OraRisk® COVID-19 RT-PCR

FINAL REPORT

ORALDNA LABS
Innovations in Salivary Diagnostics

Doe, Jane

Date Of Birth: 09/20/1980 (40 yrs)
Gender: Female
Patient Id: 123-AB-12
Patient Location: COVID Test Client

Reason for Testing: Asymptomatic
Related info: Not Provided

Ordering Provider

Ron Mcglennen MD
7400 Flying Cloud Drive
Minneapolis, MN 55344
855-672-5362

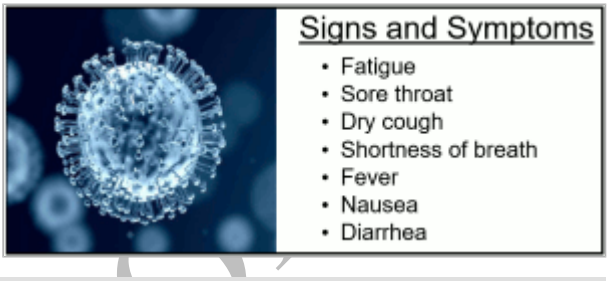
Sample Information

Specimen#: 5115335222
Accession#: 202103-16570
Specimen: Oral Rinse

Collected: 03/10/2021
Received: 03/10/2021 16:03
Reported: 03/11/2021 12:12

MOLECULAR DETECTION OF SARS-COV-2

Test Results	
SARS-CoV-2	Not Detected



Interpretation:

The submitted sample is negative (absence of the RNA) for SARS-CoV-2, the virus that causes the disease called COVID-19. See comments.

Guidance from the Centers for Disease Control and Prevention:

- General information about SARS-CoV-2:
- https://www.cdc.gov/coronavirus/2019-ncov/index.html

- Information on testing for SARS-CoV-2:
- https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html
- https://www.cdc.gov/coronavirus/2019-ncov/testing/diagnostic-testing.html

- Guidance for Healthcare Providers:
- https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html
- https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care.html
- https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html

Fact Sheets:

- Healthcare Provider:
- https://www.fda.gov/media/140291/download

- Patient:
- https://www.fda.gov/media/140292/download

Methodology: Based on 1 mL of primary sample, 300 uL is used to extract viral RNA and cellular DNA using the Chemagic Viral 300 360 HP 96 (ABI Perkin Elmer). Following this, reverse transcription is used to create cDNA of the SARS-CoV-2 viral sequence followed by polymerase chain reaction-based amplification of regions of the SAR-Cov-2 genome (ORF1a, RdRp, E and N genes). This rt-PCR test uses the components of the Logix Smart 2019 Novel Coronavirus kit (Co-Diagnostics, Salt Lake City, UT). The results of this test are based on the detection of amplified viral gene sequences along with an internal control gene marker. The results are reported as Detected, Not Detected or Inconclusive. The performance characteristics of this assay was determined by Access Genetics, LLC, d.b.a. OralDNA Labs and is assigned as a laboratory developed test. This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by Access Genetics, LLC, d.b.a. OralDNA Labs and has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests detection and/or diagnosis of COVID-19 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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Medical Director

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