Lab Dept: Molecular Diagnostics

Test Name: SARS-CoV-2 RNA DETECTION, BRONCHOSCOPY

General Information

Lab Order Codes:	COVB
Synonyms:	Severe Acute Respiratory Syndrome coronavirus-2, COVID-19, 2019 novel coronavirus, 2019-nCoV, Respiratory viruses, PCR for SARS-CoV-2, PCR for COVID-19
CPT Codes:	87635 – Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique
Test Includes:	Rapid detection of SARS-CoV-2 in lower respiratory tract infections by Reverse Transcription Polymerase Chain Reaction (RT-PCR) paired with Real time PCR. NOTE: The DiaSorin Molecular Simplexa COVID-19 Direct Assay was issued an Emergency Use Authorization (EUA) by the FDA on March 19, 2020.

Logistics

Lab Testing Sections:	Molecular Diagnostics
Phone Numbers:	MIN Lab: 612-813-7103
Test Availability:	Daily, 24 hours
Turnaround Time:	24 hours from receipt in Minneapolis lab
Special Instructions:	Requisition must state specific date/time of collection

Specimen

Specimen Type:	Bronchoalveolar Lavage (BAL) fluid, Bronchial Aspirate, Bronchial Wash
Container:	Sterile, leak proof container labeled with specimen type and identifying patient information
Draw Volume:	0.5 mL
Collection:	Bronchoscopy: Specimen obtained by physician through the biopsy channel of the bronchoscope. Transfer 1 -2 mL sample into a sterile container.

Storage/Transport:	Transport to the laboratory immediately to maintain specimen integrity. Specimens can be stored at refrigerated temperatures (2-8 °C) for 7 days.
Sample Rejection:	Any sample exceeding 1 hour after collection without refrigeration, insufficient volume, improperly labeled samples, leaking or non-sterile containers. If an unacceptable specimen is received, the patient's caregiver will be notified and another specimen will be requested before the specimen is discarded.

Interpretive

Reference Range:	Negative
Alert Values:	Positive results will be phoned to the patient's caregiver.
Limitations:	● For Emergency Use Authorization Only use only. ● For in vitro diagnostic use. ● For professional use only. ● Testing of nasal swabs even if collected by a healthcare provider is limited to patients with symptoms of COVID-19. ● Not for screening. ● False-negative results may occur if the viruses are present at a level that is below the analytical sensitivity of the assay or if the virus has genomic mutations, insertions, deletions, or rearrangements or if performed very early in the course of illness. ● As with other tests, false-positive results may occur. Repeat testing or testing with a different device may be indicated in some settings. ● This test is a qualitative test and does not provide the quantitative value of detected organisms present.
Methodology:	Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) and Real-time PCR.
References:	Simplexa COVID-19 Direct Package Insert, REF: MOL4150, Rev. 05. In. Cypress, CA: DiaSorin Molecular. World Health Organization: Coronavirus. https://www.who.int/health-topics/coronavirus Centers for Disease Control and Pevention: Coronavirus. https://www.cdc.gov/coronavirus/general-information.html Cheng ZJ, Shan JJI. 2019 Novel coronavirus: where we are and what we know. 2020:1-9. Centers for Disease Control and Prevention: Coronavirus Disease 2019 (COVID-19). US Department of Health and Human Services PHS/CDC/NIH. Biosafety in microbiology and biomendical laboratories. In. Washington DC: Government Printing Office, 2007.

Wayne P. MM3-A2 Molecular diagnostic methods for infectious disease; approved guideline, 2nd ed. In. Clinical Laboratory Standards Institute, 2006.

Simplexa COVID-19 Positive Control Pack Package Insert, REF: MOL4160, Rev. 01. In. Cypress, CA: DiaSorin Molecular.