July 14, 2021

Trisha Lauterbach
Director of Laboratory Operations
ISPM Labs, LLC
DBA Capstone Healthcare
8601 Dunwoody Pl. Ste 444
Sandy Springs, GA 30350

Device:	Genus SARS-CoV-2 Assay
EUA:	EUA200182
Laboratory:	ISPM Labs, LLC dba Capstone Healthcare
Indication:	Qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal and oropharyngeal swabs from individuals suspected of COVID-19 by their healthcare provider. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited to laboratories designated by Capstone Healthcare that are certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

Dear Ms. Lauterbach:

On August 3, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Genus SARS-CoV-2 Assay for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal and oropharyngeal swabs 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). Testing was limited to the Clinical Virology Laboratory at Capstone Healthcare, located at 8601 Dunwoody Pl. Ste. 444, Sandy Springs, GA 20250, which is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests. A technical correction to the letter was issued on August 4, 2020.

On October 20, 2020, and April 10, 2021, you requested to revise your Emergency Use Authorization (EUA). Based on these requests, and having concluded that revising the August 3, 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 3, 2020, letter in its

[1] For ease of reference, this letter will use the term "you" and related terms to refer to ISPM Labs, LLC dba Capstone Healthcare.

entirety with the revisions incorporated.[2] 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[3] 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. 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.[4]

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

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[2] The revisions to the August 3, 2020, letter and authorized labeling include: (1) updates to the intended use to limit testing to laboratories designated by Capstone Healthcare that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 42 U.S.C. §263a and meet requirements to perform high complexity tests, (2) update the EUA Summary to include the results of the FDA SARS-CoV-2 Reference Panel testing, (3) updates to the EUA Summary, Fact Sheet for Healthcare Providers and Fact Sheet to Patients to reflect the updated intended use and reflect language used in more recent authorizations, (4) updating the Conditions of Authorization as a result of the change to the intended use and to reflect language used in more recent authorizations, and (5) add two new Conditions of Authorization concerning the post authorization monitoring of SARS-CoV-2 viral variants and their potential impact on the authorized product.

[3] For ease of reference, this letter will use the term "your product" to refer to the Genus SARS-CoV-2 Assay used for the indications identified above.

[4] 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).

3. There is no adequate, approved, and available alternative to the emergency use of your product.[5]

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 respiratory specimens listed in the indication above collected from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories designated by Capstone Healthcare that are certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests.

The SARS-CoV-2 nucleic acid is generally detectable in respiratory 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 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 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 specified under Condition H 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 - RNase P (RP) control in clinical samples - an internal control is needed to verify that nucleic acid is present in every sample and is used for every sample processed. A primer/probe set detecting the human housekeeping gene RNase P is including in every patient sample reaction.
- SARS-CoV-2 Positive Template Control (PTC) - a positive template control is needed to monitor substantial reagent failure including primer and probe integrity. The PTC is a plasmid (2019 nCoV_N Positive control) that contains the target

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

regions for the nucleocapsid gene.
- Human Specimen Control (HSC) (Negative Control and Extraction Control) – a negative human extraction control is extracted concurrently with the test samples. This provides a nucleic acid extraction procedural control and a secondary negative control. The HSC monitors for failure in lysis and the extraction procedure as well as potential contamination during extraction. The human extraction control consists of previously confirmed negative patient samples.
- NTCs (No Template Control) - a negative (no template) control is needed to eliminate the possibility of sample contamination on the assay run and is used on every assay plate. The NTC is added during rRT-PCR reaction setup and consists of RNase/DNase free water.

The above described product, 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/in-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: ISPM Labs, LLC dba Capstone Healthcare - Genus SARS-CoV-2 Assay
- Fact Sheet for Patients: ISPM Labs, LLC dba Capstone Healthcare - Genus SARS-CoV-2 Assay

The above described product, when accompanied by the "CAPGEN.523 - SARS-CoV-2 (2019-nCoV) Real-Time RT-PCR Assay", "CAPGEN.521 - Nucleic Acid Extraction with MagMaxTM Viral/Pathogen Kit (Respiratory Swab)" and "CAPGEN.524 - Nucleic Acid Extraction with Omega Mag-BindTM Viral DNA/RNA 96 Kit (Respiratory Swab)" laboratory procedures, the EUA Summary (identified above) and the two Fact Sheets (collectively referenced as "authorized labeling") is authorized to be distributed and used by authorized laboratories, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

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:

ISPM Labs, LLC dba Capstone Healthcare (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)); 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 will make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

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

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 may request changes to the Scope of Authorization (Section II in this letter) of your product. Any request for changes to this EUA should be submitted 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) and require appropriate authorization from FDA prior to implementation.

I. You must evaluate the analytical limit of detection and assess traceability[6] of your product with any FDA-recommended reference material(s). After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, you will update labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

J. You must have a process in place to track adverse events, including any occurrence of false results and report to FDA pursuant to 21 CFR Part 803. Serious adverse events should immediately be reported to DMD/OHT7- OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

K. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately.

L. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA, such as those related to the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Authorized Laboratories

M. 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.

N. Authorized laboratories using your product must perform the test as outlined in the authorized labeling. Deviations from the authorized labeling, including the authorized

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

instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to perform the test are not permitted.

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

P. 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.

Q. 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 (tlauterbach@capstonehealthcare.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the test of which they become aware.

R. 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.

ISPM Labs, LLC dba Capstone Healthcare (You) and Authorized Laboratories

S. 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

T. 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, as applicable, and FDA implementing regulations.

U. 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.

V. All descriptive printed matter, including 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,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure