GUAM PUBLIC HEALTH LABORATORY GUIDELINES FOR ABBOTT ID NOW COVID-19 RAPID DIAGNOSTIC TEST

Methodology	Abbott 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.
CLIA, 42 U.S.C. §263a	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. Abbott ID NOW™ COVID-19 assay is also authorized to be distributed and used in patient care settings outside of the clinical laboratory environment.
Specimen Requirements	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**
Specimen Collection & Handling	Specimen collection should be performed by healthcare personnel who have completed training and demonstrated competency on biosafety policies and procedures and appropriate use of personal protective equipment (PPE) that should be worn at all times.

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Specimen Collection & Handling (Cont.)	**Direct Nasal Swab:** Use sterile ID NOW PATIENT SWABS, or other sterile foam swab to collect a direct nasal sample. 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. 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anterior nare parallel to the palate, leave in place for a few seconds, and then slowly rotate the swab as it is being withdrawn. **Nasopharyngeal Swab:** (Provided separately) 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.

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Specimen Transport **Note:** **Do not store swab in viral transport media or any other solution that dilutes the sample.**	**Preferred Specimen:** Direct nasal 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 in a sterile container (Red Top) 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.
Materials & Reagents	**Test Kit Content**
ID NOW™ Instrument	Provided separately. Use with ID NOW™ Instrument User Manual.
TEST BASES BASE	Orange plastic components containing two reaction tubes of lyophilized reagents for the targeted amplification of SARS-CoV-2 viral RNA and an internal control.
SAMPLE RECEIVERS RCVR	Blue plastic components containing 2.5 mL of elution buffer.
TRANSFER CARTRIDGES CARTRDG	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.
PLASTIC DISPOSABLE PIPETTES CAPABLE OF DELIVERING 200 µL VTM SAMPLE	AS INDICATED
PRODUCT INSERT	QUICK REFERENCE INSTRUCTIONS

Storage & 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.

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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 Internal 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	Use of positive and negative controls ensures 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, new lot, and once for each untrained operator. 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.
Precautions	1. ID NOW For in vitro diagnostic use. 2. For use under an Emergency Use Authorization Only.

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Precautions (Cont.)	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

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Precautions (Cont.)	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. 21. 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. 22. 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. 23. 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. 24. 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. 25. All test pieces are single use items. Do not use with multiple specimens. 26. 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. 27. At a low frequency, clinical samples can contain inhibitors that may generate invalid results. Site to site invalid rates may vary.

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Precautions (Cont.)	28. Due to the high sensitivity of the assays run on the instrument, contamination of the work. 29. 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. 30. 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. 31. 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. 32. 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. 33. All test pieces are single use items. Do not use with multiple specimens. 34. 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. 35. At a low frequency, clinical samples can contain inhibitors that may generate invalid results. Site to site invalid rates may vary. 36. 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.
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.

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Test Procedure (Cont.)	• 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.
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/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov 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

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Conditions of Authorization for Laboratory and Patient Care Settings (Cont.)	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.
Result Notification	Results at the Patient Care Settings are reported to patients within 15-30 minutes of testing specimen(s) by the medical provider or designee. Copies of results shall be forwarded to DPHSS Surveillance at dphss.surveillance@dphss.guam.gov.

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Note: **Report to Guam DPHSS Territorial Epidemiologist 671-888-WARN (9276) of any confirmed COVID-19 or disease cases with potential for serious public health impact or which may merit epidemiologic investigation.**	Results at the Laboratory are reported to the submitting healthcare facility and or medical provider. Healthcare facility and or medical provider will be responsible for reporting all test results to patients and to DPHSS Territorial Epidemiologist and Surveillance Unit. Any other request for copies of result reports, apart from that stipulated above will not be accepted.
Laboratory Contact Information	Alan Mallari, Microbiologist II (671) 300-9080 (671) 300-9989 FAX alan.mallari@dphss.guam.gov Lea Nisay, Microbiologist I, (Alternate) (671) 300-9088/9096 (671) 300-9989 FAX lea.nisay@dphss.guam.gov Anne Marie Santos, Central Laboratory Administrator (671) 300-9093/9082 (671) 300-9989 FAX annemarie.santos@dphss.guam.gov

Attachment:

1. GPHL Submission Form DPHSS_FRM_03.11.2020
2. Patient Instructions for Individuals Tested for COVID-19
3. ID NOW COVID-19 Fact Sheet for Healthcare Providers
4. ID NOW COVID-19 Fact Sheet for Patients

References:

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

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GUAM PUBLIC HEALTH LABORATORY
DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
761 South Marine Corps Drive, Tamuning, Guam 96913
Telephone: (671) 300-9085/9096/9097/9098 Fax: (671) 300-9989

(PLEASE PRINT LEGIBLY)

GPHL LABORATORY NUMBER

DATE RECEIVED

ORDERING/PRIMARY PHYSICIAN:

ADDRESS:
Street:
City: State:
Country: Zip Code:
Phone No.:

SUBMITTING LABORATORY:

ADDRESS:
Street:
City: State:
Country: Zip Code:
Phone No.:

I. PATIENT IDENTIFICATION

LAST NAME	FIRST NAME AND MIDDLE INITIAL

RESIDENT ADDRESS (Physical place of residence Street, City, Zip Code)

Street:

City: Zip Code:

PHONE NO.:
Cell/Mobile: Home: Work:

OCCUPATION	ETHNICITY (e.g. Chamorro, Filipino, etc.)	DATE OF BIRTH	SEX

CLINICAL DIAGNOSIS

DATE OF ONSET

LABORATORY EXAMINATION REQUESTED
COVID-19/SARS-COV-2 rRT-PCR

CATEGORY OF AGENT SUSPECTED

SPECIFIC AGENT SUSPECTED

II. SPECIMEN INFORMATION

1. SOURCE OF SPECIMEN
☑ HUMAN
☐ OTHER (Specify):

2. ORIGINAL MATERIAL
TYPE OF SPECIMEN (SPECIFY SITE OF COLLECTION):
NASOPHARYNGEAL

DATE AND TIME OF COLLECTION:

TRANSPORT MEDIUM:
VIRAL TRANSPORT MEDIA

COLLECTED BY (PRINT NAME):

SEROLOGY OF SPECIMEN
COLLECTION DATE:
☐ ACUTE (S1):
☐ CONVALESCENT (S2):
☐ S3:
☐ S4:
☐ OTHER (Specify):

4. SEROLOGY OF SPECIMEN
☐ PURE ISOLATE
☐ MIXED CULTURE
☐ OTHER (Specify):

DATE OF ORIGINAL CULTURE:
PRIMARY ISOLATON MEDIA:
COLLECTON SITE OF ORIGINAL SPECIMEN:
DATE OF CULTURE SUBMITTED AND TRANSPORT MEDIUM USED:
SUSPECTED IDENTIFICATION:
OTHER ORGANISMS FOUND:
OTHER INFORMATION:

III. CLINICAL HISTORY

1. CLINICAL SIGNS AND SYMPTOMS
☐ FEVER
☐ EXANTHEMA (Specify Type):
☐ RESPIRATORY SIGNS:
☐ CENTRAL NERVOUS SYSTEM INVOLVEMENT:
☐ GASTROINTESTINAL INVOLVEMENT:

2. ADDITIONAL INFORMATION
TRAVEL HISTORY:
IMMUNIZATIONS:
ANTIBIOTIC THERAPY:

DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES BCDC GPHL USE ONLY

Assay:

Result:

DATE OF REPORT:_____ INITIAL_____

3. PREVIOUS LABORATORY RESULTS/OTHER INFORMATION

The instrumentation used to conduct the test has significant sensitivity. Nevertheless few negative results should be treated with caution. Patient follow up and repeat testing, if clinically indicated, are recommended.

Patient Last Name: _____ Patient First Name: _____
Date of Birth: _____

COVID-19 Form for Mass Screening

Date of onset: _____ (*if symptomatic*)

During this illness, did the patient experience any of the following symptoms?

SYMPTOMS	YES	NO
Fever >100.4F (38C)		
Subjective fever (felt feverish		
Chills		
Muscle aches (myalgias)		
Runny nose		
Sore throat		
Cough (new or worsening)		
Shortness of breath		
Nausea or vomiting		
Headache		
Abdominal pain		
Diarrhea		
Loss of sense of smell or taste or appetite		
Congestion		
Fatigue/weakness		
Rash		
Other (specify):		

Does the patient have any pre-existing medical conditions?

CONDITION	YES	NO
Chronic lung disease (asthma, emphysema, COPD)		
Diabetes mellitus		
Cardiovascular disease		
Hypertension only (high blood pressure)		
Chronic renal disease (ESRD/CRI)		
Chronic liver disease		
Immunocompromised condition (cancer, chemo, lupus, HIV etc).		
Neurological/neurodevelopmental/intellectual disability		
Hepatitis		
Other (specify):		
Former smoker		
Current smoker		

Contact with another lab-confirmed COVID-19 patient? Yes ____No____
Previous COVID-19 testing? Yes ____No____ If *"Yes"*, Date of collection:_____

Name of Interviewer: Last _____ First _____

Date of Interview: _____

Patient Instructions For Individuals Tested For COVID-19

For more information, please call 311 or visit dphss.guam.gov • Updated: December 19, 2020

DPHSS Guidance on quarantine and isolation

The Department of Public Health and Social Services (DPHSS) reminds patients who are waiting for COVID-19 test results to remain in quarantine at home, stay away from others, monitor for symptoms of COVID-19 until they receive their results.

When to get tested

- You are a close contact to someone diagnosed with COVID-19.
- You have symptoms of COVID-19. On average, symptoms of the virus develop five to six days post exposure but the incubation period can be as long as 14 days. The best time to test for COVID-19 is 5-7 days after a probable exposure.
- You have been referred by your healthcare provider or DPHSS.

WHAT YOU SHOULD DO IF YOUR RESULTS ARE:

People who have previously tested positive for COVID-19 do not need to quarantine or get tested again for up to 3 months as long as they do not develop symptoms again. People who develop symptoms again within 3 months of their first bout of COVID-19 may need to be tested again if there is no other cause identified for their symptoms.

NEGATIVE:

Quarantine is for people who are **not sick** but may have been exposed to a person with COVID-19.

- If you had close contact* with a person who has COVID-19 — excluding people who have had COVID-19 within the past 3 months
  - – Stay home for 14 days after your last contact
  - – Watch for fever (100.4ºF), cough, shortness of breath, or other symptoms of COVID-19
  - – Stay away from people who are at higher risk for getting very sick from COVID-19, if possible.

*Someone who was within 6 feet of an infected person for a cumulative total of 15 minutes or more over a 24-hour period starting from 2 days before illness onset (or, for asymptomatic patients, 2 days prior to test specimen collection) until the time the patient is isolated.

POSITIVE:

Isolation is for people who are already **sick** with COVID-19. (Person who is COVID-19 positive is placed in isolation).

- **You must isolate** at home or at the government isolation facility for at least 10 days. If you feel that home isolation may not be possible, call the numbers below to determine proper isolation measures:
  - – From 8:00 am to 8:00 pm – 311, Option 1
  - – From 8:00 pm to 8:00 am – (671) 998-4512
- If you live with others, stay in a separate room from other household members. Use a separate bathroom, if possible. Don't share personal household items, like cups, towels, and utensils. Wear a mask when around other people.
- If you are symptomatic, you can leave isolation after:
  - – 10 days since symptoms first started, and
  - – 24 hours with no fever without the use of fever-reducing medications; and
  - – Other symptoms of COVID-19 are improving
- If you continue to have no symptoms, you can leave isolation after 10 days have passed since testing positive for COVID-19.
- If you are severely ill, advise your healthcare provider or DPHSS nurse of your symptoms or call 911.

10 THINGS YOU CAN DO TO MANAGE YOUR COVID-19 SYMPTOMS AT HOME

1. Stay home from work, school, and away from other public places.
2. Monitor your symptoms carefully. If your symptoms get worse, call your healthcare provider immediately.
3. Get rest and stay hydrated.
4. If you have a medical appointment, call your healthcare provider ahead of time and tell them that you have or may have COVID-19.
5. For medical emergencies, call 911 and notify the dispatch personnel that you have or may have COVID-19.
6. Cover your coughs and sneezes with a tissue or the inside of your elbow.
7. Wash your hands often with soap and water for at least 20 seconds, or clean your hands with hand sanitizer that contains at least 60% alcohol.
8. As much as possible, stay in a specific room and away from other people in your home. Use a separate bathroom, if available. If you need to be around other people at home, wear a mask.
9. Avoid sharing personal items with other people in your household, like dishes, towels, and bedding.
10. Clean all surfaces that are touched often, like counters, tabletops, and doorknobs. Use household cleaning sprays or wipes according to the label instructions.

Clearance from quarantine and isolation

Once you meet the criteria to be released from quarantine or isolation, you will be given a clearance from DPHSS. For more information, please call the Medical Triage Hotline at (671) 685-0358, (671) 687-7321, (671) 480-6760/6763/7859/7883, (671) 998-4442/4460/4474/4480, (671) 687-6170 (ADA/Text), or 311/Option 1, Monday - Saturday 8AM-10PM, Sunday 8AM - 5PM.

Hard copies of results

If you were tested at the Northern Region Community Health Center (NRCHC) or at a DPHSS Community Outreach and you want to receive a hard copy of your results, contact:

- NRCHC at (671) 635-7525/26
- Medical Triage Hotline: (671) 685-0358, (671) 687-7321, (671) 480-6760/6763/7859/7883, (671) 998-4442/4460/4474/4480, (671) 687-6170 (ADA/Text), or 311/Option 1
- Send email requests to covidresults@dphss.guam.gov

FACT SHEET FOR HEALTHCARE PROVIDERS

Abbott Diagnostics Scarborough, Inc. **Updated: September 17, 2020**

ID NOW COVID-19

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the ID NOW COVID-19.

The ID NOW COVID-19 is authorized for use with respiratory specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Abbott Diagnostics Scarborough, Inc. - ID NOW COVID-19.

What are the symptoms of COVID-19?
Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in "*Where can I go for updates and more information?*" section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdictions website for the most up to date information.

What do I need to know about COVID-19 testing?
Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "*Where can I go for updates and more information?*" section).

This test is to be performed only using respiratory specimens collected from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms.

- The ID NOW COVID-19 can be used to test direct nasal, nasopharyngeal or throat swabs.
- The ID NOW COVID-19 should be ordered for the detection of COVID-19 in individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms.
- The ID NOW COVID-19 is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high and moderate complexity tests.
- The ID NOW COVID-19 Test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Specimens should be collected with appropriate infection control precautions. Current guidance is available at the CDC's website (see links provided in "*Where can I go for updates and more information?*" section).

When collecting and handling specimens from individuals suspected of being infected with COVID-19, appropriate personal protective equipment should be used as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19) (*see links provided in "*Where can I go for updates and more information?*" section).

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

What does it mean if the specimen tests positive for the virus that causes COVID-19?
A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected, and therefore the patient is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should be made by a healthcare provider and follow current CDC guidelines.

The ID NOW COVID-19 has been designed to minimize the likelihood of false positive test results. However, it is still possible that this test can give a false positive result, even when used in locations where the prevalence is below 5%. In the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for the virus that causes COVID-19?
A negative test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. 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. It is possible to test a person too early or too late during COVID-19 infection to make an accurate diagnosis via the ID NOW COVID-19.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative.

If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing with an alternative method should be considered by healthcare providers in consultation with public health authorities. Additional testing may be helpful to ensure testing was not conducted too early.

Risks to a patient of a false negative test result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

What is an EUA?
The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?
There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/COVID19
Symptoms:
https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html
Healthcare Professionals:
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Information for Laboratories:
https://www.cdc.gov/coronavirus/2019-nCoV/guidance-laboratories.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-nCoV/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings:
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html
Specimen Collection: https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html
Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs:(includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas

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FACT SHEET FOR PATIENTS

Abbott Diagnostics Scarborough, Inc.
ID NOW COVID-19

Updated: September 17, 2020

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample(s) was tested for the Coronavirus Disease 2019 (COVID-19) using the ID NOW COVID-19.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:
https://www.cdc.gov/COVID19

What is COVID-19?
COVID-19 is caused by the SARS-CoV-2 virus which is a new virus in humans causing a contagious respiratory illness. COVID-19 can present with a mild to severe illness, although some people infected with COVID-19 may have no symptoms at all. Older adults and people of any age who have underlying medical conditions have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 include hospitalization and death. The SARS-CoV-2 virus can be spread to others not just while one is sick, but even before a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.). A full list of symptoms of COVID-19 can be found at the following link: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html.

What is the ID NOW COVID-19?
The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasal or oral swabs.

Why was my sample tested?
You were tested because your healthcare provider believes you may have been exposed to the virus that causes COVID-19 based on your signs and symptoms (e.g., fever, cough, difficulty breathing). Testing of the samples will help find out if you may have COVID-19.

What are the known and potential risks and benefits of the test?

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and those you come in contact with.

What does it mean if I have a positive test result?
If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. You should follow CDC guidance to reduce the potential transmission of disease.

There is a smaller possibility that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of COVID-19 infection. Your healthcare provider will work with you to determine how best to care for you based on the test results along with medical history, and your symptoms

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19.** In addition, please also contact your healthcare provider with any questions/concerns.

What does it mean if I have a negative test result?
A negative test result means that the virus that causes COVID-19 was not found in your sample.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. You might test negative if the sample was collected early during your infection. You could also be exposed to COVID-19 after your sample was collected and then have become infected.

This means that you could possibly still have COVID-19 even though the test result is negative. If your test is negative, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Is this test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency of IVDs, unless it is terminated or revoked by FDA (after which the test may no longer be used).

What are the approved alternatives?

There are no approved available alternative tests. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

- **Where can I go for updates and more information?** The most up-to-date information on COVID-19 is available at the CDC General webpage: **https://www.cdc.gov/COVID19.** In addition, please also contact your healthcare provider with any questions/concerns.