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	05/21/2020
Date Received	05/22/2020
Date Reported	05/23/2020

Analyte	Result	Reference Interval
SARS-CoV-2	Positive	Negative

Information

- This test detects specific targeted SARS-CoV-2 N1 viral genetic sequences and human beta-actin as internal control, using one-step cDNA synthesis and real-time reverse transcription polymerase chain reaction (RT-PCR) detection technology.
- This test was performed, developed and its performance characteristics determined by Kashi Clinical Laboratories, 10101 SW Barbur Blvd Suite 200 Portland, OR 97219. This test has not been FDA cleared or approved. This test has been authorized by FDA under an Emergency Use Authorization (EUA). This 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.

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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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	05/21/2020
Date Received	05/22/2020
Date Reported	05/23/2020

Analyte	Result	Reference Interval
SARS-CoV-2	Indeterminate	Negative

Information

- We are unable to reliably determine a result for the specimen due to the inconsistent or low amplification of SARS-CoV-2 components of the assay. If clinically indicated, please recollect and submit a new specimen for testing.
- This test detects specific targeted SARS-CoV-2 N1 viral genetic sequences and human beta-actin as internal control, using one-step cDNA synthesis and real-time reverse transcription polymerase chain reaction (RT-PCR) detection technology.
- This test was performed, developed and its performance characteristics determined by Kashi Clinical Laboratories, 10101 SW Barbur Blvd Suite 200 Portland, OR 97219. This test has not been FDA cleared or approved. This test has been authorized by FDA under an Emergency Use Authorization (EUA). This 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.

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Methodology: Real-Time RT-PCR

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SARS-CoV-2 RT-PCR; Nasopharyngeal swab

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	05/22/2020
Date Received	05/23/2020
Date Reported	05/24/2020

Analyte	Result	Reference Interval
SARS-CoV-2	Negative	Negative

Information

- This test detects specific targeted SARS-CoV-2 N1 viral genetic sequences and human beta-actin as internal control, using one-step cDNA synthesis and real-time reverse transcription polymerase chain reaction (RT-PCR) detection technology.
- This test was performed, developed and its performance characteristics determined by Kashi Clinical Laboratories, 10101 SW Barbur Blvd Suite 200 Portland, OR 97219. This test has not been FDA cleared or approved. This test has been authorized by FDA under an Emergency Use Authorization (EUA). This 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.

Notes:
Methodology: Real-Time RT-PCR

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SARS-CoV-2 RT-PCR; Nasopharyngeal swab

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	05/22/2020
Date Received	05/23/2020
Date Reported	05/24/2020

Analyte	Result	Reference Interval
SARS-CoV-2	Invalid	Negative

Information

- The absence of validity markers in the sample invalidates the test result. This is likely due to improper sample collection. If clinically indicated, please recollect and submit a new specimen for testing.
- This test detects specific targeted SARS-CoV-2 N1 viral genetic sequences and human beta-actin as internal control, using one-step cDNA synthesis and real-time reverse transcription polymerase chain reaction (RT-PCR) detection technology.
- This test was performed, developed and its performance characteristics determined by Kashi Clinical Laboratories, 10101 SW Barbur Blvd Suite 200 Portland, OR 97219. This test has not been FDA cleared or approved. This test has been authorized by FDA under an Emergency Use Authorization (EUA). This 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.

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Methodology: Real-Time RT-PCR

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