SARS-CoV-2 MassARRAY Variant Panel

Test Description	Assay for the simultaneous qualitative detection and differentiation of SARS-CoV-2 variants in upper respiratory specimens
Test Use	To aid in the characterization of SARS-CoV-2 in individuals with respiratory viral infection consistent with COVID-19. The SARS-CoV-2 variant panel is designed as a reflex test for samples that have already tested positive for SARS-CoV-2 RNA.
Test Department	Advanced Molecular Diagnostics Phone: (860) 920-6689, FAX: (860) 920-6721
Methodology	Multiplex RT-PCR/MALDI-TOF
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 or universal transport medium, Amies transport medium (eSwab), or sterile saline.
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	Indicate **SARS-CoV-2 Variant (or Lineage) testing** 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	This test was evaluated, and its performance characteristics determined by the CT SPHL for identification of the B.1.1.7 and B.1.617.2 SARS-CoV-2 variants only and may not be able to differentiate newly emerging SARS-CoV-2 subtypes. The impacts of vaccines, antiviral therapeutics, antibiotics, chemotherapeutic or immunosuppressant drugs have not been evaluated. Negative results do not preclude infection with SARS-CoV-2 virus and should not be the sole basis of a patient management decision.
Additional comments	Specimens of undetermined variant lineage may be further analyzed by genomic sequencing (WGS) for public health surveillance purposes. All results must be considered in conjunction with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient. Analyte targets (viral sequences) may persist in vivo, independent of virus viability. Detection of analyte target(s) does not imply that the corresponding virus(es) are infectious or are the causative agents for clinical symptoms.

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