February 19, 2021

Meghan Cupp
NDA Partners, LLC
Representing: LetsGetChecked, Inc.
40 Commerce Lane, Suite D
Rochelle, VA 22738

Device:	LetsGetChecked Coronavirus (COVID-19) Test
EUA Number:	EUA201043
Company:	LetsGetChecked, Inc.
Indication:	Qualitative detection of nucleic acid from the SARS-CoV-2 in anterior nasal swab specimens self-collected by any individuals 18 years and older at home, using the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit, including for testing individuals without symptoms or other reasons to suspect COVID-19 when ordered by a healthcare provider. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratory:	Testing is limited to the LetsGetChecked, Inc. laboratory (PrivaPath Labs d.b.a. LetsGetChecked Labs) certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, that meets the requirements to perform high complexity tests.

Dear Ms. Cupp:

On May 28, 2020, based on a request from PrivaPath Diagnostics, Inc. ("PrivaPath"), the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of LetsGetChecked Coronavirus (COVID-19) Test for the qualitative detection of nucleic acid from SARS-CoV-2 in nasal swab specimens self-collected by individuals at home, using the LetsGetChecked COVID-19 Home Collection Kit, when determined by a healthcare provider to be appropriate based on results of a COVID-19 questionnaire (based on current testing guidelines), pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing was limited to PrivaPath Labs d.b.a. LGC Labs certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests. Subsequently, on July 6, 2020, and October 23, 2020, FDA granted

PrivaPath's request to update the authorized labeling.[1,2] On August 14, 2020, based on PrivaPath's request, FDA reissued the May 28, 2020, letter in its entirety with revisions incorporated. [3]

On November 19, 2020, you[4] requested revisions to your Emergency Use Authorization (EUA), including to update the company name. Based on this request, and having concluded that revising the August 14, 2020, 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 August 14, 2020, 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 indications 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.

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[1] On July 6, 2020, your request was granted to update the authorized labeling of your product to add the Hologic Aptima SARS-CoV-2 Assay (Panther System) per the instructions (without modification), in addition, to an RNaseP gene RT-PCR as an alternative assay for use in the PrivaPath workflow for processing nasal swab specimens self-collected by individuals at home.

[2] On October 23, 2020, your request was granted via email to update the EUA Summary of your product to add the results of testing the FDA SARS-CoV-2 Reference Panel Testing. FDA posted the update to the web on October 28, 2020.

[3] The revisions to the May 28, 2020, letter and authorized labeling included: (1) extending the specimen shipping stability claim in the Standard Operating Procedure: COVID-19 Testing Specimen Receiving, Storage, and Processing and the EUA Summary, (2) removal of the RNaseP internal control requirement for self-collected samples, (3) updating labeling documents to remove the requirement to run the RNaseP internal control, (4) adding conditions of authorization specific to removal of the RNaseP internal control, (5) updating the healthcare provider and patient fact sheets to include some additional warnings/precautions around the absence of an RNaseP internal control when self-collected specimens are tested, (6) updating the PrivaPath website at FDAs request to include some considerations and warnings prior to ordering the LetsGetChecked COVID-19 Home Collection Kit, and (7) minor updates to the intended use to include "that meets the requirements" to perform high complexity tests when describing the authorized laboratory.

[4] For ease of reference, this letter will use the term "you" and related terms to refer to LetsGetChecked, Inc.

[5] The revisions to the August 14, 2020, letter and authorized labeling include: (1) updating the company name from PrivaPath Diagnostics, Inc. to LetsGetChecked Inc., (2) updating "LetsGetChecked COVID-19 Home Collection Kit" to "LetsGetChecked Coronavirus (COVID-19) Home Collection Kit" and clarifying "LGC Labs" as "LetsGetChecked Labs" in the laboratory name, (3) updating the intended use to "*nucleic acid from the SARS-CoV-2 in anterior nasal swab specimens self-collected by any individuals at home, using the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit, including for testing individuals without symptoms or other reasons to suspect COVID-19 when ordered by a healthcare provider,*" (4) removal of the Hologic Panther Fusion SARS-CoV-2 assay from the workflow, (5) removal of the questionnaire to determine eligibility for the testing, (6) updating the performance data to include winter shipping stability, (7) removal of Condition X. (from the August 14, 2020, letter) which was fulfilled, (8) updating the conditions of authorization to add a post-authorization clinical study and reflect language used in more recent authorizations (9) adding limitation related to performance with circulating variants, and (10) updating the fact sheets for healthcare provider (including with information related to performance with circulating variants) and patient.

[6] For ease of reference, this letter will use the term "your product" to refer to the LetsGetChecked Coronavirus (COVID-19) Test which is authorized for use as described in this letter with the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit, for the indication identified above.

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]

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:

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 for the qualitative detection of nucleic acid from SARS-CoV-2 in anterior nasal swab specimens self-collected by any individuals 18 years and older at home using the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit, including for testing individuals without symptoms or other reasons to suspect COVID-19 when ordered by a healthcare provider.

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

Use of this test is limited to the LetsGetChecked, Inc. laboratory (PrivaPath Labs d.b.a. LetsGetChecked Labs) certified under CLIA that meets the requirements to perform high complexity tests. The LetsGetChecked Coronavirus (COVID-19) Home Collection Kit will provide specimen collection materials and materials for mailing specimens to the authorized laboratory for testing using the LetsGetChecked Coronavirus (COVID-19) Test. Patients should follow all specimen collection and mailing instructions provided in the kit.

The SARS-CoV-2 nucleic acid 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 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 should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Specimens that are self-collected will not be tested with an internal control to confirm that the specimen was properly collected. Self-collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly.

Your product is used for detection of SARS-CoV-2 nucleic acid and is an integrated nucleic acid testing system that fully automates all steps necessary to perform sample processing through amplification, detection, and data reduction. The assay incorporates an internal control, or other authorized control materials (as may be requested under Condition S below), to monitor nucleic acid capture, amplification, and detection, as well as operator or instrument error. To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from anterior nasal swab specimens. All controls must generate expected results in order for a test to be considered valid, as outlined in the authorized procedures submitted as part of the EUA request.

Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the procedures submitted as part of the EUA request.

The labeling entitled EUA Summary (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas), "Standard Operating Procedure: COVID-19 Testing Specimen Receiving, Storage, and Processing,""Hologic Aptima SARS-CoV-2" instructions for use, and the following fact sheets pertaining to the emergency use, is collectively referenced as "authorized labeling":

- Fact Sheet for Healthcare Providers: LetsGetChecked Inc. - LetsGetChecked Coronavirus (COVID-19) Test
- Fact Sheet for Patients: LetsGetChecked Inc. - LetsGetChecked Coronavirus (COVID-19) Test

The above described product, when accompanied by the authorized labeling is authorized to be used by the authorized laboratory under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The LetsGetChecked Coronavirus (COVID-19) Home Collection Kit with the "LetsGetChecked Coronavirus (COVID-19) Home Collection Kit – Anterior Nasal Sample," is authorized to be distributed and used under this EUA as part of the above described product as set forth in this EUA.

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 for diagnosing COVID-19 and 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:

LetsGetChecked Inc. (You) and Authorized Distributor(s)[9]

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

[9] "Authorized Distributor(s)" are identified by you, LetsGetChecked Inc., in your EUA submission as an entity allowed to distribute the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit.

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 and authorized distributor(s) must make available on your website(s), if applicable, the authorized Fact Sheet for Healthcare Providers and Fact Sheet for Patients.

C. You and authorized distributor(s) must make available all instructions related to the self-collection of anterior nasal swab specimens using the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit both in the shipped kit and on your website(s).

D. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit is distributed.

E. You and authorized distributor(s) must maintain customer complaint files on record. You will report to FDA any significant complaints about usability or deviations from the established performance characteristics of the product of which you become aware.

F. You and authorized distributor(s) 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.

G. You and authorized distributor(s) using your product must ensure that any records associated with this EUA, including test usage, are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

LetsGetChecked Inc. (You)

H. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

I. You must provide authorized distributor(s) with a copy of this EUA and communicate any subsequent revisions that might be made to this EUA and its authorized accompanying materials.

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

K. You must notify the relevant public health authorities of your intent to run your product.

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

M. You will require that entities[10] using the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit, acknowledge receipt of the following disclosure "*Specimens that are self-collected will not be tested with an internal control to confirm that the specimen was properly collected. As such self-collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly*" that you must also include in test reports as required by Condition O. below.

N. You will include with result reports of your authorized test, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

O. When testing authorized specimens self-collected using the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit, you must include in the test report for specific patients whose specimen(s) were self-collected the following limitation: "*Specimens that are self-collected were not tested with an internal control to confirm that the specimen was properly collected. As such, unobserved self-collected specimens from SARS-CoV-2 positive individuals may yield negative results if the specimen was not collected properly."*

P. You must use your authorized test as outlined in the authorized test procedures submitted as part of the EUA request. Deviations from the authorized test 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.

Q. When testing authorized specimens self-collected using the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit you must follow the specimens accessioning protocol when accepting specimens for testing.

R. You must 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 authorized test of which you become aware.

S. 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. Any request for changes to this EUA should be submitted to DMD/OHT7-OIR/OPEQ/CDRH, and require concurrence of, Office of Counterterrorism and Emerging Threats

[10] As used in this condition, "entities" refers to any organization that contracts with you to conduct testing (i.e., employers who are doing back to work testing, universities, hospitals, healthcare systems, etc.).

(OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.

T. You must evaluate the analytical limit of detection and assess traceability[11] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

U. You must further evaluate the clinical performance of your product in an FDA agreed upon post authorization clinical evaluation study with asymptomatic individuals within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you will update authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

V. You must have a process in place to track adverse events, including any occurrence of false results with your product, including the LetsGetChecked Coronavirus (COVID-19) Home Collection Kit, 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).

W. 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.

Conditions Related to Printed Materials, Advertising and Promotion

X. 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 applicable requirements set forth in section 502(a), (q)(1), and (r) of the Act and FDA implementing regulations.

Y. 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.

Z. 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 by FDA under an EUA for use by the authorized laboratory;
- This product has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and,

[11] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

- 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