SARS-CoV-2 RT-PCR; saliva

Order: SAMPLE REPORT
Client #: 12345
Doctor: Sample Doctor
Doctor's Data, Inc.
3755 Illinois Ave.
St. Charles, IL 60174

Patient: Sample Patient
Age: 35
Sex: Female

Sample Collection	Date/Time
Date Collected	11/06/2020
Date Received	11/07/2020
Date Reported	11/08/2020

Analyte	Result	Reference Interval
SARS-CoV-2	Positive	Negative

Information

- Positive results are indicative of presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses.
- The PerkinElmer® New Coronavirus Nucleic Acid Detection kit uses TaqMan-based real-time PCR technique to conduct in vitro reverse transcription of SARS-CoV-2 RNA, DNA amplification and fluorescence detection. The assay targets specific genomic regions of SARS-CoV-2: nucleocapsid (N) gene and ORF1ab.
- This test has not been FDA cleared or approved. This test has been authorized by FDA under an Emergency Use Authorization (EUA) for NP,OP, NS swab samples and has been adapted for saliva samples. 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.

Notes:
Methodology: Real-Time RT-PCR

Analyzed by DOCTOR'S DATA, INC. • 3755 Illinois Avenue, St. Charles, IL 60174-2420 USA • LAB DIR: Erlo Roth, MD • CLIA ID: 14D0646470

SARS-CoV-2 RT-PCR; saliva

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Analyte	Result	Reference Interval
SARS-CoV-2	Indeterminate	Negative

Information

- The PerkinElmer® New Coronavirus Nucleic Acid Detection kit uses TaqMan-based real-time PCR technique to conduct in vitro reverse transcription of SARS-CoV-2 RNA, DNA amplification and fluorescence detection. The assay targets specific genomic regions of SARS-CoV-2: nucleocapsid (N) gene and ORF1ab.
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Sex: Female

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Date Reported	11/08/2020

Analyte	Result	Reference Interval
SARS-CoV-2	Negative	Negative

Information

- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.
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Sex: Female

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Date Received	11/07/2020
Date Reported	11/08/2020

Analyte	Result	Reference Interval
SARS-CoV-2	Invalid	Negative

Information

- This sample has been re-extracted and re-tested. We are UNABLE to reliably determine a result for the specimen due to the inconsistent amplification of all of the required SARS-CoV-2 internal control targets. If clinically indicated, please recollect an additional specimen for testing.
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