CDC Influenza SARS-CoV-2 Multiplex (Emergency Use Authorization)	
Test Description	Assay for the simultaneous qualitative detection and differentiation of nucleic acids from the SARS-CoV-2, Influenza A, and/or Influenza B viruses in upper or lower respiratory specimens
Test Use	To aid in the diagnosis of individuals suspected of respiratory viral infection consistent with COVID-19 for public health surveillance purposes or outbreak investigations
Test Department	Advanced Molecular Diagnostics Phone: (860) 920-6662, FAX: (860) 920-6661
Methodology	Real-time RT-PCR multiplexed test
Availability	Daily, Monday-Friday
Specimen Requirements	Nasopharyngeal, oropharyngeal, nasal, or mid-turbinate swab specimen collected and placed into a transport tube containing 2-3 mL viral or universal transport medium, Amies transport medium (eSwab), or sterile saline. Sputum, BAL or nasopharyngeal aspirate, and the non-bacteriostatic saline used to collect the specimen should be placed immediately into a sterile transport tube
Collection Kit/Container	Specimen collection kits can be obtained by calling the SPHL outfit room, (860) 920-6674 or (860) 920-6675, Monday- Friday, 8:00 AM to 4:00 PM. Requests may also be submitted via e-mail to dph.outfitroom@ct.gov
Collection Instructions	Use freshly collected specimens for optimal test performance. Inadequate specimen collection or improper sample handling, storage, or transport may yield erroneous results. Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html
Specimen Handling & Transport	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.
Unacceptable Conditions	Unlabeled specimen; Improper specimen type; Specimens that have leaked or containers that have broken in transit; Specimens not handled, stored, or transported as described above.
Requisition Form	Indicate **Flu/SARS-CoV-2 or Flu/COVID-19 PCR** in the "Test, Agent or Disease Not Listed" box of the OL9B Clinical Test Requisition form.
Required Information	Name and address of submitter (and/or Horizon profile #) Patient name or identifier, town of residence (city, state, zip), date of birth Specimen type or source of collection, date collected, test requested Please ensure patient name on the requisition matches that on the specimen.
Limitations	Performance of the Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay has only been established in upper and lower respiratory specimens. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Performance evaluations have shown decreased sensitivity of the influenza A target when a high titer of SARS-CoV2 or influenza B is also present in the sample.
Additional comments	The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation suggest that SARS-CoV-2 infection is possible. In the case of influenza A and B viruses, children tend to shed virus more abundantly and for longer periods of time than adults. The performance of the assay has not been established in individuals who received nasally administered influenza vaccine.

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