November 19, 2020

Mohammad Faghihi, M.D., Ph.D.
High Complexity Laboratory Director
Express Gene LLC, DBA: Express Gene Molecular Diagnostics Laboratory
9000 SW 152nd Street, Suite 209
Palmetto Bay, FL 33157

Device:	Express Gene 2019-nCoV RT-PCR Diagnostic Panel
Laboratory:	Express Gene LLC, DBA: Express Gene Molecular Diagnostics Laboratory
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in respiratory tract specimens including nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasopharyngeal aspirates/washes or nasal aspirates, and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider (HCP). This test is also for use with saliva specimens that are collected with the assistance of a HCP in a healthcare setting, by individuals suspected of COVID-19 using the mLife True Oral Fluid/Viral Collection Kit. Testing is limited to the Express Gene LLC, DBA: Express Gene Molecular Diagnostics Laboratory located at 9000 SW 152nd Street, Suite 209, Palmetto Bay, FL 33157 which is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

Dear Dr. Faghihi:

On May 22 200, based on your[1] request, the Food and Drug Administration (FDA) issued a letter determining that your product,[2] met the criteria for issuance under section 564(c) of the

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Express Gene LLC, DBA: Express Gene Molecular Diagnostics Laboratory.
[2] For ease of reference, this letter will use the term "your product" to refer to the entire test system, e.g., Express Gene 2019-nCoV RT-PCR Diagnostic Panel, mLife True Oral Fluid/Viral Collection Kit, controls, ancillary reagents, other materials - authorized under this EUA as outlined in the Scope of Authorization (Section II) and

Act to be eligible for authorization under the March 31, 2020, Emergency Use Authorization (EUA) for Molecular-based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2 (High Complexity LDT Umbrella EUA) for the qualitative detection of nucleic acid from SARS-CoV-2 in respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). As authorized under the High Complexity LDT umbrella EUA, testing of your test was limited to Express Gene LLC, DBA: Express Gene Molecular Diagnostics Laboratory, the single laboratory that developed the authorized test and that is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a to perform high complexity tests pursuant to the Scope of Authorization and Conditions of Authorization of that EUA.

On November 5, 2020, you requested to revise the Scope of Authorization, and thus the intended use as originally specified by the High Complexity LDT Umbrella EUA, to add testing of saliva specimens that are collected with the assistance of a HCP in a healthcare setting, using the mLife True Oral Fluid/Viral Collection Kit. In response to your request, and because the requested revision is beyond the Scope of Authorization of the High Complexity LDT Umbrella EUA, FDA is hereby authorizing the use of your product used for the indication identified above pursuant to Section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this letter of authorization.

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.[3]

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 included 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:

Conditions of Authorization (Section IV).

[3] 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).

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.[4]

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 test system that includes the Express Gene 2019-nCoV RT-PCR Diagnostic Panel, controls, ancillary reagents, other materials, and mLife True Oral Fluid/Viral Collection Kit. Your product is authorized to be used by Express Gene LLC, DBA: Express Gene Molecular Diagnostics Laboratory, despite the fact that your product does not meet certain requirements otherwise required by applicable federal law.

The test is a qualitative test for the detection of nucleic acid from SARS-CoV-2 in respiratory tract specimens including nasopharyngeal (NP) swabs, oropharyngeal (OP) swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasopharyngeal aspirates/washes or nasal aspirates, and bronchoalveolar lavage (BAL) specimens collected from individuals suspected of COVID-19 by their healthcare provider (HCP).

This test is also for use with saliva specimens that are collected with the assistance of a HCP in a healthcare setting, by individuals suspected of COVID-19 using the mLife True Oral Fluid/Viral Collection Kit.

Testing is limied to Express Gene LLC, DBA: Express Gene Molecular Diagnostics Laboratory located at 9000 SW 152nd Street, Suite 209, Palmetto Bay, FL 33157, which is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

The SARS-CoV-2 nucleic acid is generally detectable in respiratory and saliva specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; 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

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

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. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.

To use your test, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from the 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 described in the authorized labeling (described below).

The 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 J. below), that are processed in the same way as the patient specimens 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:

- No Template Control (NTC) - needed to check for contamination of RT-PCR assay reagents. Molecular grade, nuclease-free water is used in place of sample nucleic acid for this control. The NTC is used in one well on every assay plate.

- External Positive Control - used to verify proper assay set-up and SARS-CoV-2 reagent integrity. The positive control contains in vitro transcribed (IVT) RNA specific to the N, S, and ORF1ab regions of SARS-CoV-2. The positive control is used in one well on every assay plate.

- Negative Extraction Control (NEC) - monitors for any potential cross-contamination that could occur during the nucleic acid extraction process or RT-PCR assay. Use RNase/DNase free water with a spike-in of MS2 control that is processed through nucleic acid extraction and added to one well of the assay plate.

- MS2 Phage Internal Control - serves as an internal process control for nucleic acid extraction to ensure that clinical samples and controls contain sufficient and quality RNA to be used in the RT-PCR reactions. The MS2 control is spiked into all clinical samples and the negative extraction control prior to performing nucleic acid extraction.

The above described test is authorized to be accompanied with laboratory procedures (described below) and the EUA Summary (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas), and the following information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Express Gene LLC, DBA: Express Gene Molecular Diagnostics Laboratory - Express Gene 2019-nCoV RT-PCR Diagnostic Panel
- Fact Sheet for Patients: Express Gene LLC, DBA: Express Gene Molecular Diagnostics Laboratory - Express Gene 2019-nCoV RT-PCR Diagnostic Panel

The above described test, when accompanied by the "Express Gene 2019-nCoV RT-PCR Diagnostic Panel for Detection of SARS-CoV-2- Standard Operating Procedure for Nucleic Acid Extraction and RT-PCR Assay" laboratory procedures, the "Express Gene Specimen Receipt and Accessioning Policy" laboratory procedures, the EUA Summary (identified above) and the two Fact Sheets is authorized to be used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The mLife True Oral Fluid/Viral Collection Kit is authorized to be distributed and used as part of the above described product for use with the test as set forth in this EUA.

"Authorized labeling" is defined as "Express Gene 2019-nCoV RT-PCR Diagnostic Panel for Detection of SARS-CoV-2- Standard Operating Procedure for Nucleic Acid Extraction and RT-PCR Assay" laboratory procedures, the "Express Gene Specimen Receipt and Accessioning Policy" laboratory procedures, the EUA Summary, the two Fact Sheets, the "mLife True Oral Fluid/Viral Collection Kit Instructions for Use," and the "True Specimen Shipping 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, distribution and storage of your product.

IV. Conditions of Authorization

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

Express Gene LLC, DBA: Express Gene Molecular Diagnostics Laboratory (You)

A. Your product must comply with the following labeling requirements: 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)); 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 will inform relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.

C. You will notify the relevant public health authorities of your intent to run your product.

D. You will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.

E. You will 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.

F. You will make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

G. 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.

H. You will use your product as outlined in the authorized labeling. Deviations from the authorized laboratory procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and/or authorized materials required to use your product are not permitted.

I. You will collect information on the performance of your product. You will report to

the 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 your product of which you become aware.

J. 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 DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

K. You will evaluate the analytical limit of detection and assess traceability of your product with any FDA-recommended reference material(s), if requested by FDA.[5] After submission to and concurrence with the data by FDA, FDA will update the EUA Summary to reflect the additional testing.

L. You will have a process in place to track adverse events, including any occurrence of false results with your product and report any such events to FDA pursuant to 21 CFR Part 803.

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

N. You will 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.

O. You will track adverse events associated with the mLife True Oral Fluid/Viral Collection Kit, including occurrences of false results and report to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should be immediately reported to DMD/OHT-7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

P. You will submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using saliva specimens collected with the mLife True Oral Fluid/Viral Collection Kit, including the positivity rate for specimens collected with the authorized collection device.

Q. Upon request, you will conduct post-authorization studies and/or data analysis concerning the performance of saliva specimens with your product. Such studies and/or

[5] 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.

data analysis will be agreed upon between you and FDA. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of the data, FDA will consider whether additional action is appropriate, such as revision or revocation of the EUA.

R. You will make available all instructions related to the collection of saliva specimens using the mLife True Oral Fluid/Viral Collection Kit, both in the shipped kit and on your website.

Conditions Related to Printed Materials, Advertising and Promotion

S. All descriptive printed matter, including 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 the applicable requirements set forth in the Act and FDA regulations.

T. No descriptive printed matter, including 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.

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

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by the authorized laboratory;
- 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 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 authorization is terminated or 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure