CORONAVIRUS
SARS-CoV-2 [COVID-19] Testing

Medical Diagnostic Laboratories (MDL) now offers the SARS-CoV-2 (COVID-19) by Real-Time Reverse Transcription PCR (CDC N1, N2, RP targets) which has been approved by the New Jersey State Department of Health and in accordance with the Food and Drug Administration (FDA) emergency use authorization (EUA) policy. This test has not been FDA cleared or approved. This test has been submitted for authorization by the FDA under an EUA for use by authorized laboratories.

Coronavirus Disease 2019 (COVID-19) is an acute respiratory disease caused by a viral infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The virus, which has infected and caused deaths of over 4 million people worldwide, has rapidly escalated to pandemic status since it first appeared in Wuhan, China in December 2019. Additional cases have now been reported in the United States. An infection with coronavirus 229E, NL63, OC43, or HKU1 is not the same as a COVID-19. Patients with COVID-19 are evaluated and cared for differently than patients with common coronavirus diagnosis.

Test No. 1131 **SARS-CoV-2 [COVID-19] by Reverse Transcription Real-Time PCR (CDC N1, N2, RP targets)**

- **Nasopharyngeal swab OR Oropharyngeal swab specimen collection submitted in a COVID-*OneSwab*™ viral transport media vial**
- ***NasoSwab*® specimen collection for adult patients ONLY (may be self-collected on-site)**
- **Specimens should be refrigerated until ready for transport and shipped within 72 hours of collection**

Diagnostic Advantages…

- RNA amplification via RT-PCR technology
- High precision robotic accuracy
- High diagnostic sensitivity & specificity
- 24 - 48 hour turnaround time
- A separate ***NasoSwab***® specimen is required when ordering testing for other respiratory pathogens for differential diagnosis

What are the symptoms of COVID-19?

Common signs of infection may appear **2-14 days after exposure** and include:

- Fever
- Cough
- Shortness of breath & breathing difficulties

In severe cases, infection can cause:

- Pneumonia
- Severe acute respiratory syndrome
- Kidney failure
- Death

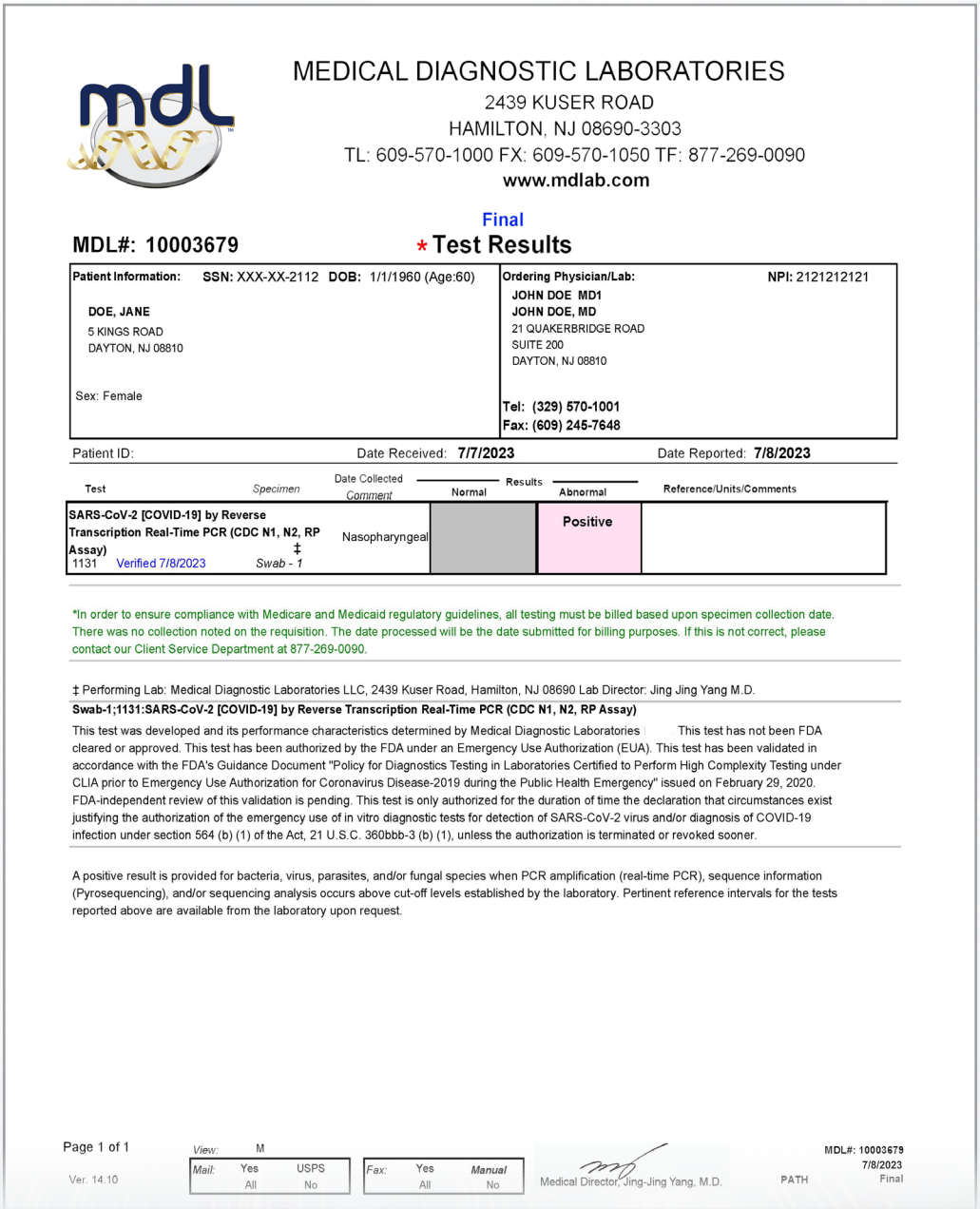
People with heart and lung disease, weakened immune systems, and older adults are at higher risk for lower respiratory tract illness.

How is COVID-19 spread?

This virus is spread person-to-person by someone who is currently sick with COVID-19 through:

- Respiratory droplets produced while coughing and sneezing
- Close personal contact (i.e., within about 6 feet)
- Touching or shaking hands

It may be possible that a person can get COVID-19 by touching a surface or object that has the virus on it and then touching their own mouth, nose, or possibly their eyes, but this is not reported to be the primary way the virus spreads.



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Final

MDL#: 10003679 * Test Results

Patient Information:	Ordering Physician/Lab:
SSN: XXX-XX-2112 DOB: 1/1/1960 (Age:60)	NPI: 2121212121
DOE, JANE 5 KINGS ROAD DAYTON, NJ 08810	JOHN DOE MD1 JOHN DOE, MD 21 QUAKERBRIDGE ROAD SUITE 200 DAYTON, NJ 08810
Sex: Female	Tel: (329) 570-1001 Fax: (609) 245-7648

Patient ID: Date Received: 7/7/2023 Date Reported: 7/8/2023

Test	Specimen	Date Collected / Comment	Results: Normal	Results: Abnormal	Reference/Units/Comments
SARS-CoV-2 [COVID-19] by Reverse Transcription Real-Time PCR (CDC N1, N2, RP Assay) ‡ 1131 Verified 7/8/2023	Nasopharyngeal Swab - 1			Positive	

*In order to ensure compliance with Medicare and Medicaid regulatory guidelines, all testing must be billed based upon specimen collection date. There was no collection noted on the requisition. The date processed will be the date submitted for billing purposes. If this is not correct, please contact our Client Service Department at 877-269-0090.

‡ Performing Lab: Medical Diagnostic Laboratories LLC, 2439 Kuser Road, Hamilton, NJ 08690 Lab Director: Jing Jing Yang M.D.

Swab-1;1131:SARS-CoV-2 [COVID-19] by Reverse Transcription Real-Time PCR (CDC N1, N2, RP Assay)

This test was developed and its performance characteristics determined by Medical Diagnostic Laboratories This test has not been FDA cleared or approved. This test has been authorized by the 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 29, 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.

A positive result is provided for bacteria, virus, parasites, and/or fungal species when PCR amplification (real-time PCR), sequence information (Pyrosequencing), and/or sequencing analysis occurs above cut-off levels established by the laboratory. Pertinent reference intervals for the tests reported above are available from the laboratory upon request.

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View: M
Mail: Yes All USPS No
Fax: Yes All Manual No

Medical Director, Jing-Jing Yang, M.D.

PATH

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Final