STATE OF CONNECTICUT

DEPARTMENT OF PUBLIC HEALTH

Renée D. Coleman-Mitchell, MPH Commissioner-Designate



Ned Lamont Governor Susan Bysiewicz Lt. Governor

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Date: 2/27/2020

From: Jafar H Razeq, Ph.D., HCLD (ABB), Laboratory Director

Matthew L. Cartter, MD, MPH, State Epidemiologist & Director of Infectious Diseases

Health Care Providers To:

Real-time reverse transcription PCR (rRT-PCR) assay for the detection of the current Re: novel coronavirus (2019-nCoV) at the State Public Health Laboratory

Dear Healthcare Staff,

Please be advised that effective 2/28/2020, the Connecticut State Public Health Laboratory (SPHL) is offering a real-time reverse transcription PCR (rRT-PCR) assay for the presumptive qualitative detection of RNA from the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), in upper and lower respiratory specimens. The assay has not been FDA cleared or approved, and is only for use under an emergency use authorization (EUA) granted by the Food and Drug Administration (FDA). Performance specifications of this assay have been established by the CDC, and limited verification studies were done at the SPHL as per the FDA/CLIA requirement for this EUA restriction. Diagnostic testing is conducted only on specimens from individuals who meet the current CDC clinical criteria for a COVID-19 patient under investigation (PUI). Clinicians must contact the CT Department of Public Health Epidemiology Program at 860-509-7994 (Monday-Friday from 8:30 am - 4:30 pm) or 860-509-8000 (after-hours/weekends) to discuss and receive approval for prior to any specimens being sent to the SPHL.

Collection and testing of multiple specimen types may be necessary to detect the presence of the virus. Acceptable upper and lower respiratory specimens include: nasopharyngeal (NP) or oropharyngeal (OP) aspirates or washes, nasopharyngeal or oropharyngeal swabs, broncheoalveolar lavage, tracheal aspirates, and sputum. Collect specimens within 3 days of symptom onset. Use only polyester or Dacron-tipped swabs with plastic or aluminum shafts. Do NOT use calcium alginate or cotton-tipped swabs, or wooden shaft swabs.

Immediately place swabs into viral transport media. Store specimen at 2-8°C up to 3 days. Transport to the laboratory with a frozen ice pack coolant. If there is a delay in shipment expected, store specimens at -70°C or lower until delivered to the laboratory.

Negative results do not preclude COVID-19 infection and should not be used as the sole basis for treatment or other patient management decisions. Inhibitors or other types of interference may produce false negative results.

The Clinical Test Requisition form (OL-9B) must be completed and submitted to the SPHL with all specimens. Please share this letter with appropriate staff. Questions about collection and handling of specimens can be directed to the SPHL Virology Laboratory at 860-920-6662.



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