GUAM PUBLIC HEALTH LABORATORY GUIDELINES FOR SEVERE ACUTE RESPIRATORY SYNDROME CORONAVIRUS 2 (SARS-CoV-2), INFLUENZA A (FLU A), INFLUENZA B (FLU B), RESPIRATORY SYNCYTIAL VIRUS (RSV)

Methodology:	U.S. Centers for Disease Control and Prevention (CDC) Influenza SARS-CoV-2 (Flu SC2) real-time Reverse Transcriptase Polymerase Chain Reaction (*r*RT-PCR) Multiplex Assay is a molecular *in vitro* diagnostic test that is intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, Influenza A virus, and/or Influenza B virus in upper or lower respiratory specimens. Cepheid GeneXpert 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, Influenza A, Influenza B, and/or Respiratory Syncytial Virus (RSV) in upper or lower respiratory specimens.
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 SARS-CoV-2, influenza A virus, and/or influenza B virus. 2. CDC Influenza SARS-CoV-2 (Flu SC2) with the Applied Biosystems (ABI) 7500 Fast DX real-time RT-PCR Instrument. Xpress SARS-CoV-2 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.
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 **GPHL Submission Form DPHSS_FRM** submit with the specimen. • Call DPHSS Guam Public Health Laboratory (GPHL) at (671) 300-9082/300-9080; alternate (671)300-9085 to inform DPHSS staff of the specimen delivery.

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	• 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.
Performed at Guam Public Health Lab:	Applied Biosystems 7500 Fast DX real-time RT-PCR CDC Flu SC2 Real-time RT-PCR Multiplex Assay is a **Food and Drug Administration** (**FDA) authorized** assay, issuing the Emergency Use Authorization (EUA) to test specimens according to the CDC criteria. • For the detection of Flu SC2 RNA in nasopharyngeal specimens, indicative of active infection with FluSC2 but do not rule out bacterial infection or co-infection with other viruses. • Positive results obtained with CDC Flu SC2 Multiplex Assay are to be interpreted and reported as "SARS-CoV-2 Positive" and results do not require confirmation at CDC.
(cont.) Performed at Guam Public Health Lab:	Cepheid GeneXpert Xpress SARS-CoV-2/Flu/RSV Assay is a rapid, real-time RT-PCR test for the qualitative detection of nucleic acid from the SARS-CoV-2, Influenza A, Influenza B, and/or RSV in upper or lower respiratory specimens. • For the qualitative detection of SARS-CoV-2/Flu/RSV nucleic acid in nasopharyngeal specimens, indicative of active infection but do not rule out bacterial infection or co-infection with other viruses. • Positive results obtained with Xpress SARS-CoV-2/Flu/RSV Assay are to be interpreted and reported and results do not require confirmation at CDC.
Criteria for Molecular/ PCR testing:	Testing of nasopharyngeal specimens with the CDC Flu SC2 RT-PCR Multiplex Assay or Xpress SARS-CoV-2/Flu/RSV Assay **should not be performed** unless the patient meets clinical signs and/or symptoms compatible with SARS-CoV-2, Influenza, and/or RSV 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, Influenza, and/or RSV virus and should not be used as the sole basis for treatment or other patient management decisions.**
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

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(cont.) Case Definition:	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 patient within 14 days of symptom onset Surveillance cases 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 and whether the patient should be tested. Most patients with confirmed 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).
Specimen Requirements	Points to consider when determining which specimen types to collect from a PUI for SARS-CoV-2, Influenza, and/or RSV 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 • Nasal specimen • 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: Annette Aguon, BCDC Administrator Contact numbers: (671) 735-7142/7143 or (671) 777-7210 ➢ Secondary Contact Person: Estelle A. Ada, ELC Program Supervisor: (671) 300-5874 or (671) 777-1706 ➢ Alternate Contact Person: Anne Marie Santos, Laboratory Administrator Contact numbers: (671) 300-9082 or (671) 683-5753
Specimen Collection Guidelines: **(cont.) 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. Nasal 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 swab immediately into the viral transport media. Nasal swab specimen 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 Nasal swabs: Insert a swab into the nostril no more than ¾ of an inch (1.5 cm) into the nose.

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	1.1.2. Slowly rotate the swab, gently pressing against the inside of the nostril at least 4 times for a total of 15 seconds. Swab both nostrils with the same swab. 1.3. 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. 1.4. 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. 1.5. 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 container. Refrigerate 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.*
Safety Precautions	• Observe Universal Precautions when handling specimens. • Use appropriate personal protective equipment (PPE) such as disposable gloves, laboratory coat/gown, mask (N-95), and eye protection when handling potentially infectious specimens. • 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 respiratory diseases, refer to CDC • 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, 761 South Marine Corps Drive, Tamuning, **no later than 4 PM, business days Mondays-Fridays.**
Rejection Criteria	• No consultation with DPHSS and BCDC prior to collection of specimens • Specimen quantity is insufficient to perform the test

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(Cont.) Rejection Criteria	• 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 submission forms (e.g., no date of onset, medical history, etc.) • Specimen label does not match the GPHL Submission Form
Result Notification	• Laboratory reports will be forwarded to the submitting healthcare facility and or provider and the BCDC Administrator via Facsimile. • Any other request for copies of laboratory reports, apart from that stipulated above will not be accepted. • Turn-Around-Time: Results are reported two (2) to three 3) business days after approval and receipt of NP and/or other specimen(s) by Guam DPHSS.
Laboratory Contact Information	Alan Mallari, Microbiologist III, GPHL (671) 300-9080 or (671) 300-9081 alanjohn.mallari@dphss.guam.gov Lea Nisay, Microbiologist II, GPHL(Alternate) (671) 300-9083 (671) 300-9098 FAX lea.nisay@dphss.guam.gov Anne Marie Santos, Central Laboratory Administrator, GPHL (671) 300-9082 or (671) 300-9085 annemarie.santos@dphss.guam.gov

Attachments:

1. GPHL Submission Form DPHSS

References:

1. CDC Influenza, SARS-CoV-2 (Flu SC2) Real-Time RT-PCR Multiplex Assay Instructions for Use, Catalog # Flu SC2-EUA, LB-122 Rev 04, August 5, 2021; www.internationalreagentresource.org; respvirus@cdc.gov
2. Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV Assay Automated Diagnostic Panel 302-3562, Rev. F January 2021; www.cepheid.com/en/CustomerSupport.

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