Aptima® SARS-CoV-2 assay (Emergency Use Authorization)	
Test Description	Nucleic acid amplification in vitro diagnostic test intended for the qualitative detection of RNA from SARS-CoV-2 in upper respiratory specimens
Test Use	To aid in the diagnosis of individuals suspected of COVID-19 by their healthcare provider, or from individuals without symptoms or other reasons to suspect COVID-19 infection.
Department	Virology Phone: (860) 920-6662, FAX: (860) 920-6661
Methodology	Target amplification nucleic acid probe performed on Hologic Panther system
Availability	Daily, Monday-Friday
Specimen Requirements	Nasopharyngeal, oropharyngeal, nasal, or mid-turbinate swab or nasopharyngeal wash/aspirate and nasal aspirate specimen collected and placed into a transport tube containing 2-3 mL viral transport medium, Amies transport medium, sterile saline, or specimen transport medium(STM). The following types of VTM/UTM can be used: Remel MicroTest M4, M4RT, M5 or M6 formulations, Copan Universal Transport Medium and BD Universal Viral Transport Medium. ***Do not use medium that may contain Guanidium thiocyanate or any guanidine- containing material.***
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 swab specimens at 2-8°C up to 96 hours. Transport to the laboratory with a frozen ice pack coolant.
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 Aptima SARS-CoV-2 assay is only for use under the U.S. Food and Drug Administration's Emergency Use Authorization. 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. A positive result indicates the detection of nucleic acid from the SARS-CoV-2 virus. Nucleic acid may persist even after the virus is no longer viable. Sample pooling has only been validated using nasopharyngeal swab specimens.
Additional comments	Use of the Aptima SARS-CoV-2 assay in a general, asymptomatic screening population is intended to be used as part of an infection control plan that may include additional preventative measures, such as a predefined serial testing plan or directed testing of high- risk individuals. Negative results must be considered in the context of an individual's recent exposures, history, and presence of clinical signs and symptoms consistent with COVID-19.

Revision: 12/07/2020