Result Report

Patient ID **65**	Accession Number **2011021287**	Collected Date **08/03/2020**	
Patient Name **Jane Doe**	Requesting Facility **PanoHealth Walk-In**	Received Date **08/03/2020**	
Date of Birth **06/11/1981 (39)**	Requesting Physician	Report Date **12/23/2020**	
Gender **Female**		Sample Type **Swab**	
		Status **Final**	

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TEST NAME	DETERMINATION	Flag	Reference Range
SARS-CoV-2 (COVID-19), RT-PCR	Not Detected (Negative)		Not Detected

Methodology: The SARS-CoV-2 (COVID-19), RT-PCR assay is intended for the qualitative detection of RNA from SARS-CoV-2 virus in human nasopharyngeal swab specimens. The PanoHealth COVID-19 1-Step High Throughput PCR Kit utilizes a fluorescent probe and a specific primer to detect two specific regions within the novel coronavirus (SARS-CoV-2) nucleocapsid protein N gene as well as a proprietary buffer which enables the use of crude saliva or swabs directly in the PCR reaction.

Disclaimer: This SARS-CoV-2 1-Step High Throughput PCR test performance characteristics were determined by PanoHealth LLC. Testing of this test is limited to PanoHealth LLC, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests. This test has not been cleared or approved by the FDA. An Emergency Use Authorization (EUA) request has been submitted by the test manufacturer in accordance with the "Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency" guidance released by the FDA.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. An individual without symptoms of COVID-19 and who is not shedding SARS-CoV-2 virus would expect to have a negative (not detected) result in this assay. False positives can be caused by PCR contamination, bacterial infection, or co-infection with other viruses.