Xpert Xpress SARS-CoV-2 (Emergency Use Authorization)	
Test Description	Assay for the qualitative detection of nucleic acids from the SARS-CoV-2 novel coronavirus in nasopharyngeal, nasal, or mid-turbinate swab and/or nasal wash/aspirate specimens
Test Use	To aid in the diagnosis of individuals suspected of COVID-19 by their healthcare provider.
Test Department	Bacteriology Phone: (860) 920-6550, FAX: (860) 920-6661
Methodology	Rapid, real-time RT-PCR performed on GeneXpert Instrument Systems.
Availability	Daily, Monday-Friday
Specimen Requirements	Nasopharyngeal, nasal, or mid-turbinate swab specimen and/or nasal wash/aspirate specimen is collected and placed into a viral transport tube containing 3 mL transport medium
Collection Kit/Container	Collection kits can be obtained by calling the 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/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	Specimens can be stored at room temperature (15–30 °C) for up to 8 hours and refrigerated (2–8 °C) up to seven days until testing is performed on the GeneXpert Instrument Systems.
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 Xpert Xpress SARS-CoV-2 test is only for use under the Food and Drug Administration's Emergency Use Authorization. Performance has only been established in nasopharyngeal swab and nasal wash/aspirate specimens. Use of the Xpert Xpress SARS-CoV-2 test with other specimen types has not been assessed and performance characteristics are unknown. 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. Contact the **CT Department of Public Health Laboratory** at 860-920-6550 (Monday-Friday from 8:00 am – 4:00 pm) or 860-509-8000 (after-hours/weekends) with questions.

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