TaqPath COVID-19 Combo Kit (Emergency Use Authorization)	
Test Description	Assay for the qualitative detection of nucleic acids from the SARS-CoV-2 novel coronavirus in upper respiratory and bronchoalveolar lavage (BAL) specimens
Test Use	To aid in the diagnosis of individuals suspected of COVID-19 by their healthcare provider
Test Department	Advanced Molecular Diagnostics Phone: (860) 920-6662, FAX: (860) 920-6661
Methodology	Real-time RT-PCR performed on Thermo Fisher Instrument Systems
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 transport medium, Amies transport medium, or sterile saline. 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	Use either the **COVID-2019** requisition or indicate **SARS-CoV-2 or 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	The TaqPath COVID-19 Combo Kit test is only for use under the U.S. Food and Drug Administration's Emergency Use Authorization. Performance has been established using nasopharyngeal and oropharyngeal swab, nasopharyngeal aspirate, and bronchoalveolar lavage samples only. Other specimen types have not been evaluated and should not be tested with this assay. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. 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.
Additional comments	Testing of nasal and mid-turbinate nasal swabs (self-collected under supervision of or collected by a healthcare provider) is limited to patients with symptoms of COVID-19. Refer to FDA's FAQs on Diagnostic Testing for SARS-CoV-2 for additional information..

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