# ID NOW COVID-19

For Use Under an Emergency Use Authorization (EUA) Only

For use with the ID NOW Instrument

For use with nasal, throat or nasopharyngeal specimens

For *in vitro* Use Only

Rx Only

## INTENDED USE

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

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

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

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

## SUMMARY AND EXPLANATION OF THE TEST

An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to WHO on December 13, 2019.[1] Chinese authorities identified a novel coronavirus (2019-nCoV), which has resulted in thousands of confirmed human infections in multiple provinces throughout China and in several Southeast Asian countries, Europe and more recently the United States. Cases of severe illness and deaths have been reported. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.[2]

ID NOW COVID-19 is a rapid (13 minutes or less), instrument-based isothermal test for the qualitative detection and diagnosis of SARS-CoV-2 from nasal, nasopharyngeal and throat swabs. The ID NOW Instrument has a small footprint and easy to use graphical user interface for convenience within a busy hospital or near patient testing environments. The ID NOW COVID-19 kit contains all components required

to carry out an assay for SARS-CoV-2 on the ID NOW Instrument.

## PRINCIPLES OF THE PROCEDURE

ID NOW COVID-19 is an automated assay that utilizes isothermal nucleic acid amplification technology for the qualitative detection of SARS-CoV-2 viral nucleic acids. It is comprised of a Sample Receiver, containing elution/lysis buffer, a Test Base, comprising two sealed reaction tubes, each containing a lyophilized pellet, a Transfer Cartridge for transfer of the eluted sample to the Test Base, and the ID NOW Instrument.

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

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

## REAGENTS AND MATERIALS

### Materials Provided

BASE

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

RCVR

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

CARTRDG

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

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

**Positive Control Swab:** The positive control swab ensures sample elution/lysis and workflow were performed correctly.

**Negative Control Swab:** The negative control swab ensures appropriate negative results are obtained.

**Package Insert**

**Quick Reference Instructions**

### Materials Required but not Provided

**ID NOW Instrument**

## PRECAUTIONS

1. For *in vitro* diagnostic use.
2. For use under an Emergency Use Authorization Only.
3. Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
4. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health laboratories.
5. To be used in conjunction with the ID NOW Instrument.
6. Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
7. Proper sample collection, storage and transport are essential for correct results.
8. Leave test pieces sealed in their foil pouches until just before use.

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

## STORAGE AND STABILITY

Store kit at 2-30°C. The ID NOW COVID-19 kit is stable until the expiration date marked on the outer packaging and containers. Ensure all test components are at room temperature before use.

## QUALITY CONTROL

ID NOW COVID-19 has built-in procedural controls. The result of the Procedural Control is displayed on the screen and is automatically stored in the instrument with each test result. This can be reviewed later by selecting Review Memory on the instrument.

### Procedural Controls:

ID NOW COVID-19 contains an internal control that has been designed to control for sample inhibition and assay reagent function. In positive samples where target amplification is strong, the internal control is ignored, and the target amplification serves as the 'control' to confirm that the clinical sample was not inhibitory, and that assay reagent performance was robust. At a very low frequency, clinical samples can contain inhibitors that may generate invalid results.

Procedural Control Valid displayed on the instrument screen indicates that the assay reagents maintained their functional integrity and the sample did not significantly inhibit assay performance.

### External Positive and Negative Controls:

Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. ID NOW COVID-19 kits contain Positive and Negative

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

## CONTROL SWAB PROCEDURE

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

***Note:*** *The ID NOW Instrument reports QC results as Pass or Fail.*

If the correct control results are not obtained, do not perform patient tests or report patient results. Contact Technical Support during normal business hours before testing patient specimens.

## SPECIMEN COLLECTION AND HANDLING

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

### Throat Swab

For optimal test performance, use the swabs provided in the test kit. Alternatively, foam, polyester, HydraFlock® and nylon flocked throat swabs can be used to collect throat swab samples.

Rayon swabs are not suitable for use in this assay.

Collect patient specimen by swabbing the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.[3]

### Nasal Swab

For optimal test performance, use the swabs provided in the test kit. Alternatively, rayon, foam, HydraFlock® Flocked swab (standard tip), HydraFlock® Flocked swab (mini tip), Copan Mini Tip Flocked Swab, or Copan Standard Flocked swabs can be used to collect nasal swab samples.

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

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

### Nasopharyngeal Swab

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

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

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

## SPECIMEN TRANSPORT AND STORAGE

Direct nasal, throat or nasopharyngeal swabs should be tested as soon as possible after collection. If immediate testing is not possible, the nasal, throat or nasopharyngeal swab can be held in its original package at room temperature (15-30°C) for up to two (2) hours prior to testing. If a direct nasal, throat or nasopharyngeal swab specimen will be held longer than two (2) hours, it must be refrigerated at 2-8°C and tested within 24 hours from the time of sample collection.

If the transport of nasal, throat or nasopharyngeal swab samples is required, the transport medias listed below are acceptable for use in ID NOW COVID-19. Elute the swab into 0.5 to 3.0 mL of saline or viral transport media by rotating the swab in the liquid for 10 seconds, within 1 hour of sample collection. Remove the swab and discard. If immediate testing is not possible, eluted swab samples can be held at room temperature (15-30°C) for up to eight (8) hours prior to testing. If the eluted swab sample will be held longer than eight (8) hours, it must be refrigerated at 2-8°C and tested within 72 hours from the time of sample collection. If needed, transport the sample at 2-8°C in a leak-proof container.

Swirl eluted swab samples in transport media gently to mix before testing.

*Note: Minimal dilution of the sample is recommended as dilution may result in decreased test sensitivity.*

**Transport Media:**

Amie's Media

Dulbecco's Modified Eagles' Medium (D-MEM)

Hank's Balanced Salt Solution

M4 Media

M4-RT Media

M5 Media

M6 Media

Phosphate Buffered Saline

Saline

Stuart's Media

Universal Transport Media

Starplex Multitrans

It has been determined that Tryptose Phosphate Broth, Brain Heart Infusion Broth, Veal Infusion Broth, and Wako's E-MEM transport media are NOT suitable for use with this test.

## TEST PROCEDURE

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

Before testing with ID NOW COVID-19:

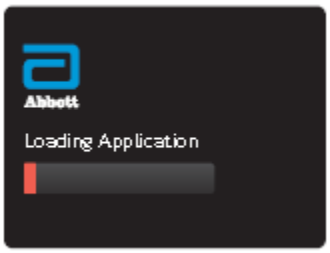
- Allow all samples to reach room temperature.
- Allow all test pieces to reach room temperature.
- Check that a reagent pellet is visible at the bottom of each of the reaction tubes prior to inserting the Test Base in the ID NOW Instrument. Do not use the Test Base if a pellet is not visible at the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

### To Perform a Test:

**Step 1**

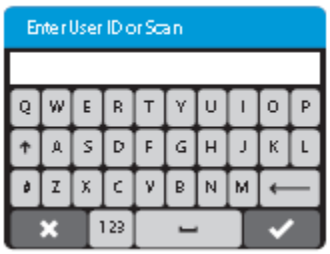
Turn on the ID NOW Instrument - press the power button ⏻ on the side of the instrument.

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



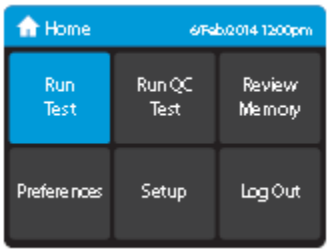

**Enter User ID**

Press '✓' after entry.



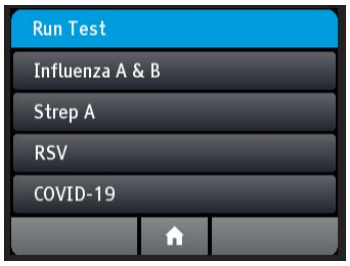

**Touch 'Run Test'**

This will begin the test process.

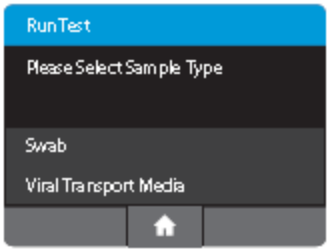



**Touch 'COVID-19 Test'**

This starts a COVID-19 test.



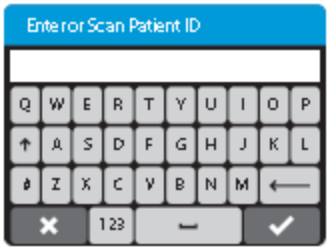
**Select Sample Type (if prompted)**
If the sample type has already been specified by the Admin, the instrument will automatically advance to the next step.




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

Touch '✓'.

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




**Step 2**

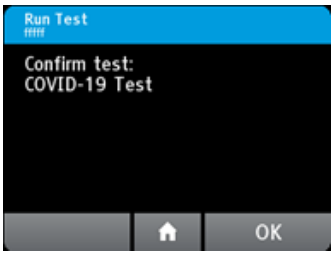
**Open the Lid and Insert Orange Test Base into Orange Test Base holder**

**Caution: Do not apply excessive force. Excessive force could damage the instrument.**

**Confirm that the correct test is displayed on the screen.**

Touch 'OK' to proceed.

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



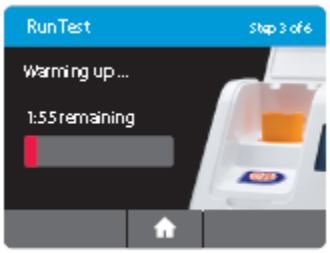

If the incorrect Test Base has been inserted, remove and dispose of the incorrect Test Base. Close the lid. The instrument will then run a self-test before proceeding to the Home screen. Press Run Test and restart the test using the correct Test Base.

**Step 3**

**Insert Blue Sample Receiver into the Blue Sample Receiver holder**

**Caution: Do not apply excessive force. Excessive force could damage the instrument.**

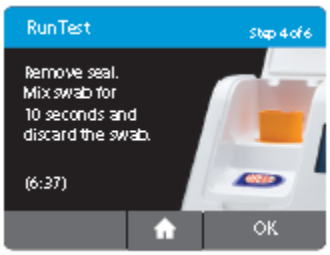
**Caution: Once the Sample Receiver has been placed in the holder, the user will have 10 minutes to start the test (Steps 3 through 5). If the test is not started within 10 minutes, the instrument will time out and all test pieces (Test Base and Sample Receiver) must be removed and discarded. The instrument will proceed to the Home screen. Press Run Test and restart the test using a new Test Base and Sample Receiver.**




**Wait for the Sample Receiver to Warm Up. Do not remove the Sample Receiver from the instrument once Warm Up begins.**

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

**Step 4**




## Direct Nasal, Throat or Nasopharyngeal Swab Test Procedure

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

**Vigorously mix the swab in the liquid for 10 seconds.** Press the swab head against the side of the Sample Receiver as you mix it. This helps remove the sample from the swab. Once the swab is removed, touch 'OK' to proceed.

**Caution: To ensure that the Sample Receiver remains in the instrument while removing the foil seal, place two fingers along the outer edge of the Sample Receiver to hold it in place. If the Sample Receiver spills after warm up, cancel the test by pressing the Home button. Remove and discard the test pieces (Sample Receiver and Test Base) and clean the instrument. Press Run Test to start a new test using a new Test Base and Sample Receiver.**

Discard the swab.
Skip to Step 5a.

## Nasal, Throat or Nasopharyngeal Swab Eluted in Transport Media Test Procedure

**When prompted, remove the foil seal and add 0.2ml of sample to the Sample Receiver using the disposable pipettes provided in the kit.**

**Vigorously mix the sample in the liquid for 10 seconds.** Use the pipette tip to swirl the liquid.
Once the sample is mixed and the pipette is removed, immediately touch 'OK' to proceed. Continue to Step 5a.

**Caution: To ensure 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.**

**Step 5a**

**Press the White Transfer Cartridge into the Blue Sample Receiver**

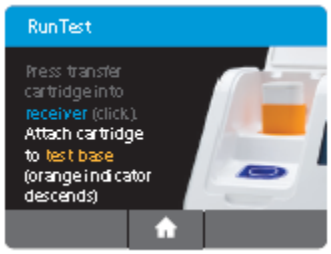
Listen for a click.

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

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

**Step 5b**

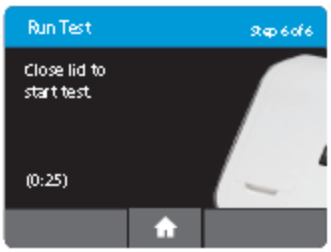
**Lift and then connect the Transfer Cartridge to the Test Base**




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

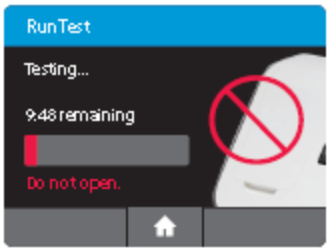
**Caution: If the orange indicator does not fully descend, not enough sample will be dispensed. This may potentially result in invalid or false test results.**

**Step 6**




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

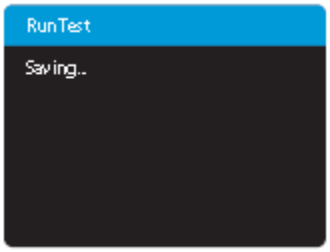
*Note: The test will be cancelled if the lid is opened.*




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

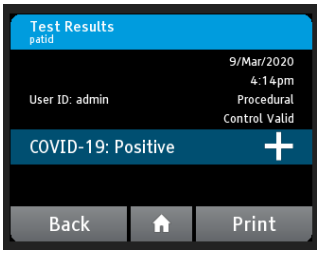
**Caution: DO NOT OPEN THE LID. The test will be cancelled and all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. A test result will not be reported or saved in the instrument memory.**

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




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

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




**Press Print to print test results, press New Test to run another test, Press Home to return to the Home screen**

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

Remove test pieces by lifting the Transfer Cartridge attached to the Test Base, and clicking it into the Sample Receiver, by pressing into the Sample Receiver.

**Caution: Do not try to remove the Sample Receiver by any other method as there is a risk of spilling the patient sample.**

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

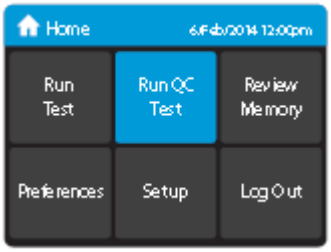
**Caution: DO NOT disassemble the Transfer Cartridge and the Test Base before disposal.**

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

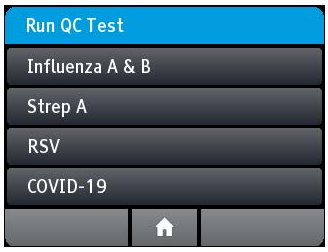
## Quality Control Swab Test Procedure

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.

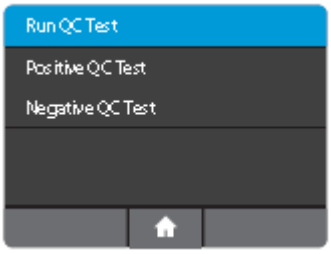
1. **Touch 'Run QC Test'**




2. **Touch 'COVID-19'**




3. **Select the QC Test to be Run**

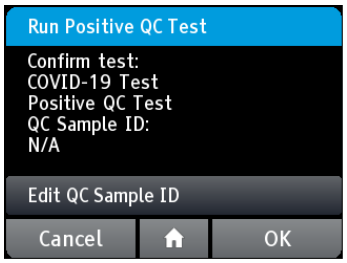


**4. Confirm Test**

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

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

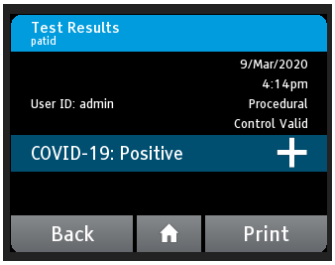


## RESULT INTERPRETATION

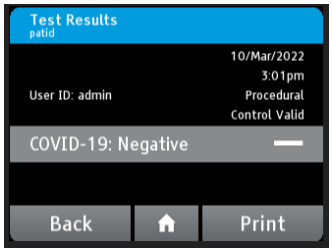
When the test is complete, the results are clearly displayed on the instrument screen.

**Instrument Display**

**Interpretation of Results and Follow-up Actions**

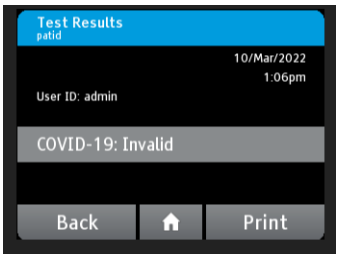



**COVID-19 Positive**




**COVID-19 Negative**

This result does not rule out co-infections with other pathogens.




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

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

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

- Remove the connected Test Base and Transfer Cartridge from the instrument and connect the Test Base portion to an open, UNUSED Sample Receiver. The connected Test Base and Transfer Cartridge MUST be attached to a Sample Receiver prior to disposal. The Sample Receiver from a new Transfer Cartridge package may be used for this.
- Remove the blue Sample Receiver separately and carefully from the instrument. The Sample Receiver should be retained and kept upright to avoid spilling the liquid contents.
- From the Home Screen, start a new test. Follow the screen prompts; however, when asked to insert the Sample Receiver, reuse the Sample Receiver and DO NOT re-elute the swab.

## LIMITATIONS

- The performance of the ID NOW COVID-19 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.
- As with any molecular test, if the virus mutates in the target region, COVID-19 may not be detected or may be detected less predictably.
- The test cannot rule out diseases caused by other bacterial or viral pathogens.

## CONDITIONS OF AUTHORIZATION FOR LABORATORY AND PATIENT CARE SETTINGS

The ID NOW COVID-19 Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/MedicalDevices/Safety/ EmergencySituations/ucm161496.htm.

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

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

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

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

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

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

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

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

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

## PERFORMANCE CHARACTERISTICS

### Clinical Study:

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

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

**ID NOW COVID-19 Test Agreement with the Expected Results by Sample Concentration**

| Target Concentration | Number Concordant/ Number Tested | % Agreement [95% CI] |
|---|---|---|
| 2X LOD | 20/20 | 100% [83.9% - 100%] |
| 5X LOD | 10/10 | 100% [72.3% - 100%] |
| Negative | 30/30 | 100% [88.7% - 100%] |

## ANALYTICAL STUDIES:

### Analytical Sensitivity (Limit of Detection)

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

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

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

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

**Limit of Detection (LOD) Study Results**

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

### Analytical Reactivity (Inclusivity)

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

### Analytical Specificity (Cross Reactivity)

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

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

**ID NOW COVID-19 Analytical Specificity Microorganisms**

| Microorganisms from the Same Genetic Family | High Priority Organisms |
|---|---|
| Human coronavirus 229E | Human adenovirus A |
| Human coronavirus OC43 | Human adenovirus B |
| Human coronavirus HKU1 | Human adenovirus B1 |
| Human coronavirus NL63 | Human adenovirus C |
| SARS-coronavirus | Human adenovirus D |
| MERS-coronavirus | Human adenovirus E |
| | Human adenovirus F |
| | Human adenovirus G |
| | Human adenovirus 7 |
| | Human adenovirus 8 |
| | Human metapneumovirus (hMPV) |
| | Human parainfluenza virus 1 - 4 |
| | Influenza A |
| | Influenza B |
| | Enterovirus A-L |
| | Human respiratory syncytial virus |
| | Rhinovirus A - C |
| | *Chlamydia pneumoniae* |
| | *Haemophilus influenzae* |
| | *Legionella pneumophila* |
| | *Mycobacterium tuberculosis* |
| | *Streptococcus pneumoniae* |
| | *Streptococcus pyogenes* |
| | *Bordetella pertussis* |
| | *Mycoplasma pneumoniae* |
| | *Pneumocystis jiroveci (PJP)* |
| | *Candida albicans* |
| | *Pseudomonas aeruginosa* |
| | *Staphylococcus epidermis* |
| | *Staphylococcus salivarius (Rhodotorula mucilaginosa)* |
| | *Streptococcus salivarius* |

**SYMBOLS**

Fragile, handle with care

| | |
|---|---|
| BASE | Test Base |
| CARTRDG | Transfer Cartridge |
| RCVR | Sample Receiver |
| Rx Only | Prescription Only |
| ⚠ | Caution, consult accompanying documents |

## ORDERING AND CONTACT INFORMATION

**Reorder numbers:**

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

US + 1 877 441 7440

**Technical Support Advice Line**

Further information can be obtained by contacting Technical Support on:

**US**

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

## REFERENCES


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



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Scarborough, Maine 04074 USA
**www.abbott.com/poct**


IVD


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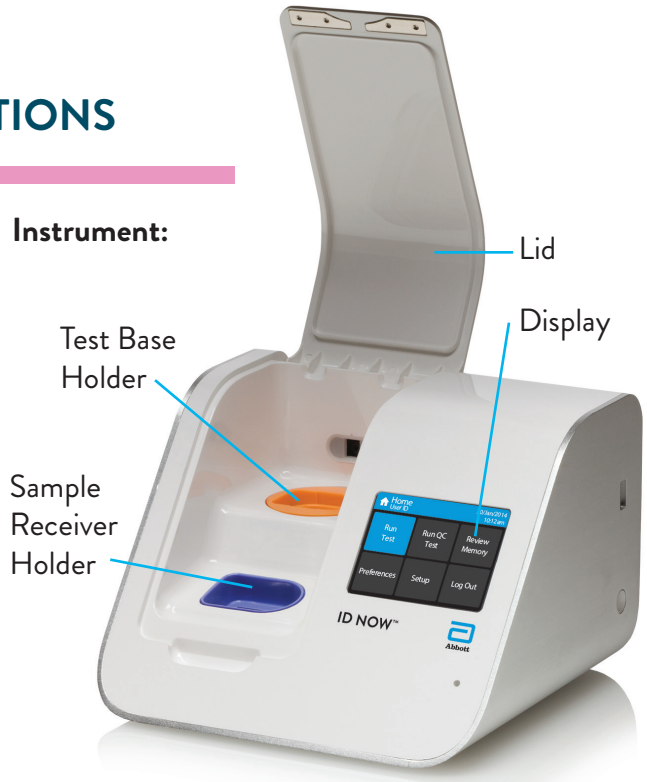
# ID NOW™ COVID-19
## QUICK REFERENCE INSTRUCTIONS

### Materials Required to Run a Test:

Test Base | Sample Receiver | Transfer Cartridge | Patient Swab

### Instrument:




**For Use Under an Emergency Use Authorization (EUA) Only.**

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

## 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. 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 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.

### Throat Swab

Collect patient specimen by swabbing the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab. Rayon swabs are not suitable for use.

### 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 |
| **Africa, Russia, CIS** | + 44 161 483 9032 | EMEproductsupport@abbott.com |
| **Asia Pacific** | + 61 7 3363 7711 | APproductsupport@abbott.com |
| **Canada** | + 1 800 818 8335 | CANproductsupport@abbott.com |
| **Europe & Middle East** | + 44 161 483 9032 | EMEproductsupport@abbott.com |
| **Latin America** | + 57 (1) 4824033 | LAproductsupport@abbott.com |

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

℞ Only

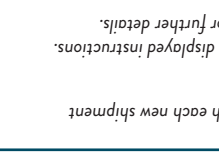
IVD

*External Positive and Negative Control Swabs 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.*

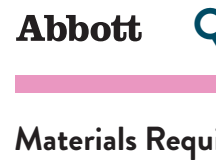
1 Touch 'Run QC Test'.

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.*

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ID NOW™

# COVID-19

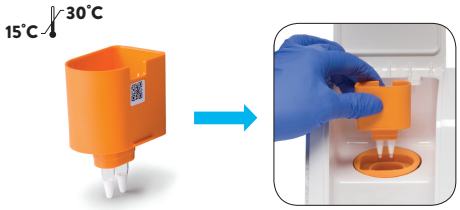
## QUICK REFERENCE INSTRUCTIONS

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

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

1

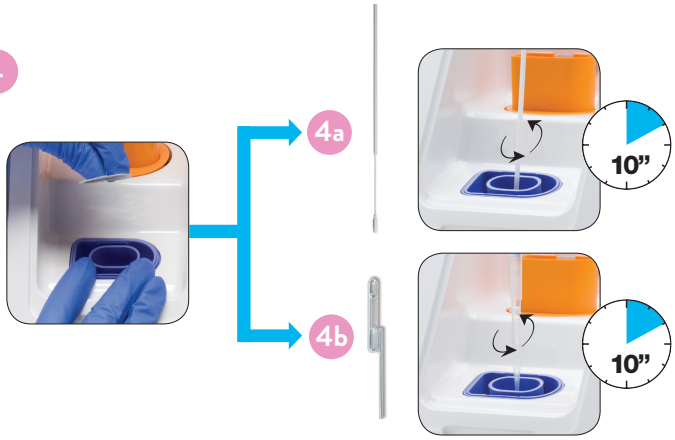
2



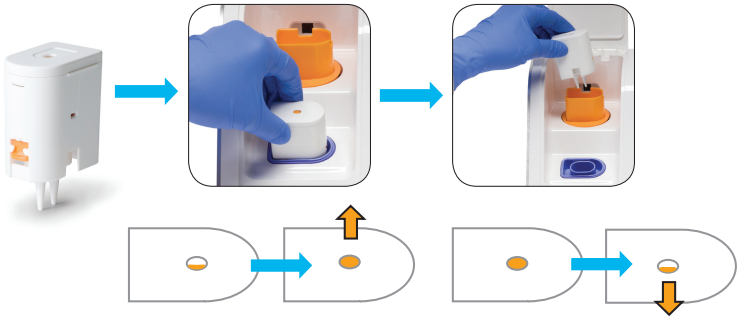

3

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

4




5



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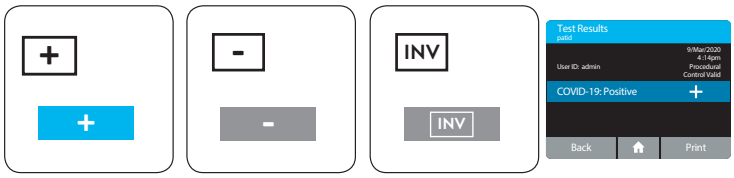


Refer to Product Insert instructions for retest procedure in the case of an Invalid result.

8

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

**Abbott**
ID NOW
COVID-19

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:** Mock-up IN190001
**Rev:** 1

**Date of Last Revision:**
1.4 2020/03/27