OraRisk® COVID-19

FINAL REPORT

ORALDNA LABS
Innovations in Salivary Diagnostics

Doe, John

Date Of Birth: 09/20/1980 (39 yrs)
Gender: Male
Patient Id: 123-AB-11
Patient Location: COVID Test Client

Reason for Testing: Symptomatic
Related info: Not Provided

Ordering Provider

Ron Mcglennen MD
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855-672-5362

Sample Information

Specimen#: 5115885663
Accession#: 202004-14411
Specimen: Swab, VTM/UTM

Collected: 04/05/2020
Received: 04/06/2020 08:54
Reported: 04/07/2020 10:51

MOLECULAR DETECTION OF SARS-COV-2

Test Results	
SARS-CoV-2	Detected

Interpretation:

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

Comments:

- Significance: A respiratory disease called COVID-19 is caused by a novel coronavirus called SARS-CoV-2. Symptoms of this disease include fatigue, sore throat, dry cough, shortness of breath, fever, and occasionally nausea and diarrhea.

- Consider: The course of COVID-19 is varied depending upon your age, the amount of virus in your body and whether you have any high-risk conditions affecting health. Persons with diseases such as high blood pressure and or heart disease, lung disease, diabetes and other chronic conditions are at high risk for complications of this infection including death.

- Recommendations: These test results are critical and require that you discuss with a healthcare professional. Treatment may be necessary even if you experience only mild symptoms. Importantly, you are contagious and must take precautions to protect others by staying at least 6 feet from nearby people, covering your mouth and secretions and disinfecting things that you touch.

Methodology: Viral RNA is extracted from 1 mL of the combined swab/rinse sample using the Chemagic Viral 300 360 HP 96 (ABI Perkin Elmer). Following this viral sequence cDNA and amplification of the SAR-Cov-2 genome (ORF1a, RdRp, E and N genes) is performed using the Logix Smart 2019 Novel Coronavirus kit (Co-Diagnostics, Salt Lake City, UT). The results of this test are based on extracted RNA and the presence of amplified DNA 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 and is assigned as a laboratory developed test. These tests have not been FDA cleared or approved. These tests have been authorized by FDA under an EUA for use by authorized laboratories and have been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. These tests are 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.

References:

- CDC. (2020, Feb 13). Coronavirus Disease 2019 (COVID-19): Evaluating and Reporting Persons Under Investigation (PUI). Retrieved Feb 19, 2020, from Centers for Disease Prevention and Control: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html
- WHO. (2020, Jan 17). Laboratory testing for 2019 novel coronavirus (2019-nCoV) in suspected human cases > Interim guidance 17 Jan 2020. Retrieved Feb 19, 2020, from World Health Organization: https://www.who.int/publications-detail/laboratory-testing-for-2019-novel-coronavirus-in-suspected-human-cases-20200117

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