2019-Novel Coronavirus (Emergency Use Authorization)	
Test Description	Assay for the presumptive qualitative detection of RNA from the 2019-Novel Coronavirus (2019-nCoV) in upper and lower respiratory specimens
Test Use	To aid in the diagnosis of individuals who meet the CDC clinical criteria for a 2019-nCoV patient under investigation (PUI)
Test Department	Virology Phone: (860) 920-6662, FAX: (860) 920-6661
Methodology	Real-time Reverse Transcription Polymerase Chain reaction (rRT-PCR)
Availability	Daily, Monday-Friday
Specimen Requirements	Upper and lower respiratory specimens including: nasopharyngeal (NP) and oropharyngeal (OP) aspirates or washes, nasopharyngeal or oropharyngeal swabs, broncheoalveolar lavage, tracheal aspirates, and sputum. Collection and testing of multiple specimen types may be necessary to detect the presence of the virus.
Collection Kit/Container	For NP/OP swab, use M4RT viral transport tube; Sterile polyester–tipped sampling swab; Category B shipping box with cold pack. To obtain collection kit, refer to Collection Kit Ordering Information.
Collection Instructions	Collect sample within 3 days of symptom onset. Use only synthetic fiber swabs with plastic shafts. Do NOT use calcium alginate swabs or swabs with wooden shafts as they may contain substances that inactivate some viruses and inhibit PCR testing. Place swabs immediately into sterile tubes containing 2-3 mls of viral transport media. NP and OP specimens may be kept in separate vials or combined into a single vial at time of collection.
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	Clinical Test Requisition (In box on lower right under **Test, Agent or Disease, Not Listed (Specify),** write in **2019-nCoV PCR**)
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	Diagnostic testing is conducted only on specimens from individuals who meet the CDC clinical criteria for a 2019-nCoV 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) and submit a "2019-nCoV Patient Under Investigation (PUI) Form"
Additional comments	Negative results do not preclude 2019-nCoV 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. An interference study evaluating the effect of common cold medications was not performed.

Revision: 03/11/2020