Abbott

ID NOW™

COVID-19 2.0

PRODUCT INSERT

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

INTENDED USE

ID NOW™ COVID-19 2.0 assay 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 viral RNA in direct nasal or nasopharyngeal swabs from individuals who are suspected of COVID-19 with or without symptoms.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory samples during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.

If inconsistent with clinical signs and symptoms or necessary for patient management, negative results may be treated as presumptive and should be tested with different authorized or cleared molecular tests. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

ID NOW COVID-19 2.0 is intended for use by trained operators who are proficient in performing tests using the ID NOW Instrument. For professional, near-patient testing. Not for self-testing.

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.

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. The ID NOW COVID-19 2.0 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 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 sample to the Test Base, and the ID NOW Instrument.

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

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

REAGENTS and MATERIALS

Materials Provided

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 sample extract from the Sample Receiver to the Test Base.
Patient Swabs (24):	Sterile swabs (foam) for use with the ID NOW COVID-19 2.0 Test.
Positive Control Swab (1):	The positive control swab is coated with inactivated SARS-CoV-2 virus and 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 (1)	
Quick Reference Instructions (1)	

Materials Required but not Provided

ID NOW Instrument

Nasopharyngeal Swabs

Optional Materials Available but not Required

COVID-19 Swab Transport Tube Accessory Pack

ID NOW COVID-19 2.0 Control Swab Kit

PRECAUTIONS

1. For *in vitro* diagnostic use.
2. To be used in conjunction with the ID NOW Instrument.
3. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
4. Proper sample collection, storage and transport are essential for correct results.
5. Leave test pieces sealed in their foil pouches until just before use.
6. Do not tamper with test pieces prior to or after use.
7. Do not use kit past its expiration date.
8. Do not mix ID NOW COVID-19 2.0 components from different kit lots.
9. Solutions used to make the positive control swab are inactivated using standard methods. However, patient samples, controls, and test pieces should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
10. Wear clean personal protection equipment and gloves when running each test. Change gloves between the handling of specimens suspected of COVID-19.
11. **If any assay components are dropped, cracked, found to be damaged or opened when received, DO NOT USE and discard. Do not use scissors or sharp objects to open foil pouches as damage to test pieces can occur.**
12. Do not open the Sample Receiver before placing in the instrument. It will prohibit the Elution Buffer from reaching temperature and may impact test performance.
13. If the Sample Receiver is spilled while opening, clean the instrument per instructions provided in the instrument User Manual and cancel test. Repeat test with a new Sample Receiver.
14. All test pieces must be removed from the instrument according to removal instructions displayed on the instrument and disposed of according to country and local requirements. **Pieces must not be separated once they are assembled.**
15. All test pieces are single use items. Do not use with multiple specimens.
16. Once reacted, the Test Base contains large amounts of amplified target (Amplicon). **Do not disassemble the Test Base and Transfer Cartridge.** In the case of a positive sample, this could lead to amplicon leakage and potential ID NOW COVID-19 2.0 false positive test results.
17. At a low frequency, clinical samples can contain inhibitors that may generate invalid results. Site to site invalid rates may vary.
18. Due to the high sensitivity of the assays run on the instrument, contamination of the work area with previous positive samples may cause false positive results. Handle samples according to standard laboratory practices. Clean instruments and surrounding surfaces according to instructions provided in the cleaning section of the instrument User Manual. Refer to Section 1.6, Maintenance & Cleaning, for further information.

STORAGE and STABILITY

Store kit at 2-30°C. The ID NOW COVID-19 2.0 kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use. Test components 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. 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 2.0 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 2.0 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. It is recommended to test these swabs once with each new shipment received and once for each untrained operator. Further controls may be tested in order to conform with local, state and/or federal regulations, accrediting groups, or your lab's standard Quality Control procedures.

If additional Positive or Negative Control Swabs are required, the ID NOW COVID-19 2.0 Control Swab Kit can be purchased separately. The 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 sample handling/storage/transport may yield erroneous results. Nasal swab samples may be collected by trained test administrators or by patients under supervision of test administrators. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html.

ID NOW COVID-19 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 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.

Nasal Swab

For optimal test performance, use the swabs provided in the test kit. Alternatively, Puritan Rayon (regular tip), and HydraFlock® Flocked swab (standard tip) swabs can be used to collect nasal swab samples.

Puritan PurFlock Standard Tip Ultra Flocked Swabs, Copan Rayon Standard Tip Swabs, and Jiangsu Changfeng Medical Industry Foam Swabs are not suitable for use in this assay.

To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (1 to 1.5 cm into the nostril). Rotate the swab several times against the nasal wall then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril.

Nasopharyngeal Swab

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

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

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

To ensure proper collection, the swab should be passed a distance that is halfway of that from the nose to the tip of the ear. This is about half the length of the swab. **DO NOT USE FORCE** while inserting the swab. The swab should travel smoothly with minimal resistance; if resistance is encountered, withdraw the swab a little bit without taking it out of the nostril. Then elevate the back of the swab and move it forward into the nasopharynx.

SPECIMEN TRANSPORT and STORAGE

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, dispose of sample. A new sample must be collected for testing. **DO NOT RETURN THE SWAB TO ITS ORIGINAL PACKAGING.**

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

A single patient sample 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.

- The 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 sample types for sequential testing.
- Sequential ID NOW COVID-19 2.0 and Influenza A & B 2 testing requires an ID NOW Influenza A & B 2 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 sample.

After performing the ID NOW COVID-19 2.0 Test Procedure beginning on page 6, proceed to page 13 for the ID NOW Influenza A & B 2 Test Procedure.

TEST PROCEDURE – ID NOW™ COVID-19 2.0

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

If a sequential ID NOW COVID-19 2.0 followed by an ID NOW Influenza A & B 2 test is desired, follow the testing procedure as described below for the ID NOW COVID-19 2.0 assay prior to beginning testing with the ID NOW Influenza A & B 2 assay. **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 13.

Before testing with ID NOW COVID-19 2.0:

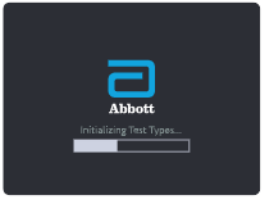
- **Put on a clean pair of gloves.**
- Allow all samples to reach room temperature.
- Allow all test pieces to reach room temperature.
- Check that a reagent pellet is visible at the bottom of each of the reaction tubes prior to inserting the Test Base in the ID NOW Instrument. Do not use the Test Base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

To Perform a Test:

Step 1

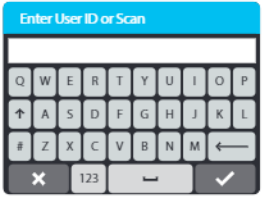
Turn on the ID NOW Instrument - press the power button ⏻ on the side of the instrument.

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



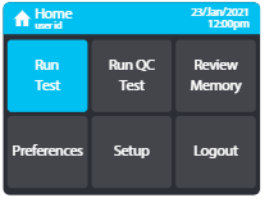
Enter User ID

Press '✓' after entry.



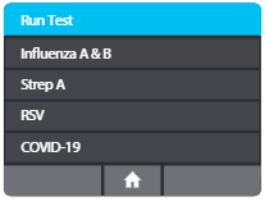
Touch 'Run Test'

This will begin the test process.



Touch 'COVID-19'

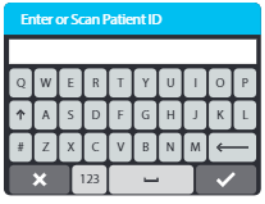
This starts a COVID-19 test.



Enter Patient ID using on screen keyboard or barcode scanner.

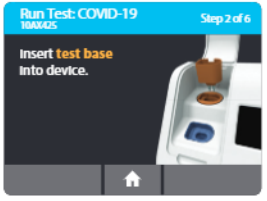
Touch '✓'.

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



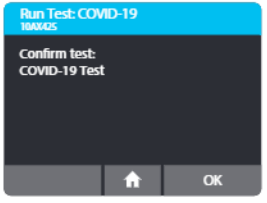
Step 2

Open the Lid and Gently Insert Orange Test Base into Orange Test Base holder



Confirm that the correct test is displayed on the screen.

Touch 'OK' to proceed.

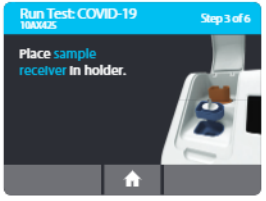


⚠ **Caution: Once the Test Base has been placed in the holder, the user will have 3 minutes to confirm the test. If the test is not confirmed within 3 minutes, the instrument will time out and the Test Base must be removed and discarded.**

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.

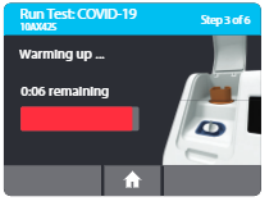
Step 3

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.

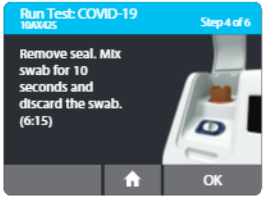


⚠ **Caution: DO NOT REMOVE THE FOIL SEAL UNTIL PROMPTED BY THE INSTRUMENT.**
DO NOT close the lid or insert the sample until prompted by the instrument.

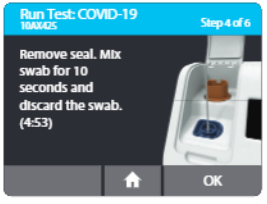
Step 4

Direct Nasal 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.**



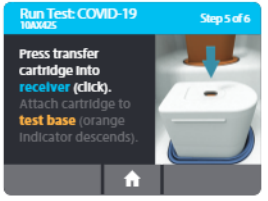
Immerse the swab head completely in the Sample Receiver buffer and with a strong swirling motion, mix the swab in the liquid for 10 seconds. This helps remove the sample from the swab. Lift the swab out of the liquid and press the swab head against the side of the Sample Receiver to remove excess liquid.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

Discard the swab into a biohazard waste container.

Step 5a

Press the White Transfer Cartridge into the Blue Sample Receiver.
With both hands, press down firmly on the top of the White Transfer Cartridge.

Listen for a click.

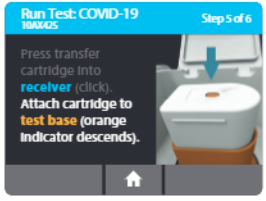


When the Transfer Cartridge is properly attached to the Sample Receiver, the orange indicator on the Transfer Cartridge will rise. If the orange indicator does not rise, continue pushing onto the Sample Receiver until it does.

⚠ **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 White Transfer Cartridge to the Test Base. With both hands, press down firmly on the top of the White Transfer Cartridge. Closely observe the orange indicator located in the center of the White Transfer Cartridge.

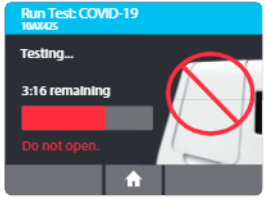


When the Transfer Cartridge is properly attached to the Test Base, the orange indicator on the Transfer Cartridge will descend. If the orange indicator does not descend, continue pushing onto the Test Base until it does.

⚠ **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.

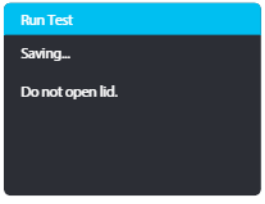


DO NOT OPEN THE LID until the **Test Complete** message appears on the screen.

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

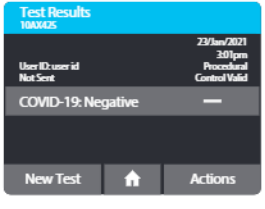
⚠ **Caution: This screen will be displayed for 30 seconds once the Transfer Cartridge is detected. If the instrument does not detect that the lid has been closed by then, it will time out and all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. The instrument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

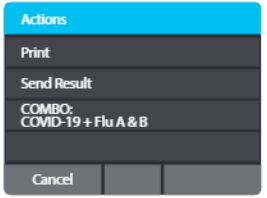
The **Test Results** screen displays either a Negative or Positive result for a successfully completed test. If a test error occurs, the display will read 'Invalid'. Refer to the Result Interpretation Section for Interpretation of Results.



Press New Test or Home to complete testing with this patient sample.

Press Actions to print or send test results or to initiate an ID NOW Influenza A & B 2 test utilizing the same Blue Sample Receiver.

If COMBO: COVID-19 + Flu A & B is selected, proceed to Page 14, TEST PROCEDURE - Workflow for Sequential ID NOW COVID-19 2.0 and ID NOW Influenza A & B 2 Assays. Do not remove the USED Blue Sample Receiver.

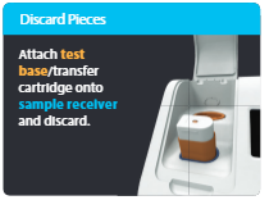


After printing, or if New Test or Home are selected, the instrument will prompt to open the lid and discard the used test pieces.

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.

⚠ **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.**

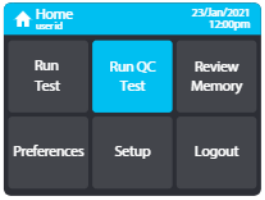
Close the lid. The instrument will then run a Self-Test before showing the Home screen or Enter Patient ID screen, depending on the previous selection.

Remove and dispose of gloves.

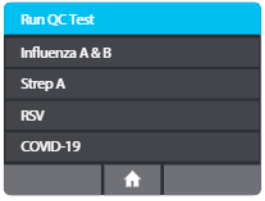
Quality Control Swab Test Procedure

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

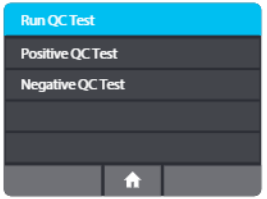
1 **Touch 'Run QC Test'**



2 **Touch 'COVID-19'**



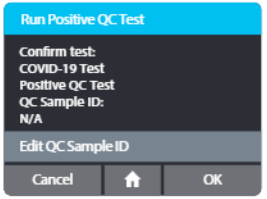
3 Select the QC Test to be Run



4 Confirm Test

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

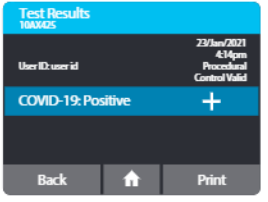
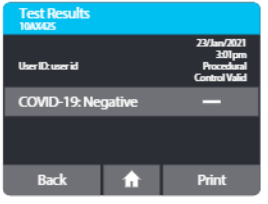
The user has the option to enter an ID for the QC Sample being run.

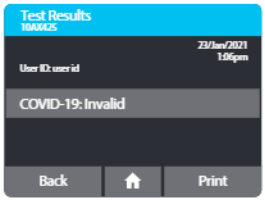
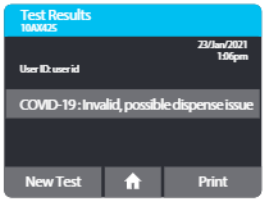


Note: *The QC test is run in the same manner as a Direct Nasal/ Nasopharyngeal Swab Patient Test. See the* ***To Perform a Test*** *section above for step by step instructions for direct nasal/nasopharyngeal swab samples.*

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.
	**COVID-19 Negative** A negative result does not rule out co-infections with other pathogens.

Instrument Display	Interpretation of Results and Follow-up Actions
 	**The presence or absence of COVID-19 Viral RNAs cannot be determined.** "Invalid, possible dispense issue" will display if an insufficient amount of sample was transferred to the test base. Repeat testing of the sample using new test components. If repeated Invalid results are obtained, results should be confirmed by another method prior to reporting the results.

If an Invalid result is received, one additional test may 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 testing repeated using a new patient sample.

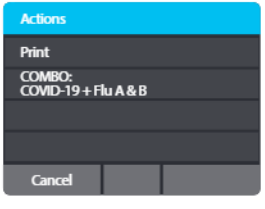
TEST PROCEDURE - WORKFLOW for SEQUENTIAL ID NOW™ COVID-19 2.0 and ID NOW™ INFLUENZA A & B 2 ASSAYS

To Perform a Test:

Step 1

After selecting **COMBO: COVID-19 + Flu A & B** the instrument will prompt to open the lid and discard the used Orange Test Base and Transfer Cartridge.

Remove the UNUSED Blue **ID NOW Influenza A & B 2 Sample Receiver** from the ID NOW Influenza A & B 2 test kit.



While holding the UNUSED Blue Sample Receiver, carefully remove the foil seal.

⚠ **Caution: Do not spill or touch the liquid in the Sample Receiver.**

Lift the USED **ID NOW COVID-19 2.0** Orange Transfer Cartridge attached to the Test Base from the instrument and firmly press them into the UNUSED Blue **ID NOW Influenza A & B 2 Sample Receiver**.

The connected test pieces can now be disposed of according to federal, state, and local regulations.

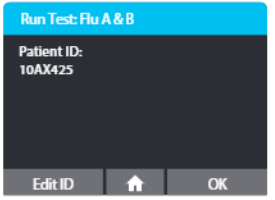
⚠ **Caution: DO NOT disassemble the Transfer Cartridge and the Test Base before disposal.**

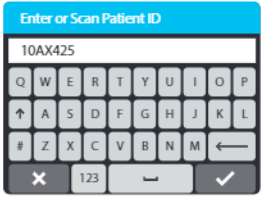
Close the lid. The instrument will then run a Self-Test before showing the Home screen or Enter Patient ID screen, depending on the previous selection. The Sample Receiver can remain in the instrument during the instrument self-test.

Remove and dispose of gloves.

Verify that the Patient ID was entered correctly.

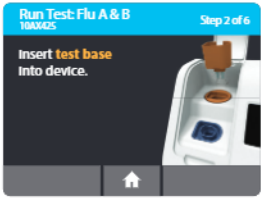
Touch Edit ID to scan or enter a new Patient ID, then touch '✓' to confirm entry.





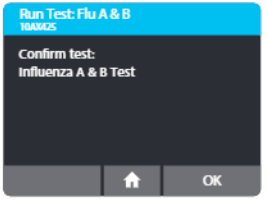
Step 2

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



Confirm that the correct test is displayed on the screen.

Touch 'OK' to proceed.



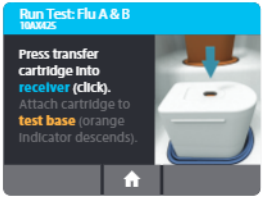
⚠ **Caution: Once the Test Base has been placed in the holder, the user will have 10 minutes to confirm the test. If the test is not confirmed within 10 minutes, the instrument will time out and the Test Base must be removed and discarded.**

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 3a

Press the White Transfer Cartridge into the Blue Sample Receiver. With both hands, press down firmly on the top of the White Transfer Cartridge.

Listen for a click.

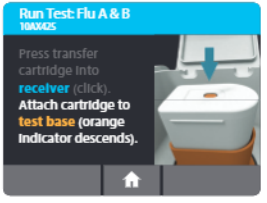


When the Transfer Cartridge is properly attached to the Sample Receiver, the orange indicator on the Transfer Cartridge will rise. If the orange indicator does not rise, continue pushing onto the Sample Receiver until it does.

⚠ **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 3b

Lift and then connect the White Transfer Cartridge to the Test Base. With both hands, press down firmly on the top of the White Transfer Cartridge. Closely observe the orange indicator located in the center of the White Transfer Cartridge.

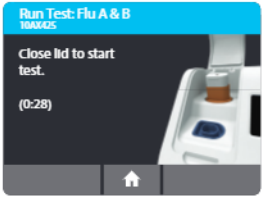


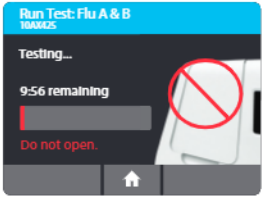
When the Transfer Cartridge is properly attached to the Test Base, the orange indicator on the Transfer Cartridge will descend. If the orange indicator does not descend, continue pushing onto the Test Base until it does.

⚠ **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 4

Close the Lid.



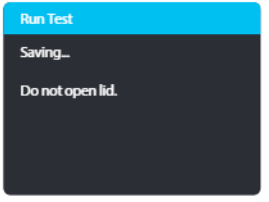


DO NOT OPEN THE LID until the **Test Complete** message appears on the screen.

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

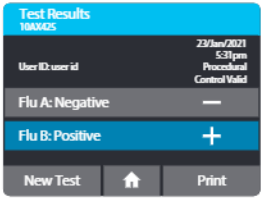
⚠ **Caution: This screen will be displayed for up to 30 seconds once the Transfer Cartridge is detected. If the instrument does not detect that the lid has been closed by then, it will time out and all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. The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

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.



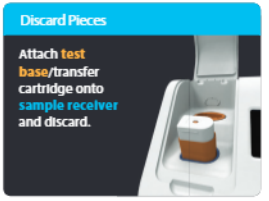
Press Print to print test results. Press New Test to run another test. Press Home to return to the Home screen.

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.



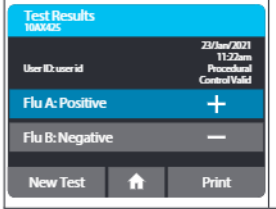
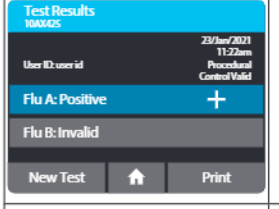
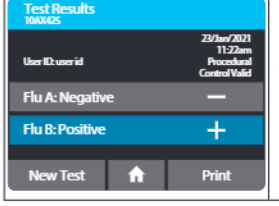
⚠ **Caution: DO NOT disassemble the Transfer Cartridge and the Test Base before disposal.**

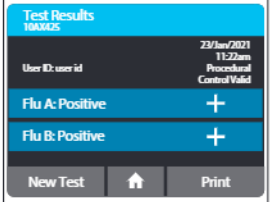
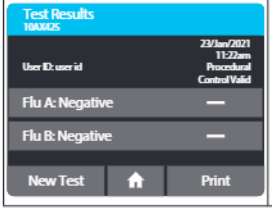
Close the lid. The instrument will then run a Self-Test before showing the Home screen or Enter Patient ID screen, depending on the previous selection.

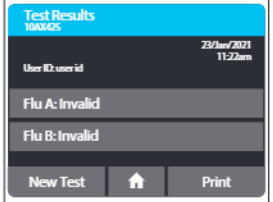
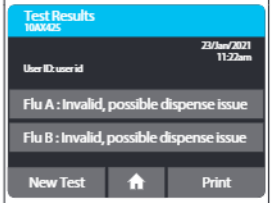
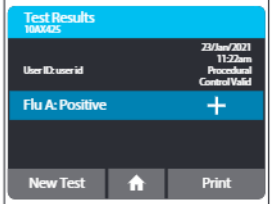
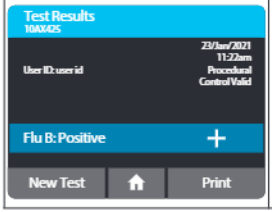
Remove and dispose of gloves.

RESULT INTERPRETATION – ID NOW™ INFLUENZA A & B 2

When the test is complete, the results are clearly displayed on the instrument screen. An individual result for both influenza A and influenza B will be provided.

Instrument Display	Interpretation of Results and Follow-up Actions
	**Flu A Viral RNA Detected; Flu B Viral RNA Not Detected** This result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.
	**Flu A Viral RNA Detected; The presence or absence of Flu B Viral RNA cannot be determined** This result does not rule out co-infections with other pathogens or identify any specific influenza A virus subtype.
	**Flu B Viral RNA Detected; Flu A Viral RNA Not Detected** This result does not rule out co-infections with other pathogens or identify any specific influenza B virus lineage.

Instrument Display	Interpretation of Results and Follow-up Actions
	**Flu A Viral RNA Detected; Flu B Viral RNA Detected** Dual infections of Flu A and Flu B are rare. Repeat testing with a new specimen. If the results is still dual positive, repeat testing with another method before reporting results. This result does not rule out co-infections with other pathogens or identify any specific influenza A or influenza B virus lineage.
	**Flu A Viral RNA Not Detected; Flu B Viral RNA Not Detected**

Instrument Display	Interpretation of Results and Follow-up Actions
 	**The presence or absence of Flu A or Flu B Viral RNAs cannot be determined.** "Invalid, possible dispense issue" will display if an insufficient amount of sample was transferred to the test base. Repeat testing of the sample using new test components. If repeated Flu A and Flu B Invalid results are obtained, results should be confirmed by another method prior to reporting the results.
	**Flu A Viral RNA Detected**
	**Flu B Viral RNA Detected**

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 testing repeated using a new patient sample.

LIMITATIONS

- 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, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate levels of viruses are present in the specimen. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
- Abbott ID NOW COVID-19 2.0 test targets a highly conserved region of the SARS-CoV-2 genome which was shown to be unlikely to be altered by variants or mutations. As with any molecular test, mutations within the target regions of the Abbott ID NOW COVID-19 2.0 test could affect primer and/or probe binding resulting in failure to detect the presence of the virus.
- The test cannot rule out diseases caused by other bacterial or viral pathogens.
- ID NOW COVID-19 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 samples that are near the limit of detection of the test.
- Swab samples eluted in VTM are not appropriate for use in this test.
- Mucin may interfere with COVID-19 detection at levels greater than 1% w/v.
- The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- The performance of this device has not been assessed in a population vaccinated against COVID-19.

PERFORMANCE CHARACTERISTICS

Clinical Study:

Clinical performance characteristics of ID NOW COVID-19 2.0 was 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) investigational study sites throughout the U.S. participated in the study. To be enrolled in the study, patients had to be presenting at the participating study centers with suspected COVID-19. 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 as the composite comparator method to establish Patient Infected Status (PIS) for this study: In cases where the qualitative results between the first two comparator tests differed, or one of the first two comparator tests did not have a valid result, the third comparator method was required to determine PIS.

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 sample 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 sample testing each day, at all study sites.

The performance of ID NOW COVID-19 2.0 was established with 1672 nasal or nasopharyngeal swabs collected from individual suspected of COVID-19.

ID NOW™ COVID-19 2.0 PERFORMANCE

The performance of ID NOW COVID-19 2.0 with positive results stratified by the comparator method cycle threshold (Ct) counts were collected and assessed to better understand the correlation of assay performance to the cycle threshold, estimating the viral titer present in the clinical sample. Ct values for PIS positive subjects were assigned by priority amongst the three comparator PCR methods (method 2 if method 1 not detected). As presented below, the positive agreement of ID NOW COVID-19 2.0 is higher with samples of a Ct count <30 and <33.

ID NOW™ COVID-19 2.0 Performance against Patient Infected Status – by Cycle Threshold Counts – All Subjects

ID NOW™ COVID-19 2.0	Patient Infected Status (Positive by Ct Category)	
	Ct < 30	Ct < 33
Positive	191	230
Negative	2	7
Total	193	237
Positive Agreement (95% CI)	99.0 (96.3, 99.9)	97.0 (94.0, 98.8)

In samples with Ct ≥30 and ≤32, Positive Agreement was 86.7 (69.3, 96.2).

In samples with Ct ≥33, Positive Agreement was 65.3% (55.0, 74.6).

The performance of ID NOW COVID-19 2.0 from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19 is presented in the table below.

ID NOW™ COVID-19 2.0 Performance within 7 days of symptom onset against Patient Infected Status

ID NOW™ COVID-19 2.0	Patient Infected Status		
	Positive	Negative	Total
Positive	237	9	246
Negative	17*	605	622
Total	254	614	868
Positive Agreement: 237/254	93.3% (95% CI: 89.5% - 96.1%)		
Negative Agreement: 605/614	98.5% (95% CI: 97.2% - 99.3%)		

*12 of the discrepant samples had high Ct values (≥33) when tested by the comparator method.

During the clinical study, the initial invalid rate (before repeat testing per the product instructions) was 0.71% (7/989) (95% CI: 0.29% to 1.45%). After repeat testing per the product instructions, the invalid rate was 0.20% (2/989) (95% CI: 0.02% to 0.73%).

ID NOW™ COVID-19 2.0 Performance within 7 days of symptom onset against Patient Infected Status – By Sample Type

ID NOW™ COVID-19 2.0	Anterior Nasal Swab			Nasopharyngeal Swab		
	Patient Infected Status			Patient Infected Status		
	Positive	Negative	Total	Positive	Negative	Total
Positive	111	5	116	126	4	130
Negative	9	313	322	8	292	300
Total	120	318	438	134	296	430
Positive Agreement:	92.5% (95% CI: 86.2% - 96.5%)			94.0% (95% CI: 88.6% - 97.4%)		
Negative Agreement:	98.4% (95% CI: 96.4% - 99.6%)			98.6% (95% CI: 96.6% - 99.6%)		

Clinical performance of ID NOW COVID-19 2.0 from individuals suspected of COVID-19 (including both symptomatic and asymptomatic patients) was determined to have positive agreement of 87.8% (95% CI: 83.8-91.1%) and negative agreement of 98.4% (95% CI: 97.6-99.0%).

ANALYTICAL STUDIES:

Reproducibility

A reproducibility study of ID NOW COVID-19 2.0 was conducted by operators from three sites using panels of blind coded specimens containing negative, high negative, low positive (near the limit of detection), and moderate positive (above the limit of detection) SARS-CoV-2 samples.

Participants tested multiple samples of each panel member on five different days. The percent agreement with expected results for the moderate positive

and low positive samples were 98.1% (263/268) and 96.3% (260/270), respectfully. 99.6% (267/268) of the true negative samples generated negative test results. There were no significant differences observed within run (replicates tested by one operator), between run (five different days), between sites (three sites), or between operators (nine operators).

The Reproducibility Study site-to-site qualitative results (agreements with expected results) are presented in the table below:

The Reproducibility Study Site-To-Site Qualitative Result

Sample Category		Site			Overall Percent Agreement and 95% CI	
		Site 1	Site 2	Site 3		
LP[1]	Percent Agreement	97.8%	94.4%	96.7%	96.3% (260/270)	(93.3%, 98.2%)
	Count	88/90	85/90	87/90		
MP[1]	Percent Agreement	98.9%	96.6%	98.9%	98.1% (263/268)	(95.7%, 99.4%)
	Count	89/90	86/89	88/89		
HN[1]	Percent Agreement	87.8%	90.9%	90.0%	89.6% (240/268)	(85.3%, 92.9%)
	Count	79/90	80/88	81/90		
TN[1,2]	Percent Agreement	100.0%	100.0%	98.9%	99.6% (267/268)	(97.9%, 100.0%)
	Count	90/90	89/89	88/89		

[1] Low Positive (LP), Moderate Positive (MP), High Negative (HN), True Negative (TN)

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

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.

Presumed negative natural nasal swab specimens were eluted in Universal Transport Media. Swab elutes 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.

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

The confirmed LOD in natural 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)
SARS-CoV-2 RNA	Nasal Swab	500
	Nasopharyngeal Swabs	500

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 or clinical isolates were diluted in natural nasal swab matrix to generate virus dilutions for testing.

Contrived swab samples were prepared by coating 50 microliters of virus dilution onto each swab.

The starting dilution concentration selected for testing in this study was 1.75x higher than the established LOD in the Limit of Detection study. Each starting dilution per virus strain was tested n = 5 replicates. A concentration level was considered "reactive/positive" in this study if all five replicates generated a positive result.

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

Analytical Reactivity Study Results

SARS-CoV-2 Strain	Concentration (copies/reaction)
Hong Kong/VM200001061/2020	60
Italy-INMI1	60
P.2 (Zeta)	26
P.1 (Gamma)	61.1
B.1.1.7 (Alpha)	45.9
B.1.429 (Epsilon)	18.7
B.1.1.318	28.8
WA1-wt	41
B.1.351 (Beta)	23
B.1.1.7 (Alpha)	100.4
B.1.617.1 (Kappa)	19
B.1.617.1 (Kappa)	40.5
B.1.617.2 (Delta)	22.4
B.1.617.2 (Delta)	20.7

In-Silico Analysis

An alignment was performed with the oligonucleotide primer and probe sequences of the ID NOW COVID-19 2.0 assay 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.

Analytical Specificity (Cross Reactivity)

To determine the analytical specificity of ID NOW COVID-19 2.0, 37 commensal and pathogenic microorganisms (23 viruses, 12 bacteria, and 2 yeast) 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 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	*Chlamydia pneumoniae*	*Pneumocystis jirovecii (PJP)*
Human Adenovirus 7	*Legionella pneumophila*	
Human Parainfluenza virus 2	*Staphylococcus aureus*	
Human Parainfluenza virus 3	*Mycoplasma pneumoniae*	
Rhinovirus 1	*Haemophilus influenzae*	
Rhinovirus 2	*Mycobacterium tuberculosis avirulent*	
Human Echovirus 7	*Staphylococcus epidermidis*	
Human Metapneumovirus (hMPV)	*Streptococcus salivarius*	
Human Influenza A/ California/7/2009	*Streptococcus pneumoniae*	
Human Influenza A/ Texas/50/2012	*Streptococcus pyogenes*	
Human Influenza B/ Wisconsin/1/2010	*Pseudomonas aeruginosa*	
Human Influenza B/ Malaysia/2506/04		
Respiratory Syncytial Virus (RSV) A		
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		

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 microorganism. None of the organisms maintained genomic sequence that was significantly similar to the ID NOW COVID-19 2.0 target sequences.

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*	

Viruses	Bacteria	Yeast
Echovirus E9	*Pseudomonas aeruginosa*	
Echovirus E11	*Staphylococcus aureus*	
Epstein Barr virus	*Staphylococcus epidermidis*	
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 was diluted in clinical matrix to 1.75 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 x 10^5 $TCID_{50}$/mL
Human Adenovirus 7	1.0 x 10^5 $TCID_{50}$/mL
Human Coronavirus 229E	1.0 x 10^5 $TCID_{50}$/mL
Human Coronavirus NL63	1.17 x 10^5 $TCID_{50}$/mL
Human Coronavirus OC43	1.0 x 10^5 $TCID_{50}$/mL
Human Coronavirus HKU1	1.0 x 10^8 copies/mL
MERS-Coronavirus	1.0 x 10^5 GE/mL
Enterovirus 70	1.0 x 10^5 $TCID_{50}$/mL
Human Echovirus 7	1.0 x 10^5 $TCID_{50}$/mL
Human Metapneumovirus (hMPV)	1.0 x 10^5 U/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
Respiratory Syncytial Virus, Type A	1.0 x 10^5 IU/mL
Respiratory Syncytial Virus, Type 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 cells/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
Staphylococcus 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

Panel	Concentration
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 3x LOD sample and were found not to affect test performance.

Substance	Concentration
Mucin	1% w/v[1]
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	10% m/v[2]
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
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	1.0 x 10^6 cells/mL
Fluticasone furoate	20% v/v

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

[2] When tested at 20% w/v in the presence of SARS-CoV-2, 1/5 invalid results 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 carryover or cross-contamination in the ID NOW COVID-19 2.0 test. 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.

SYMBOLS

 Fragile, handle with care	BASE Test Base
CARTRDG Transfer Cartridge	RCVR Sample Receiver
 Caution, consult accompanying documents.	IVD *In Vitro* Diagnostics

ORDERING and CONTACT INFORMATION

Reorder numbers:

193-000: 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

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REFERENCES

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

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CE IVD

IN193000 Rev.1 2022/05

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ID NOW
COVID-19 2.0

PI - OUS

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

Printed Colors

CMYK

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

PMS 2995 U
Primary Blue

PMS 224 U
Magenta-Pink

PMS 303 U
Dark Blue

PN: IN193000
Rev: 1

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