



COVID-19 REPORT
04/10/2020

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Patient: Ashley Doe
Patient Date of Birth: 01/01/2001
Date of Receipt: 04/10/2020
Date of Report: 04/10/2020
Ordering Physician: Dennis Hooper
Real Time Laboratories
4100 Fairway Court, Suite 600, Carrollton, TX 75010

Accession No: 041020SATEST
MRN:
Date of Service: 04/10/2020
Specimen: Nasal Swab

COVID-19 PANEL RESULT
SARS-CoV-2 POSITIVE

TaqPath COVID-19 Combo Kit (Thermo Fisher Scientific Inc.) is for use only under Emergency Use Authorization (EUA). Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests. The test has been validated in accordance with the FDA's Guidance Document (Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency) issued on February 29th, 2020. FDA independent review of this validation is pending. This test is only authorized for the duration of time the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for 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.

Director Signature _____