

Patient: Stroschein, Jason M

DOB: 01/08/77

Sample ID: LC20851

Collected: 11/20/20

Received: 11/23/20

Reported: 11/23/20

Specimen Info: Viral Transport Media / Red (M4)

Source: Nasopharyngeal (NP) Swab

Clinician: Larimer County Department of Health and Environment (Larimer County Public Health)

Laboratory: The Colorado State University VDL in partnership with the CSU Health Network

Molecular Tests

**Thermo Fisher Scientific TaqPath™ COVID-19
Combo Kit (SARS-CoV-2 real-time PCR)¹**

Current Results

Detected

1. This assay is designed to detect ribonucleic acid (RNA) of Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) using reverse transcriptase qualitative polymerase chain reaction (RT-qPCR). SARS-CoV-2 is the virus which causes Coronavirus Disease 2019 (COVID-19). Results are reported as Not detected, Detected or Inconclusive. The expected result is Not Detected, which would mean SARS-CoV-2 RNA was not detected in the sample. A "Not Detected" result does not preclude the possibility of SARS-CoV-2 infection since the adequacy of sample collection, specimen type, variants of nucleic acids at the primer binding sites and/or low viral burden may result in the presence of viral nucleic acids below the analytical sensitivity of this test method. A "Not Detected" result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. The possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing should be considered. Risks of a false negative include lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community. Test parameters have not been validated for screening in asymptomatic patients. This test has been verified by Thermo Fisher Scientific. Testing fact sheets are available at dlab.colostate.edu/coronavirus. This test is only authorized for the duration of the declaration and the circumstances that exist to justify the authorization of the emergency use of in vitro diagnostic tests for the detection of SARS-CoV-2 virus and/or diagnosis of COVID-19 infection under section 564(b)(1) of the Act, 21 U.S.C. 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner. The Colorado State University VDL is certified under CLIA-88 as a qualified laboratory to perform high complexity testing. This testing was performed at Colorado State University, Fort Collins, CO (CLIA License 06D2180914). FDA review of the validation is pending.