

LCGBOSTON1 Waichi Wong, MD LCGBoston 867 Boylston Street, 5th Floor BOSTON, MA 02199

PartnerPartnerPartnerLab MRNPHONEDOBAGESEREQUISITION #COLLECTED DATERECEIVED DATERECEIVED DATEOKDERING MDSAUWS4FMTSQTZHS2/28/2021 12:35 PM2/28/2021 9:07 PMWong, WalchiTest DescriptionResultsAbnormalReference RangeUnitsLabCovid19_DiagnosticSource: AN SWAB(Status: F 02/28/2021 21:07)SARS-Cov2 Real-time ReverseNEGATIVENegativeCRSPTranscriptase (RT)-PCR DiagnosticSource: AN SWAB(Status: F 02/28/2021 21:07)SARS-cov2 Real-time ReverseNEGATIVENegativeCRSP2019-novel Coronavirus (2019-nCov) not detected by the gRT-PCR assay.Consider testing for other respiratory viruses or re-collecting for2019-novel Coronavirus (2019-nCov) not detected by the gRT-PCR assay.Coronavirus (2019-nCov)CRSP2019-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.Virus.Wethods and Limitations:This Laboratory Developed Test is a high-throughput version of the CDCCollege of American Pathologists (Mar 19, 2020) and the FDA (Feb 29th, 2020). This test has not been FDACleared or approved but is Isolated from respiratory ypecimens usingMadWAX-96 Viral RNA Isolation Kits (Thermo Fisher Scientific); RNA is reverse transcribed to CONA, and subsequently amplified in a Real-TimePCKInstrument (Applied Biosystems VilA?). This system providesMadMAX-96 Viral RNA Isolation kits (Thermo Fisher Scientific); RNA is			-					-		
Hametner, JuveC1780045786-624-923603/16/197446 YrsMREQUISITION #COLLECTED DATE2/28/2021 12:35 PM2/28/2021 9:07 PMORDERING MDTest DescriptionResultsAbnormalReference RangeUnitsLabCovid19_DiagnosticSource: AN SWAB(Status: F02/28/2021 21:07)SARS-COV2 Real-time Reverse Transcriptase (RT)-PCR DiagnosticNEGATIVENegativeCRSP2019-novel Coronavirus (2019-nCoV) not detected by the gRT-PCR assay. Consider testing for other respiratory viruses or re-collecting for 2019-ncov testing. Net optimum timing for pak 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 Realitime RT-PCR test and has been validated in accordance with tig gloaned they for both for period way and they specimens using MagMAX-96 viral RNA is isolated from respiratory specimens using MagMAX-96 viral RNA isolated from respiratory specimens using MagMAX-96 viral RNA isolated from sks-Cov-2. For more detailed information on the test methods and limitations as well as for Fact SRE-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 and Healthcare providers see https://sites.broadinstitute.org/safe-for-school/how-does-covid-19-testi ng-work-0 Positive results are indicative of active infection with other viruses. The agent detected may not be the definite cause of disease. Negative results may on the the definite cause of disease. Negative results may oc	PATIENT NAME		PATIENT ID		LAB MRN		PHONE	DOB	AGE	SEX
REQUISTION # COLLECTED DATE RECUISED DATE ORDERING HD SAUWS4FMTSQTZHS 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 NEGATIVE Negative CRSP Transcriptase (RT)-PCR Diagnostic Assay 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 C019-ncov Realtime RT-PCR test and has been validated in accordance with the guidance issued by the College of American Pathologists (Mar Naboratory Developed test is a brigh throughput version of the CDC C1919-ncov Realtime RT-PCR test and bas been validated for dry nasal swabs. Method: RNA is isolated from respiratory specimens using MagMAX-P6 Viral RNA Isolation Kits (Thermo Fisher Scientific): RNA is respiratory system provides <td< td=""><td colspan="2">Hametner, Uwe</td><td colspan="2"></td><td colspan="2">C1780045</td><td>786-624-9236</td><td>03/16/1974</td><td>46 Yrs</td><td>M</td></td<>	Hametner, Uwe				C1780045		786-624-9236	03/16/1974	46 Yrs	M
SAIWS4FMTSQT2HS2/28/2021 12:35 PM2/28/2021 9:07 PMWong, WaichiTest DescriptionResultsAbnormalReference RangeUnitsLabCovid19_DiagnosticSource: AN SWAB(Status: F02/28/2021 21:07)SARS-Cov2 Real-time ReverseNEGATIVENegativeCRSPTranscriptase (RT)-PCR DiagnosticASsay2019-novel Coronavirus (2019-ncov) not detected by the gRT-PCR assay. Consider testing for other respiratory viruses or re-collecting for 2019-ncov testing. Note: 0ptimum 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.Wethods 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 Vira). This system provides gualitative detection of nucleic acid from SARS-CoV-2. For more detailed information on the test methods and limitations as well as for Fact SRE-cov2-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 are indicative of active infection and should not be used as the sole basis for patient	REQUISITION #	COLLECTED D	DATE	RECEI	VED DATE		ORD	DERING MD		-
Test DescriptionResultsAbnormalReference RangeUnitsLabCovid 9_DiagnosticSource: AN SWAB(Status: F02/28/2021 21:07)SARS-COV2 Real-time Reverse transcriptase (RT)-PCR DiagnosticNEGATIVENegativeCRSP2019-novel Coronavirus (2019-ncov) not detected by the gRT-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 is olation Kits (Thermo Fisher Scientific); RNA is reverse transcribed to cONA, and subsequently amplified in a Real-Time PCC Instrument (Applied Biosystems ViiA7). This system provides gualitative detection of nucleic acid from SARS-CoV-2. Infection with SARS-CoV-2 but do not rule out bacterial infection or co-infection with SARS-CoV-2 but do not rule out bacterial infection or co-infection with SARS-CoV-2 but do not rule out bacterial infection and should not be used as the sole basis for patient management decisions. False negative results do not preclude SARS-COV-2 infection and should not be used as the sole basis for patient management decisions. False negativ	5AJWS4FMTSQTZHS	2/28/2021 12	2:35 PM 2/28/202		21 9:07 PM		Wor	ng, Waichi		
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	SARS-CoV2 Real-time Rever Transcriptase (RT)-PCR Di Assay 2019-novel Coronavirus (2 Consider testing for other 2019-nCoV testing. Note: (infections caused by 2019- multiple specimens from the virus. Methods and Limitations: This Laboratory Developed 2019-nCoV Realtime RT-PCR the guidance issued by the 19,2020) and the FDA (Feb cleared or approved but is Authorization (EUA) mechan swabs. Method: RNA is iso MagMAX-96 Viral RNA Isolar reverse transcribed to CDP PCR Instrument (Applied B qualitative detection of a information on the test me Sheets for both Patients a https://sites.broadinstitu ng-work-0 Positive results SARS-CoV-2 but do not rulo other viruses. The agent of disease. Negative results may in the specimen or if inad specimen due to improper of virus mutates in the RT-PC detected or may be detecto of interference may product	Test is a high respiratory optimum timing -nCoV have not he same patier Test is a high test and has e College of A 29th, 2020). s being run ur nism. This test lated from respiration kits (The van kits (The van kits (The van kits (The van kits (The tends and line and Healthcare ute.org/safe-f e are indication to not preclut sole basis for y occur if amp dequate number collection, tr CR target regind e a false negotial ce a false negotial	NEGATIV detected viruses for pea t been de t may be det throug been va American This tes not the st was va spiratory ermonfis approvide for-schoo ive of ac al infect of patier of ansport ion, SARS- cransport ion, SARS- cransport	E d by the or re-co ak viral etermined e necessa d phput ver lidated i Patholog st has no FDA's Em alidated / specime har Scien amplified s system S-COV-2. s as well ers see ol/how-do ctive infi tion or co tive infi COV-2 in nt manage ganisms a ation, or S-COV-2 m. Inhibitor esult.	qRT-PCR assa llecting for levels durin . Collection ry to detect sion of the n accordance ists (Mar t been FDA ergency Use for dry nasa ns using tific); RNA in a Real-T provides For more det as for Fact es-covid-19- ection with o-infection te cause of fection and ment decisio itors are pr re present i handling. I ay not be s or other t	y. of the CDC with is ime ailed testi with ms. f the cypes	Negative		CRS	ŞΡ

Speidi Pehn

Performing Laboratory Information

Test run under the direction of:

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