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

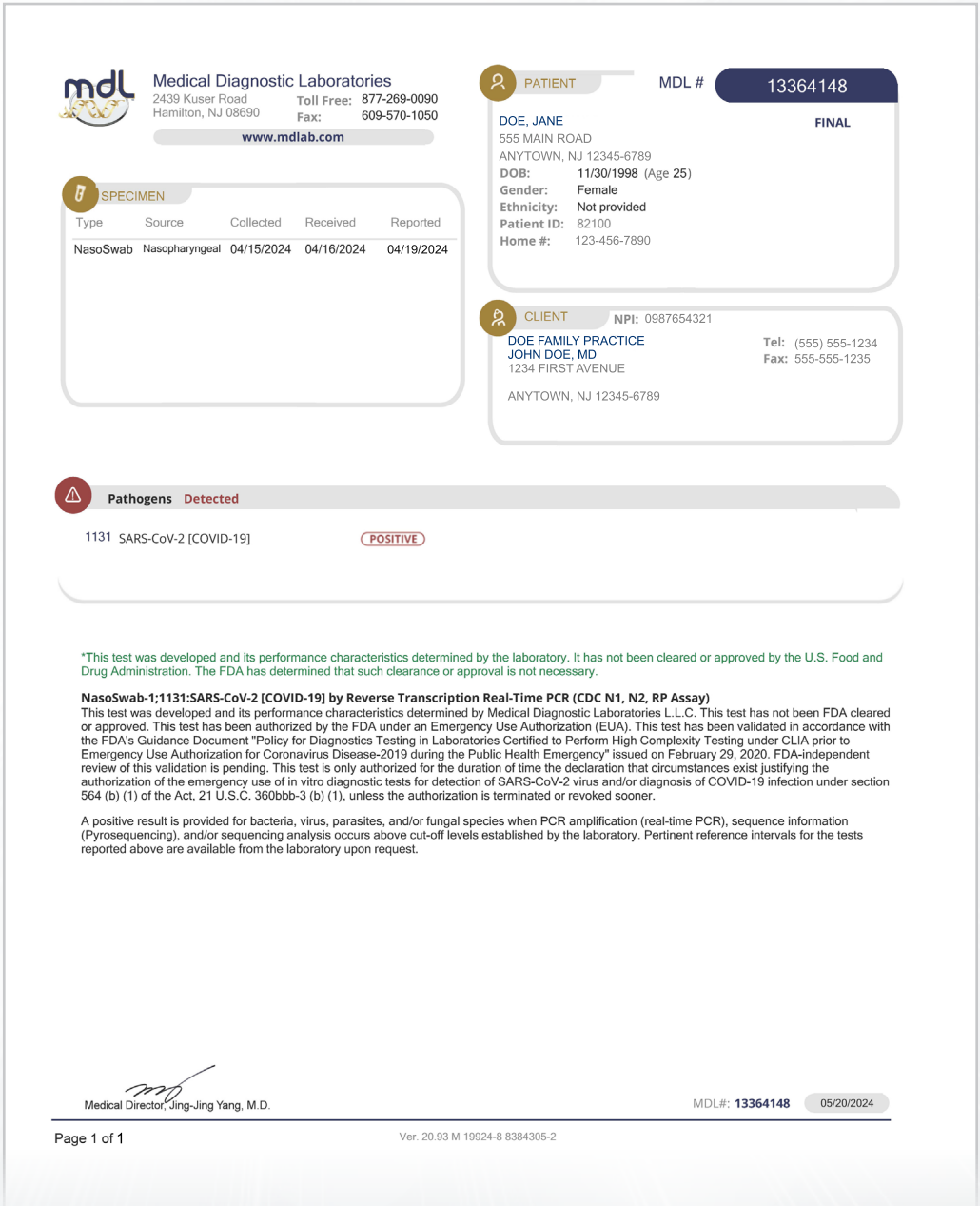
People with heart and lung disease, weakened immune systems, and older adults are at higher risk for lower respiratory tract illness.

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.



Medical Diagnostic Laboratories
2439 Kuser Road
Hamilton, NJ 08690
Toll Free: 877-269-0090
Fax: 609-570-1050
www.mdlab.com

PATIENT
MDL # 13364148
DOE, JANE
555 MAIN ROAD
ANYTOWN, NJ 12345-6789
DOB: 11/30/1998 (Age 25)
Gender: Female
Ethnicity: Not provided
Patient ID: 82100
Home #: 123-456-7890
FINAL

SPECIMEN

Type	Source	Collected	Received	Reported
NasoSwab	Nasopharyngeal	04/15/2024	04/16/2024	04/19/2024

CLIENT
NPI: 0987654321
DOE FAMILY PRACTICE
JOHN DOE, MD
1234 FIRST AVENUE
ANYTOWN, NJ 12345-6789
Tel: (555) 555-1234
Fax: 555-555-1235

Pathogens Detected

1131 SARS-CoV-2 [COVID-19] POSITIVE

*This test was developed and its performance characteristics determined by the laboratory. It has not been cleared or approved by the U.S. Food and Drug Administration. The FDA has determined that such clearance or approval is not necessary.

NasoSwab-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 L.L.C. 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.

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