Abbott

ID NOW™

COVID-19 PRODUCT INSERT

ID NOW™
COVID-19
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For use with the ID NOW™ Instrument
For use with nasal, throat or nasopharyngeal specimens
For *in vitro* Use 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 from individuals who are suspected of COVID-19 by their healthcare provider.

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.

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

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.

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 ß genus. The virus can cause mild to severe respiratory illness and has spread globally, including the United States.

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

PRINCIPLES of the PROCEDURE

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

The reaction tubes in the Test Base contain the reagents required for amplification of SARS-CoV-2, as well as an internal control. The templates (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.

Package Insert

Quick Reference Instructions

Materials Required but not Provided

ID NOW Instrument

Nasopharyngeal Swabs

PRECAUTIONS

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

18. Due to the high sensitivity of the assays run on the instrument, contamination of the work area with previous positive samples may cause false positive results. Handle samples according to standard laboratory practices. Clean instruments and surrounding surfaces according to instructions provided in the cleaning section of the instrument User Manual. Refer to Section 1.6, Maintenance & Cleaning, for further information.

STORAGE and STABILITY

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

QUALITY CONTROL

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

Procedural Controls:

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

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

External Positive and Negative Controls:

Good laboratory practice suggests the use of positive and negative controls to ensure that test reagents are working and that the test is correctly performed. ID NOW COVID-19 kits contain a Positive Control Swab and Sterile Swabs that can be used as a Negative Control Swab. These swabs will monitor the entire assay. Test these swabs once with each new shipment received and once for each untrained operator. Further controls may be tested 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. 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 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.

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.[1]

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 (or placed in a conical tube and capped tightly) 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 swab is to be returned to its package for transport, carefully return to allow the swab head to only come into contact with the lower portion of the packaging. Avoid touching the outside of the wrapper with the swab. If preferred, the swab may also be placed into an uncoated conical tube for storage prior to testing. If placing in a conical tube for storage or transport, ensure the swab fits securely within the tube and the cap is tightly closed.

If samples will be shipped, pack and ship suspected and confirmed SARS-CoV-2 patient specimens as UN 3373 Biological Substance, Category B, in accordance with the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulations.[2] Personnel must be trained to pack and ship according to the regulations and in a manner that corresponds to their function-specific responsibilities.

TEST PROCEDURE

Please refer to the ID NOW Instrument User Manual for full instructions.
Before testing with ID NOW COVID-19:

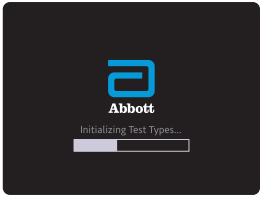
- **Put on a clean pair of gloves.**
- Allow all samples to reach room temperature.
- Allow all test pieces to reach room temperature.
- Check that a reagent pellet is visible at the bottom of the reaction tubes prior to inserting the Test Base in the ID NOW Instrument. Do not use the Test Base if a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

To Perform a Test:

Step 1

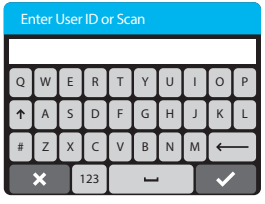
Turn on the ID NOW Instrument - press the power button ⏻ on the side of the instrument.

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

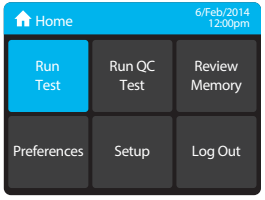
Press '✓' after entry.



To Perform a Test:

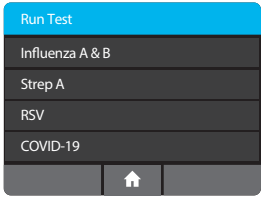
Touch 'Run Test'

This will begin the test process.



Touch 'COVID-19 Test'

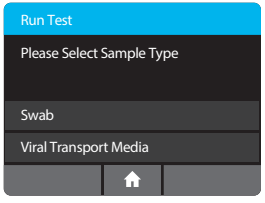
This starts a COVID-19 test.



Select Swab Sample Type (if prompted)

If the sample type has already been specified by the Admin, the instrument will automatically advance to the next step.

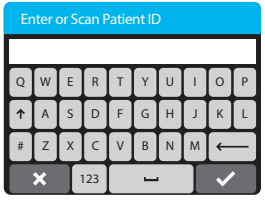
⚠ **Caution: VTM Samples are not an appropriate sample type for the ID NOW COVID-19 test.**



Enter Patient ID using on screen keyboard or barcode scanner.

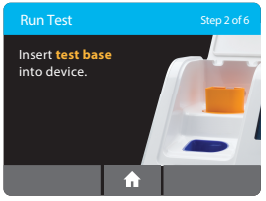
Touch '✓'.

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



To Perform a Test:

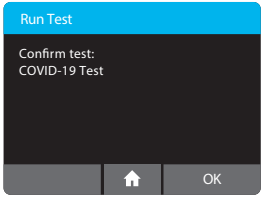
Step 2



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.

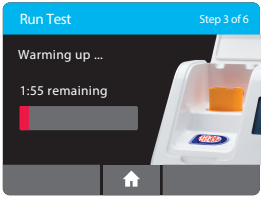
To Perform a Test:

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.

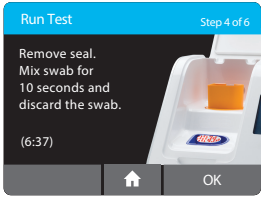
⚠ **Caution: DO NOT REMOVE THE FOIL SEAL UNTIL PROMPTED BY THE INSTRUMENT.**
DO NOT close the lid or insert the sample until prompted by the instrument.

To Perform a Test:

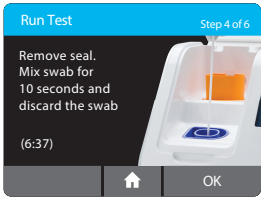
Step 4

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.



Mix the swab in the liquid for 10 seconds. This helps remove the sample from the swab. Lift the swab out of the liquid and press the swab head against the side of the Sample Receiver to remove excess liquid. Once the swab is removed, touch 'OK' to proceed.



Discard the swab into a biohazard waste container.

⚠ **Caution: To ensure that the Sample Receiver remains in the instrument while removing the foil seal, place two fingers along the outer edge of the Sample Receiver to hold it in place. If the Sample Receiver spills after 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.**

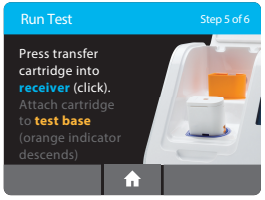
To Perform a Test:

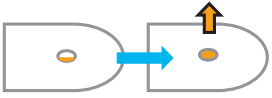
Step 5a

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.



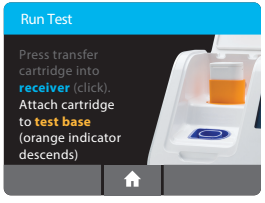


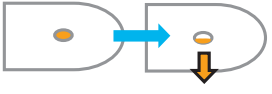
⚠ **Caution: The orange indicator should be observed closely. If the orange indicator does not fully rise, the Transfer Cartridge may not collect enough sample.**

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.**

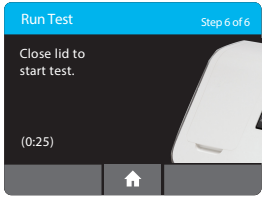
To Perform a Test:

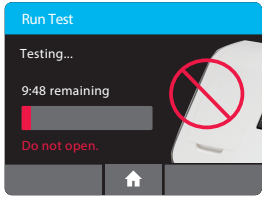
Step 6

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.*

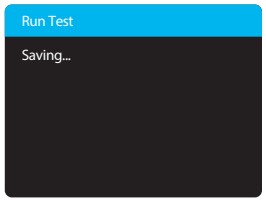




⚠ **Caution: This screen will be displayed for up to 30 seconds once the Transfer Cartridge is detected. If the instrument does not detect that the lid has been closed by then, it will time out and all test pieces (Sample Receiver, Test Base, and Transfer Cartridge) must be removed and discarded. The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

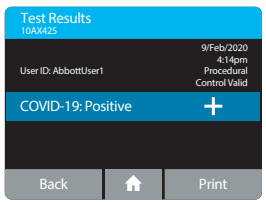
When amplification and detection is complete, the instrument will automatically save the data before advancing to the results screen.



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

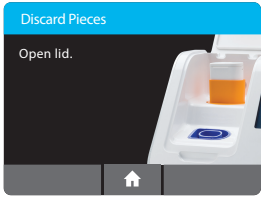
The **Test Results** screen displays either a Negative or Positive result for a successfully completed test. If a test error occurs, the display will read 'Invalid'. Refer to the Result Interpretation Section for Interpretation of Results.

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



To Perform a Test:

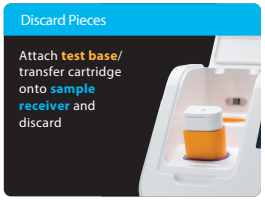
After printing, or if New Test or Home are selected, the instrument will prompt to open the lid and discard the used test pieces.



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.**

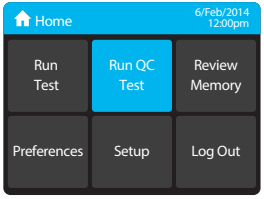
Close the lid. The instrument will then run a Self-Test before showing the Home screen or Enter Patient ID screen, depending on the previous selection.

Remove and dispose of gloves.

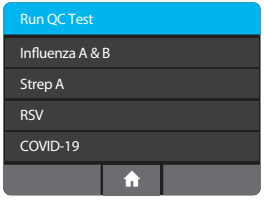
Quality Control Swab Test Procedure

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.

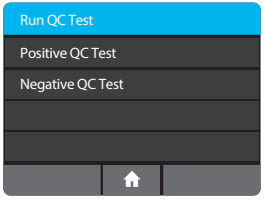
1 Touch 'Run QC Test'



2 Touch 'COVID-19'



3 Select the QC Test to be Run

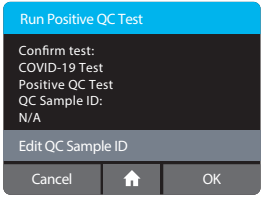


4 Confirm Test

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

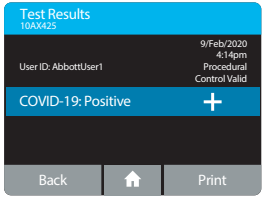
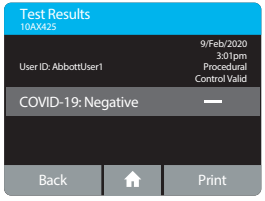
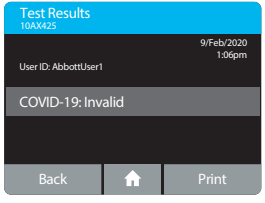
The user has the option to enter an ID for the QC Sample being run.

Note: *The QC test is run in the same manner as a Direct Nasal/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** Positive results do not rule out bacterial infection or co-infection with other viruses.
	**COVID-19 Negative** Negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with an alternative molecular assay. A negative result does not rule out co-infections with other pathogens.
	**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 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 tested with an alternative authorized molecular assay, if necessary for clinical management, including infection control.
- 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 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 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.

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 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

Microorganisms from the Same Genetic Family	High Priority Organisms
	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	 Caution, consult accompanying documents.	CE Mark
IVD *In Vitro* Diagnostics	EUA For Use Under an Emergency Use Authorization Only (Applies to US only)	

ORDERING and CONTACT INFORMATION

Reorder numbers:

191-000: ID NOW COVID-19 Test Kit

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

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OUS +1 321 441 7200

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REFERENCES

1. Manual of Clinical Microbiology, 11th Edition, Vol. 1, ASM. (2015) pg. 279.
2. https://www.iata.org/en/programs/cargo/dgr

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CE IVD

IN191000 Rev.1 2020/09

Abbott
ID NOW
COVID-19

PI - EN

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

Printed Colors

CMYK

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

PMS 2995 U
Primary Blue

PMS 224 U
Magenta-Pink

PMS 303 U
Dark Blue

PN: IN191000
Rev: 1

Date of Last Revision:
1.2 2020/09/11