EMERGENCY USE AUTHORIZATION (EUA) SUMMARY

Quaeris SARS-CoV-2 Assay

Harvard University Clinical Laboratory (HUCL)

For *In vitro* Diagnostic Use
Rx Only
For use under Emergency Use Authorization (EUA) only

(The Quaeris SARS-CoV-2 Assay will be performed at the Harvard University Clinical Laboratory, located at B139 Northwest Laboratories, 52 Oxford Street Cambridge MA02138, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets the requirements to perform high complexity tests. The Laboratory Standard Operating Procedures were reviewed by the FDA under this EUA.)

INTENDED USE

The Quaeris SARS-CoV-2 Assay is a real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 virus in self-collected (unsupervised) or healthcare provider-collected anterior nasal swab specimens at home or in a healthcare setting (which includes in a community-based setting) using the COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory (HUCL) by individuals 18 years of age or older suspected of COVID-19, when determined to be appropriate by a healthcare provider. Specimens collected using the COVID-19 Self-Swab Collection Kit for Harvard University Clinical Laboratory (HUCL) can be transported dry for testing.

Testing is limited to the Harvard University Clinical Laboratory (HUCL), located at B139 Northwest Laboratories, 52 Oxford Street, Cambridge MA 02138 which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in anterior nasal swab specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results 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. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

The Quaeris SARS-CoV-2 Assay is intended for use by qualified laboratory personnel specifically instructed and trained in molecular testing and in vitro diagnostic procedures. The Quaeris SARS-CoV-2 assay and the COVID-19 Self-Swab Collection Kit for HUCL are only for use under the Food and Drug Administration's Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

1) *COVID-19 Self-Swab Collection Kit for HUCL*

The COVID-19 Self-Swab Collection Kit for HUCL consists of a sterile packaged medical-grade hydrophobic polymer nasal swab (polypropylene P9M7R-056, Flint Hills) with a threaded lid attached, a dry collection tube with a threaded end, a barcode card, instructions for use, a biohazard bag, and, when shipped, an absorbent pad, a rigid outer safety box with UN3373 marking, and a FedEx shipping envelope with a prepaid return address label.

a) Home Collection Kit Ordering and Processing:

The COVID-19 Self-Swab Collection Kit for HUCL is offered as part of a community-based distribution framework that is physician ordered. Healthcare providers (HCPs) who are licensed and have prescriptive authority in their respective states use a COVID-19 eligibility questionnaire that is based on current CDC testing guidelines to evaluate patient acceptability. Ordering physicians must be licensed in the state where the kits will be provided or shipped.

Harvard University Clinical Laboratory (HUCL) has an agreement with Color Health, Inc. to provide services related to the self-collection kit. Color provides an online HIPAA-compliant portal for patient registration, pre-test kit activation, and post-test access to results. In addition, Color assembles the collection kit for distribution. At the physician's discretion, the patient is directed to access the Color website (http://home.color.com/covid/check) and answers questions related to patient exposure, symptoms, as well as underlying health conditions and other risk factors. This task is to document the patient's responses and link the patient with a specific kit and barcode that will be used for accessioning at the testing laboratory.
The COVID-19 Self-Swab Collection Kit for HUCL can be provided at designated on-site collection locations that are part of a centrally coordinated community-based distribution framework when physician-ordered. The self-collection kit can also be ordered by a healthcare provider and shipped to the patient's home via 2-day or overnight shipping.

b) Shipping:

Self-collected nasal swab samples are transported under dry conditions in a sterile collection container to the HUCL laboratory for processing with the Quaeris SARS-CoV-2 Assay (referred to as Quaeris assay in this document).

c) Specimen Accessioning:

Specimens collected with the COVID-19 Self-Swab Collection Kit for HUCL must be checked for the following criteria upon receipt at HUCL prior to processing:

- Sample collection tube must be intact and not visibly damaged.
- The tube barcode label must be present and readable by a barcode scanner.
- The tube cap must be properly secured onto the tube.
- The tube must contain a swab.
- Accession date is within 56 hours of the collection time.

Specimens not received in the HUCL-approved collection kits, damaged vials, vials containing swabs that are received without a top properly closed, vials without swabs, and specimens not labeled with kit barcode labels are not acceptable for testing. These specimens will be rejected upon receipt. Additionally, visibly bloody specimens will not be accepted for testing. Another specimen will be requested. Specimens must be tested within 56 hours of collection. Any specimen received more than 56 hours after collection will be rejected.

Upon accessioning into SampleManager (LIMS), the LIMS will query the Color registration database with the scanned barcode. SampleManager will record whether the barcode is in the registration database. If the barcode is in the registration database, the sample can be processed; if the barcode is not in the registration database, the sample should not be processed.

2) Quaeris SARS-CoV-2 Assay

The Quaeris SARS-CoV-2 Assay is a real-time reverse transcription polymerase chain reaction (rRT -PCR) test using the Luna Probe One-Step RT-qPCR Kit (No ROX) [NEB E3007]. The SARS-CoV-2 primer and probe set is designed to detect RNA from the SARS-CoV-2 N1 and RdRP genes and the human RNase P gene in nasal specimens from suspected patients. The test consists of three processes in a single tube: 1) reverse transcription of target RNA to cDNA, 2) PCR amplification of target and internal control, and 3) simultaneous detection of all three target amplicons using different fluorescent dye labeled probes.

During the amplification process, the probe anneals to the three specific target sequences located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5’ nuclease activity of Taq polymerase degrades the bound probe, causing the reporter dye to separate from the quencher dye, generating a fluorescent signal.

The Quaeris assay to be used with the COVID-19 Self-Swab Collection Kit for HUCL employs a RNaseP internal control to determine that the self-collection resulted in a sample of appropriate quality and quantity of RNA.

Anterior nasal (AN) swab specimens are collected and shipped in a dry collection tube. When received by the laboratory, samples are first rehydrated with 300 µl phosphate buffered saline (PBS), then inactivated at 65ºC and subsequently used directly as input for the Quaeris assay. There is **no extraction step**. rRT-PCR is performed on an Applied Biosystem Quantstudio 7 instrument (software version 1.7). Liquid handling is automated using either the Tecan Fluent 1080, or the Hamilton Star, or the Multidrop combi dispenser.

INSTRUMENTS USED WITH TEST

RT-PCR is performed using the following realtime fluorescence PCR instruments and associated software:

- Applied Biosystems QuantStudio 7 Real-Time PCR Instrument 384-well block with QuantStudio Design and Analysis Desktop Software v1.7.

EQUIPMENT, REAGENTS AND MATERIALS

The following equipment/reagents/materials are required to run this test in additional to common laboratory reagents and the consumables for the extraction and PCR process es are summarized in the tables below:

Table 1: Equipment / Instruments for use with the Quaeris SARS-CoV-2 Assay

Equipment	Manufacturer	Catalog Number
Quant Studio 7 Flex	ABI/Thermo Fisher	4485690
Quant Studio Real-Time PCR Software V1.3 or V1.7	ABI/Thermo Fisher	n/a
Tecan Fluent 1080 COVID Robot System	Tecan	30042031
Hamilton Microlab STARline Liquid Handling System	Hamilton	173000
Hamilton LabElite ID DeCapper	Hamilton	193601
Refrigerator (2-8°C)	VWR	10791-618
Freezer (-20°C)	VWR	10819-408
Freezer (-80°C)	VWR	76307-978
Centrifuge (Model 5430)	Eppendorf	022620511
PlateLoc Thermal Plate Sealer	Agilent	G5585B
Biosafety Cabinets (Class II Type A/B3)	Nuaire	NU-425-400
PCR Workstation	VWR	10783-132
Hybex Microsample Incubator	SciGene	1057-30-O
Advanced Dry Block Heater	VWR	75838-296
Microplate shaker	VWR	10027-120

Table 2: Reagents and materials for use with the Quaeris SARS-CoV-2 Assay

Reagent/Material	Manufacturer & Catalog Number (specified or equivalent)	
384-well microplate (barcoded) MicroAmp Optical microplates	Thermo Fisher	4343814
Flat-Top 96-Well PCR Plate	VWR	490003-750
Sample tube rack	LVL	2DNC-105-NC-PS- PLP-L
PCR strips	VWR	53509-304
Sterile Filter tips for P1000	Olympus Plastics	Genesee #24-801C
Sterile Filter tips for P200	Olympus Plastics	Genesee #24-412C
Sterile Filter tips for P20	Olympus Plastics	Genesee #24-701C
Sterile Filter tips for P10	Olympus Plastics	Genesee #24-800C
Eppendorf Research plus, 12-channel (10-100µL)	Eppendorf	3125000044
Eppendorf Research plus, 8-channel (0.5-10µL)	Eppendorf	3125000010
Adjustable single-channel pipettes: Gilson PIPETMAN P2, P20, P200, P1000	VWR	76207-552
Drummond Pipet-Aid	Drummond Scientific	4-000-100
Serological pipets (5mL, 10mL, 25mL)	VWR	82051-182 82050-482 89130-896
Microfuge tube rack	VWR	82024-469
50 mL tube holder	Fisher Scientific	03-448-12
Corning Round Ice Bucket with Lid, 4L	VWR	07-210-122
PBS - Phosphate-Buffered Saline (10X) pH 7.4, RNase-free	Thermo Fisher	AM9624
Luna Universal Probe One-Step RT-qPCR kit (No ROX) (store at -20°C)	NEB	E3007E
MicroAmp Optical Adhesive Film	Thermo Fisher	4311971
Silicone adhesive film for PCR plates	VWR	89134-428
RNaseIn Plus RNase inhibitor (store at -20°C)	Promega	N2615
Nuclease-Free Water (not DEPC-Treated)	Thermo Fisher	4387936
Primers for master mix N1 (store at -20°C)	IDT	n/a
Primers for master mix RP (store at -20°C)	IDT	n/a
Primers for master mix RdRp (store at -20°C)	IDT	n/a
TE, pH 7.0, RNase-free	ThermoFisher	AM9861
15mL nuclease free conical tube	VWR	21008-216
50mL nuclease free conical tube	VWR	21008-940
Eppendorf Tubes 5.0 mL	Millipore	0030108310
1.5 mL DNA Lo-Bind Eppendorf Tubes	VWR	80077-230
MicroAmp Adhesive Film Applicator	ThermoFisher	4333183
96 well metal block	CoolerSci_logo	A-7079

Table 2: Reagents and materials for use with the Quaeris SARS-CoV-2 Assay

Reagent/Material	Manufacturer & Catalog Number (specified or equivalent)	
	(Ordered from Light Labs)	
384 well metal block	CoolerSci logo (Ordered from Light Labs)	A-7083-S
Nitrile examination gloves (Small)	VWR	89428-748
Nitrile examination gloves (Medium)	VWR	89428-750
Nitrile examination gloves (Large)	VWR	89428-752
Face Shields	American Drug Test	11000-000
Bleach	Amazon.com	n/a
Spray bottles	Amazon.com	n/a
Disinfecting wipes (Harvard Central Stockpile)	Oxivir	10477982
70% Ethanol		

Table 3: Home collection Kit Components

FedEx soft shipping envelope with prepaid return shipping label*
Rigid box outer safety box with UN3373 marking*
Instruction for use – Shipping*
A biohazard bag
Absorbent pad*
Sterile packaged medical grade hydrophobic polymer swab (polypropylene P9M7R-056 from Flint Hills)
Sterile collection tube
Barcode card
Instructions for use - Self-collection

* Not applicable to unmonitored on-site collection

CONTROLS TO BE USED WITH THE QUAERIS SARS-COV-2 ASSAY

Table 4: Controls to be used with the Quaeris SARS-CoV-2 Assay

Control Type	Description	Source/Catalog Number	Purpose	Frequency of Testing
Negative Template Control 1	1x PBS - Phosphate-Buffered Saline pH 7.4	VWR 75800-990	To monitor for cross-contamination	1 per 384-well assay plate
Negative Template Control 2	Nuclease-Free Water (not DEPC-Treated)	ThermoFisher 4387936	To monitor for cross-contamination	1 per 384-well assay plate

Table 4: Controls to be used with the Quaeris SARS-CoV-2 Assay

Control Type	Description	Source/Catalog Number	Purpose	Frequency of Testing
SARS-CoV-2 Positive Control (at 5x LoD each[1])	2019-nCoV_N_Positive Control, 2019-nCoV_RdRp_Positive Control, 2019-nCoV_RPP30 Positive Control	IDT 10006625 IDT 10006626 IDT 10006897	To monitor the integrity of the rRT-PCR reagents and process	2 per 384-well assay plate
Internal control (process control)	Same primer and probe pair to detect RNase P RNA as used in the CDC 2019-nCoV assay	From each patient sample	To ensure the sample collection was properly performed and to monitor sample	Every tested specimen

- **No Template Controls (NTC1 & NTC2)**
  A negative (no template) control must be used to monitor sample contamination during all processing steps, including sample inactivation (NTC1) and rRT-PCR assay set-up (NTC2). Two negative controls are included on each 384-well plate. Phosphate buffered saline (pH 7.4) (NTC-1), which is added as a rehydration buffer, and molecular grade, nuclease-free water [not DEPC treated] (NTC-2) should be added to a sterile collection tube during the dry swab rehydration step and processed as if it were a clinical sample (e.g., it should be heat inactivated).

- **SARS-CoV-2 Positive Control (PC)**
  A positive SARS-CoV-2 control is needed to verify proper assay set-up and SARS-CoV-2 reagent integrity. A positive control consists of molecular grade, nuclease-free water spiked with a mixture of control plasmids from IDT at a concentration of 5x LoD each. The positive control must be used on every assay plate starting at master mix addition.

- **Endogenous Internal Control (Process Control)**
  An internal control targeting RNaseP is needed to verify that nucleic acid is present in every sample and is used for every sample that processed with the assay. Detection of the RNase P gene in the patient test samples verifies proper assay setup, sample integrity, and collection of human biological material. The Quaeris assay utilizes the same primer and probe pair to detect RNase P RNA as the CDC 2019-nCoV EUA assay.

[1] The Quaeris assay SOP has been revised to state that positive controls should be included at 5x LoD (previously stated ~1000x LoD). HUCL has performed a bridging study in which the positive controls were run 60x, and from this distribution, HUCL has defined a Ct cut-off of 35 for the positive control

INTERPRETATION OF RESULTS

All test controls must be examined prior to interpretation of patient results. If the controls are not valid, the patient results cannot be interpreted. Result interpretation for patient samples was established based on a cutoff of Ct ≤35 for the SARS-CoV-2 targets.

1) Interpretation of Controls

All test controls should be examined prior to interpretation of patient results. If N1 and RdRp Ct values for 2 positive controls is >35 or is <35 for the 3 negative template controls the run is considered invalid. If the controls are not valid (first three decision blocks in Figure 1), the patient results cannot be interpreted. The whole plate should be invalidated and all samples on the plate should be re-run.

2) Interpretation of Patient Samples

- The patient results are interpreted according to the criteria shown in Figure 1. All positive and negative results should be confirmed by manually inspecting the amplification curve to ensure the automated call of Ct is not erroneous.
    - If either N1 or RdRp is equal or below a cycle threshold (Ct) of 30, the sample is positive.
    - If both N1 and RdRp are equal or below a Ct of 38, the sample is Positive
    - If both N1 and RdRp are undetermined or above a Ct of 38 and RNaseP is equal or below a Ct of 34, the sample is Negative (fourth and fifth decision blocks).
    - If both, N1 and RdRp are negative and RNaseP is negative or has a Ct above 34 the sample is Inconclusive.

Table 5: Interpretation of Quaeris SARS-CoV-2 Assay results (expected cycle thresholds, Ct): Initial Run

2019	2019	RP	Result	Report	Actions
<30	N/A	N/A	2019-nCoV detected	Positive 2019-nCoV	Report results to public health authorities and sender.
N/A	<30	N/A			
<38	<38	N/A			
>38	>38	<34	2019-nCoV not detected	Not Detected	Report results to public health authorities and sender.
>38	>38	>34	Inconclusive Result A	Inconclusive A	Perform Rerun A and interpret per **Inconclusive A Interpretation** (see table 6 below)
<38	>38	N/A	Inconclusive Result B	Inconclusive B	Perform Rerun B and interpret per **Inconclusive B Interpretation** (see table 7 below)
>38	<38	N/A			

Samples that are Inconclusive should be rerun and interpreted as shown Tables 6 and 7.

- Rerun A is likely the result of either of poor sample collection (i.e., patient error) or sample processing error (e.g. clogged pipette tip); these samples will repeatedly have an RNaseP Ct above the 34 Ct cutoff.
- Rerun B is either a false positive or a low viral titer positive; these samples will have inconsistent results between the N1 and RdRp, i.e., one Ct value will be above the 38 Ct cutoff and the other will be below the 38 Ct cutoff.

Table 6: Inconclusive - Rerun A Interpretation (expected cycle thresholds, Ct)

2019 nCoV_N1	2019 nCov_RdRp	RP	Result Interpretation	Report	Actions
<30	N/A	N/A	2019-nCoV detected	Positive 2019-nCoV	Report results to public health authorities and sender.
N/A	<30	N/A			
<38	<38	N/A			
>38	>38	<34	2019-nCoV not detected	Not Detected	Report results to sender.
>38	>38	>34	Inconclusive Result	Inconclusive	Report results to sender. Consider collecting a new specimen from patient.
<38	>38	N/A			
>38	<38	N/A			

Table 7: Inconclusive – Rerun B Interpretation (expected cycle thresholds, Ct)

2019 nCoV_N1	2019 nCov_RdRp	RP	Result Interpretation	Report	Actions
<30	N/A	N/A	2019-nCoV detected	Positive 2019-nCoV	Report results to public health authorities and sender.
N/A	<30	N/A			
<38	<38	N/A			
<38	>38	N/A			
>38	<38	N/A			
>38	>38	<34	2019-nCoV not detected	Not Detected	Report results to sender.
>38	>38	>34	Inconclusive Result	Inconclusive	Report results to sender. Consider collecting a new specimen from patient.

PERFORMANCE EVALUATION

1) Limit of Detection (LoD) - Analytical Sensitivity:

The LoD of the Quaeris SARS-CoV-2 Assay was determined using quantified inactivated SARS-CoV-2 virus (ATCC VR-1986HK). LoD was determined by testing a range of SARS-CoV-2 concentrations, between 15 copies/µl and 1.25 copies/mL, in a two-fold dilution series. Samples were prepared by spiking inactivated virus into pooled clinical negative, anterior nasal swab matrix, and 20 replicates were tested at each concentration. These replicates were individually processed according to the laboratory SOP and tested on QuantStudio 7 real-time PCR instruments.

The initial LoD determination of the Quaeris SARS-CoV-2 RT-PCR Assay is 2.5 copies/µL.

Table 8: Limit of Detection of Quaeris SARS-CoV-2 Assay

Target Level	Valid tested replicates	SARS-CoV-2 N1 Positive			SARS-CoV-2 RdRp Positive			Positive results per result interpretation
		n	Mean Ct	Detection Rate	n	Mean Ct	Detection Rate	
15 cp/µL	20	20	32.9	100%	19	34.2	95%	20/20
7.5 cp/µL	20	20	33.9	100%	15	36.0	75%	20/20
5 cp/µL	20	20	34.1	100%	14	35.8	70%	20/20
2.5 cp/µL	20	20	35.9	100%	4	35.9	20%	20/20
1.25 cp/µL	20	14	36.6	70%	2	36.6	10%	14/20

2) Analytical Inclusivity/Specificity:

a) Inclusivity

Inclusivity of the Quaeris SARS-CoV-2 Assay was assessed in a in silico analysis that calculated the number of mismatches between the Quaeris SARS-CoV-2 Assay primer and probe sequences and known SARS-CoV-2 variants. All available full-length SARS-CoV-2 genomic sequences in NCBI database as of 2/11/2021 were downloaded and aligned to the N1 and RdRp primers and probes. The results of the analysis are summarized in the table below

Table 9. Primer and Probe Mismatches with Sequenced SARS-CoV-2 Isolates

N1			RdRp		
Mismatch	**Sample**	**Count**	**Mismatch**	**Sample**	**Count**
0	Forward Primer	41775	0	Forward Primer	42028
1	Forward Primer	328	1	Forward Primer	73
0	Probe	41936	0	Probe	42061
1	Probe	134	1	Probe	38
2	Probe	1			
0	Reverse Primer	41993	0	Reverse Primer	42105
1	Reverse Primer	112	1	Reverse Primer	2
2	Reverse Primer	1			

Of the ~44,000 sequences downloaded for the N1 gene (the full genome was downloaded and segmented into sequences) there were only 328 variants with a single mismatch in the forward primer, 134 variants with a single mismatch in the probe, and 112 variants with a single mismatch in the reverse primer.

Of the ~44,000 sequences downloaded for RdRp there were only 73 variants with a single mismatch in the forward primer, 38 variants with a single mismatch in the probe, and 2 variants with a single mismatch in the reverse primer.

The single base mismatches were never in the 3' end of the Quaeris primers and should be detected equivalently to the sequence with no mismatches.

The Quaeris SARS-CoV-2 Assay should be unaffected by the UK, Brazil, South Africa, New York, and California variants for two reasons:

1. The probes and primer sequences do not contain any mismatches with these variants.
2. The clinical validation included three samples of the B.1.1.7 variant, based on sequencing analyses of samples performed.
3. Multiple individuals with the E484K mutations have been detected using the Quaeris SARS-CoV-2 Assay outside of the clinical validation study.

b) Cross-Reactivity

i. Wet testing of other Coronaviruses

Synthetic N-gene and RdRp DNA were cloned from SARS-CoV-1, MERS, huCoV-HKU1, huCoV-OC43, huCoV-NL63, and huCoV-229E. The resulting plasmids were sequence verified and quantified. The DNA was then directly tested for cross reactivity at individual concentrations of 10^6 cps/µL for the N-gene and $2x10^6$ cps/µL for the

RdRp gene. The reactions were performed in triplicate in three independent runs with different MasterMix on each assay. All assays included a positive control for SARS-CoV-2 at 10^5 cps/mL in duplicate to serve as a positive control for the reaction mixes. Results are shown below in Table 10 below

Table 10: Cross Reactivity Study (Summary)

Pathogen	N1 Reactivity	RdRp Reactivity
huCoV-229e	0/9	0/9
huCoV-HKU1	0/9	0/9
huCoV-OC43	0/9	0/9
huCoV-NL63	0/9	0/9
MERS	0/9	0/9
SARS-CoV-1	0/9	0/9
Controls	N1 Reactivity	RdRp Reactivity
SARS-CoV-2	9/9	9/9
Water	0/9	0/9
RNaseP (detected with RNAseP primers)	9/9	9/9

The SARS-CoV-2 N1, RdRp and RNaseP Positive Controls confirmed the assay was performing well. None of the other coronavirus' N1 and RdRp genes had any cross-reactivity with the N1 and RdRp primers and probes designed for the Quaeris SARS-CoV-2 Assay. The SARS-CoV-2 N1, RdRp and RNaseP Positive Controls confirmed the assay was performing well. For each gene, the Quaeris SARS-CoV-2 Assay positive controls were detected within the expected Ct range and, compared to the lack of reactivity of the other coronaviruses, demonstrated the specificity of the SARS-CoV-2 primer and probes used in the Quaeris SARS-CoV-2 Assay.

ii. In Silico analysis for Cross Reactivity to viral and bacterial pathogens

The Quaeris SARS-CoV-2 Assay primers and probes were tested in silico for potential cross reactivity with sequences of other respiratory viral and bacterial pathogens listed in Table 11 below.

Table 11. In Silico Analysis of Microbial Cross Reactivity

Accession	Description	N1			RdRP		
		FWD P	REV P	PROB E	FWD P	REV P	PROB E
NC_001405.1	Human adenovirus C, complete genome.	<80	<80	<80	<80	<80	<80
NC_039199.1	Human metapneumovirus isolate 00-1, complete genome.	<80	<80	<80	<80	<80	<80
NC_021928.1	Human parainfluenza virus	<80	<80	<80	<80	<80	<80

Accession	Description	N1			RdRP		
		FWD P	REV P	PROB E	FWD P	REV P	PROB E
	4a viral cRNA, complete genome, strain: M25						
NC_002204.1	Influenza B virus RNA 1, complete sequence.	<80	<80	<80	<80	<80	<80
NC_038308.1	Human enterovirus 68 strain Fermon, complete genome	<80	<80	<80	<80	<80	<80
NC_001803.1	Respiratory syncytial virus, complete genome.	<80	<80	<80	<80	<80	<80
NC_038311.1	Human rhinovirus 1 strain ATCC VR-1559, complete genome	<80	<80	<80	<80	<80	<80
NC_005043.1	*Chlamydia pneumoniae* TW-183, complete sequence	<80	<80	<80	<80	<80	<80
NZ_CP009610.1	*Haemophilus influenzae* strain Hi375 chromosome, complete genome	<80	<80	<80	<80	<80	<80
NZ_CP013742.1	*Legionella pneumophila* strain Philadelphia-1 isolate AE chromosome, complete genome	<80	<80	<80	<80	<80	<80
NC_000962.3	*Mycobacterium tuberculosis* H37Rv, complete genome	<80	<80	<80	<80	<80	<80
NZ_UYIP01000002.1	*Streptococcus pneumoniae* strain NCTC11032, whole genome shotgun sequence	<80	<80	<80	<80	<80	<80
NZ_CP010450.1	*Streptococcus pyogenes* strain NGAS638 chromosome, complete genome	<80	<80	<80	<80	<80	<80
NC_018518.1	*Bordetella pertussis* 18323, complete sequence	<80	<80	<80	<80	<80	<80

Accession	Description	N1			RdRP		
		FWD P	REV P	PROB E	FWD P	REV P	PROB E
NZ_CP010546.1	*Mycoplasma pneumoniae* FH chromosome, complete genome	<80	<80	<80	<80	<80	<80
NW_017264775.1	*Pneumocystis jirovecii* RU7 chromosome Unknown supercont1.1, whole genome shotgun sequence	<80	<80	<80	<80	<80	<80
CM016738.1 - CM016745.1	*Candida albicans* strain NCYC 4146, whole genome shotgun sequencing	<80	<80	<80	<80	<80	<80
NC_002516.2	*Pseudomonas aeruginosa* PAO1, complete genome	<80	<80	<80	<80	<80	<80
NZ_CP035288.1	*Staphylococcus epidermidis* strain ATCC 14990 chromosome, complete genome	<80	<80	<80	<80	<80	<80
NZ_LR793266.1	*Streptococcus salivarius* isolate clinical strain from anonymous patient of Limoges Hospital, whole genome shotgun sequence	<80	<80	<80	<80	<80	<80
MW892702.1	P.1 Brazil - Severe acute respiratory syndrome coronavirus 2 isolate SARS-CoV-2/human/USA/MN-MDH-4780/2021, complete genome	100	100	100	100	100	100
MW674797.1	B.1.429 California - Severe acute respiratory syndrome coronavirus 2 isolate SARS-CoV-2/human/USA/NM DOH-	100	100	100	100	100	100

Accession	Description	N1			RdRP		
		FWD P	REV P	PROB E	FWD P	REV P	PROB E
	2021054037/2021, complete genome						
MW664409.1	B.1.526 New York - Severe acute respiratory syndrome coronavirus 2 isolate SARS-CoV-2/human/USA/MD-MDH-1069/2021, complete genome	100	100	100	100	100	100
MW580244.1	B.1.351 South Africa - Severe acute respiratory syndrome coronavirus 2 isolate SARS-CoV-2/human/FRA/ZA-1/2021, complete genome	100	100	100	100	100	100
MW664384.1	B.1.1.7 UK - Severe acute respiratory syndrome coronavirus 2 isolate SARS-CoV-2/human/USA/MD-MDH-1044/2021, complete genome	100	100	100	100	100	100
NC_004718.3	SARS-CoV-1 coronavirus strain Tor2, complete genome	100	87	96	97	83	91
NC_019843.3	Middle East respiratory syndrome-related coronavirus isolate HCoV-EMC/2012, complete genome.	57	53	33	67	80	84
NC_002645.1	Human coronavirus 229E, complete genome	43	47	63	90	57	78
NC_005831.2	Human Coronavirus NL63, complete genome	47	63	75	77	63	78
NC_006213.1	Human Coronavirus NL63, complete genome	47	43	67	93	37	19

Accession	Description	N1			RdRP		
		FWD P	REV P	PROB E	FWD P	REV P	PROB E
NC_006577.2	Human coronavirus HKU1, complete genome	57	30	46	97	63	72

The sequence identity of the primers and probes chosen for the Quaeris SARS-CoV-2 Assay is less than 80% homologous between all other pathogens and organisms listed in FDA's EUA template.

Individual primer and probe sequences were found with >80% homology to other coronaviruses. However, these viruses were wet-tested and were found to not cross react with the Quaeris SARS-CoV-2 Assay.

c) Interfering Substances Studies

To assess substances with the potential to interfere with the performance of the Quaeris SARS-CoV-2 Assay, positive sample S000566067 was tested (3 replicates) with the addition of potentially interfering substances. This sample has a SARS-CoV-2 target concentration that is approximately 3x LoD of the Quaeris SARS-CoV-2 Assay.

The majority of samples were positive even in the presence of the interfering substance and the Ct value of the sample was unaffected. This demonstrates that the Quaeris SARS-CoV-2 Assay test performance was not affected by most of the 10 potentially interfering substances listed in Table 8 below at the concentrations tested. Interference was only seen at extremely high concentrations of interfering species, i.e., 50% w/v blood, 10% and 50% w/v tobramycin, and 10% and 50% w/v oseltamivir phosphate. Interference at this level would not be seen naturally with any of the three substances and hence no limiting statement in the labeling is necessary.

Table 12. Interfering Substances

		N1		RdRp		RNaseP		
Interfering Substance	**Concentration**	**Avg Ct**	**Std Dev**	**Avg Ct**	**Std Dev**	**Avg Ct**	**Std Dev**	**Call**
None	**N/A**	33.2	0.7	34.2	1.0	27.0	0.4	**Positive**
Dymista	**0.1% v/v**	32.9	0.7	35.2	1.5	25.3	1.6	**Positive**
	1% v/v	31.7	0.6	33.4	0.8	26.8	0.7	**Positive**
	10% v/v	31.9	0.5	34.8	0.6	27.5	0.8	**Positive**
	50% v/v	31.7	0.6	34.2	0.9	26.7	1.1	**Positive**
Human Blood	**0.1% v/v**	32.4	0.2	35.0	1.5	26.4	0.2	**Positive**
	1% v/v	31.7	0.5	34.3	0.6	28.0	0.3	**Positive**
	10% v/v	33.5	1.1	36.1	1.1	27.8	0.5	**Positive**
	50% v/v	>40	N/A	>40	N/A	28.1	N/A	**Negative**[2]

[2] This negative result is acceptable because a sample with 50% v/v human blood would not occur or be tested in practice.

		N1		RdRp		RNaseP		
Interfering Substance	**Concentration**	**Avg Ct**	**Std Dev**	**Avg Ct**	**Std Dev**	**Avg Ct**	**Std Dev**	**Call**
Nasacort	**0.1% v/v**	32.4	1.2	35.2	0.3	27.5	1.2	**Positive**
	1% v/v	31.7	0.6	34.6	0.6	27.8	0.3	**Positive**
	10% v/v	31.8	0.9	33.5	0.4	27.3	1.2	**Positive**
	50% v/v	32.3	0.7	34.5	0.2	27.1	0.2	**Positive**
Nasogel	**0.1% v/v**	32.6	1.2	34.8	1.0	27.1	1.1	**Positive**
	1% v/v	32.5	2.0	35.0	2.0	28.9	2.0	**Positive**
	10% v/v	31.6	0.6	33.5	0.3	27.6	0.4	**Positive**
	50% v/v	32.1	0.9	34.2	0.4	26.3	0.7	**Positive**
Mupirocin Ointment	**0.1% w/v**	32.5	1.4	35.8	1.3	29.0	0.5	**Positive**
	1% w/v	33.9	1.2	36.6	1.0	29.2	0.6	**Positive**
	10% w/v	33.0	1.3	>40	N/A	26.7	1.4	**Positive**
	50% w/v	32.3	0.7	>40	N/A	27.1	0.9	**Positive**
Similasan	**0.1% v/v**	33.6	0.9	36.8	0.2	29.4	0.2	**Positive**
	1% v/v	34.0	0.6	>40	N/A	30.1	0.4	**Positive**
	10% v/v	32.1	0.9	34.6	1.9	28.4	0.3	**Positive**
	50% v/v	31.3	0.3	34.0	1.7	26.6	1.3	**Positive**
Chloraseptic	**0.1% w/v**	34.5	1.7	35.5	2.1	28.3	1.2	**Positive**
	1% w/v	32.4	2.3	35.4	1.9	28.6	0.4	**Positive**
	10% w/v	32.2	0.0	34.8	0.6	27.8	0.3	**Positive**
	50% w/v	33.0	0.1	37.0	1.6	28.8	0.5	**Positive**
Tobramycin[3]	**0.1% v/v**	33.6	1.6	36.2	2.6	28.2	1.5	**Positive**
	1% v/v	32.6	2.0	34.6	1.8	28.0	2.4	**Positive**
	10% v/v	>40	N/A	>40	N/A	27.7	1.3	**Inconclusive**
	50% v/v	>40	N/A	>40	N/A	>40	N/A	**Negative**
Oseltamivir phosphate[4]	**0.1% v/v**	32.4	1.7	>40	N/A	28.6	1.1	**Positive**
	1% v/v	33.1	1.7	34.8	0.8	28.4	0.2	**Positive**
	10% v/v	>40	N/A	>40	N/A	30.7	2.5	**Negative**
	50% v/v	>40	N/A	>40	N/A	>40	N/A	**Inconclusive**
Mucin	**0.002% w/v**	32.6	1.5	34.5	0.6	27.9	0.3	**Positive**
	0.02% w/v	32.3	0.5	33.9	0.2	27.0	0.6	**Positive**
	0.20% w/v	31.8	0.2	33.3	0.3	26.6	0.5	**Positive**
	2% w/v	32.4	1.3	32.9	0.8	25.9	0.2	**Positive**
Water	**50% v/v**	33.7		33.8		26.7		**Positive**
	50% v/v	32.9		33.9		26.7		**Positive**
	50% v/v	32.2		33.3		26.8		**Positive**
	50% v/v	32.7		36.1		26.5		**Positive**
	50% v/v	**33.9**		**34.6**		**27.7**		**Positive**
	50	33.7		33.7		27.2		**Positive**

[3] A limitations statement is included in the Quaeris assay SOP noting that false negative or inconclusive results may occur due to high concentrations of interfering Tobramycin.
[4] A limitations statement is included in the Quaeris assay SOP noting that false negative or inconclusive results may occur due to high concentrations of interfering oseltamivir phosphate (Tamiflu).

3) *Clinical Evaluation:*

a) Clinical Performance Against FDA Authorized Highly Sensitive Comparator Test

Clinical performance of the Quaeris SARS-COV-2 assay was assessed against an FDA authorized highly sensitive comparator with 47 positive and 37 negative de-identified clinical remnant samples purchased from Boca Biolistics and reanalyzed at the HUCL laboratory. All samples were NP swaps from suspected (symptomatic or close contact) patients in 3 ml of transport media (VTM, MTM or UTM depending on specimen sourcing). The study contained 47% (22/47) of low positive samples with Ct values within 3 Ct of the mean Ct of the comparator test's LoD (i.e., N1≥32 and N2 ≥33). Of these low positive samples 5 were initially invalid and required retesting with Quaeris assay.

The Quaeris SARS-COV-2 assay agreed with the comparator in 45 of 47 positive patient results and in 37 of 37 negative patients. This gives a Positive Percent Agreement (PPA) of 95.7%, and a Negative Percent Agreement (NPA) of 100%.

Table 13. Clinical Performance

		FDA Authorized Comparator	
		Positive	**Negative**
Quaeris SARS-COV-2 Assay	**Positive**	45	0
	Negative	2	37
	Total	**47**	**37**
Performance		**PPA=95.7%** (95% CI: 85.8-96.8%)	**NPA=100%** (95% CI: 90.6-100%)

There were two patient samples for which the comparator result was positive, but the Quaeris SARS-CoV-2 Assay returned a negative result. In both cases, the sample was at or below the LoD for the Quaeris Assay (one sample was N1 35.8, RdRp 34.7; the other was N1 33.7, RdRp 35.4).

b) Clinical Correspondence by Swab

Clinical performance of samples obtained with Rhinostics swab (COVID-19 Self-Swab Collection Kit) was compared to samples obtained with second FDA cleared swab. Paired anterior nares swabs were collected from 210 known positive and negative individuals with the Rhinostics swab as well as a second FDA cleared/ authorized swab following specific collection instructions. The paired samples were tested with either

the Quaeris test or Quaeris test for Rhinostic swabs and a comparator EUA authorized test for the comparator swab.

Of the 210 paired samples, 47 participants swabbed with Copan FLOQ and Rhinostics swab and SARS-COV-2 presence in both swabs was tested with the Quaeris SARS-Cov-2 assay. For the second subset of 145 cases, paired samples were collected on the same day with Rhinostics swab and the swab provided CRPS SARS-CoV-2 test (Broad Institute authorized COVID-19 test) at the Broad institute. The samples collected with Rhinostics swab were tested with the Quaeris SARS-CoV-2 test and the paired swab with the CRSP SARS-CoV-2 test per the authorized protocol. An additional third subset, 18 of the participants, swabbed with the Rhinostics swab within 1 day of receiving a test result from a CLIA approved testing lab using an FDA cleared swab (identity of swab unknown). These individuals received a positive test result at a hospital or clinic and then enrolled the study within one day of receiving their test result. The assay used in each of these cases is unknown but per regulations was performed at a CLIA lab using an EUA approved assay (Table 14).

In the 210 participant collections, the Rhinostic swab reported 42 positives and 168 negatives while the approved anterior nares swabs included 43 positives and 167 negatives. This corresponds to a PPA of 98%, and a NPA of 100%.

Table 14: Comparison of Rhinostic Swab to Cleared Swabs

		FDA Cleared Swab	
		Pos	**Neg**
Rhinostic Swab	**Pos**	42	0
	Neg	1	167
	Total	**43**	**167**
Agreement		**PPA** = 97.7% (95% CI:87.9% -99.6%)	**NPA** = 100% (95% CI: 97.8- 100%)

4) Sample Stability (COVID-19 Self -Swab Collection Kit for UUCL)

Stability of samples collected with COVID-19 Self-Swab Collection Kit for HUCL was assessed with clinical samples that were wither negative or 2x and 5x LoD of the Quaeris SARS-CoV-2 Assay. 1 µL of each sample (NP swab eluate in VTM) was pipetted onto the tip of a Rhinostic swab. The viral loaded swab was allowed to dry for 30 minutes and subject to summer or winter cycling and subject to summer and winter cycling temperatures summarized in the tables below. After cycling, the samples were processed in accordance with the Quaeris SARS-CoV-2 Assay, i.e., resuspended in 300 µL of PBS with 2 µL being used as input into the rRT-PCR reaction. For each sample, 10 replicate swabs were made for the summer cycling, 10

replicates were made for the winter cycling, and 13-16 replicates (depending on the amount of total sample) were made as "no cycling" controls for the seasonal temperature studies.

Table 15a. Summer Profile Temperature Cycle

Temperature (°C)	Cycle Period	Cycle Period (hours)	Total Time (hours)
40	1	8	8
22	2	4	12
40	3	2	14
33	4	36	50
40	5	6	56

Table 15b. Winter Profile Temperature Cycle

Temperature (°C)	Cycle Period	Cycle Period (hours)	Total Time (hours)
-10	1	8	8
18-22	2	4	12
-10	3	2	14
10	4	36	50
-10	5	6	56

There was no significant change in the Ct values for N1 or RdRp after summer or winter temperature cycling for any of the samples (Tables 16). Based on the criteria set out in Tables 5-7 (Result Interpretation), all 30 positive samples would be called as positive for the winter cycle and 29 of the 30 would be called as positive for the summer cycle (one inconclusive). Of the 10 negative samples one replicate for summer cycle (swab #8) and one replicate for the winter cycle (swab #1) were inconclusive.

Based on the results of the winter and summer cycling stability studies, the samples are stable for 56 hours after collection. If a delay in testing or shipping is expected, specimens are stored at -70°C or below.

Table 16. Summer and Winter Shipping Stability Summary Results

			Summer			Winter		
Sample (xLoD)	**Time/Difference**		**N gene**	**RdRp**	**RNase P**	**N gene**	**RdRp**	**RNase P**
5x	**0hrs**	**Avg Ct (n=10)**	**32.5**	**36.4**	**34.8**	**32.5**	**36.4**	**34.8**
		% CV	0.5	1	0.8	0.5	1	0.8
	56hrs	**Avg Ct (n=10)**	32.5	34.9	32.9	32.8	34.4	32.8
		% CV	0.5	0.5	0.8	1.1	1.1	0.9
	D Ct 56-0		0	-1.5	-1.9	0.3	-2	-2
2x	**0hrs**	**Avg Ct (n=10)**	**33.4**	**36.8**	**36.4**	**33.4**	**36.8**	**36.4**
		% CV	0.6	0.6	1.2	0.6	0.6	1.2
	56hrs	**Avg Ct (n=10)**	32.5	34.8	34.8	32.8	34.9	34.7
		% CV	0.5	0.8	1	1.1	1.1	1.3
	D Ct 56-0		-0.9	-2	-1.6	-0.6	-1.9	-1.7
10x	**0hrs**	**Avg Ct (n=10)**	**30.5**	**34.8**	**34.9**	**30.5**	**34.8**	**34.9**
		% CV	3.1	1.3	0.6	3.1	1.3	0.6
	56hrs	**Avg Ct (n=10)**	30.8	33.2	34.1	31.5	33.3	35.1
		% CV	0.9	0.9	1.8	1.4	1.5	1.5
	D Ct 56-0		0.3	-1.6	-0.8	1	-1.5	0.2
negative	**0hrs**	**Avg Ct (n=10)**	**N/A**	**N/A**	**33.5**	**N/A**	**N/A**	**33.5**
		% CV	N/A	N/A	0.8	N/A	N/A	0.8
	56hrs	**Avg Ct (n=10)**	N/A	N/A	31.7	N/A	N/A	31.9
		% CV	N/A	N/A	1.3	N/A	N/A	1.3
	D Ct 56-0		N/A	N/A	-1.8	N/A	N/A	-1.6

5) Usability Studies

A usability study was performed to demonstrate that the COVID-19 Self-Swab Collection Kit for HUCL could be used safely and effectively by the intended users, for the intended uses, and in the intended use environments. A total of 49 participants were prospectively recruited to represent the general adult population, including a mix of ages and education levels. All participants were over age 18 and collected the

samples in their home environment. The participants were observed using the collection kit through videoconferencing.

Thirty-one (31) of the individuals returned their samples via FedEx, 18 participants returned their samples at an approved drop-off location. Color's process for test kit registration and results delivery has already been reviewed and authorized by FDA in connection with Color's self-collection kit EUA authorizations (EUA210221, EUA202423, and EUA203116). The demographic information for the 49 study participants is summarized in the table below.

Table 17. Usability Study Demographics

Characteristics of Study Population		N	Percent
Gender	Male	25	51.0%
	Female	23	46.9%
	Non-binary/third gender	1	2.0%
Age	18-30	6	12.2%
	31-40	13	26.5%
	41-50	11	22.4%
	51-64	10	20.4%
	>=65	9	18.4%
Ethnicity	Hispanic or Latino	3	6.1%
	Other	46	93.9%
Race	Asian	6	12.2%
	Black or African American	3	6.1%
	Other	4	8.2%
	White or Caucasian	36	73.5%
Marital Status	Divorced	4	8.2%
	Never Married	15	30.6%
	Other	2	4.1%
	Married	28	57.1%
Employment Status	Employed for wages full time	30	61.2%
	Employed for wages part time	1	2.0%
	Homemaker	2	4.1%
	Out of work for less than one year	2	4.1%
	Retired	8	16.3%
	Self Employed	5	10.2%
	Student	1	2.0%
Education Level	Grade 12 or GED	3	6.1%
	Associate degree	2	4.1%
	Bachelor's degree	12	24.5%
	Some college, no degree	2	4.1%

Characteristics of Study Population		N	Percent
	Graduate or professional degree	30	61.2%
Geographic Location (State or District)	CA	7	14.3%
	CO	2	4.1%
	GA	3	6.1%
	IL	1	2.0%
	MA	20	40.8%
	MN	1	2.0%
	NJ	2	4.1%
	NV	1	2.0%
	PA	4	8.2%
	SC	3	6.1%
	TX	4	8.2%
	Washington DC	1	2.0%

a) Results - RNase P & Accessioning

Of the 49 kits that were distributed all kits (100%) were received by the laboratory in acceptable condition for processing according to the laboratory accessioning SOP. RNaseP was detected with the Quaeris SARS-CoV-2 Assay in 48/49 (98.0%) samples, indicating successful collection and amplification of human biological material. The RNaseP level detected ranged from a Ct of 20.0 to 31.9 with a mean Ct of 26.9, a median Ct of 26.8, and a standard deviation of 3.0 Cts. All these samples were well below the 34 Ct cutoff required to consider the sample valid. There was no known reason or explanation for the lack of RNaseP detection in the one sample that was missed.

b) Results - Observation

During the actual use testing, designated staff observed users following the instructions included with the collection kit. Most participants did not deviate from the Instructions for Use. The only deviation was that some participants activated the kit after swabbing. All but one participant successful used the swabs swabbing in both nostrils for roughly the amount of time as would be expected. That individual swabbed only one nostril. The exact number of circular motions or up and down motions with the swab was hard to determine by video.

The results and video observation show that the IFU is sufficient for people to self-collect and safely return the samples by mail or drop-off (note the drop-off procedure is identical to the current drop-off procedure being implemented at Harvard).

Table 18: Video- Observer Notes on Self- Collection

	Tip No Longer Visible	In for 10 Seconds	In both Nostrils
Swab Usage (Correct/Total)	49/49 (100%)	49/49 (100%)	48/49 (98%)

	Activated before return	Activated before collection
Kit Activation	49/49 (100%)	38/49 (77.6%)*

* Activating the kit after swabbing had no effect on the Quaeris SARS-CoV- 2 Assay results.

6) Collection Device Stability

COVID-19 Self-swab collection kit stability was assessed in a study with swabs that were manufactured 4 or 6 months prior with a batch of swabs that were less than a week old. Two healthy SARS-CoV-2 negative individuals swabbed ten times over the course of ten minutes, 5 times with the new and 5 times with the old swab. The old and new swab were alternated between each swabbing. In addition, two old and two new swabs were included without collecting patient samples (i.e., without swabbing) to make a total of 24 swabs. The samples were then processed by laboratorians who were blinded to the swab identity. The Quaeris SARS-CoV-2 Assay was performed and the RNaseP Ct values are reported in Table 19. The old and new swabs performed indistinguishably. All four swabs that were not used to collect patient samples had no detectable amplification.

Table 19. 4-Month and 6-Month Swab Stability Tests

4-month stability test – RNaseP Ct values					
Individual 1			**Individual 2**		
Replicate	Old swab	New swab	Replicate	Old swab	New swab
1	29.0	28.1	1	27.3	30.0
2	28.2	28.4	2	28.2	28.6
3	29.0	28.9	3	29.0	29.4
4	28.4	29.3	4	28.9	25.2
5	26.1	28.3	5	30.0	29.6
Mean	28.2	28.6	mean	28.7	28.6
Std	1.2	0.5	std	1.0	1.9

6-month stability test – RnaseP Ct values					
Individual 1			**Individual 2**		
Replicate	Old swab	New swab	Replicate	Old swab	New swab
1	27.2	26.8	1	26.5	28.6
2	27.6	27.9	2	28.6	27.1
3	30.0	26.5	3	29.3	28.6
4	28.5	26.7	4	28.8	26.4
5	28.1	27.9	5	27.1	28.8
Mean	28.3	27.2	Mean	28.1	27.9
Std	1.1	0.7	Std	1.2	1.1

Based on the results of the completed swab stability testing, the COVID-19 Self-Swab Collection Kit for HUCL has a 6-month shelf life. The shelf life will be updated in the future following completion of further real-time stability testing.

WARNINGS:

- For in vitro diagnostic use.
- Rx only.
- For use under Emergency Use Authorization (EUA).
- Members of the infectious disease laboratory will be trained to perform this assay and competency will be assessed and documented per CAP regulations.
- The Quaeris SARS-CoV-2 assay has not been FDA cleared or approved;
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.
- Specimens should always be treated as if infectious and/or biohazardous in accordance with safe laboratory procedures.
- Follow necessary precautions when handling specimens. Use personal protective equipment (PPE) consistent with current guidelines for the handling of potentially infectious sample.
- Do not use reagents after the expiry date
- Dispose of waste in compliance with local, state, and federal regulations.
- Positive results are indicative of the presence of SARS-CoV-2 RNA.

LMITATIONS:

- A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if amplification inhibitors are present in the specimen or if inadequate numbers of organisms are present in the specimen.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of specimens may hinder the ability of the assay to detect the target sequences.
- Results from the Quaeris SARS-CoV-2 Assay should be used as an adjunct to clinical observations and other information available to the physician. The result is only for clinical reference, and the clinical management of patients should be considered in combination with their symptoms/signs, history, other laboratory tests and treatment responses.
- Although the detected target sequences of this kit are in conserved regions of the SARS-CoV-2 genome, rare mutations may lead to negative results.
- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Optimum specimen types and timing for peak viral levels during infections caused by SARS-CoV-2 have not been determined.
- The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- False negative or inconclusive results may occur due to high concentrations of interfering tobramycin.
- False negative or inconclusive results may occur due to high concentrations of interfering oseltamivir phosphate (Tamiflu).