New Vision Medical Laboratories Putnam County Ambulatory Care Center Ottawa, Ohio Technical Procedure		Procedure Number: nvml.pcacc.kit.012.ABBOTT.COVID 19

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SUBJECT: Abbott ID NOW COVID 19 (Alere)

❖ FOR EMERGENCY USE AUTHORIZATION ONLY ❖

1. PRINCIPLE:

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 COVID-19 kit contains all components required to carry out an assay for SARS-CoV-2 on the ID NOW Instrument. Results are for the identification of SARS-CoV-2 RNA.

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.

2. CLINICAL SIGNIFICANCE:

An outbreak of respiratory illness of unknown etiology in Wuhan City, Hubei Province, China was initially reported to WHO on December 13, 2019. 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. Significant numbers of cases of severe illness and deaths have been reported. The International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2.

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 should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with different authorized of

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 resent exposure, history, 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. The ID NOW COVID-19 test is only for use under the Food and Drug Administration's Emergency Use Authorization.

3. SPECIMEN:

A. COLLECTION AND PROCESSING:

- Use freshly collected specimens for optimal test performance.
- Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results.

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.

B. REJECTION:

- Improperly collected specimens.
- Improperly stored specimens. See Storage and Preservation instructions below.
- Specimens not received within the acceptable time frame for testing.
- Improperly labeled specimens.

C. STORAGE AND PRESERVATION:

SPECIMEN TRANSPORT and STORAGE

- Direct nasopharyngeal swabs should be tested as soon as possible after collection.
- If immediate testing is not possible, the nasopharyngeal swab can be held in its original package at room temperature (15-30°C) for up to two (1) hours prior to testing.
- Submit the properly labeled nasopharyngeal swab to the laboratory within its original package inside a biohazard bag. Only 1 specimen per bag to eliminate cross contamination.

NOTE: Any swabs eluted in transport media are ***NO longer suitable*** for use with this test. (Any dilution of the sample will result in decreased test sensitivity.)

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.

4. REAGENTS, STANDARDS, AND CONTROLS:

A. PREPARATION:

Ensure all test components are at room temperature before use.

Materials Provided :

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

B. CONTROL PROCEDURE:

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 and lot

number received.

Record control results in the appropriate Microbiology QC program.

Further required quality control will be determined post on-site verification studies.

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.

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' Home
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.

B. FAILURE/REMEDIAL ACTION:

Send to reference laboratory.

5. EQUIPMENT:

A. INSTRUMENTS:

ID NOW Instrument

Maintenance & Cleaning of ID NOW instrument:

- The ID NOW Instrument is maintenance-free and has no serviceable parts.
- In the case of instrument failure or damage, contact Abbott Technical Support.
- Acceptable cleaning agents include the following:
  a. 70% ethanol - available in commercial wipes or on a damp, lint free cloth •
  b. 70% isopropanol - available in commercial wipes or on a damp, lint free cloth
  c. 10% bleach - on a damp, lint free cloth only

- Do not spray or pour solution directly onto instrument when cleaning.
- Ensure no excess liquid is used when cleaning as it may damage the instrument.
- Abbott recommends that the exterior instrument surfaces and the surfaces visible under the open lid be cleaned daily.
- Clean surrounding bench area.
- Clean instrument and surrounding areas immediately after possible patient sample contamination.
- Do not disassemble the instrument for cleaning.
- Do not immerse in water or cleaning solutions.
- Do not clean with soap or other solutions.

Instrument Calibration: The ID NOW Instrument is factory calibrated and does not require any further calibration and verification. However, if the instrument was transported or moved, a performance check using ID NOW positive and negative controls is recommended to ensure proper functionality.

B. MICROSCOPIC EXAMINATIONS (AND REJECTIONS):

Not applicable

6. PROCEDURE:

A. PERFORMANCE:

Appropriate Proper Personal Protective Equipment (PPE) is required for all personnel that collect and/or process ID NOW COVID-19 specimens. Specimen manipulation and cartridge inoculation may be performed under a biological safety hood but is not required.

In order to prevent cross contamination leading to false positive results the following process controls must be followed:

- ***Clean gloves must be donned prior to performing each patient testing procedure. (If you walk away or initiate another patient test a new pair of gloves must be donned prior to resuming testing procedure.***
- ***Manufacturer recommends the exterior of the instrument and the surfaces visible under the open lid be cleaned daily and as needed if sample contamination has occurred.***
- ***Clean surrounding bench area daily and as needed if sample contamination has occurred.***
- ***The test pieces must remain sesaled in their foil poiches until just before use – they must be inserted into the analyzer directly from the foil pouch.***
- ***Do not separate the test base and transfer cartridge upon removal from the analyzer. All pieces must be removed from the instrument according to removal instructions.***
- ***All test pieces are single use. A separate test system must be used for each patient.***

****Please remember when processing all samples to maintain a clean working environment.***

****Instrument MUST be cleaned between EACH test or QC run to avoid any possible cross contamination. See Maintenance & Cleaning of ID NOW under "Instruments".***

- 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 ONE:

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.

2. Enter User ID: Press '√ ' after entry.

3. Touch 'Run Test': This will begin the test process.

4. Touch 'COVID-19 Test': This starts a COVID-19 test.

5. 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.

6. Enter Patient ID using on screen keyboard or barcode scanner. Touch '√ '. Verify that the ID was entered correctly, then touch '√ ' to confirm entry.

STEP TWO:

7. Open Lid.
   Insert test base into device. 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.

8. 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 THREE:

9. Place sample receiver in holder.
   - 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.

a. The instrument will proceed to the Home screen.
b. Press Run Test and restart the test using a new Test Base and Sample Receiver.
c. Wait for the Sample Receiver to Warm Up. Do not remove the Sample Receiver from the instrument once Warm Up begins.
d. Caution: DO NOT REMOVE THE FOIL SEAL UNTIL PROMPTED BY THE INSTRUMENT.
e. DO NOT close the lid or insert the sample until prompted by the instrument.

STEP FOUR:

Direct Nasopharyngeal Swab Test Procedure:

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

c) Discard the swab.
d) Skip to Step 5a.

STEP FIVE A (5a)

a) Press the White Transfer Cartridge into the Blue Sample Receiver
b) Listen for a click.
c) 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 FIVE B (5b)

a) Lift and then connect the Transfer Cartridge to the Test Base
b) 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 SIX

a) Close the lid.
b) 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.

c) 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.

d) 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 as biohazard waste.

- 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.

****Please remember when processing all samples to maintain a clean working environment.*

****Instrument MUST be cleaned between EACH test or QC run to avoid any possible cross contamination. See Maintenance & Cleaning of ID NOW under "Instruments".***

B. CALCULATIONS:

Not applicable

C. INTERPRETATION OF RESULTS:

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

- COVID-19 Positive

  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.

- COVID-19 Negative

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

  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.

  ✓ 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.

- COVID-19 Invalid

  a) The presence or absence of COVID-19 Viral RNAs cannot be determined.
  b) Repeat testing of the sample using new test components.
  c) If repeated Invalid results are obtained, results should be confirmed by another method prior to reporting the results.

7. CALIBRATION AND CALIBRATION VERIFICATION

A. CALIBRATION AND CALIBRATION VERIFICATION

Not applicable

8. EXPECTED RESULTS:

A. REPORTABLE RANGE:

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

- COVID-19 Positive

  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.

- COVID-19 Negative

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

  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.

  ✓ 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.

- COVID-19 Invalid

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

  b) Repeat testing of the sample using new test components.

  c) If repeated Invalid results are obtained, results should be confirmed by another method prior to reporting the results.

In order to monitor for the presence of false positive results process controls have been implemented and all physician inquiries will be reviewed and investigated.

B. REFERENCE RANGE:

Not applicable

10. REPORTING RESULTS:

All final Covid results are reported ASAP or within 24 hours to all appropriate care providers and to all responsible State authorities.

A. NORMAL VALUES:

Not applicable

B. CRITICAL VALUES:

- Call all positive patients, as these patients MUST be put into CONTACT, DROPLET PLUS ISOLATION

- Critical values must be called to the attending physician or appropriate nursing personnel. The person receiving critical value is to recite back the result. Document this information in the LIS according to critical value policy nvml.101.

10. PROCEDURAL NOTES:

a) For in vitro diagnostic use.
b) For use under an Emergency Use Authorization Only.
c) Federal Law restricts this device to sale by or on the order of a licensed practitioner (US only).
d) Laboratories within the United States and its territories are required to report all positive results to the appropriate public health laboratories.
e) To be used in conjunction with the ID NOW Instrument.
f) Treat all specimens as potentially infectious. Follow universal precautions when handling samples, this kit and its contents.
g) Proper sample collection, storage and transport are essential for correct results.
h) Leave test pieces sealed in their foil pouches until just before use.
i) Do not tamper with test pieces prior to or after use.
j) Do not use kit past its expiration date.
k) Do not mix components from different kit lots or from other ID NOW assays.
l) 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.
m) 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.
n) 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.
o) 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.
p) 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.
q) All test pieces are single use items. Do not use with multiple specimens.
r) 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.
s) At a low frequency, clinical samples can contain inhibitors that may generate invalid results. Site to site invalid rates may vary.
t) 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 Maintenance & Cleaning, for further information.

A. BACKUP FOR INOPERABLE SYSTEM

Send to reference laboratory.

B. REFERAL OF SPECIMENS:

Submit specimen to reference testing area.

C. SUBMISSION/HANDLING OF REFERRAL SPECIMENS:

Submit specimen to reference testing area.

11. LIMITATIONS AND INTERFERRING SUBSTANCES:

- 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.
- 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, the relevant Conditions of Authorization are listed below:

A. Authorized laboratories and patient care settings using this product will include with result reports of this 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 this product will use this 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 this product are not permitted.
C. Authorized laboratories and patient care settings that receive this product will notify the relevant public health authorities of intent to run this product prior to initiating testing.
D. Authorized laboratories and patient care settings using this 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 this 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 this product of which the user becomes aware.
F. All operators using this product must be appropriately trained in performing and interpreting the results of this product, use appropriate personal protective equipment when handling this kit, and use this product in accordance with the authorized labeling.

G. Authorized distributors, and authorized laboratories and patient care settings using this 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.

- 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.

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.

- **Limit of Detection (LOD) Study Results**
  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
	Rhinovirus A - C
	Human respiratory syncytial virus
	Chlamydia pneumoniae
	Haemophilus influenzae
	Legionella pneumophila
Microorganisms from the Same Genetic Family	High Priority Organisms
	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

12. METHOD VALIDATION:

November 2020

13. REFERENCES:

a. Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/index.html. Accessed February 9, 2020.
b. bioRxiv. (https://www.biorxiv.org/content/10.1101/2020.02.07.937862v1). Accessed March 3, 2020.
c. Manual of Clinical Microbiology, 11th Edition, Vol. 1, ASM. (2015) pg. 279.
d. 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
e. Abbott Diagnostics Scarborough, Inc. 10 Southgate Road Scarborough, Maine 04074 USA www.abbott.com/poct

Technical Support Advice Line Further information can be obtained by contacting Technical Support on: US +1 855 731 2288 ts.scr@abbott.com

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