June 11, 2021

Kenneth Butz
Associate Director, Regulatory Affairs
PPD, LLC
Representing: Fulgent Therapeutics
3900 Paramount Parkway
Morrisville, NC 27560

Device:	Fulgent COVID-19 by RT-PCR Test
EUA Number:	EUA200156
Company:	Fulgent Therapeutics
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal, nasopharyngeal, and oropharyngeal swab specimens from individuals suspected of COVID-19 by a healthcare provider and anterior nasal swab specimens from individuals without symptoms or other reasons to suspect COVID-19. This test is also for use with anterior nasal swab specimens that are either (1) self-collected using the Picture COVID-19 Home Collection Kit at home or in a healthcare setting by individuals, 18 years of age and older, including individuals without symptoms or other reasons to suspect COVID-19, when determined to be appropriate by a healthcare provider, or (2) collected using the Everlywell COVID-19 Test Home Collection Kit when used consistent with its authorization. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratory:	Testing is limited to laboratories designated by Fulgent Genetics which are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests.

Dear Mr. Butz:

On May 15, 2020, based on a request from Fulgent Therapeutics, LLC, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Fulgent COVID-19 by RT-PCR Test, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3), for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory specimens (nasal, nasopharyngeal, and oropharyngeal swabs) from individuals suspected of COVID-19 infection by their healthcare provider. This test was also intended 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, specified in the authorized tests' authorized labeling, when determined to be appropriate by a healthcare provider. Testing was limited to Fulgent Genetics' laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests. Subsequently, based on your[1] requests, FDA granted updates to the authorized labeling on June 15, 2020[2] and July 23, 2020,[3] as well as reissued the letter on April 12, 2021.[4]

On March 24, 2021, you requested to amend the Emergency Use Authorization (EUA). Based on that request and having concluded that revising the April 12, 2021, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the April 12, 2021, letter in its entirety with the revisions incorporated.[5] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product[6] is now intended for the indication described above.

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[7]

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[1] For ease of reference, this EUA will use the term "you" and related terms to refer to Fulgent Therapeutics.

[2] On June 15, 2020, your request was granted to include use of nasal swab specimens that are self-collected at home or in a healthcare setting by individuals using the Picture COVID-19 Home Collection Kit, as an authorized home collection kit, when determined to be appropriate by a healthcare provider.

[3] On July 23, 2020, your request was granted via email to update the EUA Summary to add the results of testing the FDA SARS-CoV-2 Reference Panel Testing.

[4] On April 12, 2021, the revisions to the May 15, 2020, letter and authorized labeling include: (1) addition of the Apostle RNA Extraction method, (2) removal of the Qiagen Extraction method, (3) revision of the Intended Use statement to reflect more recent authorizations including naming the authorized home collection kits for use with the Fulgent COVID-19 by RT-PCR Test and specifying nasal swabs as anterior nasal swabs, (4) addition of winter specimen shipping/stability study data for the Picture COVID-19 Home Collection Kit, (5) update of the Healthcare Provider and Patient Fact Sheets to reflect language used in more recent authorizations, (6) removal of Condition U. (from the May 15, 2020, letter) which was fulfilled, (7) update and consolidate conditions of authorization to reflect language used in more recent authorizations, including addition of authorized distributors of the Picture COVID-19 Home Collection Kit (8) addition of limitations, including a statement regarding performance with circulating variants, (9) update the company name from Fulgent Therapeutics, LLC to Fulgent Therapeutics, and (10) update the definition of the "authorized laboratory" to reflect language used in more recent authorizations.

[5] The revisions to the April 12, 2021, letter and authorized labeling include: (1) expanding testing to laboratories designated by Fulgent Genetics, (2) testing of anterior nasal swab specimens collected from individuals without symptoms or other reasons to suspect COVID-19, (3) limiting the distribution of the Picture COVID-19 Home Collection Kit to Fulgent Genetics, and (4) addition of Conditions to reflect testing by designated laboratories and sole distribution of the Picture COVID-19 Home Collection Kit by Fulgent Genetics.

[6] For ease of reference, this letter will use the term "your product" to refer to the Fulgent COVID-19 by RT-PCR Test used for the indication identified above.

[7] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the EUA Summary (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and,

3. There is no adequate, approved, and available alternative to the emergency use of your product.[8]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a qualitative test for the detection of nucleic acid from SARS-CoV-2 in anterior nasal, nasopharyngeal, and oropharyngeal swab specimens from individuals suspected of COVID-19 by a healthcare provider and anterior nasal swab specimens from individuals without symptoms or other reasons to suspect COVID-19.

This test is also for use with anterior nasal swab specimens that are either (1) self-collected using the Picture COVID-19 Home Collection Kit at home or in a healthcare setting by individuals, 18 years of age and older, including individuals without symptoms or other reasons to suspect COVID-19, when determined to be appropriate by a healthcare provider, or (2) collected using the Everlywell COVID-19 Test Home Collection Kit when used consistent with its authorization. Testing is limited to laboratories designated by Fulgent Genetics, which are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

[8] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

The SARS-CoV-2 RNA is generally detectable in upper respiratory 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. 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.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from anterior nasal, nasopharyngeal, and oropharyngeal swab specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument as outlined in the authorized labeling (described below).

Your product uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized labeling.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition L below), that are processed in the same way as the patient samples and are required to be included with each batch of specimens tested with your product. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the authorized labeling:

- Internal Control – targeting human RNase P (RP) mRNA - controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.
- Positive Template Control - monitors the integrity of the PCR reagents and process.
- No Template (Negative) Control - nuclease-free, molecular-grade water used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.
- Negative Extraction Control – previously characterized negative patient sample to monitor for cross-contamination and to validate the RNA extraction.

The above described product is authorized to be accompanied with the EUA summary (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas), as well as the Standard Operating Procedures (SOP) for the Fulgent COVID-19 by RT-PCR Test and the following Fact Sheets pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Fulgent Therapeutics - Fulgent COVID-19 by RT-PCR Test
- Fact Sheet for Patients: Fulgent Therapeutics - Fulgent COVID-19 by RT-PCR Test

The above described product, when accompanied by the EUA Summary, the Standard Operating Procedures (SOP) for the Fulgent COVID-19 by RT-PCR Test, and the two Fact Sheets is authorized to be used and distributed under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The Picture COVID-19 Home Collection Kit with the "Picture COVID-19 Home Collection Kit Instructions" is authorized to be distributed and used as part of the aboved described product as set forth in this EUA.

"Authorized labeling" refers to the EUA Summary, the Standard Operating Procedures (SOP) for the Fulgent COVID-19 by RT-PCR Test, the two Fact Sheets, and the "Picture COVID-19 Home Collection Kit Instructions".

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, when used consistent with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that your product (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of your product under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of your product.

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Fulgent Therapeutics (You)

A. Your product must comply with the following labeling requirements under FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You must make your product available with the authorized labeling to authorized laboratories.

C. You must make available on your website(s) the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

D. You must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

E. You must ensure that the authorized laboratories using your product have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

F. You must maintain records of the laboratories you designate as authorized laboratories and you must also maintain records of test usage by all such authorized laboratories.

G. You must collect information on the performance of your product. You will report to Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUA-Reporting@fda.hhs.gov) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware.

H. You must make available all instructions related to the self-collection of anterior nasal swab specimens using the Picture COVID-19 Home Collection Kit, both in the shipped kit and on your website.

I. Through a process of inventory control, you must maintain records of the numbers and locations to which the Picture COVID-19 Home Collection Kit is distributed.

J. You must maintain customer complaint files on record. You must report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.

K. You are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

L. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling. Such requests should be submitted to the DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

M. You must evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s) , if requested by FDA.[9] After submission to and concurrence by FDA, DMD/OHT7-OIR/OPEQ/CDRH will update the EUA summary to reflect the additional testing.

L. You must have lot release procedures for lots of reagents needed to run the Fulgent COVID-19 by RT-PCR Test, and the lot release procedures, including the study design, acceptance criteria and statistical power, must be sufficient to ensure that your product can achieve the clinical and analytical performance claimed in the authorized labeling. You must make lot numbers of qualified lots available to designated laboratories to use with your product.

M. You must submit to DMD/OHT7-OIR/OPEQ/CDRH on a quarterly basis (unless otherwise notified by DMD/OHT7-OIR/OPEQ/CDRH) a current list of the authorized laboratories designated by you to use the Fulgent COVID-19 by RT-PCR Test.

N. You must have a process in place to track adverse events, including any occurrence of false results with you product, including the Picture COVID-19 Home Collection Kit, and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7- OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

Authorized Laboratories

O. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

P. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.

[9] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your product.

Q. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.

R. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

S. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (Tel: 888-354-8168, qualitymanagement@fulgentgenetics.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product, including with the Picture COVID-19 Home Collection Kit, of which they become aware.

T. All laboratory personnel using your product must be appropriately trained in molecular techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

U. When testing authorized specimens collected using the Picture COVID-19 Home Collection Kit or the Everlywell COVID-19 Test Home Collection Kit, authorized laboratories must follow any Specimens Accessioning protocols provided with the collection kit when accepting specimens for testing.

Fulgent Therapeutics (You) and Authorized Laboratories

V. You and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Conditions Related to Printed Materials, Advertising and Promotion

W. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act and FDA implementing regulations.

X. No descriptive printed matter, advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the detection of SARS-CoV-2.

Y. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- 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; and,

- 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.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

_____
RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure