



PREMIER MEDICAL LABORATORY, INC
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COMPLETE

Doctor:	Premier Medical Laboratory	Patient:	TEST, ADULT M	Acc #:	843280
Address:	35-37 Progress St.,ste A2	Birth:	08/05/1951	Home Phone:	(732)776-3919
CSZ:	Edison, NJ 08820	Age:	71	Collection Date:	03/08/2023 11:12 AM
Location:		Gender:	Male	Received Date:	03/08/2023 11:12 AM

Result Comment:

Test Name	In Range	Outside Range	Reference Range	Units
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Respiratory Panel w/ Covid-19

QIAstat-Dx Respiratory SARS-CoV-2 Panel is based on FDA approved QIAstat-Dx respiratory panel expanded for the detection and identification of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) nucleic acid in human respiratory samples (Nasopharyngeal Swab). The test uses RT-PCR followed by bead hybridization for detection of SARS-CoV-2 specific genes. The performance characteristics of the test were validated by Premier Medical Laboratory in agreement 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 29th, 2020. This test has been authorized by FDA under an Emergency Use Authorization (EUA). FDA independent revision of this EUA has been performed and approved. 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.

Reported: 03/08/2023 11:49 AM

Adenovirus	Negative		Negative	
Coronavirus 229E	Negative		Negative	
Coronavirus HKU1	Negative		Negative	
Coronavirus NL63		Positive	Negative	
Coronavirus OC43	Negative		Negative	
Human Metapneumovirus A+B	Negative		Negative	
Influenza A	Negative		Negative	
Influenza A H1	Negative		Negative	
Influenza A H3	Negative		Negative	
Influenza A H1N1 / pdm09	Negative		Negative	
Influenza B	Negative		Negative	
Parainfluenza Virus 1	Negative		Negative	
Parainfluenza Virus 2	Negative		Negative	
Parainfluenza Virus 3	Negative		Negative	
Parainfluenza Virus 4	Negative		Negative	
Rhinovirus / Enterovirus	Negative		Negative	
Respiratory Syncytial Virus A+B	Negative		Negative	
Bordetella pertussis	Negative		Negative	
Chlamydomphila pneumoniae	Negative		Negative	
Mycoplasma pneumoniae	Negative		Negative	
SARS-CoV-2 (Covid-19) by PCR	Negative		Negative	

Out of Range Results:

Test Name	Result	Flag	Reference Range
Coronavirus NL63	Positive	ABNORMAL	Negative

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Donald L. Warkentin, PhD

Laboratory Director for NYS + NJ