Abbott

ID NOW™

COVID-19 2.0

PRODUCT INSERT

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ID NOW™
COVID-19 2.0
PRODUCT INSERT

For use with the ID NOW™ Instrument
For use with anterior nasal swab or nasopharyngeal swab specimens
For *in vitro* Diagnostic Use
℞ Only

CLIA COMPLEXITY: WAIVED

A Certificate of Waiver is required to perform this test in a CLIA Waived setting. To obtain CLIA waiver information and a Certificate of Waiver, please contact your state health department. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at www.cms.hhs.gov/CLIA.

Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived classification.

INTENDED USE

ID NOW™ COVID-19 2.0 performed on the ID NOW Instrument is a rapid molecular *in vitro* diagnostic test utilizing an isothermal nucleic acid amplification technology (NAAT) intended for the qualitative detection of nucleic acid from SARS-CoV-2 in direct anterior nasal (nasal) or nasopharyngeal swabs from individuals with signs and symptoms of respiratory tract infection. ID NOW COVID-19 2.0 performed on the ID NOW Instrument is intended for use as an aid in the diagnosis of COVID-19 if used in conjunction with other clinical, epidemiologic, and laboratory findings. SARS-CoV-2 RNA is generally detectable in nasal and nasopharyngeal swab specimens during the acute phase of infection.

Positive results are indicative of the presence of SARS-CoV-2 RNA. Positive results do not preclude co-infection with bacteria or other viruses and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions.

A negative test result is presumptive, and it is recommended these results be confirmed by another molecular SARS-CoV-2 assay. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. This test is intended for prescription use only and can be used in Point-of-Care settings.

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 2.0 is a rapid (positive results as early as 6 minutes, negative results in 12 minutes), instrument-based molecular isothermal nucleic acid amplification technology (NAAT) test for the qualitative detection and diagnosis of SARS-CoV-2 from nasal and nasopharyngeal swabs. The ID NOW Instrument has a small footprint and easy to use graphical user interface to allow convenience and ease of use. The ID NOW Instrument enables timely diagnostic and actionable treatment decisions for rapid disposition in a variety of traditional diagnostic and decentralized near-patient environments. ID NOW COVID-19 2.0 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 2.0 is an automated assay that utilizes molecular isothermal nucleic acid amplification technology (NAAT) 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 specimen 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 specimen 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

Test Bases (24): BASE — Orange plastic components containing two reaction tubes of lyophilized reagents for the targeted amplification of SARS-CoV-2 viral RNA and an internal control.

Sample Receivers (24): RCVR — Blue plastic components containing 2.5 mL of elution buffer comprised of a weak acid, detergent, salts and an antimicrobial agent.

Transfer Cartridges (24): CARTRDG — White plastic components used to transfer 2 x 100 µL of specimen extract from the Sample Receiver to the Test Base.

Patient Swabs (24): Sterile anterior nasal swabs (foam) for use with ID NOW COVID-19 2.0.

Positive Control Swab (1): The positive control swab is coated with inactivated SARS-CoV-2 virus and ensures specimen elution/lysis and workflow were performed correctly.

Negative Control Swab: The use of a sterile swab provided in the kit ensures appropriate negative results are obtained.

Package Insert (1)

Quick Reference Instructions (1)

Materials Required but not Provided

ID NOW Instrument - For more information on the ID NOW Instrument, please refer to the User Manual provided with the ID NOW Instrument. The ID NOW Instrument User Manual can also be found at globalpointofcare.eifu.abbott.

Nasopharyngeal Swabs - For more information on nasopharyngeal swabs that have been evaluated and can be used to collect nasopharyngeal specimens, please, see the Section titled "**SPECIMEN COLLECTION and HANDLING - Nasopharyngeal Swab**", below.

Materials Available as an Optional Accessory

COVID-19 Swab Transport Tube Accessory Pack

ID NOW COVID-19 2.0 Control Swab Kit - contains twelve (12) Positive Control Swabs and twelve (12) sterile swabs for negative controls.

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. For prescription use only.
3. Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
4. To be used in conjunction with the ID NOW Instrument.
5. Treat all specimens as potentially infectious. Follow universal precautions when handling specimens, this kit and its contents.
6. The test was validated with fresh specimens only. Proper specimen collection, storage and transport are essential for correct results.
7. Leave test pieces (Sample Receiver, Transfer Cartridge, Test Base, Positive Control Swab, Sterile Patient Swab) sealed in their foil pouches until just before use.
8. Do not tamper with test pieces prior to or after use.
9. Do not use kit past its expiration date. Use of expired tests can lead to incorrect results.
10. Do not mix components from other ID NOW assays. If performing sequential testing using a single patient specimen, components from assays indicated for sequential testing may be mixed.
11. Do not mix ID NOW COVID-19 2.0 components from different kit lots.
12. The positive control swab contains inactivated SARS-CoV-2. However, all specimens, controls, and test pieces should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
13. Wear clean personal protection equipment and gloves when running each test. Change gloves between handling of each specimen.
14. **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.**
15. Do not open the Sample Receiver before placing in the instrument. It will prohibit the Elution Buffer in the Sample Receiver from reaching the appropriate temperature and may impact test performance.
16. If the liquid within the Sample Receiver is spilled while opening, clean the instrument per instructions provided in the ID NOW Instrument User Manual and cancel test. Repeat test with a new Sample Receiver.
17. 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. **Test pieces must not be separated once they are assembled**.
18. All test pieces provided in the kit are single use items. Do not use with multiple specimens. The ID NOW Instrument is reusable.
19. Once the test run is complete, 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 specimen, this could lead to amplicon exposure and cross-contamination as well as potential ID NOW COVID-19 2.0 false positive test results.
20. Due to the high sensitivity of the assays run on the instrument, contamination of the work area with previous positive specimens may cause false positive results. Do not touch the heads of the Control Swabs as cross-contamination could occur. Handle specimens 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.
21. Visibly bloody specimens must not be used with ID NOW COVID-19 2.0.

STORAGE and STABILITY

Store kit at 2-30°C. ID NOW COVID-19 2.0 kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test pieces are at room temperature before use. Test pieces should be used immediately upon opening and not stored for later use.

QUALITY CONTROL

ID NOW COVID-19 2.0 has built-in procedural controls (described below in the section titled, Procedural Controls). The result of the Quality 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 2.0 contains an internal control that has been designed to control for specimen inhibition and assay reagent function. In positive specimens where target amplification is strong, the internal control is ignored, and the target amplification serves as the 'control' to confirm that the clinical specimen was not inhibitory, and that assay reagent performance was robust.

'Procedural Control Valid' displayed on the instrument screen indicates that the assay reagents maintained their functional integrity and potential specimen inhibitors did not significantly affect 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 2.0 kits contain a Positive Control Swab and Sterile Patient Swabs that can be used as a Negative Control Swab. These swabs will monitor the entire assay. It is recommended to run a QC test using these swabs once with each new shipment of test kits received and once for each untrained operator. Additional 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.

If additional Positive or Negative Control Swabs are required, ID NOW COVID-19 2.0 Control Swab Kit can be purchased separately. ID NOW COVID-19 2.0 Control Swab Kit contains the same Positive and Negative Control Swabs that are provided in the ID NOW COVID-19 2.0 kit.

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

Use freshly collected specimens for optimal test performance. Inadequate specimen collection or improper specimen handling may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

ID NOW COVID-19 2.0 is intended for testing a swab directly without elution in viral transport media as dilution will result in decreased detection of low positive specimens 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 specimen collection, it is recommended to widely open the package by pulling from the top down. Carefully remove the swab and perform specimen collection.

Anterior Nasal (Nasal) Swab

For optimal test performance, use the swabs provided in the test kit. Alternatively, the following swab types have been analytically validated and can be used to collect nasal swab specimens:

Puritan® Regular Rayon Tip Swabs, Puritan® HydraFlock® Flock Swabs – Standard Tip, Copan Standard Flocked Swab, MRC Technology, Ltd. Foam Tipped Applicator, Foamtec Int'l Swab, Sterile CleanFOAM Diagnostic, and FA Polyurethane Foam Swabs.

Note: Puritan® PurFlock Ultra® Flocked Swabs-Standard Tip, Copan™ Rayon Standard Tip Swab, and Jiangsu Changfeng Medical Industry (JCF) Polyurethane Foam swabs are not suitable for use in this assay.

To collect a nasal swab specimen, 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 (about 2.5 cm into the nostril). Rotate the swab several times against the nasal wall then slowly remove from the nostril. Using the same swab, repeat specimen collection in the other nostril.

Nasopharyngeal Swab

Use sterile, foam, Puritan® HydraFlock® Flocked swab (mini tip), Puritan® Small Foam Tip Swabs, or Copan Mini Tip Flocked Swabs to collect nasopharyngeal swab specimens.

Note: Puritan® Mini Rayon Tip and Puritan® PurFlock Ultra® Flocked Swabs-Mini Tip are not suitable for use in this assay.

To collect a nasopharyngeal swab specimen, 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 inserted up to a distance that is halfway 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 HANDLING

For best performance, direct nasal 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 that the nasal 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, discard the specimen. **DO NOT RETURN THE SWAB TO ITS ORIGINAL PACKAGING.** A new specimen must be collected for testing.

OPTIONAL WORKFLOW - SEQUENTIAL ID NOW™ COVID-19 2.0 and INFLUENZA A & B 2 TESTING UTILIZING a SINGLE PATIENT SPECIMEN and SAMPLE RECEIVER

A single patient specimen can be used to run both an ID NOW COVID-19 2.0 assay and an ID NOW Influenza A & B 2 assay by reusing the Sample Receiver. If a sequential ID NOW COVID-19 2.0 followed by an ID NOW Influenza A & B 2 test is desired, **DO NOT dispose of the ID NOW COVID-19 2.0 Sample Receiver**. Retain it for use in the ID NOW Influenza A & B 2 portion of the testing procedure. See **TEST PROCEDURE - Workflow for Sequential ID NOW COVID-19 2.0 and ID NOW Influenza A & B 2 Assays** on page 14. Please refer to the ID NOW Influenza A & B 2 Product Insert for full instructions for use, including precautions, limitations and performance characteristics.

- ID NOW COVID-19 2.0 assay must be run **BEFORE** the ID NOW Influenza A & B 2 assay.
- Direct (no VTM storage) Nasal or Nasopharyngeal swabs are the ONLY appropriate specimen types for sequential testing.
- Sequential ID NOW COVID-19 2.0 and Influenza A & B 2 testing requires both an ID NOW Influenza A & B 2 test kit and an ID NOW COVID-19 2.0 test kit.
- No more than 30 minutes should be allowed to elapse following the conclusion of the ID NOW COVID-19 2.0 assay before initiating the ID NOW Influenza A & B 2 assay.
- Up to three tests can be performed during sequential testing. If two invalid results are obtained, the Sample Receiver MUST be discarded, and testing repeated using a new patient specimen.

TEST PROCEDURE – ID NOW™ COVID-19 2.0

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

Before testing with ID NOW COVID-19 2.0:

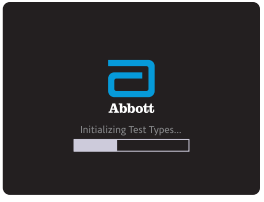
- **Put on a clean pair of gloves.**
- Allow all specimens to reach room temperature.
- Allow all test pieces to reach room temperature.
- Check that a reagent pellet is visible at the bottom of each of the reaction tubes of the Test Base prior to inserting the Test Base in the ID NOW Instrument. Do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

To Perform a Test:

Step 1

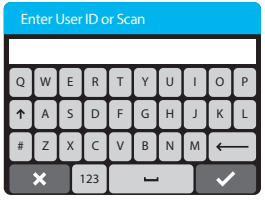
Turn on the ID NOW Instrument - press the power button ⏻ on the side of the instrument.

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



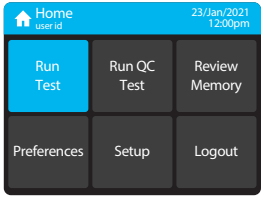
Enter User ID

Press '✓' after entry.



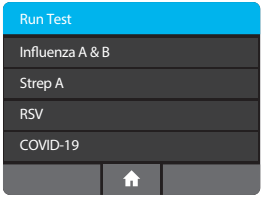
Press '**Run Test**'

This will begin the test process.



Press '**COVID-19**'

This starts a COVID-19 test.

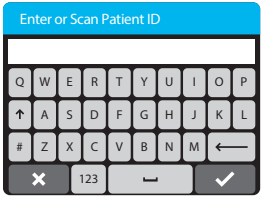


Enter **Patient ID** using on screen keyboard or barcode scanner.

Press '✓'.

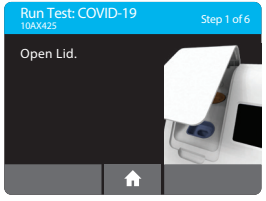
Verify that the ID was entered correctly, then press '✓' to confirm entry.

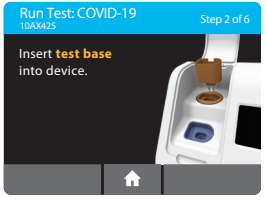
Confirmation is required as Patient ID is not editable once testing has commenced.



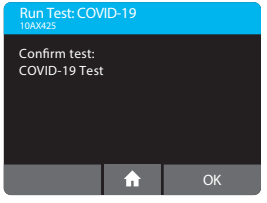
Step 2

Open the Lid and Gently Insert orange Test Base into orange Test Base holder.





Confirm that the correct test is displayed on the screen.



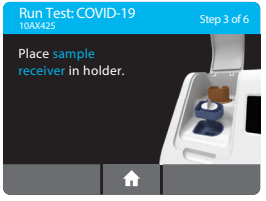
Press **'OK'** to proceed.

Caution: Once the Test Base has been placed in the holder, the user will have 3 minutes to confirm the test. If the test is not confirmed within 3 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.

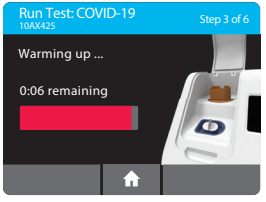
Step 3

Gently **INSERT** blue Sample Receiver into the blue Sample Receiver holder.



Caution: Once the Sample Receiver has been placed in the holder, the user will have 8 minutes to start the test (Steps 3 through 5). If the test is not started within 8 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.

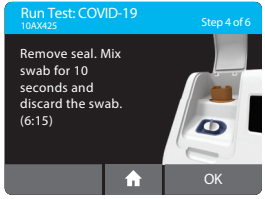


Caution: DO NOT OPEN the Sample Receiver before placing into the instrument. **DO NOT** close the lid or insert the specimen until prompted by the instrument.

Step 4

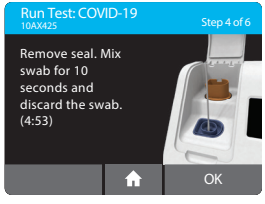
Direct Nasal or Nasopharyngeal Swab Test Procedure

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



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.

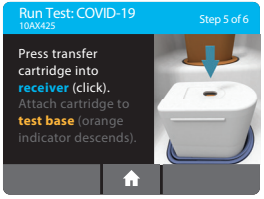
Immerse the swab head completely in the Sample Receiver buffer and with a strong swirling motion, mix the swab in the liquid for **10 seconds**. This helps remove the specimen from the swab. Lift the swab out of the liquid and press the swab head against the inside wall of the Sample Receiver to remove excess liquid. Once the swab is removed, press **'OK'** to proceed.



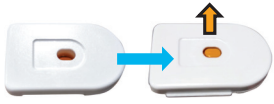
Discard the swab into a biohazard waste container.

Step 5a

1. Press the white Transfer Cartridge into the blue Sample Receiver.
2. With **BOTH HANDS**, press **FIRMLY** on the top of the white Transfer Cartridge.
3. Listen for **CLICK(S)**.
4. Confirm orange indicator has risen up **FULLY** to top of Transfer Cartridge.

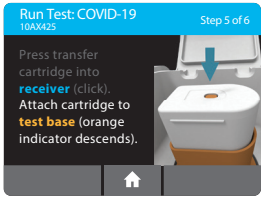


Caution: If the orange indicator **DOES NOT FULLY RISE**, the Transfer Cartridge may not collect enough specimen.

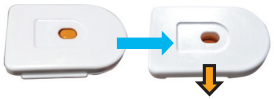


Step 5b

1. Lift and press the white Transfer Cartridge into the Test Base.
2. With **BOTH HANDS**, press **FIRMLY** on the top of the white Transfer Cartridge.
3. Listen for **MULTIPLE CLICKS**.
4. Confirm orange indicator is **FULLY DOWN** to the top of white Transfer Cartridge.

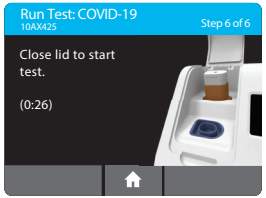


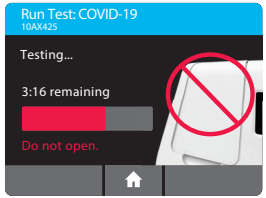
STOP **CHECK:** Is the orange indicator down? If orange indicator is not fully down, **NOT ENOUGH SPECIMEN** will be dispensed. If not, press down again before closing lid.
Note: *Failure to fully press down may cause an* ***INVALID*** *or* ***FALSE*** *test result.*



Step 6

Close the Lid.



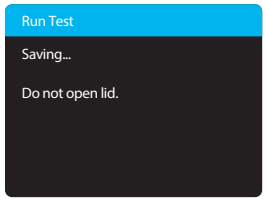


DO NOT OPEN THE LID until the **Test Results** appear on the screen.

Note: *The test will be cancelled if the lid is opened. A test result will not be reported or saved in instrument memory.*

⚠ **Caution:** This message will be displayed on the screen for 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 specimen from the patient. Press **'Run Test'** and restart the test using a new Test Base and Sample Receiver.

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



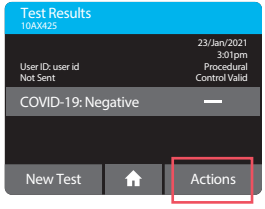
⚠ **Caution:** The test is not saved until the completed result is displayed. Do not open the lid until the results are displayed.

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.

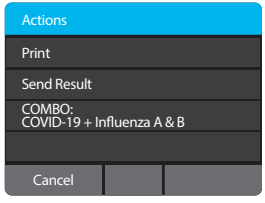
Press **'New Test'** or **'Home'** to complete testing with this patient specimen.

Press **'Actions'** to

1. **Print** test results
2. **Send** test results
3. Run an **ID NOW Influenza A & B 2** test utilizing the same blue Sample Receiver.

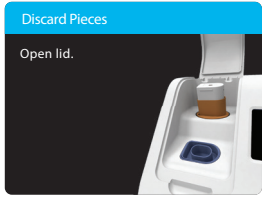


Press **'Actions'** to print or send test results or to run an ID NOW INFLUENZA A & B 2 test utilizing the same blue Sample Receiver.



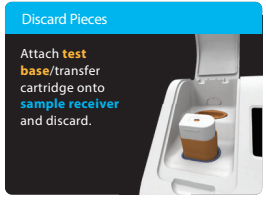
After printing, or if New Test or Home are selected, the instrument will prompt to open the lid and discard the used test pieces.

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.



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

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.



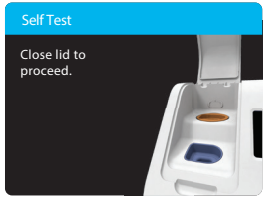
If COMBO: COVID-19 + Flu A & B is selected:

- **DO NOT REMOVE** the used blue Sample Receiver;
- Proceed to **Page 14:** use the TEST PROCEDURE for Workflow for Sequential ID NOW COVID-19 2.0 and ID NOW Influenza A & B 2.

Caution: DO NOT try to remove the Sample Receiver by any other method as there is a risk of spilling the patient specimen.

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

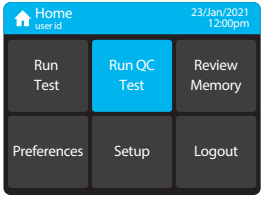
Remove and dispose of gloves.



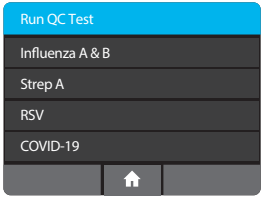
Quality Control Swab Test Procedure

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.

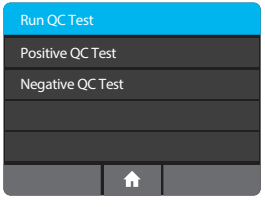
1. Press **'Run QC Test'**



2. Press **'COVID-19'**



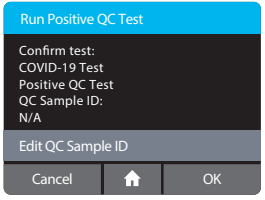
3. Select the QC Test to be Run



4. **Confirm Test**

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

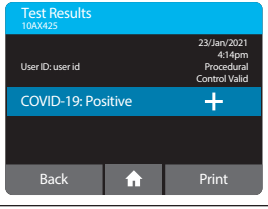
The user has the option to enter an ID for the QC Sample being run.

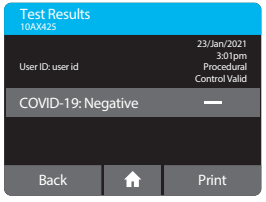
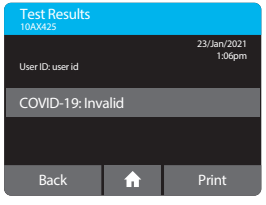
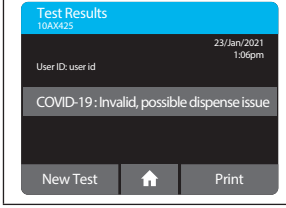


Note: *The QC test is run in the same manner as a Direct Nasal/ Nasopharyngeal Swab Patient Test. See the* ***To Perform a Test*** *section above for step by step instructions for direct nasal/nasopharyngeal swab specimens.*

RESULT INTERPRETATION – ID NOW™ COVID-19 2.0

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.

Instrument Display	Interpretation of Results and Follow-up Actions
	**COVID-19 Negative** Negative results do not preclude SARS-CoV-2 infection. A negative test result is presumptive, and it is recommended these results be confirmed by another lab based highly sensitive molecular SARS-CoV-2 assay.
 	**The presence or absence of COVID-19 Viral RNAs cannot be determined.** 'Invalid, possible dispense issue' will display if an insufficient amount of specimen was transferred to the test base. Repeat testing of the specimen using new test pieces. If repeated Invalid results are obtained, a new specimen should be collected and results confirmed by another method prior to reporting the results.

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

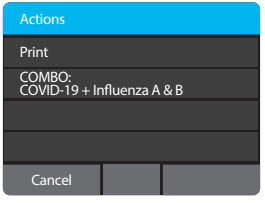
- Remove the connected Test Base and Transfer Cartridge from the instrument and connect the Test Base portion to an open, UNUSED Sample Receiver. The connected Test Base and Transfer Cartridge MUST be attached to a Sample Receiver prior to disposal. The Sample Receiver from a new Transfer Cartridge package 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. **Put on a clean pair of gloves after handling the Sample Receiver.**
- If performing sequential ID NOW COVID-19 2.0 and ID NOW Influenza A & B 2, up to three tests can be performed during sequential testing. If two invalid results are obtained, the Sample Receiver MUST be discarded and a new patient specimen should be collected.

TEST PROCEDURE - Workflow for Sequential ID NOW™ COVID-19 2.0 and ID NOW™ Influenza A & B 2

To Perform a Test:

Step 1

After selecting **COMBO: COVID-19 + Flu A & B**



1. The instrument will prompt to open the lid and discard the used orange **Test Base** and **Transfer Cartridge**.
2. Remove the **UNUSED** blue ID NOW Influenza A & B 2 Sample Receiver from the ID NOW Influenza A & B 2 test kit.
3. While holding the **UNUSED** blue Sample Receiver, carefully **REMOVE** the foil seal.
4. Lift the **USED** ID NOW COVID-19 2.0 orange **Transfer Cartridge** attached to the **Test Base** from the instrument.
5. Firmly press them into the **UNUSED** blue ID NOW Influenza A & B 2 **Sample Receiver**.

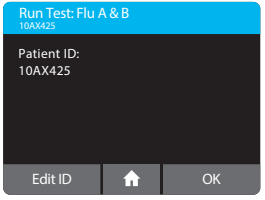
Caution: Do not spill or touch the liquid in the Sample Receiver. The connected test pieces can now be disposed of according to federal, state, and local regulations.

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

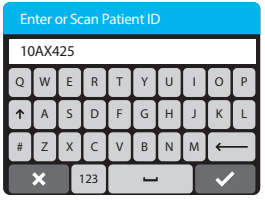
Close the lid. The instrument will then run a Self Test before showing the Home screen or Enter Patient ID screen, depending on the previous selection. The Sample Receiver can remain in the instrument during the instrument Self Test.

Verify that the Patient ID was entered correctly.

Press **Edit ID** to scan or enter a new Patient ID, then press '✓' to confirm entry.



Confirmation is required as Patient ID is not editable once testing has commenced.

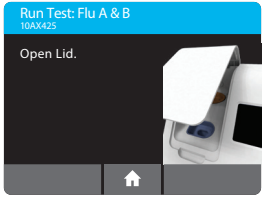


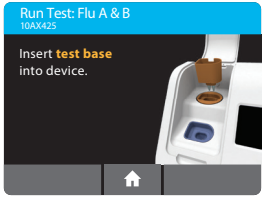
Step 2

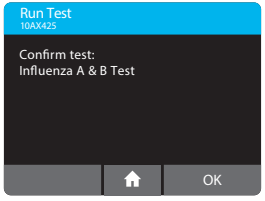
Open the Lid and Insert orange **TEST BASE** into orange **TEST BASE** holder.

Confirm that the correct test is displayed on the screen.

Press **'OK'** to proceed.





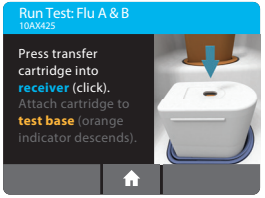


Caution: Once the Test Base has been placed in the holder, the user will have 10 minutes to confirm the test. If the test is not confirmed within 10 minutes, the instrument will time out and the Test Base must be removed and discarded.

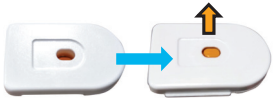
If the incorrect Test Base has been inserted, remove and dispose of the incorrect Test Base. Close the lid. The instrument will then run a Self Test before proceeding to the Home screen. Press **'Run Test'** and restart the test using the correct Test Base.

Step 3a

1. Press the white Transfer Cartridge into the blue Sample Receiver.
2. With **BOTH HANDS**, press **FIRMLY** on the top of the white Transfer Cartridge.
3. Listen for **CLICK(S)**.
4. Confirm orange indicator has risen up **FULLY** to top of Transfer Cartridge.

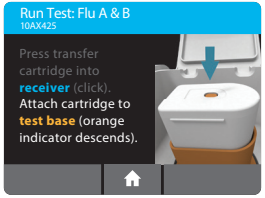


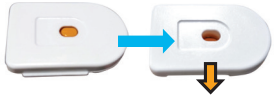
Caution: If the orange indicator **DOES NOT FULLY RISE**, the Transfer Cartridge may not collect enough specimen.



Step 3b

1. Lift and press the white Transfer Cartridge into the Test Base.
2. With **BOTH HANDS**, press **FIRMLY** on the top of the white Transfer Cartridge.
3. Listen for **MULTIPLE CLICKS**.
4. Confirm orange indicator is **FULLY DOWN** to the top of white Transfer Cartridge.

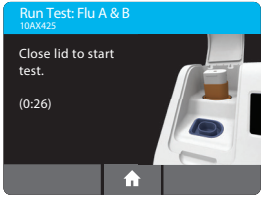


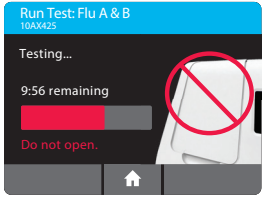


STOP **CHECK:** Is the orange indicator down? If orange indicator is not fully down, **NOT ENOUGH SPECIMEN** will be dispensed. If not, press down again before closing lid.
Note: *Failure to fully press down may cause an* ***INVALID*** *or* ***FALSE*** *test result.*

Step 4

Close the Lid.



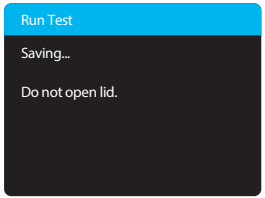


DO NOT OPEN THE LID until the **Test Results** appear on the screen.

Note: *The test will be cancelled if the lid is opened. A test result will not be reported or saved in instrument memory.*

⚠ **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 specimen from the patient. Press '**Run Test**' and restart the test using a new Test Base and Sample Receiver.

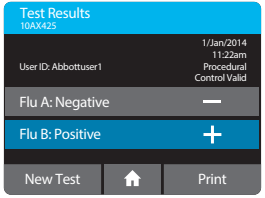
When amplification and detection is complete, the instrument will automatically save the data before advancing to the results screen.



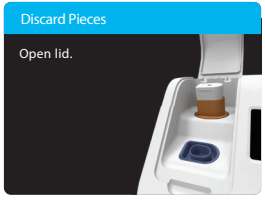
⚠ **Caution:** The test is not saved until the completed result is displayed. Do not open the lid until the results are displayed.

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.



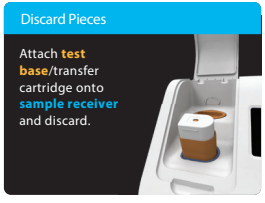
After printing, or if New Test or Home are selected, the instrument will prompt to open the lid and discard the used test pieces.



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.

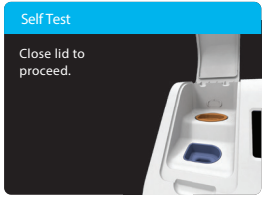
Caution: DO NOT try to remove the Sample Receiver by any other method as there is a risk of spilling the patient specimen.

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 – ID NOW™ INFLUENZA A & B 2

Refer to the ID NOW Influenza A & B 2 Package Insert for Result Interpretation.

LIMITATIONS

- For Prescription Use Only.
- The performance of the ID NOW COVID-19 2.0 test 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 or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if virus present in the specimen is below the detection limit of the test. 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 ID NOW COVID-19 2.0 could affect primer and/or probe binding resulting in failure to detect the presence of the virus. There is a risk of erroneous results (i.e., false negatives) due to the presence of novel, emerging respiratory viral variants (e.g., specific strains or isolates).

- A negative result is presumptive. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.
- A negative test result does not preclude the possibility of infection with other bacteria or viruses.
- Positive and negative predictive values are highly dependent on disease prevalence. False negative test results are more likely during peak activity when prevalence of disease is high. False positive test results are more likely during periods when prevalence of upper respiratory infection is low in the community.
- ID NOW COVID-19 2.0 is intended for testing a swab directly without elution in viral transport media as dilution will result in decreased detection of low positive specimens that are near the limit of detection of the test.
- Puritan® PurFlock Ultra® Flocked Swabs – Standard Tip, Puritan® Mini Rayon Tip, Puritan® PurFlock Ultra® Flocked Swabs – Mini Tip, Copan Rayon (Standard Tip) Swabs, and Jiangsu Changfeng Medical Industry (JCF) Polyurethane Foam Swabs are not suitable for use in this assay.
- Mucin may interfere with COVID-19 detection at levels greater than 1% w/v.
- Zincum gluconium, Zincum aceticum may interfere with COVID-19 detection at levels greater than 10% w/v.
- This test should not be used beyond the expiration date listed on the packaging. Use of expired tests can lead to incorrect results.
- The clinical performance characteristics of this device were established during the 2020-2021 SARS-CoV-2 pandemic, when the Alpha variant was prevalent; due to the propensity of the virus to mutate, new strains emerge over time which may affect the performance of this device and may have serious public health implications. Additional testing with a molecular test and/or sequencing should be considered in situations where a new virus strain or variant is suspected.
- The performance of this device has not been specifically assessed in individuals without signs or symptoms of respiratory infection.
- FluMist was not evaluated to assess potential interference.

PERFORMANCE CHARACTERISTICS

Clinical Study:

Clinical performance characteristics of ID NOW COVID-19 2.0 were evaluated in a multi-site prospective study in the U.S. in which patients were sequentially enrolled and tested. A total of twenty-one (21) sites throughout the U.S. in 2020/2021 participated in the study. A total of 60 different operators, across the sites tested subjects with ID NOW COVID-19 2.0. The study sites and the test operators used in this clinical study were representative of the CLIA waived setting. To be enrolled in the study, patients had to be presenting at the participating study centers showing signs and symptoms of upper respiratory infection. Two nasal or nasopharyngeal swabs were collected from each patient and tested using ID NOW COVID-19 2.0 at all study sites. Three (3) FDA Emergency Use Authorized real-time Polymerase Chain Reaction (RT-PCR) assays for the detection of SARS-CoV-2 were utilized in a composite comparator method for each subject.

At all sites, one nasal or nasopharyngeal swab was tested directly in ID NOW COVID-19 2.0 according to product instructions and the other swab was eluted in Universal Transport Media (UTM). All sites shipped the UTM specimen to a central testing laboratory for RT-PCR testing with the composite comparator.

External control testing, using ID NOW COVID-19 2.0 Positive and Negative Controls, was performed prior to specimen testing each day, at all study sites.

A total of 1,044 nasal or nasopharyngeal swab specimens collected from symptomatic patients were enrolled in this study. Of those, 130 nasal or nasopharyngeal swab specimens did not meet eligibility criteria for the method comparison. The performance of ID NOW COVID-19 2.0 was established with 914 specimens, including 460 anterior nasal swabs and 454 nasopharyngeal swabs collected from individuals showing signs and symptoms of upper respiratory infection.

ID NOW™ COVID-19 2.0 PERFORMANCE

ID NOW COVID-19 2.0 performance, from individual symptomatic patients, including 95% confidence intervals (Wilson score), is provided below.

ID NOW™ COVID-19 2.0 Performance against Composite Comparator (Nasal and Nasopharyngeal Swabs Combined)

ID NOW™ COVID-19 2.0	Composite Comparator Result		
	Positive	Negative	Total
Positive	254	10	264
Negative	23	627	650
Total	277	637	914
Positive Agreement: 254/277	91.7% (95% CI: 87.8% - 94.4%)		
Negative Agreement: 627/637	98.4% (95% CI: 97.1% - 99.1%)		

During the clinical study, the initial invalid rate (before repeat testing per the product instructions) was 0.67% (7/1,042) (95% CI: 0.33% to 1.38%). After repeat testing per the product instructions, the invalid rate was 0.19% (2/1,042) (95% CI: 0.05% to 0.70%). Of the 1,044 specimens enrolled, two (2) were ineligible for the invalid rate analysis.

ANALYTICAL STUDIES

Reproducibility

A reproducibility study of ID NOW COVID-19 2.0 was conducted by nine operators at three sites over five different days using panels of four SARS-CoV-2 samples contrived in clinical matrix.

A total of 450 replicates were tested per site. The Reproducibility Study site-to-site qualitative results (agreements with expected results) are presented in the table below:

Specimen Category		Site			Overall Agreement and 95% CI	
		Site 1	Site 2	Site 3		
1.16x LoD	Percent Agreement	97.8%	94.4%	96.7%	96.3% (260/270)	93.3%, 98.0%
	Count	88/90	85/90	87/90		
1.74x LoD	Percent Agreement	98.9%	96.6%	98.9%	98.1% (263/268)	95.7%, 99.2%
	Count	89/90	86/89[2]	88/89[2]		
0.0235x LoD (High Negative)	Percent Agreement	87.8%	90.9%	90.0%	89.6% (240/268)	85.3%, 92.7%
	Count	79/90	80/88[2]	81/90		
Virus Free Negative[1]	Percent Agreement	100.0%	100.0%	98.9%	99.6% (267/268)	97.9%, 99.9%
	Count	90/90	89/89[2]	88/89[2]		

Specimen Category		Site			Overall Agreement and 95% CI	
		Site 1	Site 2	Site 3		
Positive Control	Percent Agreement	100%	100%	100%	100% (137/137)	97.3% - 100%
	Count	45/45	46/46	46/46		
Negative Control	Percent Agreement	100%	100%	100%	100% (137/137)	97.3% - 100%
	Count	45/45	46/46	46/46		

[1]Percent Agreement correlates to the percent of negative results.

[2]Sample(s) excluded due to protocol deviation.

Analytical Sensitivity (Limit of Detection)

ID NOW COVID-19 2.0 limit of detection (LoD) in natural nasal swab matrix was determined by evaluating different concentrations of inactivated SARS-CoV-2 virus (USA-WA1/2020).

Presumed negative natural nasal swab specimens were eluted in Universal Transport Media. Swab eluates were combined and mixed thoroughly to create a clinical matrix pool to be used as the diluent. SARS-CoV-2 virus was diluted in this natural nasal matrix pool to generate virus dilutions for testing.

A point estimate was determined using Probit analysis and the LoD was confirmed as the lowest concentration that was detected ≥95% of the time.

The confirmed LoD in natural nasal swab matrix is presented in the table below. Equivalent performance was also verified in natural nasopharyngeal swab matrix.

Limit of Detection (LoD) Study Results

Virus	Swab Matrix	Claimed LoD	
		(copies/swab)	(copies/reaction)
SARS-CoV-2 RNA	Nasal Swab	500	20
	Nasopharyngeal Swab	500	20

Analytical Reactivity (Inclusivity)

Wet Testing

An Analytical Reactivity (inclusivity) study was performed to determine whether ID NOW COVID-19 2.0 is able to detect a variety of SARS-CoV-2 strains.

Vendor provided stocks of SARS-CoV-2 strains were diluted in natural nasal swab matrix to approximately 1 – 3 times the limit of detection. Contrived swab samples were prepared by coating 50 microliters of virus dilution onto each swab.

A concentration level was considered “reactive/positive” in this study if all five replicates generated a positive result. If 5/5 COVID-19 positive results were not obtained across all three device lots at the concentration tested, the isolate was tested at increasing concentrations until 5/5 positive results were obtained.

ID NOW COVID-19 2.0 detected all strains tested at the concentrations indicated in the table below:

Analytical Reactivity Study Results

SARS-CoV-2 Strain	Detected Concentration (copies/reaction)	Detected Concentration (copies/swab)
Hong Kong/ VM200001061/2020	60	1,500
Italy-INMI1	60	1,500
SARS-CoV-2-USA- WA1/2020	58.3	1,457.5
P.2 (Zeta)	26	650
P.1 (Gamma)	61.1	1,527.5
B.1.1.7 (Alpha)	45.9	1,147.5
B.1.429 (Epsilon)	18.7	467.5
B.1.1.318	28.8	720
WA1-wt	41	1,025
B.1.351 (Beta)	23	575
B.1.1.7 (Alpha)	100.2	2,505
B.1.617.1 (Kappa)	19	475
B.1.617.1 (Kappa)	40.5	1,012.50
B.1.617.2 (Delta)	22.4	560
B.1.617.2 (Delta)	20.7	517.5
B.1.1.529 (Omicron)	60	1,500
BA.2.12.1 (Omicron)	60	1,500
BA.4.6 (Omicron)	60	1,500
BA.5.1 (Omicron)	60	1,500
BA.5.2 (Omicron)	80	2,000
BE.1 (Omicron)	60	1,500
BF.5 (Omicron)	100	2,500
BF.7 (Omicron)	80	2,000
BA.4.1 (Omicron)	60	1,500
BQ.1 (Omicron)	60	1,500
BQ.1.1 (Omicron)	60	1,500
XBB.1 (Omicron)	80	2,000
XBB.6 (Omicron)	60	1,500

In Silico Analysis

An alignment was performed with the oligonucleotide primer and probe sequences of the ID NOW COVID-19 2.0 with all publicly available SARS-CoV-2 genomic sequences submitted to NCBI Genbank and GISAID databases between December 1, 2019 and December 3-4, 2021. A total of 431,147 high quality SARS-CoV-2 sequences (<1% Ns, unknown

or unidentified nucleotides) plus a reference genome were available from NCBI GenBank, and 4,252,920 from GISAID databases. Both datasets contained sequences obtained from human hosts only. 217,267 sequences were present in both databases. To avoid redundancy only the GISAID copies of the duplicated sequences were retained for analysis bringing the total number of high quality human SARS-CoV-2 sequences available from both databases to 4,466,800. Of the total number of sequences analyzed, 3,274 sequences contained at least 1 ambiguous or unidentified nucleotide within the target region, bringing the total number of isolates suitable for inclusivity analysis down to 4,463,526. From this analysis 99.58% of the sequences provided 100% homology to the ID NOW COVID-19 2.0 primer and probe sequences.

An additional alignment was performed with the oligonucleotide primer and probe sequences of the ID NOW COVID-19 2.0 with all publicly available SARS-CoV-2 genomic sequences collected within the United States and submitted to the GISAID database between October 17, 2022 and April 17, 2023. The dataset contained sequences obtained from human hosts only and totaled 382,309 sequences. ID NOW COVID-19 2.0 provided 100% sequence homology across 99.51% of the sequences.

Analytical Specificity (Cross Reactivity)

To determine the analytical specificity of ID NOW COVID-19 2.0, 38 commensal and pathogenic microorganisms (24 viruses, 12 bacteria, and 2 yeasts) that may be present in the nasal cavity or nasopharynx were tested. All of the following microorganisms were negative when tested at concentrations ranging from 10^6 to 10^7 cells/mL, IFU/mL, or CFU/mL (bacteria), 10^5 to 10^8 $TCID_{50}$/mL, copies/mL, GE/mL or IU/mL (viruses), and 10^6 to 10^7 cells/mL or CFU/mL (yeast).

Viruses	Bacteria	Yeast
Human coronavirus HKU1	*Bordetella pertussis*	*Candida albicans*
Human adenovirus 1	*Legionella pneumophila*	*Pneumocystis jirovecii (PJP)*
Human adenovirus 7	*Staphylococcus aureus*	
Human parainfluenza virus 2	*Mycoplasma pneumoniae*	
Human parainfluenza virus 3	*Haemophilus influenzae*	
Rhinovirus 1	*Mycobacterium tuberculosis* avirulent	
Rhinovirus 2	*Staphylococcus epidermidis*	
Human echovirus 7	*Streptococcus salivarius*	
Human metapneumovirus (hMPV)	*Streptococcus pneumoniae*	
Human influenza A/ California/7/2009	*Streptococcus pyogenes*	
Human influenza A/ Texas/50/2012	*Pseudomonas aeruginosa*	
Human influenza B/ Wisconsin/1/2010	*Chlamydia pneumoniae*	
Human influenza B/ Malaysia/2506/04		

Viruses	Bacteria	Yeast
Respiratory syncytial virus A (RSV A)		
Respiratory syncytial virus B (RSV B)		
Enterovirus 70		
Human parainfluenza virus 4a		
Human parainfluenza virus 1		
Mumps virus		
Human coronavirus 229E		
Human coronavirus OC43		
Human coronavirus NL63		
MERS-coronavirus		
SARS-coronavirus		

In addition, *in silico* analysis was performed to determine whether there is any significant overlap between ID NOW COVID-19 2.0 target nucleic acid sequence and the genomes of the following upper respiratory tract microorganisms. Based on this analysis, none of the evaluated microorganisms are predicted/expected to cross-react with the ID NOW COVID-19 2.0.

Viruses	Bacteria	Yeast
Human coronavirus 229E	*Bordetella pertussis*	*Candida albicans*
Human coronavirus OC43	*Bordetella bronchiseptica*	*Pneumocystis jirovecii (PJP)*
Human coronavirus HKU1	*Chlamydia pneumoniae*	
Human coronavirus NL63	*Chlamydia trachomatis*	
SARS-coronavirus	*Corynebacterium diphtheriae*	
MERS-coronavirus	*Escherichia coli*	
Human adenovirus 1	*Haemophilus influenzae*	
Human adenovirus 2	*Klebsiella pneumoniae*	
Human adenovirus 3	*Lactobacillus plantarum*	
Human adenovirus 4	*Legionella pneumophila*	
Human adenovirus 5	*Moraxella catarrhalis*	
Human adenovirus 7	*Mycobacterium tuberculosis*	
Human adenovirus 11	*Mycoplasma pneumoniae*	
Human adenovirus 14	*Neisseria gonorrhoeae*	
Human adenovirus 31	*Neisseria meningitidis*	
Cytomegalovirus	*Neisseria mucosa*	
Echovirus E6	*Proteus mirabilis*	
Echovirus E7	*Proteus vulgaris*	
Echovirus E9	*Pseudomonas aeruginosa*	
Echovirus E11	*Staphylococcus aureus*	
Epstein-Barr virus	*Staphylococcus epidermidis*	

Viruses	Bacteria	Yeast
Human metapneumovirus (hMPV)	*Streptococcus pneumoniae*	
Influenza A	*Streptococcus pyogenes*	
Influenza B	*Streptococcus salivarius*	
Measles virus		
Mumps virus		
Parainfluenza Type 1		
Parainfluenza Type 2		
Parainfluenza Type 3		
Parainfluenza Type 4a or 4b		
RSV A		
RSV B		
Rhinovirus: Coxsackievirus B4 Human rhinovirus B35 Enterovirus 70 (VR-836) Other rhinoviruses		

Microbial Interference

ID NOW COVID-19 2.0 test performance in the presence of non-SARS-CoV-2 respiratory pathogens was evaluated. Vendor provided stocks of SARS-CoV-2 virus were diluted in clinical matrix to 1.74 times the limit of detection and tested in the presence of RSV A, RSV B, Flu A/California, Flu A/Texas, Flu B/Wisconsin, and Flu B/Malaysia at concentrations shown below; all others were tested with SARS-CoV-2 virus diluted in clinical matrix to 3 times the limit of detection. Contrived SARS-CoV-2 positive swab specimens were prepared by coating 50 microliters of virus dilution onto each swab. The following panel of non-SARS-CoV-2 viruses, bacteria, and yeast were tested at the concentration provided in the table below and were found not to affect test performance.

Panel	Concentration
Viruses	
Human adenovirus 1	1.0×10^5 $TCID_{50}$/mL
Human adenovirus 7	1.0×10^5 $TCID_{50}$/mL
Human coronavirus 229E	1.0×10^5 $TCID_{50}$/mL
Human coronavirus NL63	1.17×10^5 $TCID_{50}$/mL
Human coronavirus OC43	1.0×10^5 $TCID_{50}$/mL
Human coronavirus HKU1	1.0×10^8 copies/mL
MERS-coronavirus	1.0×10^5 GE/mL
SARS-coronavirus	2.0×10^5 copies/mL
Enterovirus 70	1.0×10^5 $TCID_{50}$/mL
Human echovirus 7	1.0×10^5 $TCID_{50}$/mL

Panel	Concentration
Human metapneumovirus (hMPV)	1.0 x 10^5 U/mL
Human parainfluenza virus 1	2.0 x 10^5 $TCID_{50}$/mL
Human parainfluenza virus 2	1.0 x 10^5 $TCID_{50}$/mL
Human parainfluenza virus 3	1.0 x 10^5 $TCID_{50}$/mL
Human parainfluenza virus 4a	1.0 x 10^5 $TCID_{50}$/mL
RSV A	1.0 x 10^5 IU/mL
RSV B	1.0 x 10^5 IU/mL
Human influenza A/California/7/2009	1.0 x 10^5 IU/mL
Human influenza A/Texas/50/2012	1.0 x 10^5 IU/mL
Human influenza B/Wisconsin/1/2010	1.0 x 10^5 IU/mL
Human influenza B/Malaysia/2506/04	1.0 x 10^5 IU/mL
Mumps virus	1.0 x 10^5 $TCID_{50}$/mL
Rhinovirus 1	1.0 x 10^5 $TCID_{50}$/mL
Rhinovirus 2	1.0 x 10^5 $TCID_{50}$/mL
Bacteria	
Bordetella pertussis	1.0 x 10^6 CFU/mL
Chlamydia pneumoniae	1.0 x 10^6 IFU/mL
Haemophilus influenzae	1.0 x 10^6 CFU/mL
Legionella pneumophila	1.0 x 10^6 CFU/mL
Mycobacterium tuberculosis	1.0 x 10^6 CFU/mL
Mycoplasma pneumoniae	1.0 x 10^6 CFU/mL
Pseudomonas aeruginosa	1.0 x 10^6 CFU/mL
Staphyloccocus aureus	1.0 x 10^6 CFU/mL
Staphylococcus epidermidis	1.0 x 10^6 CFU/mL
Streptococcus salivarius	1.0 x 10^6 CFU/mL
Streptococcus pneumoniae	1.0 x 10^6 CFU/mL
Streptococcus pyogenes	1.0 x 10^6 CFU/mL
Yeast	
Candida albicans	1.0 x 10^6 cells/mL
Pneumocystis jirovecii (PJP)	1.0 x 10^6 CFU/mL

Interfering Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the nasal cavity or nasopharynx, were evaluated with ID NOW COVID-19 2.0 at the concentrations listed below in a negative sample and in a positive sample with SARS-CoV-2 concentrations at 3 times the limit of detection and were found not to affect test performance.

Substance	Concentration
Mucin[1]	1% w/v
Whole Blood	1% v/v
Post nasal lavage discharge	1% v/v
Phenylephrine	20% v/v
Oxymetazoline	20% v/v
Sodium chloride with preservatives	20% v/v
Cromolyn sodium	20% v/v
Alkalol	20% v/v
Phenol	20% v/v
Zincum gluconium, Zincum aceticum[2]	10% w/v
Galphimia glauca, Histaminum hydrochloricum, Luffa opperculata, Sulfur	20% v/v
Beclomethasone	0.068 mg/mL
Fluticasone propionate	20% v/v
Dexamethasone	0.48 mg/mL
Flunisolide	0.04 mg/mL
Triamcinolone	0.04 mg/mL
Budesonide	0.051 mg/mL
Mometasone	0.04 mg/mL
Zanamivir (Relenza)	0.284 mg/mL
Mupirocin	4.3 mg/mL
Tobramycin	1.44 mg/mL
Remdesivir (Brand Name: Veklury)	0.12 mg/mL
Throat Lozenge (Benzocaine, Menthol)	0.63 mg/mL
Toothpaste (Fluoride)	1% w/v
Tobacco	0.1% w/v
Nicotine	0.1% w/v
Oral Rinse	10% v/v
Leukocytes	1.1×10^6 cells/mL
Fluticasone furoate	20% v/v

[1]Mucin at 2% w/v in the absence of SARS-CoV-2 yielded 1/5 invalid result and therefore was tested at a lower concentration.

[2]When Zincum gluconium, Zincum aceticum was tested at 20% w/v in the presence of SARS-CoV-2, 1/5 invalid result was generated and therefore was tested at a lower concentration.

Carry-Over/Contamination

An analytical carry-over study was performed to demonstrate that when recommended laboratory practices are followed, there is little risk of false positive results caused by carry-over or cross-contamination in the ID NOW COVID-19 2.0 . Vendor provided stocks of inactivated SARS-CoV-2 virus were diluted in UTM to approximately 30 times the limit of detection. Contrived COVID-19 positive swab specimens were prepared by coating 50 microliters of virus dilution onto each swab. Testing of the contrived positive swabs was alternated with testing of a negative swab sample for a total of 15 rounds. There were no false positive results obtained.

CLIA Waiver Studies:

The same data from the prospective study described in the Performance Characteristics section above were used to determine the accuracy of ID NOW COVID-19 2.0 when used by untrained operators at CLIA waived sites. In this study testing was conducted by 60 operators across twenty-one (21) study sites that were representative of CLIA waived settings. No training on the use of the test was provided to the operators. Overall, 914 specimens, including 460 anterior nasal swab and 454 nasopharyngeal swab specimens were tested with ID NOW COVID-19 2.0 and the results were compared to three (3) FDA Emergency Use Authorized real-time Polymerase Chain Reaction (RT-PCR) assays for the detection of SARS-CoV-2. The performance of ID NOW COVID-19 2.0 is presented in the clinical study section above.

Study with Samples Near the Limit of Detection

As part of the Reproducibility study, the performance of ID NOW COVID-19 2.0 was evaluated with weakly reactive samples when tested by untrained users. Randomized blind-coded panels, containing negative and low positive (close to the limit of detection {LoD} or assay cutoff) samples were tested with ID NOW COVID-19 2.0 at 3 sites that were representative of CLIA waived settings (538 tests in total). Nine untrained users participated in the study. The testing was conducted over a minimum of 5 days at each site, and was integrated into the users' daily work flow. The performance of ID NOW COVID-19 2.0 in the hands of untrained users with negative samples and samples near the assay cutoff was acceptable, as shown in the table below.

ID NOW COVID-19 2.0 Testing of Samples Near the Assay Cutoff (LoD)

Sample Type	% Agreement with Expected Results	95% CI
1.16x LoD	96.3% (260/270)	93.3%, 98.0%
True Negative	99.6% (267/268)[1]	97.9%, 99.9%

[1]Sample(s) excluded due to protocol deviation.

Using risk analysis as a guide, analytical flex studies were conducted on ID NOW COVID-19 2.0. The testing evaluated various sources of potential human errors and environmental factors that could affect the accuracy of results, including those related to sample handling, reagent handling, and extremes of operational conditions. The studies demonstrated that the test is robust to usage variation and environmental factors that may be encountered.

SYMBOLS

 Fragile, handle with care	BASE Test Base
CARTRDG Transfer Cartridge	RCVR Sample Receiver
Rx Only Prescription Only (Applies to US only)	 Caution, consult accompanying documents.
IVD *In Vitro* Diagnostics	

ORDERING and CONTACT INFORMATION

Reorder numbers:

192-000: ID NOW COVID-19 2.0 Test Kit

192-080: ID NOW COVID-19 2.0 External Control Kit

190-010: COVID-19 Swab Transport Tube Accessory Pack

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

REFERENCES

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

Abbott

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www.globalpointofcare.abbott

IVD

IN192000 Rev. 3 2023/09
SAP: 40003874

Abbott
ID NOW
COVID-19 2.0

PI - EN

Size:
Flat size: 8.375 in x 10.75 in
Finished: 8.375 in x 5.375 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

PMS 185 U
Red

PN: IN192000
Rev: 3
SAP: 40003874

Date of Last Revision:
3.9 2023/09/20