



Analytical Report

COVID-19 RT-PCR Test

Patient:	Client Name	Specimen:	2011001-361A
DOB:	January 01, 19XX	Specimen Type:	Nasal Swab
Gender:	Male	Date Collected:	Nov 17, 2020 08:56
		Date Analyzed:	Nov 17, 2020 12:20

Test	Result
COVID-19	POSITIVE

Disclaimer:

- The procedure, interpretation of results and quality control measures of this test are equivalent to those of the Centers for Disease Control and Prevention Method CDC-006-00019, Revision 03. MAI COVID-19 Test is a laboratory developed RT-PCR test based on Center for Disease Control And Prevention's (CDC) 2019-nCoV Real-Time RT-PCR Diagnostic Panel (CDC) Molecular Test CDC-006-00019, Revision 03.
- This test has not been FDA cleared or approved. This method has been authorized by the FDA under an Emergency Use Authorization (EUA), and its practice is only sanctioned through the duration of such order which allows the use of the in vitro diagnostic test for the detection of SARS-CoV-2 also known as COVID-19, unless such authorization is retracted sooner (section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. Â§ 360bbb-3)).
- Validation of this test has been performed in accordance to CLIA certification requirements for laboratories performing high complexity testing; however, independent FDA validation of this method is under review.

Informational:

- Negative results do not preclude SARS-COV-2 infection and should not be used as the sole basis for patient management decisions. Negative results should be considered in the context of a patient's recent exposure, history and the presence of clinical signs and symptoms consistent with COVID-19.
- MAI cannot offer any medical advice or treatment plan. If you have questions about what health measures to take next, please consult with your healthcare provider.