EMERGENCY USE AUTHORIZATION (EUA) SUMMARY
COVID-19 by RT-PCR TEST
(FULGENT THERAPEUTICS, LLC)

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

INTENDED USE

The Fulgent COVID-19 by RT-PCR test is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in upper and lower respiratory specimens (nasal, nasopharyngeal, and oropharyngeal swabs) from individuals suspected of COVID-19 infection.

This test is also for use with nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using an authorized home collection kit when determined to be appropriate by a healthcare provider.

Testing is limited to Fulgent Genetics, a Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a certified high-complexity laboratory.

Results are for the identification of SARS-CoV-2 RNA. SARS-CoV-2 RNA is generally detectable in nasal, nasopharyngeal, or oropharyngeal 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 cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities. Fulgent Genetics will be one of these laboratories.

Negative results do not preclude COVID-19 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. Fulgent COVID-19 by RT-PCR test final reports will state this information.

The COVID-19 by RT-PCR test is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time RT-PCR and in vitro diagnostic procedures. The COVID-19 by RT-PCR test is only for use under the Food and Drug Administration’s Emergency Use Authorization.

DEVICE DESCRIPTION AND TEST PRINCIPLE

The Fulgent COVID-19 by RT-PCR test is a real-time reverse transcription polymerase chain reaction test. The methods described in this application have been adapted from the "CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel" document effective March 30, 2020. This test uses two SARS-CoV-2 primer and probe sets to detect regions in the N gene of SARS-CoV-2 in respiratory specimens from nasal, nasopharyngeal, or oropharyngeal swab samples. A third primer and probe set that detects human RNase P (RP) is used as an internal control. RNA is isolated from nasal, nasopharyngeal, or oropharyngeal swabs and reverse transcribed to cDNA. Amplification and detection of the SARS-CoV-2 markers and control targets are performed using the QuantStudio 6 and QuantStudio 7 Real-Time PCR System.

1. Nucleic acids (RNA) are isolated and purified from nasal, nasopharyngeal, or oropharyngeal swabs using the Qiagen QIAamp Viral RNA Mini Kit or Zymo *Quick*-RNA Viral Kit RNA Extraction Kits.
2. Final extracted RNA is eluted into 50 µL of elution buffer.
3. The purified nucleic acid is reverse transcribed using TaqPath 1-Step RT-qPCR Master Mix, followed by the target amplification and fluorescent probe detection in the same reaction vials.
4. Fluorescence intensity is monitored at each PCR cycle by the QuantStudio 6 or QuantStudio 7 Real-Time PCR System and the QuantStudio Real-Time PCR Software.

Picture Genetics is a testing platform, offering the Picture COVID-19 Home Collection Kit, supported by the company Fulgent Genetics, a Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a certified high-complexity laboratory. While Fulgent Genetics performs testing for clinicians and medical institutions, Picture Genetics uses an at-home testing platform under the umbrella of Fulgent Genetics. All in-lab processes for Picture Genetics and Fulgent Genetics are the same, including the same laboratory facility, standards, accreditations, and personnel. The RT-PCR test for the Picture COVID-19 Home Collection Kit will be performed using the FDA-authorized COVID-19 test from Fulgent Genetics.

INSTRUMENTS USED WITH TEST

Instruments

The Fulgent COVID-19 by RT-PCR test is to be used with the Qiagen QIAamp Viral RNA Mini Kit or Zymo *Quick*-RNA Viral Kit RNA Extraction Kits and the QuantStudio 6 or QuantStudio 7 Real-Time PCR System.

Sample Collection Kits

- This assay can be used with the Everlywell COVID-19 test home collection kit. Everlywell has granted Fulgent Genetics a right of reference to the data supporting use of this authorized home collection kit.

- This assay can be used with the Picture COVID-19 Home Collection Kit manufactured by Fulgent Genetics.

Fulgent COVID-19 by RT-PCR Test Reagents

The primary reagents used in this assay, including primer and probe designs, are adapted from the "CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel" document effective March 30, 2020.

Kits and Reagents	Manufacturer	Catalog #
Qiagen QIAamp Viral RNA Mini Kit	Qiagen	52906
Zymo Quick-RNA Viral Kit RNA Extraction Kit	Zymo	R1035/R1041
TaqPath 1-Step RT-qPCR Master Mix, CG	ThermoFisher	A15300/15299
Primer: COVID-19_N1-F	IDT	Custom
Primer: COVID-19_N1-R	IDT	Custom
Probe: COVID-19_N1-P	IDT	Custom
Primer: COVID-19_N2-F	IDT	Custom
Primer: COVID-19_N2-R	IDT	Custom
Probe: COVID-19_N2-P	IDT	Custom
Primer: RP-F	IDT	Custom
Primer: RP-R	IDT	Custom
Probe: RP-P	IDT	Custom
Template: 2019-nCoV_N_Positive Control	IDT	10006625
Template: Hs_RPP30 Positive Control	IDT	10006626

Picture COVID-19 Home Collection Kit

Nasal Swab Kit Components	Manufacturer	Catalog #
FedEx Pak (Poly Padded Mailer)	FedEx	139380

Custom External Shipping Box (Corrugated Fiberboard)	Imagen	Custom
Custom Instructional Inserts (Collection, Shipping, and Packaging)	Imagen	Custom
Transport Media (0.85% Saline) aliquoted into a Tube	Nest Scientific, USA or Zymo Research	Nest:202005 or A-01
Nasal Swab (Round Foam w/Polystyrene Handle, 80mm Breakpoint)	Nest Scientific, or Jiangsu Hanheng Medical Technology Company	N/A: swabs are supplied with saline tubes
Therapak Absorbent Materials (Absorbent Sheet)	Therapak 10300	22-130-039
Specimen Biohazard Bag 6x9	U-Line	S-2968
FedEx Express UN3373 Pak (with Return Shipping Label)	FedEx	163034

CONTROLS TO BE USED WITH THE FULGENT COVID-19 BY RT-PCR TEST

1. A “no template” control (NTC) serves as a negative control and is included in every assay plate to identify specimen contamination. Molecular grade, nuclease free water is used as the NTC.

2. A positive template control (2019-nCoV_N_Positive Control) is included in each assay plate to ensure the reagents and instruments are performing optimally. The positive control is a synthetic DNA plasmid containing the entire sequence of gene N of the COVID-19 virus. Two markers in gene N, as defined by the “CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel” document effective March 30, 2020, will be targeted and detected by the primer and probe sets, COVID-19_N1 and COVID-19_N2.

3. An internal control (Hs_RPP30 Positive Control) targeting human RNase P mRNA (RP) is used to verify optimal RNA extraction, amplification, and the presence of nucleic acid in the samples.

Sample Intake - Inspection of Samples

A detailed laboratory protocol (SOP) has been submitted and reviewed by FDA.

Picture COVID-19 collection kits received at the laboratory will be checked for the following criteria before entering the lab workflow. Samples with the following issues will be rejected and may require user follow-up and re-sampling:

- No sample collection tube included with the kit
- No blue tinted media within sample collection tube
- No barcode identifier attached to the sample collection tube
- Sample collection tube leaked resulting in no sample for testing
- Kit not registered/activated on the Picture platform
- Accession date is greater than 1 calendar day from the specimen collection date

INTERPRETATION OF RESULTS

Expected RT-PCR Results for Controls

Controls	Control Target	Expected Results
Negative	NTC	Ct Not Detected
Positive	2019-nCoV_N_Positive Control / N1	Ct<40
Positive	2019-nCoV_N_Positive Control / N2	Ct<40
Internal	Human RNase P (RP)	Ct<40

- NTC controls should not have detectable readouts. False-positive readings, growth curve cycle thresholds (Ct) less than 40, indicates contamination of the assay or reagents.
- Positive controls should exhibit fluorescence growth curves that cross the threshold line and have Ct<40.
- Internal controls should exhibit fluorescence growth curves that cross the threshold line and have Ct<40.
- Any deviations from the expected results shown in the table above invalidates the entire assay. All samples from the run must be repeated starting from extracted RNA.

COVID-19 RT-PCR Patient Result Interpretation Table

COVID-19 Marker: N1	COVID-19 Marker: N2	RP	Interpretation/Protocol	Report/Follow-Up
+	+	+ / –	SARS-CoV-2 detected	COVID-19 Positive
If only one of two targets are positive		+	- Inconclusive result - Repeat assay	Inconclusive
–	–	+	SARS-CoV-2 not detected	COVID-19 Negative
–	–	–	- Invalid result - Repeat assay	Invalid/QNS, request new sample

- When all controls exhibit the expected performance, a clinical specimen is considered positive for COVID-19 if the N1 and N2 marker growth curves cross the cycle threshold line and Ct<40. In this scenario, the COVID-19 positive result is still valid regardless if the RP target is or is not detected as described above.
- When all controls exhibit the expected performance, a clinical specimen is considered negative for COVID-19 if the N1 and N2 marker growth curves do not cross the threshold line. The RP target growth curve must cross the threshold line for the COVID-19 result to be valid.
- When all controls exhibit the expected performance, but the growth curves for the N1 and N2 markers and the RP target DOES NOT cross the cycle threshold line, the result is invalid. The extracted RNA from the clinical specimen must be re-tested. If residual RNA is not available, re-extract RNA from residual specimen and re-test. If a second invalid result occurs, a new specimen from the patient is needed.
- When all controls exhibit the expected performance and the cycle threshold growth curve for any one marker (N1 or N2), but not both, crosses the threshold line, the result is inconclusive for COVID-19. Re-extract RNA from residual specimen and re-test.

Clinician Involvement and Oversight for Picture COVID-19 Home Collection Kit

The Picture Genetics testing platform is closely integrated with PWNHealth (www.pwnhealth.com), a national clinician network. While all laboratory processes are run by Fulgent Genetics, all medical interactions are handled by PWNHealth. This includes clinician review and approval of each test ordered, oversight of all materials produced, and contact with patients after testing is completed.

Ordering is restricted to adults (18 years and older) living in the United States, and kits are limited to one per person (or one "active" order at any time). Each individual intending to order a test must first complete an eligibility screener. This screener is intended to ensure that Picture COVID-19 Home Collection Kits are provided only where testing is most needed and most responsible. In addition, the screener collects necessary information on exposure, symptoms, and risk. Screening guidelines are based on the most current CDC guidelines on COVID-19 testing and are strictly enforced. Individuals who are experiencing severe symptoms to the point of requiring medical attention are not eligible for testing but are advised to seek immediate medical assistance.

Upon confirmation of eligibility, users are directed into an order flow where they will order the test and complete additional relevant personal and demographic information which is passed to PWNHealth for review, documentation, and approval. Upon approval, kits are shipped to users using FedEx 2-day shipping.

When a patient's report is ready, they are notified via email that their report is accessible via their private Picture Genetics portal. Patients may receive positive, negative, or indeterminate results. Patients with indeterminate results will be encouraged to retest. Positive and negative reports include self-quarantine/isolation guidelines as well as resources such as the CDC and WHO (supplementary: Sample Positive Report; Isolation and Quarantine Guide). Negative reports also include information on the risk of false negatives (supplementary: Sample Negative Report). This content is reviewed and approved by the independent clinician network at PWNHealth. PWNHealth shares updated content requirements weekly based on the latest requirements and recommendations from the CDC. Should there be any new guidelines coming from the CDC to be implemented immediately, PWNHealth will inform Picture Genetics directly.

Every patient is informed of the opportunity to speak with a health professional at PWNHealth about their test results, regardless of whether their result was positive, negative, or indeterminate. PWNHealth reaches out to positive patients directly to discuss results. PWNHealth also reports relevant results and information to the appropriate public health authorities.

PERFORMANCE EVALUATION

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

The tentative LoD was identified by extracting and testing 10-fold serial dilutions of the control plasmid (2019-nCoV_N_Positive Control), which contains the whole sequence of the SARS-CoV-2 N gene. Serial dilutions of the positive control template were tested in triplicates.

The lowest concentration at which all three replicates were positive was treated as the tentative LoD for each test.

Confirmation of the final LoD was determined using 2-fold serial dilutions of viral RNA (5 copies/µL and 2.5 copies/µL) in 20 extracted replicates. The final LoD of each test was determined to be the lowest concentration resulting in positive detection in 100% of the replicates (20/20). As shown in the summary table below (Summary of the Limit of Detection Confirmation for COVID-19 by RT-PCR Test), the final LoD determined for this test is 5 copies/µL.

Tentative LoD: Results of triplicate testing of serial dilutions of the positive control

Target	Serial 10-Fold Dilution Factor	Concentration in Dilution Tested	Replicate 1 (Ct)	Replicate 2 (Ct)	Replicate 3 (Ct)	Call Rate	Lowest Concentration with Uniform Positivity per Analyte
N1	1:10	20,000 copies/µL	24.233	24.214	24.114	100%	20 copies/µL
	1:100	2000 copies/µL	29.198	27.553	27.743	100%	
	1:1000	200 copies/µL	34.435	31.763	33.234	100%	
	1:10,000	20 copies/µL	40.866	34.785	36.287	100%	
	1:100,000	2 copies/µL	41.856	36.609	39.250	67%	
N2	1:10	20,000 copies/µL	25.256	25.412	25.322	100%	20 copies/µL
	1:100	2000 copies/µL	28.889	31.641	29.101	100%	
	1:1000	200 copies/µL	42.698	36.083	37.153	100%	
	1:10,000	20 copies/µL	37.878	35.621	37.775	100%	
	1:100,000	2 copies/µL	43.606	Undetermined	Undetermined	33%	

Ct Values for Final LoD Confirmatory Test Results Using Viral RNA

	Marker N1 (Ct)		**Marker N2 (Ct)**	
Replicant	**5 copies/µL**	**2.5 copies/µL**	**5 copies/µL**	**2.5 copies/µL**
1	33.04	35.76	37.01	37.73
2	33.27	34.23	36.83	37.29
3	33.34	33.97	35.92	37.73
4	33.97	31.90	35.78	34.44
5	32.96	35.22	35.98	38.68

	Marker N1 (Ct)		Marker N2 (Ct)	
Replicant	**5 copies/µL**	**2.5 copies/µL**	**5 copies/µL**	**2.5 copies/µL**
6	33.08	34.80	36.03	38.30
7	33.91	35.13	35.34	38.02
8	33.22	35.93	36.02	36.56
9	33.09	34.73	36.57	Undetermined
10	33.86	37.12	35.47	37.13
11	32.71	35.22	36.40	37.73
12	33.74	32.65	36.18	35.52
13	34.17	35.92	35.95	37.57
14	32.20	34.78	34.38	37.02
15	32.14	36.06	35.86	36.89
16	32.79	Undetermined	35.14	38.89
17	33.56	34.13	35.91	38.81
18	33.87	34.89	35.40	Undetermined
19	32.67	Undetermined	36.46	Undetermined
20	33.22	Undetermined	36.03	37.51

Summary of the LoD Confirmation for COVID-19 by RT-PCR Test Using Viral RNA

	Marker N1		Marker N2	
RNA Concentration	**5 copy/µL**	**2.5 copy/µL**	**5 copy/µL**	**2.5 copy/µL**
Positive Detection/Total	20/20	17/20	20/20	17/20
Mean Ct	33.24	34.85	35.93	37.40
Standard Deviation Ct	0.57	1.26	0.60	1.14

2) Inclusivity (Analytical Sensitivity):

An *in-silico* inclusivity analysis was performed by aligning each of the primer and probe sequences to all 1298 complete (>29kb), "high coverage only" hCoV-19 sequences submitted to GISAID (https://www.gisaid.org/) as of March 26, 2020 ("hCoV-19" is the name GISAID uses instead of SARS-CoV-

2). All primers and probes have perfect identity to >99% of the 1298 sequences (see table below).

Identity of primers and probes to GISAID hCoV-19 sequence submissions

Primers & Probes	Sequences Aligned	Count (#) or Percentage (%) of hCoV-19 aligned with identity			
		# <100%	% <100%	# at 100%	% at 100%
COVID-19_N1-F	1,298	3	0.2%	1,295	99.8%
COVID-19_N1-P	1,298	10	0.8%	1,288	99.2%
COVID-19_N1-R	1,298	6	0.5%	1,292	99.5%
COVID-19_N2-F	1,298	0	0.0%	1,298	100.0%
COVID-19_N2-P	1,298	1	0.1%	1,297	99.9%
COVID-19_N2-R	1,298	2	0.2%	1,296	99.8%

3) Cross-Reactivity (Analytical Specificity)

This COVID-19 by RT-PCR test uses the sequence provided by the CDC per the “2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel” document effective March 30, 2020. The *in-silico* analysis for primer and probe design has been addressed by the U.S. CDC in the same document. We performed a similar *in-silico* analysis and confirmed that there are no significant homologies with the human genome, other coronaviruses, or human microflora that would generate potential false positive test results.

An *in-silico* exclusivity analysis was performed by aligning each of the primer and probe sequences to all 77,943 complete genome sequences in the viral sequences division ("vrl") of GenBank as of March 27, 2020, including all human coronavirus reference genomes but excluding SARS-CoV-2 sequences. Only one significant (zero or one mismatch) alignment was found to reference virus genomes, but no primer pair has a significant alignment on the same sequence, so no amplicons are expected (see table below).

Significant (zero or one mismatch) alignments to virus reference genomes

Primer		Virus Sequence		Alignment Results				Primer Sequence			Virus Sequence		
qseqid	qlen	sseqid	slen	mismatch	gaps	pident	evalue	qstart	qseq	qend	sstart	sseq	send
COVID-19_N2-F	20	ref|NC_004718.3| SARS coronavirus	29,751	0	0	100.0	0.0130	1	**TTACAAACATTGGCCGCAAA**	20	29,013	**TTACAAACATTGGCCGCAAA**	29,032

4) Clinical Evaluation:

Orthogonal Performance Validation

A total of 94 clinical specimens, 30 positives and 64 negatives, were used to evaluate the performance of the COVID-19 RT-PCR test. Clinical samples were a mix of upper respiratory swab samples including NP, OP and mid-turbinate swabs. The concordance of positive and negative COVID-19 status was 100% for the Fulgent COVID-19 by RT-PCR test compared to a validated molecular SARS-CoV-2 assay.

Inter-laboratory Performance Evaluation

An inter-lab study was performed with Altru Dx (8562 Katy Freeway, Houston, TX 77024; CLIA #45D2128678) to independently confirm Fuglent's COVID-19. Five COVID-19 positive and five negative samples were used in this test. Results demonstrate 100% concordance of the COVID-19 results between the two labs. Clinical samples were a mix or upper respiratory swab samples including NP, OP and mid-turbinate swabs).

Specimen #	Fulgent	Altru Dx	% Concordance
1	Negative	Negative	100%
2	Positive	Positive	100%
3	Negative	Negative	100%
4	Negative	Negative	100%
5	Negative	Negative	100%
6	Negative	Negative	100%
7	Positive	Positive	100%
8	Positive	Positive	100%
9	Positive	Positive	100%
10	Positive	Positive	100%

Conclusion

Positive and negative percent agreement to expected result was 100% for the known patient samples. Results of positive and negative clinical specimens were also confirmed by secondary testing.

5) Picture COVID-19 Home Collection Kit Sample Stability Studies

The stability study of the nasal swab sample transported in saline has been conducted by the Quantigen Biosciences, with support from The Gates Foundation and UnitedHealth Group.

Quantigen Biosciences has granted a right of reference to any sponsor wishing to pursue an EUA to leverage their COVID-19 swab stability data as part of that sponsor's EUA request.

Briefly, nasal swabs were dipped in one of two concentrations (2XLoD and 10XLoD) of SARS- CoV-2 positive patient sample pools. Swabs were then placed into 1 mL of saline and incubated at 40℃ for 12 hours, followed by 32℃ for 18 or 42 hours, respectively. Samples were tested using an EUA authorized assay at time 0, 30, and 54 hours post-incubation

Average Ct Values for Each Time Point for Both Sample Dilutions

Swab	Time Point	N	MS2	N Gene	ORF1ab	S Gene
2xLoD swab in Saline	0h	5	23.74	32.23	30.03	31.80
10xLoD swab in Saline	0h	5	23.27	29.46	27.58	28.67
2xLoD swab in Saline	30h	20	26.00	32.69	31.33	34.59
10xLoD swab in Saline	30h	10	26.19	29.54	28.37	28.69
2xLoD swab in Saline	54h	20	25.70	32.03	31.09	32.10
10xLoD swab in Saline	54h	10	26.11	28.73	27.25	25.09

Results from this study demonstrated that positive nasal swab sample in saline transport medium is stable with over-night or 48-hour shipping and the findings support the stability of the Picture COVID-19 Home Collection Kit.

6) Picture COVI-19 Home Collection Kit Self-Collection Validation Studies

A self-collection study for nasal swab specimens was performed for 24 participants. After acknowledging consent for testing, the participants were each given 2 tubes of saline-based transport media and 2 nasal swabs, and were shown the sample collection instructional video. Each participant provided 2 self-collected samples. After sample collection, one sample from

each participant was spiked with a known COVID-19 positive clinical sample in the laboratory. Each sample was then packaged and shipped back to the lab via FedEx Overnight (according to established packaging and shipping protocol). Upon arrival at the lab, the samples were unpacked and tested following the Fulgent COVID-19 RT-PCR test (as indicated in the EUA200156 for Fulgent Genetics). This study evaluated the users' ability to properly collect a nasal swab sample as well as the packaging/shipping protocol while samples were in possession of FedEx. The results of the self-collection validation were consistent with expected results. All positives (24/24) remained positive after shipment. All negative samples (24/24) remained negative for COVID-19. All 48 samples showed Ct <40 for the internal Human RNaseP control, which implies successful sample collection.

	Original Samples				Inactivated COVID-19 Spiked Samples			
Participant	**N1 (Ct)**	**N2 (Ct)**	**RP (Ct)**	**COVID-19 Status**	**N1 (Ct)**	**N2 (Ct)**	**RP (Ct)**	**COVID-19 Status**
1	-	-	29.078	Negative	33.640	34.866	26.414	Positive
2	-	-	28.669	Negative	34.722	36.631	24.964	Positive
3	-	-	25.453	Negative	33.717	34.775	24.075	Positive
4	-	-	31.198	Negative	32.983	34.846	27.219	Positive
5	-	-	34.314	Negative	32.351	33.954	28.614	Positive
6	-	-	30.246	Negative	33.911	35.959	24.854	Positive
7	-	-	28.326	Negative	32.767	35.015	26.574	Positive
8	-	-	28.976	Negative	34.009	36.500	25.173	Positive
9	-	-	31.122	Negative	33.154	34.873	27.974	Positive
10	-	-	28.947	Negative	33.824	35.640	26.458	Positive
11	-	-	28.105	Negative	34.060	35.164	26.002	Positive
12	-	-	34.078	Negative	32.734	34.236	28.054	Positive
13	-	-	32.394	Negative	32.495	33.604	27.601	Positive
14	-	-	31.309	Negative	33.562	34.959	27.785	Positive
15	-	-	31.457	Negative	34.489	35.437	25.018	Positive
16	-	-	31.887	Negative	33.235	34.722	28.143	Positive
17	-	-	34.401	Negative	32.947	34.680	27.739	Positive
18	-	-	30.205	Negative	34.404	36.523	27.314	Positive
19	-	-	30.437	Negative	35.065	37.531	24.826	Positive
20	-	-	30.610	Negative	34.851	35.726	27.027	Positive
21	-	-	30.556	Negative	35.919	38.044	27.657	Positive
22	-	-	30.573	Negative	34.995	38.896	23.324	Positive
23	-	-	30.561	Negative	34.929	36.780	27.543	Positive
24	-	-	28.917	Negative	34.595	36.976	27.021	Positive

Warnings:

- This test has not been FDA cleared or approved;

- This test has been authorized by FDA under an EUA for use by Fulgent Genetics certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meets requirements to perform high complexity tests;
- This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.