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PATIENT NAME	PATIENT ID	LAB MRN	PHONE	DOB	AGE	SEX
Hametner , Uwe		C1780045	786-624-9236	03/16/1974	46 Yrs	M

REQUISITION #	COLLECTED DATE	RECEIVED DATE	ORDERING MD
5AJWS4FMTSQTZHS	2/28/2021 12:35 PM	2/28/2021 9:07 PM	Wong, Waichi

Test Description	Results	Abnormal	Reference Range	Units	Lab
Covid19_Diagnostic	**Source: AN SWAB**		**(Status: F 02/28/2021 21:07)**		
SARS-CoV2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay	NEGATIVE		Negative		CRSP

2019-novel Coronavirus (2019-nCoV) not detected by the qRT-PCR assay. Consider testing for other respiratory viruses or re-collecting for 2019-nCoV testing. Note: Optimum timing for peak viral levels during infections caused by 2019-nCoV have not been determined. Collection of multiple specimens from the same patient may be necessary to detect the virus.

Methods and Limitations:
This Laboratory Developed Test is a high-throughput version of the CDC 2019-nCoV Realtime RT-PCR test and has been validated in accordance with the guidance issued by the College of American Pathologists (Mar 19,2020) and the FDA (Feb 29th, 2020). This test has not been FDA cleared or approved but is being run under the FDA's Emergency Use Authorization (EUA) mechanism. This test was validated for dry nasal swabs. Method: RNA is isolated from respiratory specimens using MagMAX-96 Viral RNA Isolation Kits (Thermo Fisher Scientific); RNA is reverse transcribed to cDNA, and subsequently amplified in a Real-Time PCR Instrument (Applied Biosystems ViiA7). This system provides qualitative detection of nucleic acid from SARS-CoV-2. For more detailed information on the test methods and limitations as well as for Fact Sheets for both Patients and Healthcare providers see https://sites.broadinstitute.org/safe-for-school/how-does-covid-19-testing-work-0 Positive results are indicative of active infection with SARS-CoV-2 but do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. False negative results may occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen due to improper collection, transportation, or handling. If the virus mutates in the RT-PCR target region, SARS-CoV-2 may not be detected or may be detected less predictably. Inhibitors or other types of interference may produce a false negative result.

Test run under the direction of: Heidi Rehm

Performing Laboratory Information

CRSP - Broad Institute - Clinical Research Sequencing Platform, LLC 320 Charles Street CAMBRIDGE MA 02141 Heidi Rehm, Ph.D.