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

PATIENT

MDL # 13364148

FINAL

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

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 Not Detected

NasoSwab
(Nasopharyngeal)
Other Pathogens

1131 SARS-CoV-2 [COVID-19]
A Not Detected result does not exclude COVID-19 and should not be used as the sole basis for patient management or treatment decisions.

*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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