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LABORATORY REPORT

PATIENT	SPECIMEN	PHYSICIAN
Name: **TEST, TEST** 123 TEST NEW YORK, NY 10010 Date of Birth: **01/01/2019** Gender: **Male** Accession #: **2005275001**	Specimen Type: **NASOPHARYNX** Collection Date: **05/27/20 10:00** Received Date: **05/27/20 10:43** Reported Date: **05/27/20 10:44**	Name: **ULTIMATE DX TERENCE MCGEE M.D.** Address: **516 N. LARCHMONT BLVD LOS ANGELES, CA 90004** Phone: **(800) 799-7248**

SARS-CoV-2 (COVID-19)

Test Name	Within Range	Outside Range	Prev. Result	Reference Range	Units
SARS-CoV-2 (COVID-19) RT-PCR					
SARS-CoV-2 (COVID-19) PCR	DETECTED			NOT DETECTED	

RESULT INTERPRETATION

DETECTED (Positive) results do not rule out bacterial co-infection with other viruses. A positive test result indicates that RNA from the SARS-CoV-2 virus was detected in the patient sample. Patients infected with this virus are presumed to be contagious and may be asymptomatic. Patient results can change at every testing event.

NOT DETECTED (Negative) results do not preclude SARS-CoV-2 virus infection and should not be used as the sole basis for diagnostic decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. A negative test result means that the virus that causes COVID-19 was not found in your sample at the time the sample was taken. For COVID-19, a negative test result for a sample collected while a person has symptoms usually means that COVID-19 did not cause the recent illness. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative.

INDETERMINATE results can occur when there is poor sample collection or the viral load is very low so to not warrant a positive or a negative result. This patient should be tested again as soon as possible to determine efficacy.

The UDX SARS CoV-2 Molecular Assay is a laboratory developed test (LDT) for the COVID-19 disease. This test has not been FDA cleared or approved. This test has been authorized by the FDA under an Emergency Use Authorization (EUA) and it 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. 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.