MEDICAL DIAGNOSTIC LABORATORIES

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Final

MDL#: 8875032

Test Results

Patient Information: **SSN:** N/A **DOB:** 1/1/1978 (Age:43) **DOE, JANE** 123 MAIN ROAD MARLTON, NJ 08053 Sex: Female **Home: (856) 555-5555**	**Ordering Physician/Lab:** **NPI:** 1234567890 **DOE WOMANS GROUP** **JOHN DOE, MD** 555 SMITH STREET ANYTOWN, NJ 55555 **Tel: (856) 555-5552** **Fax: (856) 555-5553**

Patient ID: Date Received: **3/13/2020** Date Reported: **3/13/2020**

Test	Specimen	Date Collected / Comment	Results: Normal	Results: Abnormal	Reference/Units/Comments
SARS-CoV-2 [COVID-19] by Reverse Transcriptase Real-Time PCR (CDC N1, N2, RP Assay) * 1131 Verified 3/13/2020	*Swab - 1*	3/12/2020 Nasopharyngeal			***Invalid. Please recollect specimen.**

*This test was developed and its performance characteristics determined by Medical Diagnostic Laboratories, L.L.C. 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.

Swab-1;1131:SARS-CoV-2 [COVID-19] by Reverse Transcriptase 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, 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.

View:	M				
Mail:	Yes	USPS	Fax:	Yes	*Manual*
	None	Yes		None	No

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