GUAM PUBLIC HEALTH LABORATORY GUIDELINES FOR SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-CoV-2)

Methodology:	U.S. Centers for Disease Control and Prevention (CDC) 2019-Novel Coronavirus (2019-nCoV) real-time Reverse Transcriptase Polymerase Chain Reaction (*r*RT-PCR) Diagnostic Panel Assay is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis of COVID-19. U.S. Centers for Disease Control and Prevention (CDC) Influenza SARS-CoV_2 (Flu SC2) Multiplex real-time Reverse Transcriptase Polymerase Chain Reaction (*r*RT-PCR) Assay is a molecular *in vitro* diagnostic test that aids in the detection and diagnosis of COVID-19. Cepheid Xpert Xpress SARS-CoV-2 Assay is a rapid, real-time RT-PCR test for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper respiratory specimens that aids in the detection and diagnosis of COVID-19. Cepheid Xpert Xpress SARS-COV-2 FLU RSV Multiplex Assay is a rapid, real-time RT-PCR test for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper respiratory specimens that aids in the detection and diagnosis of COVID-19.
Product Support:	1. Guam Public Health Laboratory (GPHL) contacts the CDC Division of Viral Disease and or CDC International Reagent Resource (IRR) directly for technical and product support. 2. For reagents sourced from other than the CDC IRR, GPHL refers to the manufacturer's instructions provided with the commercial materials.
Intended for Use:	1. For the qualitative detection of nucleic acid from the 2019-nCoV also known as SARS-CoV-2. 2. CDC 2019-nCoV panel assay and (CDC) Influenza SARS-CoV_2 (Flu SC2) multiplex assay with the Applied Biosystems (ABI) 7500 Fast DX real-time RT-PCR Instrument. Xpert Xpress SARS-CoV-2 assay and Xpert Xpress SARS-COV-2 FLU RSV multiplex assay with the Cepheid GeneXpert DX System. 3. With Upper and Lower Respiratory specimens collected from persons who meet the CDC criteria for COVID-19 testing. 4. By Laboratories designated by CDC as qualified, and in the United States and Territories, certified under the Clinical Laboratory Improvement Amendments (CLIA) to perform high complexity tests.

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Performed at **Guam Public Health Lab:**	Applied Biosystems 7500 Fast DX real-time RT-PCR CDC 2019-nCoV Real-time RT-PCR Assay and CDC Influenza SARS-CoV_2 (Flu SC2) Multiplex Assay are **Food and Drug Administration (FDA) authorized** assays, issuing the Emergency Use Authorization (EUA) to test specimens according to the CDC criteria. • For the detection of 2019-nCoV RNA in nasopharyngeal specimens, indicative of active infection with 2019-nCoV but do not rule out bacterial infection or co-infection with other viruses. • Positive results obtained with CDC 2019-nCoV Real-time RT-PCR Diagnostic Panel Assay and CDC Influenza SARS-CoV_2 (Flu SC2) Multiplex Assay are to be interpreted and reported as "positive for 2019-nCoV" and results do not require confirmation at CDC. Cepheid Xpert Xpress SARS-CoV-2 Assay and Xpert Xpress SARS-COV-2 FLU RSV Multiplex Assay are rapid, real-time RT-PCR tests for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper respiratory specimens that aids in the detection and diagnosis of COVID-19. They are authorized for use by the **Food and Drug Administration (FDA) authorized** under the Emergency Use Authorization (EUA). • For the qualitative detection of SARS-CoV-2 nucleic acid in nasopharyngeal specimens, indicative of active infection with COVID-19 but do not rule out bacterial infection or co-infection with other viruses. • Positive results obtained with Xpert Xpress SARS-CoV-2 Assay and Xpert Xpress SARS-COV-2 FLU RSV Multiplex Assay are to be interpreted and reported as "SARS-CoV-2 positive" and results do not require confirmation at CDC.
Criteria for Molecular/ PCR testing:	Testing of nasopharyngeal specimens with the CDC 2019-nCoV Real-time RT-PCR Assay, CDC Influenza SARS-CoV_2 (Flu SC2) Multiplex Assay, Xpert Xpress SARS-CoV-2 Assay and/or Xpert Xpress SARS-COV-2 FLU RSV Multiplex Assay **should not be performed** unless the patient meets clinical signs and/or symptoms compatible with SARS-CoV-2 virus infection and/or specimens meeting the case definition set and/or updated by the CDC and/or the Bureau of Communicable Disease Control (BCDC) under the Division of Public Health of the Department of Public Health and Social Services (DPHSS). **Note: Negative results obtained with this test do not preclude the diagnosis of SARS-CoV-2 virus and should not be used as the sole basis for treatment or other patient management decisions.**

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Case Definition:	**Guam considers a Person Under Investigation (PUI) based on the following criteria:** • **Hospitalized patients** with fever and signs/symptoms of lower respiratory illness (e.g. cough or shortness of breath) AND A history of travel from affected geographic areas[1] within 14 days of symptom onset -OR- • **Hospitalized patients** with fever with severe acute lower respiratory illness (e.g. pneumonia, acute respiratory distress syndrome [ARDS]) without alternative explanatory diagnosis (e.g., influenza) -OR- • Fever and signs/symptoms of a lower respiratory illness (e.g., cough or shortness of breath) AND A history of close contact with a laboratory confirmed COVID-19 patient within 14 days of symptom onset Surveillance cases of COVID-19 will be evaluated on a case-by-case basis. Testing of surveillance cases may be capped based on testing availability. Clinicians should work with DPHSS to coordinate testing through GPHL. Clinicians should use their judgment to determine if a patient has signs and symptoms compatible with COVID-19 and whether the patient should be tested. Most patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). Clinicians are strongly encouraged to test for other causes of respiratory illness (e.g., influenza). [1] International Areas with Ongoing Transmission listed at https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html
Specimen Requirements **Note: GPHL performs testing only on NP specimen.**	Points to consider when determining which specimen types to collect from a PUI for 2019-nCoV include: • The number of days between specimen collection and symptom onset • Symptoms at the time of specimen collection Preferred Specimen • Nasopharyngeal (NP) specimen Other Acceptable Specimens that may be sent to CDC upon CDC approval • Lower Respiratory tract specimens – Sputum, bronchoalveolar lavage, tracheal aspirate, pleural fluid • Serum – to be collected along with lower respiratory tract specimen if symptom onset was 14 or more days ago. *Note: Specimens should be collected as soon as possible after symptoms begin, ideally within 7 days.*

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Pre-Collection Guidelines:	**Prior to collection of any specimen**, call the Department of Public Health and Social Services (DPHSS), Bureau of Communicable Disease Control (BCDC) for consultation. **No** specimen(s) will be accepted at GPHL without consultation. ➢ Primary Contact Person: Dr. Ann Pobutsky, Territorial Epidemiologist: (671) 735-7136 or (671) 888-9276 ➢ Secondary Contact Person: Annette Aguon, BCDC Administrator Contact numbers: (671) 735-7142/7143 or (671) 777-7210 ➢ Alternate Contact Person: Estelle A. Ada, ELC Program Supervisor: (671) 735-7136 or (671) 777-1706 ➢ Alternate Contact Person: Anne Marie Santos, Laboratory Administrator Contact numbers: (671) 300-9093
Specimen Collection Guidelines:	Specimens collected by healthcare facility, perform collection process following CDC guidance. Nasopharyngeal specimens will be transported to GPHL and other specimens as needed will be sent to the CDC for testing. Specimen Types and General Guidelines: 1. Respiratory Specimens 1.1. Nasopharyngeal swabs (NP swabs) Use only synthetic fiber swabs with plastic shafts. Do not use calcium alginate swabs or cotton swabs with wooden shafts. Use viral swabs (sterile Dacron or rayon) in the VTM or UTM viral transport media kit provided by DPHSS Public Health Laboratory. Place swabs immediately into the viral transport media. NP and OP specimens should be kept in separate vials. Refrigerated specimen at 2-8°C up to 72 hours; freeze if longer than 72 hours. 1.1.1. Nasopharyngeal swabs: Insert a swab into the nostril parallel to the palate. 1.1.2. Leave the swab in place for a few seconds to absorb secretions. Swab both nasopharyngeal areas with the same swab. 1.2. Nasopharyngeal wash/aspirate or Nasal aspirates Collect 2-3 ml into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C up to 72 hours; freeze if longer than 72 hours. 1.3. Bronchoalveolar lavage, tracheal aspirate, pleural fluid Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container. Refrigerate specimen at 2-8°C up to 72 hours; freeze if more than 72 hours. 1.4. Sputum Patient should rinse the mouth with water and then expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap sputum collection sterile dry

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(cont.) Specimen Collection Guidelines	container. Refrigerate specimen at 2-8°C up to 72 hours, freeze if more than 72 hours. 2. Blood Components 2.1. Serum for serological testing: recommended only when RT-PCR is not available. 2.2. Serum for *r*RT-PCR testing: for detection of virus, not antibodies. 2.3. Collect serum specimen during the first week after symptom onset, preferably within 4-7 days after symptom onset. *Children and Adults:* Collect 5-10 ml of whole blood in a serum separator tube (SST). Spin, separate and transfer serum (minimum of 200 µl) into a sterile tube container. Refrigerate specimen at 2-8°C. *Infants:* Collect 1 ml of whole blood in a serum separator tube (SST). If only 1 ml can be obtained, use SST. Refrigerate specimen at 2-8°C. *Note:* Serum separator tubes should be stored upright for at least 30 minutes, and then centrifuged at 1000-1300 relative centrifugal force (RCF) for 10 minutes before removing the serum and placing it in a separate sterile tube for shipping (such as cryovial). Refrigerate the serum specimen at 2-8°C up to 72 hours, freeze if more than 72 hours. *Note: Label each specimen container with the patient's name, ID number, specimen type, the date and time the sample was collected.*
Specimen Submission Guidelines	• Submit appropriate type of specimen, label each specimen container with the patient's name and ID number (e.g., medical record number), unique specimen ID (e.g., lab requisition number), specimen type (e.g., serum), the date and time the sample was collected, and symptoms at the date and time of specimen collection. Refer to Specimen Collection instructions above for acceptable specimens. • Fill out COMPLETELY the **2019-nCoV Patient Under Investigation (PUI) case investigation form** (https://www.cdc.gov/coronavirus/2019-ncov/php/reporting-pui.html) and **GPHL Submission Form DPHSS_FRM_03.11.2020** and **submit** with the specimen. • Call DPHSS Guam Public Health Laboratory (GPHL) at (671) 300-9093/300-9096; alternate (671) 300-9080/300-9082/300-9088 to inform DPHSS staff of the specimen delivery. • Follow storage and transport requirements for each specimen type. • Once final result is completed at GPHL, physicians/providers will be notified of the result by GPHL Laboratory Technologist.

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Safety Precautions	• Observe Universal Precautions when handling specimens from 2019-nCoV PUI. • Use appropriate personal protective equipment (PPE) such as disposable gloves, laboratory coat/gown, mask (N-95), and eye protection when handling potentially infectious specimens from 2019-nCoV PUI. • Observe droplet and contact precautions for Upper Respiratory (URT) specimens; airborne precautions for Lower Respiratory (LRT) specimens. • For more detailed safety precautions when dealing with PUI for 2019-nCoV, refer to CDC-Interim Infection Prevention and Control Recommendations for Patients with Known or Patients Under Investigation for 2019 Novel Coronavirus (2019-nCoV) In a Healthcare Setting at http://www.cdc.gov/coronavirus/mers/2019-nCoV/hcp/infection-control.html • Specimens for transport to GPHL must be placed in a sealed bag and placed in a sealed, decontaminated primary container. • All disposable wastes and PPE used for collection should be autoclaved.
Specimen Transport Guidelines	Transport specimens with cold packs (2-8°C), with dry ice if exceeding 72 hours. Deliver specimens to GPHL at RAN-CARE Commercial Building, 3rd Floor, West Wing, 761 South Marine Corps Drive, Tamuning **no later than 4 PM, business days Mondays-Fridays; no later than 11 AM Saturdays.**
Rejection Criteria	• No consultation with DPHSS and BCDC prior to collection of specimen. • Specimen quantity is insufficient to perform the test; • Dry swabs • NP or OP specimens collected in calcium alginate swabs or cotton swabs with wooden shafts. • Specimen received in a container that is leaking. • Specimen is not collected in a proper container or special handling instruction is not followed; • Specimen is not received at 2-8°C/ packed on cold packs; • Unlabeled specimens, incomplete label on specimen (Refer to Specimen Collection Guidelines). • Illegible/ incomplete 2019-nCoV forms (e.g., no date of onset, travel history, etc.) • Specimen label does not match the 2019-nCoV form.

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Result Notification	• Laboratory reports will be forwarded to the submitting healthcare facility and or provider, Territorial Epidemiologist, and the Chief Public Health Officer via Facsimile and/or encrypted email. • Any other request for copies of laboratory reports, apart from that stipulated above will not be accepted. • Turn-Around-Time: Results are reported one (1) to three 3) business days after approval and receipt of NP specimen(s) by Guam DPHSS.
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) 300-9085/9093 (671) 300-9989 FAX annemarie.santos@dphss.guam.gov

Attachments:

1. GPHL Submission Form DPHSS_FRM_03.11.2020
2. Patient Instructions for Individuals Tested for COVID-19
3. CDC 2019-Novel Coronavirus (2019-nCoV) rRT-PCR Diagnostic Panel Assay Fact Sheet for Healthcare Providers
4. CDC 2019-Novel Coronavirus (2019-nCoV) rRT-PCR Diagnostic Panel Assay Fact Sheet for Patients
5. CDC Influenza SARS-CoV_2 (Flu SC2) Multiplex rRT-PCR Assay Fact Sheet for Healthcare Providers
6. CDC Influenza SARS-CoV_2 (Flu SC2) Multiplex rRT-PCR Assay Fact Sheet for Patients
7. Cepheid Xpert Xpress SARS-CoV-2 Assay Fact Sheet for Healthcare Providers
8. Cepheid Xpert Xpress SARS-CoV-2 Assay Fact Sheet for Patients
9. Cepheid Xpert Xpress SARS-CoV-2 FLU RSV Assay Fact Sheet for Healthcare Providers
10. Cepheid Xpert Xpress SARS-CoV-2 FLU RSV Assay Fact Sheet for Patients

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References:

1. Updated Guidance on Evaluating and Testing Persons for Coronavirus Disease 2019 (COVID-19), June 22, 2021; https://www.cdc.gov/coronavirus/2019-ncov/index.html
2. CDC Interim Guidance on Specimen Collection, Processing and Testing for Patients for 2019 Novel Coronavirus, February 26, 2021; Reviewed June 22, 2021; https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
3. CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with 2019 Novel Coronavirus (2019-nCoV), June 12, 2021; Reviewed June 22, 2021; https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html
4. CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel Instructions for Use, Catalog #2019-nCoVEU; www.internationalreagentresource.org; respvirus@cdc.gov
5. Xpert Xpress SARS-CoV-2 Automated Diagnostic Panel 302-3562, Rev. C April 2020; www.cepheid.com/en/CustomerSupport.

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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

Centers for Disease Control and Prevention (CDC) **Updated: December 1, 2020**

CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

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 Centers for Disease Control and Prevention (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is authorized for use with respiratory specimens collected from individuals consistent with the Emergency Use Authorization (EUA).

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Centers for Disease Control and Prevention (CDC) - CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

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 consistent with the EUA.

- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel can be used to test upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate).
- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel should be ordered for the detection of COVID-19 in individuals suspected of COVID-19 by their healthcare provider.
- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel can also be used to test pooled samples containing up to four of the individual upper respiratory swab specimens (nasopharyngeal (NP), oropharyngeal (OP), NP/OP combined, or nasal swabs) that were collected using individual vials containing transport media from individuals suspected of COVID-19 by their healthcare provider.
- The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity tests.

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

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**

*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).

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 CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel 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. It is possible to test a person too early or too late during COVID-19 infection to make an accurate diagnosis via CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

Specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing. Your interpretation of negative results should take into account clinical and epidemiological risk factors. If a patient's clinical signs and symptoms are inconsistent with a negative result or results are necessary for patient management, then the patient should be considered for individual testing.

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 using a new sample with a sensitive method or without pooling 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

Manufacturer: CDC

CDC Emergency Operations Center (EOC)
1600 Clifton Road
Atlanta, Georgia, USA, 30329
Phone: **CDC EOC (770-488-7100)**

FACT SHEET FOR PATIENTS

Centers for Disease Control and Prevention (CDC)
CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel

Updated: December 1, 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 Centers for Disease Control and Prevention's (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel.

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 CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel?
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), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

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.

- **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 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

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.

Laboratories may use pooling when testing your specimen, which means they combine your sample with other individuals samples prior to testing. If your test result indicates your specimen was pooled and you have a negative test result there a small chance that your result is incorrect. You should talk with your healthcare provider if you are concerned.

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.

FACT SHEET FOR HEALTHCARE PROVIDERS

CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay **July 2, 2020**

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 Centers for Disease Control and Prevention's (CDC's) Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay.

Testing is to be conducted on specimens from individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider. Symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

What are the signs and symptoms of COVID-19?
Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat or new loss of taste or smell. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median incubation period is approximately 5 days. For further information on the symptoms of COVID-19 please see the link at the end of the document.

Public health officials have identified cases of COVID-19 throughout the world, including in 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) for the most up to date information.

All individuals whose specimens are tested with this assay must receive the *Fact Sheet for Patients: CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay*

What are the signs and symptoms of influenza?
The signs and symptoms of influenza usually develop suddenly and are similar to those of COVID-19. Common signs and symptoms of influenza are fever, cough, sore throat, runny/stuffy nose, body aches, headaches, and fatigue.

This test is to be performed using respiratory specimens collected from individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider.

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). The Flu SC2 Multiplex Assay:

- can be used to test upper and lower respiratory specimens (such as nasopharyngeal, oropharyngeal, or nasal swab specimens; bronchoalveolar lavage specimens, sputum; lower respiratory tract aspirates; nasopharyngeal wash/aspirates; or nasal aspirates).
- should be ordered for the detection and differentiation of nucleic acid from SARS-CoV-2, influenza A, and/or influenza B viruses in individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider.
- is authorized for use in laboratories in the United States certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a that meet requirements to perform high complexity tests.

Specimens should be collected using 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 at the end of this document).

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*

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**

Specimens Associated with Coronavirus Disease 2019 (COVID-19). For additional information, refer to the CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) (*see links provided in "Where can I go for updates and more information" section at the end of this document).

Can I use the CDC Flu SC2 Multiplex Assay to test asymptomatic individuals?
Asymptomatic or pre-symptomatic individuals can be tested if they are suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider. This can include consideration of epidemiologic reason to do so, including contact with persons with probable or confirmed cases of COVID-19 and/or influenza or travel to areas where these viruses are actively circulating.

Negative results obtained from individuals who are not exhibiting clinical signs and symptoms associated with respiratory viral infection at the time of specimen collection should be interpreted with caution. Negative results in asymptomatic or pre-symptomatic individuals cannot be used as definitive evidence that the individual has not been exposed to or infected with SARS-CoV-2, influenza A, and/or influenza B viruses, or to determine whether an individual may be contagious.

This test is not authorized for use as a broad screening tool.

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

The Flu SC2 Multiplex Assay has been designed to minimize the likelihood of false-positive test results. However, in the event of a false-positive result, risks to individuals 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 might increase contact with other individuals with COVID-19, limits in the ability to work, delayed diagnosis and treatment for the actual infection causing the symptoms, and unnecessary prescription of a treatment or therapy.

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

What does it mean if the specimen tests negative for SARS-CoV-2, the virus that causes COVID-19?
A negative test result for SARS-CoV-2 means that RNA from this virus 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.

When diagnostic testing results are 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 test results for other causes of illness (e.g., other respiratory illnesses) are negative. If COVID-19 is still suspected based on exposure history and clinical findings, retesting should be considered by healthcare providers in consultation with public health authorities.

Risks to an individual from a false-negative Flu SC2 Multiplex Assay result include delayed or lack of supportive treatment; lack of monitoring of infected patients 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 does it mean if the specimen tests positive for influenza A and/or B viruses?
A positive test result for influenza A virus or influenza B virus indicates that RNA from one or both of these viruses was detected, the patient is infected with the virus(es) and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data in making a final diagnosis. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines.

The Flu SC2 Multiplex Assay has been designed to minimize the likelihood of false-positive test results. However, in the event of a false-positive result, risks to individuals 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 of friends, limits in the ability to work, delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of an antiviral medication or other therapy, or other unintended adverse effects.

What does it mean if the specimen tests negative for influenza viruses?
A negative test result for influenza viruses means that influenza A and/or B RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out influenza virus infection and should not be used as the sole basis for treatment or patient management decisions.

When diagnostic testing results are 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 influenza. The possibility of a false-negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that influenza is likely, and diagnostic test results for other causes of illness (e.g., other respiratory illness) are negative. If influenza is still suspected based on exposure history and clinical findings, re-testing should be considered by healthcare providers in consultation with public health authorities.

Risks to a individuals from a false-negative Flu SC2 Multiplex Assay result for influenza A or B include: delayed or lack of supportive treatment; lack of monitoring of infected patients and their household or other close contacts for symptoms, resulting in increased risk of spread of influenza within the community; or other unintended adverse events. Risks to an asymptomatic patient from a false-negative Flu SC2 Multiplex Assay result for influenza A or B include: lack of monitoring of infected patients and their household or other close contacts for symptoms, resulting in increased risk of spread of influenza within the community; or other unintended adverse events.

Laboratory test results should always be considered in the context of clinical findings and observations and/or epidemiological data in making a final diagnosis. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines.

What does it mean if the specimen tests positive for SARS-CoV-2 and one or both influenza (A and/or B) viruses? Is co-infection possible?
Yes, it is possible for an individual to be infected with influenza A virus, influenza B virus, and/or SARS-CoV-2 simultaneously. A positive test result for the viruses that cause COVID-19 and influenza A and/or B indicates that RNA from these viruses was detected, the patient may be co-infected, and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data in making a final diagnosis. Patient management decisions should be made with a healthcare provider and follow current CDC guidelines.

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 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 the detection of the virus that causes 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?
FDA has approved influenza tests, however there are no approved available alternative tests for the combined detection and differentiation of nucleic acid from SARS-CoV-2, influenza A, and/or influenza B viruses. 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:

COVID-19:
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

Influenza:
https://www.cdc.gov/flu/index.htm

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

Manufacturer: CDC

CDC Emergency Operations Center (EOC)
1600 Clifton Road
Atlanta, Georgia, USA, 30329
Phone: **CDC EOC (770-488-7100)**

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**

FACT SHEET FOR PATIENTS

CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay **July 2, 2020**

Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your sample was tested for the viruses that cause Coronavirus Disease 2019 (COVID-19), influenza A, and influenza B using the Centers for Disease Control and Prevention's (CDC's) Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19 and/or influenza. If you have questions or would like to discuss the information provided after you read this Fact Sheet, please talk with 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

For the most up to date information on Influenza, please visit the CDC Influenza webpage: https://www.cdc.gov/flu

Why was my sample tested?
Your sample was tested because your healthcare provider believes you might have been exposed to the virus that causes COVID-19 based on your signs and symptoms and/or because:

- You have been in close contact with a person who might have, or who is known to have, COVID-19, and/or
- You live in or have recently traveled to a place where transmission of the virus that cause COVID-19 is known to occur.

Your samples will help your doctor determine if you have the virus that causes COVID-19 or if another respiratory virus may be the cause..

What is COVID-19?
COVID-19 is a contagious respiratory illness caused by the SARS-CoV-2 virus. COVID-19 can cause a mild to severe illness and has now spread worldwide, including in the United States. Older adults and people of any age who have underlying medical conditions might have a higher risk of severe illness from COVID-19. Serious outcomes of COVID-19 can result in hospitalization or death. The virus that causes COVID-19 can be spread to others before and after 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 Influenza?
Influenza (flu) is a contagious respiratory illness caused by influenza viruses. Influenza viruses can cause mild to severe illness. Serious outcomes of the flu can result in hospitalization or death. Some people, such as older people, young children, and people with certain underlying health conditions, are at higher risk for serious flu complications. There are two main types of influenza viruses: types A and B. Both type A and B influenza viruses regularly spread in people, and are responsible for seasonal flu each year. Influenza viruses can be spread to others before and after a person shows signs and symptoms of being sick.

What is the CDC Influenza SARS-CoV-2 Multiplex Assay?
The test is designed to simultaneously detect three types of viruses: two types that cause influenza (type A and type B) and the virus that causes COVID-19 (SARS-CoV-2) in respiratory specimens, for example nasal or oral swabs.

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 are the known and potential risks and benefits of the test?
Potential risks include:

- Possible discomfort or other complications 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 decisions about your care.
- The results of this test may help limit the spread of the viruses that cause COVID-19, influenza A, and/or influenza B to your family and others in your community.

What does it mean if I have a positive test result for SARS-CoV-2?
If you have a positive test result for the presence of SARS-CoV-2, it is very likely that you have COVID-19. Therefore, it is also likely that specific isolation or social distancing actions will be recommended so that you can avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results, medical history, and your symptoms.

What does it mean if I have a positive test result for influenza A and/or B viruses?
If you have a positive test result for the presence of influenza A and/or influenza B viruses, it is very likely that you have the flu. If you have a positive result for an influenza virus, your healthcare provider will determine the best way to care for you based on the test results along with other factors in your medical history. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results, medical history, and your symptoms.

What does it mean if I have a positive test result for SARS-CoV and influenza (A and/or B) viruses?
It is possible for an individual to be infected with influenza A virus, influenza B virus, and/or SARS-CoV-2 virus at the same time. Your healthcare provider will work with you to determine how best to care for you based on these test results, your medical history, and your symptoms.

What does it mean if I have a negative test result for SARS-CoV-2, influenza A, or influenza B viruses?
A negative test result for any of the viruses detected by this test means that these viruses were not found in your sample. For COVID-19 and influenza, a negative test result for a sample collected while a person has symptoms usually means that SARS-CoV-2, influenza A or influenza B viruses are unlikely to be the cause your current illness.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19 or influenza. This means that you could possibly still have COVID-19 or influenza even though the test is negative. Your healthcare provider will consider the test result together with your symptoms, possible exposures and other health information in deciding how to care for you. It is possible that your healthcare provider may collect another sample in order to repeat the test or conduct other tests.

It is important that you talk with your healthcare provider to help you understand what your results mean and the next steps you should take.

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.

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 COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying emergency use 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 approved influenza tests, but there is not yet an approved available alternative test for influenza combined with COVID-19 in one test. 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#2019-ncov.

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.

FACT SHEET FOR HEALTHCARE PROVIDERS

Cepheid
Xpert® Xpress SARS-CoV-2

Updated: August 8, 2020

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 Xpert® Xpress SARS-CoV-2 test.

The Xpert Xpress SARS-CoV-2 test is authorized for use with respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Cepheid - Xpert Xpress SARS-CoV-2 test.

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 suspected of COVID-19 by their healthcare provider.

- The Xpert Xpress SARS-CoV-2 test should be ordered for the detection of COVID-19 in individuals suspected of COVID-19 by their healthcare provider.
- The Xpert Xpress SARS-CoV-2 test can be used to test nasopharyngeal, oropharyngeal, nasal, or mid-turbinate swab and nasal wash/aspirate specimens using the GeneXpert Dx and GeneXpert Infinity systems in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests in accordance with the Xpert Xpress SARS-CoV-2 Instructions for Use - For Use with GeneXpert Dx or GeneXpert Infinity systems.
- The Xpert Xpress SARS-CoV-2 test can be used to test nasopharyngeal, nasal, or mid-turbinate swab specimens using the GeneXpert Xpress System (Tablet and Hub Configurations) in patient care settings outside of the clinical laboratory environment in accordance with the point of care Xpress SARS-CoV-2 Instructions for Use - For Use with GeneXpert Xpress System, Quick Reference Instructions for Xpert Xpress SARS-CoV-2 and GeneXpert Xpress System (Hub configuration), and Quick Reference Instructions for Xpert Xpress SARS-CoV-2 and GeneXpert Xpress System (Tablet configuration).

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).

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 Xpert Xpress SARS-CoV-2 test 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. It is possible to test a person too early or too late during COVID-19 infection to make an accurate diagnosis via Xpert Xpress SARS-CoV-2 test.

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

Cepheid
Xpert® Xpress SARS-CoV-2

Updated: August 8, 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 Xpert® Xpress SARS-CoV-2 test.

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 Xpert Xpress SARS-CoV-2 test?
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), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

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.

- **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 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

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.

FACT SHEET FOR HEALTHCARE PROVIDERS

Cepheid
Xpert Xpress SARS-CoV-2/Flu/RSV

Updated: October 1, 2020

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 Xpert Xpress SARS-CoV-2/Flu/RSV test.

The Xpert Xpress SARS-CoV-2/Flu/RSV test is authorized for use with certain respiratory specimens collected from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Cepheid – Xpert Xpress SARS-CoV-2/Flu/RSV.

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 certain respiratory specimens collected from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider.

- The Xpert Xpress SARS-CoV-2/Flu/RSV test can be used to test nasopharyngeal swabs, nasal swabs or nasal wash/aspirate specimens.
- The Xpert Xpress SARS-CoV-2/Flu/RSV test can be ordered for the simultaneous detection and differentiation of nucleic acid from SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV) in individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider.
- The Xpert Xpress SARS-CoV-2/Flu/RSV test is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high or moderate complexity tests.
- The Xpert Xpress SARS-CoV-2/Flu/RSV test is also authorized for use for testing in only nasopharyngeal or nasal swab specimens 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

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**

links provided in "*Where can I go for updates and more information?*" section).

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 Xpert Xpress SARS-CoV-2/Flu/RSV test 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. It is possible to test a person too early or too late during COVID-19 infection to make an accurate diagnosis via the Xpert Xpress SARS-CoV-2/Flu/RSV test.
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.

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 does it mean if the specimen tests positive for influenza A, influenza B, and/or RSV?
A positive test result for influenza A virus, influenza B virus and/or respiratory syncytial virus (RSV) indicates that RNA from one or more of these viruses was detected, the patient is infected with the virus(es) and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data in making a final diagnosis. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines.

The Xpert Xpress SARS-CoV-2/Flu/RSV test has been designed to minimize the likelihood of false-positive test results. However, in the event of a false-positive result, risks to individuals 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 of friends, limits in the ability to work, delayed diagnosis

and treatment for the true infection causing the symptoms, unnecessary prescription of an antiviral medication or other therapy, or other unintended adverse effects.

What does it mean if the specimen tests negative for influenza A, influenza B and/or RSV?
A negative test result for influenza A, influenza B, and/or RSV means that influenza A, influenza B and/or RSV RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out influenza A, influenza B, and/or RSV infection and should not be used as the sole basis for treatment or patient management decisions.

When diagnostic testing results are 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 influenza. The possibility of a false-negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that influenza A, influenza B and/or RSV is likely, and diagnostic test results for other causes of illness (e.g., other respiratory illness) are negative. If influenza A, influenza B and/or RSV is still suspected based on exposure history and clinical findings, re-testing should be considered by healthcare providers in consultation with public health authorities.

Risks to a individuals from a false-negative Xpert Xpress SARS-CoV-2/Flu/RSV test result for influenza A, influenza B and/or RSV include: delayed or lack of supportive treatment; lack of monitoring of infected patients and their household or other close contacts for symptoms, resulting in increased risk of spread of influenza A, influenza B and/or RSV within the community; or other unintended adverse events.

Laboratory test results should always be considered in the context of clinical findings and observations and/or epidemiological data in making a final diagnosis. Patient management decisions should be made by a healthcare provider and follow current CDC guidelines.

What does it mean if the specimen tests positive for SARS-CoV-2, influenza A, influenza B and/or RSV viruses? Is co-infection possible?
Yes, it is possible for an individual to be infected with more than one virus simultaneously. A positive test result for the viruses that cause COVID-19, influenza A, influenza B and/or RSV indicates that RNA from these viruses was detected, the patient may be co-infected, and is presumed to be contagious. Laboratory test results should always be considered in the context of clinical findings and observations and epidemiological data in making a final diagnosis. Patient management decisions should be made with a healthcare provider and follow current CDC guidelines

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 FDA cleared tests for influenza A virus, influenza B virus, and RSV, but there are no FDA approved or cleared multiplexed tests for simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, influenza B virus, and RSV nucleic acids. 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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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**

FACT SHEET FOR PATIENTS

Cepheid
Xpert Xpress SARS-CoV-2/Flu/RSV

Updated: October 1, 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 Xpert Xpress SARS-CoV-2/Flu/RSV test.

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 Xpert Xpress SARS-CoV-2/Flu/RSV test?
The test is designed to detect the virus that causes COVID-19 in respiratory specimens, for example nasopharyngeal swabs, nasal swabs, or nasal wash/aspirate specimens.

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), and/or because:

- You live in or have recently traveled to a place where transmission of COVID-19 is known to occur, and/or
- You have been in close contact with an individual suspected of or confirmed to have COVID-19.

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 for SARS-CoV-2?
If you have a positive test result, it is very likely that you have COVID-19. Therefore, it is also likely that specific isolation or social distancing action will be recommended so that you can avoid spreading the virus to others. You should follow CDC guidance to reduce the potential transmission of disease. There is a very small chance that this test can give a positive result that is wrong (a

- **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.

false positive result). 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.

What does it mean if I have a positive test result for influenza A, influenza B, and/or RSV?
If you have a positive test result for the presence of influenza A, influenza B, and/or RSV viruses, it is very likely that you are infected with a virus. If you have a positive result for an influenza A, influenza B, and/or RSV, your healthcare provider will determine the best way to care for you based on the test results along with other factors in your medical history. There is a very small chance that this test can give a positive result that is wrong (a false positive result). Your healthcare provider will work with you to determine how best to care for you based on the test results, medical history, and your symptoms.

What does it mean if I have a positive test result for SARS-CoV and influenza A, influenza B, and/or RSV viruses?
It is possible for an individual to be infected with one or more viruses at the same time. Your healthcare provider will work with you to determine how best to care for you based on these test results, your medical history, and your symptoms.

What does it mean if I have a negative test result for SARS-CoV-2, influenza A, influenza B, and/or RSV viruses?
A negative test result for any of the viruses detected by this test means that these viruses were not found in your sample. For COVID-19, influenza A, influenza B, or RSV, a negative test result for a sample collected while a person has symptoms usually means that SARS-CoV-2, influenza A, influenza B, or RSV viruses are unlikely to be the cause of your current illness.

However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19, influenza or RSV. This means that you could possibly still have COVID-19, influenza or RSV even though the test is negative. Your healthcare provider will consider the test result together with your symptoms, possible exposures and other health information in deciding how to care for you. It is possible that your healthcare provider may collect another sample in order to repeat the test or conduct other tests.

It is important that you talk with your healthcare provider to help you understand what your results mean and 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.