARS ON THE SCREEN.**

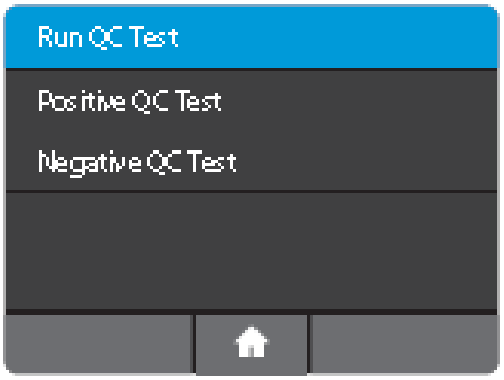


14. When results are complete, document control results on the Maintenance sheet.



15. Press the home button at the bottom of the screen
16. Return to step 1 to begin running the negative control

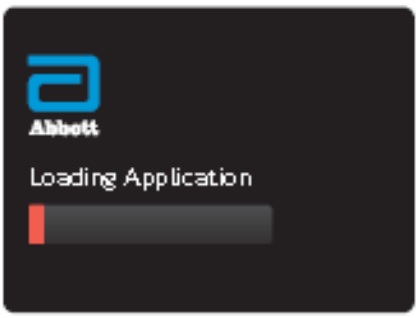
17. At step 3, select **Negative QC Test**



18. Repeat steps 1 through 13, utilizing the Positive control swab instead of the blank swab and choose Negative QC test in step 3.
19. Date and initial in the appropriate areas on the Maintenance sheet.

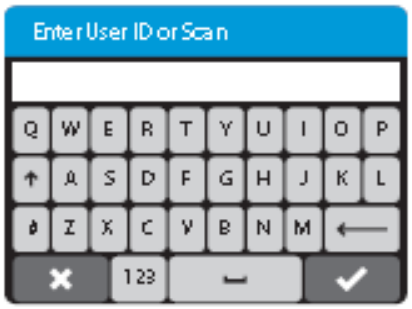
Procedure for Patient Swabs

Step 1
Turn on the ID NOW Instrument - press the power button on the side of the instrument.

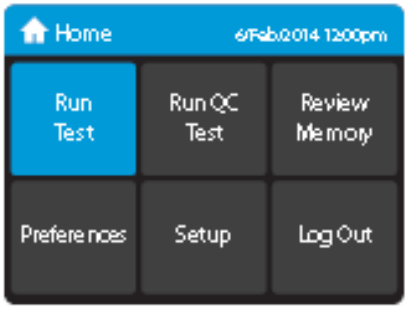


NOTE: If the unit is unattended for one hour, the instrument will go to a black screen power save mode. Touch the screen to return the unit to active display operation.

Enter User ID

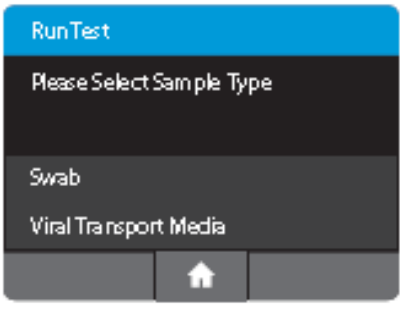


Press '√' after entry.
Touch 'Run Test'



This will begin the test process.
Touch 'COVID-19 Test'
This starts a COVID-19 test.

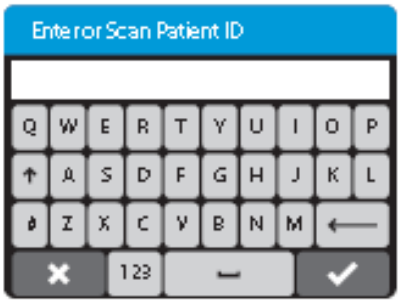
Select Swab Sample Type (if prompted)
If the sample type has already been specified by the Admin, the instrument will automatically advance to the next step.



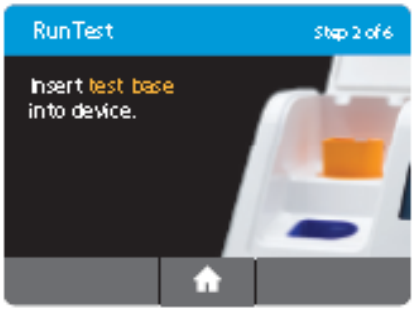
CAUTION: VTM Samples are not an appropriate sample type for the ID NOW COVID-19 test.

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.

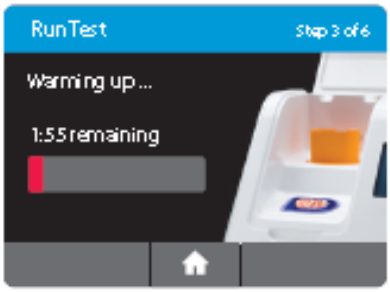
Step 3

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 Warm Up begins.



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

Step 4

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

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 warming up, cancel the test by pressing the Home button. Remove and discard the test pieces (Sample Receiver and Test Base) and clean the instrument. Press Run Test to start a new test using a new Test Base and Sample Receiver.

Step 5a

Press the White Transfer Cartridge into the Blue Sample Receiver

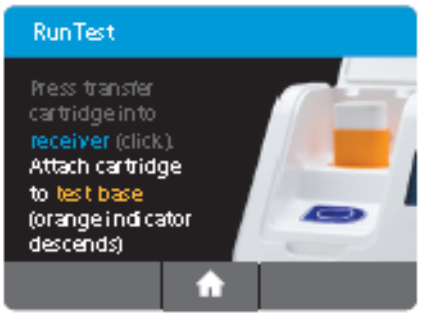
Listen for a click.

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

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

Step 5b

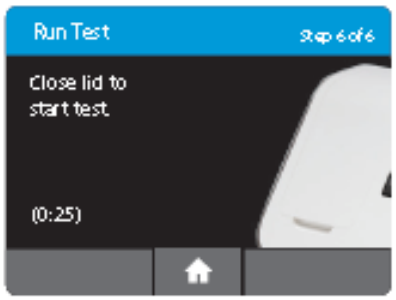
Lift and then connect the Transfer Cartridge to the Test Base



When the Transfer Cartridge is properly attached to the Test Base, the orange indicator on the Transfer Cartridge will descend. If the orange indicator does not descend, continue pushing onto the Test Base until it does.

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

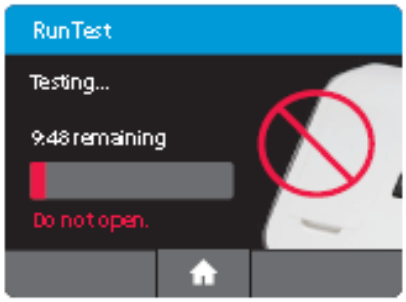
Step 6
Close the Lid.



DO NOT OPEN THE LID until the Test Complete message appears on the screen.

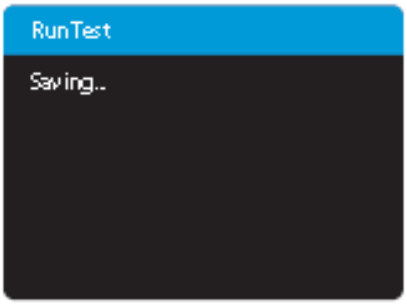
NOTE: The test will be cancelled if the lid is opened.

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.



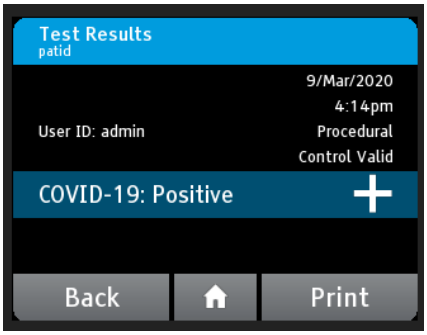
CAUTION: DO NOT OPEN THE LID. The test will be cancelled and all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. A test result will not be reported or saved in the instrument memory.

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.

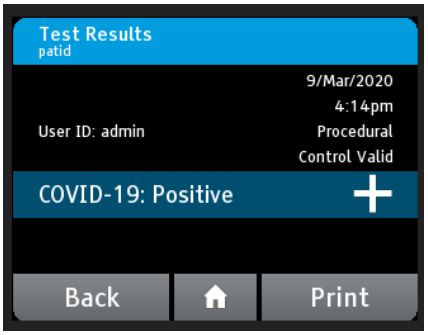
Close the lid. The instrument will then run a Self-Test before showing the Home screen or Enter Patient ID screen, depending on the previous selection.

Remove and dispose of gloves.

Result Interpretation

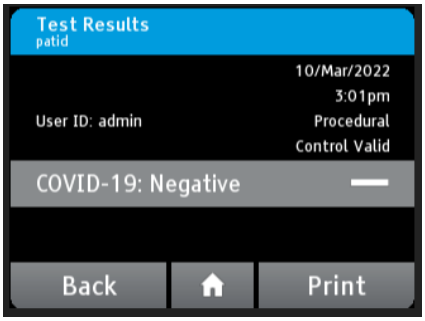
When the test is complete, the results are clearly displayed on the instrument screen.

COVID-19 Positive



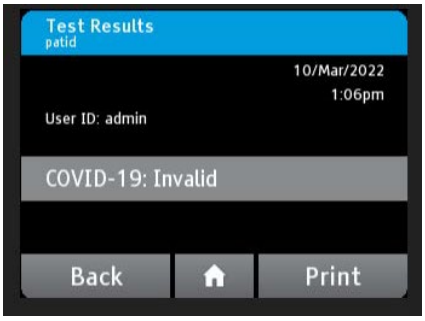
Positive results do not rule out bacterial infection or co-infection with other viruses.

COVID-19 Negative



Negative results should be treated as presumptive 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.

INVALID



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.

NOTE: 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.

Quick Reference Sheet:

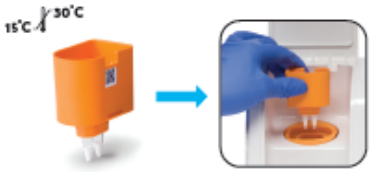
ID NOW™
COVID-19
QUICK REFERENCE INSTRUCTIONS

Before performing this test, refer to the ID NOW COVID-19 Product Insert and User Manual for complete Test Procedure and additional information.

Follow the step-by-step instructions shown on the instrument screen.

1

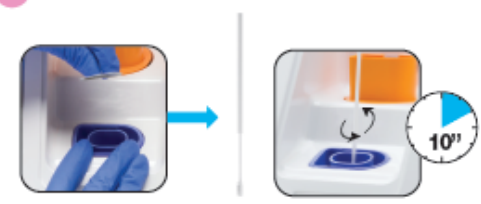
2



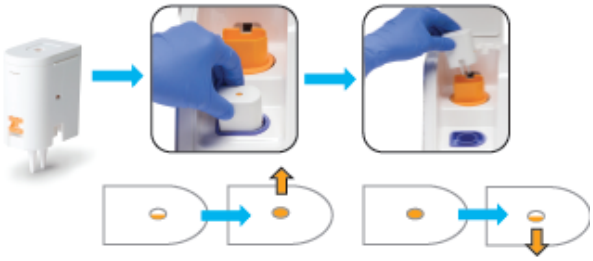
3

Do not open the Sample Receiver before placing in the instrument.

4



5



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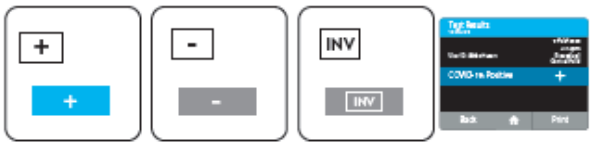

Refer to Product Insert instructions for retest procedure in the case of an Invalid result.

8

Refer to the Product Insert for instructions on safe handling and disposal of samples and test components.

Maintenance and Qc Log:

Abbott ID now Maintenance Log

MCI DIAGNOSTIC CENTER
Redefining Diagnostic Imaging

Month: _____

Serial Number: _____ Year: _____

Maintenance Steps NOT IN USE - Place an "X" when not in use	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Daily Maintenance																															
Perform daily cleaning																															
Operator's Initials																															
Quality Control Performance for New Lot	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Did the Positive Cotrol swab produce a Positive result?																															
Did the Negative Cotrol swab produce a Negative result?																															
Lot #_____																															
Lot Expiration_____																															
Operator's Initials																															
Quality Control Performance for New Operator	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Did the Positive Cotrol swab produce a Positive result?																															
Did the Negative Cotrol swab produce a Negative result?																															
Lot #_____																															
Lot Expiration_____																															
Operator's Initials																															
As needed Maintenance	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
BD Veritor System Verification Cartridge Test																															
Operator's Initials																															

Reviewed by:_____ Date:_____