Abbott

ID NOW™

COVID-19 2.0

PRODUCT INSERT

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For Use Under an Emergency Use Authorization Only - US only EUA
For use with the ID NOW™ Instrument
For use with anterior nasal swab or nasopharyngeal swab specimens
For *in vitro* Diagnostic 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 in direct anterior nasal (nasal) or nasopharyngeal swab specimens from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate or waived complexity tests. The ID NOW COVID-19 2.0 assay is also authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory samples during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Testing facilities within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be confirmed with a different authorized or cleared molecular test in a CLIA-certified laboratory that meets the requirements to perform high or moderate complexity 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 must be combined with clinical observations, patient history, and/or epidemiological information.

ID NOW COVID-19 2.0 is intended for use by trained operators who are proficient in performing tests using the ID NOW Instrument. The ID NOW COVID-19 2.0 assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

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 isothermal 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 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 isothermal nucleic acid amplification technology for the qualitative detection of SARS-CoV-2 viral nucleic acids. It is comprised of a Sample Receiver, containing elution/lysis buffer, a Test Base, comprising two sealed reaction tubes, each containing a lyophilized pellet, a Transfer Cartridge for transfer of the eluted sample to the Test Base, and the ID NOW Instrument.

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

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

REAGENTS and MATERIALS

Materials Provided

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

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

CARTRDG **Transfer Cartridges:** White plastic components used to transfer 2 x 100 µL of sample extract from the Sample Receiver to the Test Base.

Patient Swabs: Sterile swabs (foam) for use with the ID NOW COVID-19 2.0 Test.

Positive Control Swab: 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

Quick Reference Instructions

Materials Required but not Provided

ID NOW Instrument

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

Swab Transport Tubes (for sample transport, if immediate testing is not possible). Clean, unused tube that can be capped to contain the swab for sample transport.

Materials Available as an Optional Accessory

COVID-19 Swab Transport Tube Accessory Pack

PRECAUTIONS

1. For *in vitro* diagnostic use under the FDA Emergency Use Authorization.
2. For prescription use only.
3. This product has not been FDA cleared or approved; but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
4. Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
5. This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
6. This emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
7. Laboratories within the United States and its territories are required to report all results to the appropriate public health laboratories.
8. To be used in conjunction with the ID NOW Instrument.
9. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
10. Proper sample collection, storage and transport are essential for correct results.
11. Leave test pieces sealed in their foil pouches until just before use.
12. Do not tamper with test pieces prior to or after use.
13. Do not use kit past its expiration date.
14. Do not mix ID NOW COVID-19 2.0 components from different kit lots.
15. 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.
16. Wear clean personal protection equipment and gloves when running each test. Change gloves between the handling of specimens suspected of COVID-19.

17. **If any assay components are dropped, cracked, found to be damaged or opened when received, DO NOT USE and discard. Do not use scissors or sharp objects to open foil pouches as damage to test pieces can occur.**
18. Do not open the Sample Receiver before placing in the instrument. It will prohibit the Elution Buffer from reaching temperature and may impact test performance.
19. If the Sample Receiver is spilled while opening, clean the instrument per instructions provided in the instrument User Manual and cancel test. Repeat test with a new Sample Receiver.
20. All test pieces must be removed from the instrument according to removal instructions displayed on the instrument and disposed of according to country and local requirements. **Pieces must not be separated once they are assembled**.
21. All test pieces are single use items. Do not use with multiple specimens.
22. Once reacted, the Test Base contains large amounts of amplified target (Amplicon). **Do not disassemble the Test Base and Transfer Cartridge**. In the case of a positive sample, this could lead to amplicon leakage and potential ID NOW COVID-19 2.0 false positive test results.
23. At a low frequency, clinical samples can contain inhibitors that may generate invalid results. Site to site invalid rates may vary.
24. Due to the high sensitivity of the assays run on the instrument, contamination of the work area with previous positive samples may cause false positive results. Handle samples according to standard laboratory practices. Clean instruments and surrounding surfaces according to instructions provided in the cleaning section of the instrument User Manual. Refer to Section 1.6, Maintenance & Cleaning, for further information.

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.

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

CONTROL SWAB PROCEDURE

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.

Anterior Nasal (Nasal) Swab

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

Puritan Regular Foam Tip Swabs, Puritan HydraFlock™ Flock Swabs – Standard Tip, Copan Standard Rayon Tip Swab, MRC Technology, Ltd. Foam Tipped Applicator, Foamtec Int'l Swab, Sterile CleanFOAM diagnostic.

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

Nasopharyngeal Swab

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

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, test direct nasal or nasopharyngeal swabs as soon as possible after collection. If immediate testing is not possible, place the nasal or nasopharyngeal swab 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.**

TEST PROCEDURE

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

Before testing with ID NOW COVID-19 2.0:

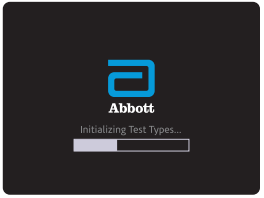
- **Put on a clean pair of gloves.**
- Allow all samples to reach room temperature.
- Allow all test pieces to reach room temperature.
- Check that a reagent pellet is visible at the bottom of each of the reaction tubes prior to inserting the Test Base in the ID NOW Instrument. Do not use the Test Base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

To Perform a Test:

Step 1

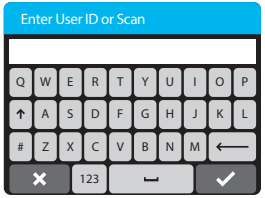
Turn on the ID NOW Instrument - press the power button ⏻ on the side of the instrument.

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

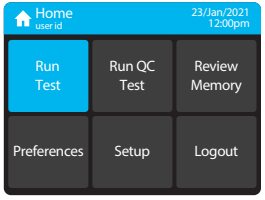
Press '✓' after entry.



To Perform a Test:

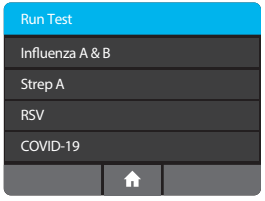
Touch 'Run Test'

This will begin the test process.



Touch 'COVID-19 Test'

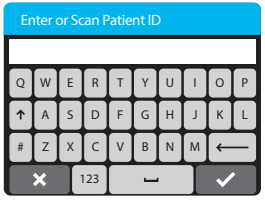
This starts a COVID-19 test.



Enter Patient ID using on screen keyboard or barcode scanner.

Touch '✓'.

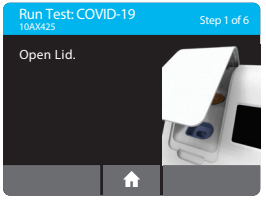
Verify that the ID was entered correctly, then touch '✓' to confirm entry.

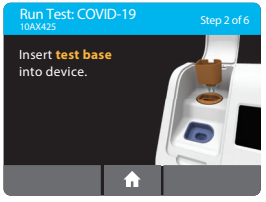


To Perform a Test:

Step 2

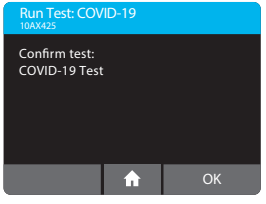
Open the Lid and Gently Insert Orange Test Base into Orange Test Base holder





Confirm that the correct test is displayed on the screen.

Touch 'OK' to proceed.

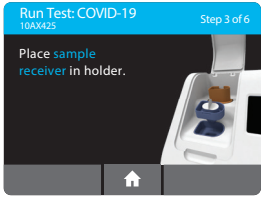


⚠ **Caution: Once the Test Base has been placed in the holder, the user will have 3 minutes to confirm the test. If the test is not confirmed within 3 minutes, the instrument will time out and the Test Base must be removed and discarded.**

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.

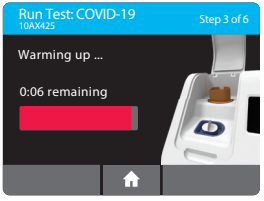
To Perform a Test:

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.

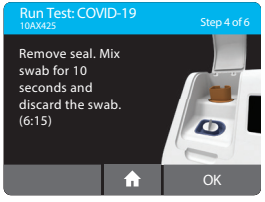
⚠ **Caution: DO NOT REMOVE THE FOIL SEAL UNTIL PROMPTED BY THE INSTRUMENT.**
DO NOT close the lid or insert the sample until prompted by the instrument.

To Perform a Test:

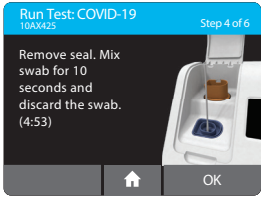
Step 4

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.

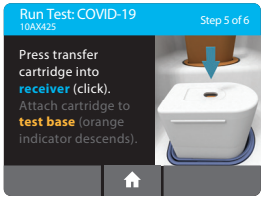
To Perform a Test:

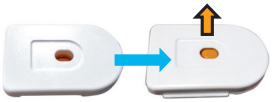
Step 5a

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.



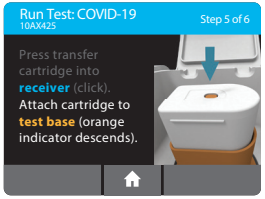


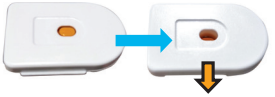
⚠ **Caution: The orange indicator should be observed closely. If the orange indicator does not fully rise, the Transfer Cartridge may not collect enough sample.**

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.

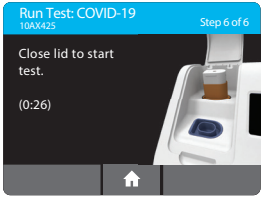


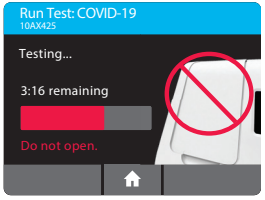


⚠ **Caution: If the orange indicator does not fully descend, not enough sample will be dispensed. This may potentially result in invalid or false test results.**

To Perform a Test:

Step 6





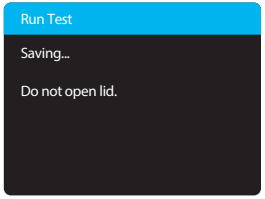
Close the Lid.

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

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

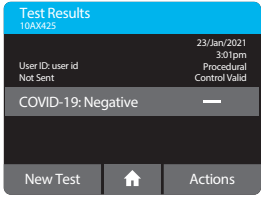
When amplification and detection is complete, the instrument will automatically save the data before advancing to the results screen.



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

Step 7

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.

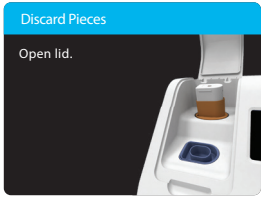


Press New Test or Home to complete testing with this patient sample. Press Actions to print or send test results.

To Perform a Test:

Step 8

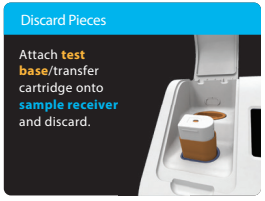
After printing, or if New Test or Home are selected, the instrument will prompt to open the lid and discard the used test pieces.



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.**

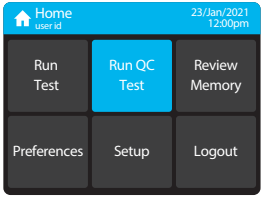
Close the lid. The instrument will then run a Self-Test before showing the Home screen or Enter Patient ID screen, depending on the previous selection.

Remove and dispose of gloves.

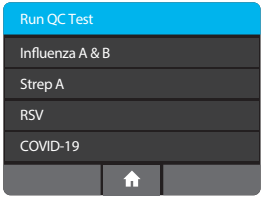
Quality Control Swab Test Procedure

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.

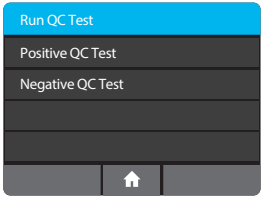
1 Touch 'Run QC Test'



2 Touch 'COVID-19'



3 Select the QC Test to be Run

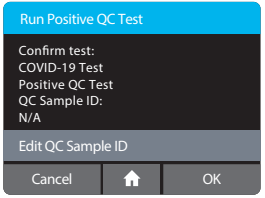


4 Confirm Test

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

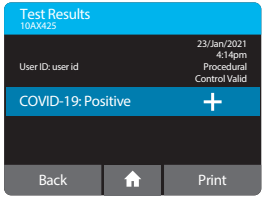
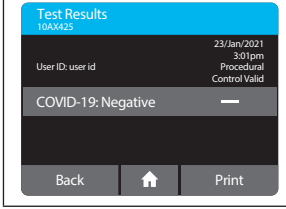
The user has the option to enter an ID for the QC Sample being run.

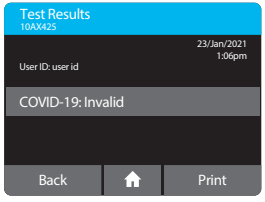
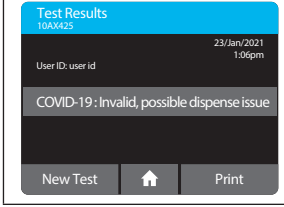
Note: *The QC test is run in the same manner as a Direct Nasal/Nasopharyngeal Swab Patient Test. See the* ***To Perform a Test*** *section above for step by step instructions for direct nasal/nasopharyngeal swab samples.*



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** Negative results do not preclude SARS-CoV-2 infection.

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 COVID-19 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.**

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.
- Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be confirmed with a different authorized or cleared molecular test in a CLIA-certified laboratory that meets the requirements to perform high or moderate complexity tests.
- False negative results may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate levels of viruses are present in the specimen. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
- As with any molecular test, mutations within the target regions of the Abbott ID NOW COVID-19 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.
- Puritan PurFlock Ultra Flocked Swabs – Standard Tip, Puritan Mini Rayon Tip and Puritan PurFlock Ultra Flocked Swabs – Mini Tip are not suitable for use in this assay.
- 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.

CONDITIONS of AUTHORIZATION for LABORATORIES

The ID NOW COVID-19 2.0 Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas.

However, to assist clinical laboratories and patient care settings (authorized laboratories[1]) using the ID NOW COVID-19 2.0 ("your product" in the conditions below), the relevant Conditions of Authorization are listed below:

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

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

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

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

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

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

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

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

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 POC 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 at least one symptom of 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-CV-2 were utilized as the 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.

A total of 989 nasal or nasopharyngeal swab specimens were enrolled in this study. Of those, 121 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 868 specimens, including 438 anterior nasal swabs and 430 nasopharyngeal swabs collected from individual suspected of COVID-19 by their healthcare worker within 7-days of symptom onset.

ID NOW™ COVID-19 2.0 PERFORMANCE.

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. Performance of the ID NOW COVID-19 2.0 was similar for nasal and nasopharyngeal swabs.

ID NOW™ COVID-19 2.0 Performance within 7 days of symptom onset against Patient Infected Status (Nasal and Nasopharyngeal Swabs Combined)

ID NOW™ COVID-19 2.0 (anterior nasal and nasopharyngeal swab data combined)	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%)			

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%)		

ANALYTICAL STUDIES:

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 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:

Limit of Detection (LOD) Study Results

Virus	Claimed LOD (copies/swab)
SARS-CoV-2 RNA	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 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 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	34.8
Italy-INMI1	34.8

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, 21 commensal and pathogenic microorganisms (15 viruses, 5 bacteria, and 1 fungi) 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 $\geq 10^6$ cells/mL or CFU/mL (bacteria), $\geq 10^5$ $TCID_{50}$/mL or IU/mL (viruses), and 10^6 cells/mL (yeast).

Viruses	Bacteria	Yeast
Human Coronavirus HKU1	*Bordetella pertussis*	*Candida albicans*
Human Adenovirus 1	*Chlamydia pneumoniae*	
Human Adenovirus 7	*Legionella pneumophila*	
Human Parainfluenza virus 2	*Staphylococcus aureus*	
Human Parainfluenza virus 3	*Mycoplasma pneumoniae*	
Rhinovirus 1		
Rhinovirus 2		
Human Echovirus 7		
Human Metapneumovirus (hMPV)		
Human Influenza A/ California/7/2009		
Human Influenza A/ Texas/50/2012		

Viruses	Bacteria	Yeast
Human Influenza B/ Wisconsin/1/2010		
Human Influenza B/ Malaysia/2506/04		
Respiratory Syncytial Virus (RSV) A		
RSV B		

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. Based on this analysis, none of the evaluated microorganisms are predicted/ expected to cross-react with the ID NOW COVID-19 2.0 assay.

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*	

Viruses	Bacteria	Yeast
Human adenovirus 2	*Klebsiella pneumoniae*	
Human adenovirus B3	*Lactobacillus plantarum*	
Human adenovirus E4	*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*	
Human Metapneumovirus (hMPV)	*Streptococcus pneumoniae*	
Influenza A	*Streptococcus pyogenes*	
Influenza B	*Streptococcus salivarius*	
Measles virus		
Mumps virus		
Parainfluenza Type 1		

Viruses	Bacteria	Yeast
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 1.75x 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 and bacteria were tested at the concentration provided in the table below and were found not to affect test performance.

Panel	Concentration
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
Mycoplasma pneumoniae	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 1.75x LOD sample and were found not to affect test performance.

Substance	Concentration
Mucin	1% w/v*
Whole Blood	1% v/v
Post nasal lavage discharge	5% v/v
Phenylephrine	20% v/v
Oxymetazoline	20% v/v
Cromolyn sodium	20% v/v
Sodium chloride with preservatives	20% v/v
Alkalol	20% v/v

Substance	Concentration
Galphimia glauca, Histaminum hydrochloricum, Luffa opperculata, Sulfur	20% v/v
Fluticasone furoate	20% v/v
Fluticasone propionate	20% v/v
Zincum gluconium, Zincum aceticum	20% m/v
Phenol	20% v/v
Beclomethasone	0.068 mg/mL
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

*Mucin at 2% w/v in the presence of SARS-CoV-2 at 34.8 copies/reaction yielded 1/5 false negative results and therefore was tested at a lower concentration.

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	EUA For Use Under an Emergency Use Authorization Only (Applies to US only)	

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

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

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

IVD

IN192000 Rev. 2 2022/09

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

PN: IN192000
Rev: 2

Date of Last Revision:
2.4 2022/09/08

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

To collect a nasal swab sample, carefully insert the swab into the nostril exhibiting the most visible drainage, or the nostril that is most congested if drainage is not visible. Using gentle rotation, push the swab until resistance is met at the level of the turbinates (less than one inch into the nostril). Rotate the swab several times against the nasal wall then slowly remove from the nostril. Using the same swab, repeat sample collection in the other nostril. Puritan PurFlock Standard Tip Ultra Flocked Swabs, Puritan PurFlock Mini Tip Ultra Flocked Swabs and Copan Standard Rayon Tip Swabs are not suitable for use.

Nasopharyngeal Swab

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 tripping 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.

Reference

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

Technical Support Advice Line

Further information can be obtained from your distributor, or by contacting Technical Support on:

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

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

IVD Rx Only

IN192001 Rev.1 2022/05

External Positive and a Sterile Swab for Negative Control should be tested once with each new shipment received and once for each untrained operator.

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 Select 'COVID-19' from the menu.

3 Select the QC Test to be Run.

4 Confirm Test

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

Note: *The QC test is run in the same manner as a Direct Nasal Swab Patient Test. See the other side for step by step instructions.*

ID NOW™ COVID-19 2.0 QUICK REFERENCE INSTRUCTIONS

Abbott

This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA for use by authorized laboratories.

This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).

Materials Required to Run a Test:

Test Base | Sample Receiver | Transfer Cartridge | Patient Swab

Instrument:

For Use Under an Emergency Use Authorization Only - US only. EUA

Refer to the ID NOW COVID-19 2.0 Product Insert and User Manual for complete instructions.

ID NOW™

COVID-19 2.0

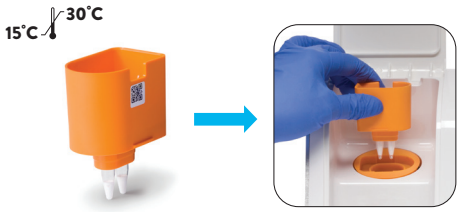
QUICK REFERENCE INSTRUCTIONS

Before performing this test, refer to the ID NOW COVID-19 2.0 Product Insert and User Manual for complete Test Procedure and additional information.

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

1

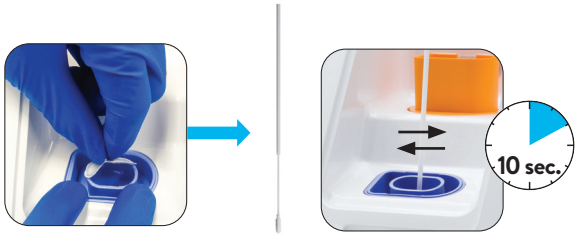
2



3

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

4



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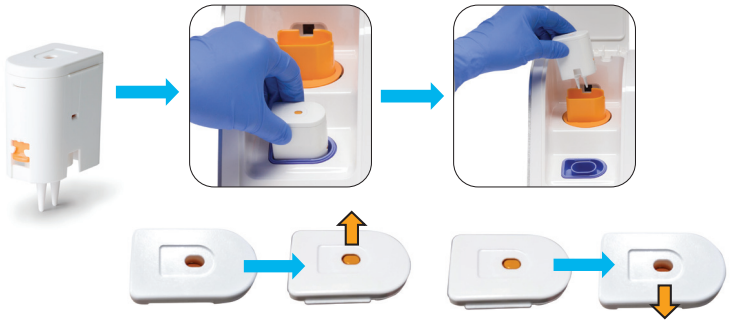
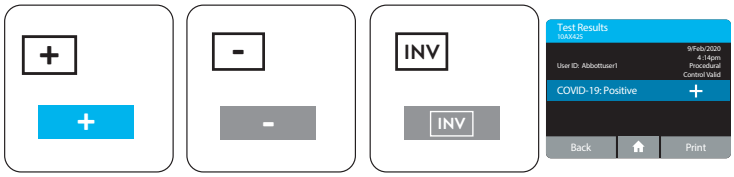


6

7



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

8

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

Abbott
ID NOW
COVID-19 2.0 - EUA

QRI, EN

Size:
8.5 in. x 11 in.

Printed Colors

CMYK

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

PMS 2995 U
Primary Blue

PMS 303 U
Dark Blue

PMS 224 U
Magenta-Pink

PN: IN192001
Rev: 1

Date of Last Revision:
1.8 2022/05/04