U.S. FOOD & DRUG ADMINISTRATION

April 11, 2022

Susan Harrington, Ph.D.
Medical Director
The Cleveland Clinic Foundation
9500 Euclid Avenue
Cleveland, OH 44195

Device:	SelfCheck cobas SARS-CoV-2 + Flu Assay
EUA Number:	EUA220184
Company:	Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute
Indication:	This test is authorized for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus RNA in anterior nasal swab specimens that are self-collected at home using the SelfCheck Nasal Swabbing Kit, by individuals (18 years of age or older) who are suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider based on either a telemedicine visit or an in-person visit with a healthcare provider. Emergency use of this test is limited to the authorized laboratory.
Authorized Laboratory:	Testing is limited to the Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute, located at 9500 Euclid Ave/LL2, Cleveland, OH 44195, which is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meets requirements to perform high complexity tests.

Dear Dr. Harrington:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,[2] pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute.
[2] For ease of reference, this letter will use the term "your product" to refer to the SelfCheck cobas SARS-CoV-2 + Flu Assay used for the indication identified 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.[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 contained in the EUA Summary (identified below). There is an FDA-approved/cleared test for the qualitative detection and identification of SARS-CoV-2, influenza A virus, and influenza B virus along with some other organism types and subtypes not targeted by your product, but this is not an adequate and available alternative to your product. Respiratory viral infections caused by the influenza A and B viruses and SARS-CoV-2 can have similar clinical presentation and diagnostic considerations. Thus, to differentially detect SARS-CoV-2, information from a test that detects and differentiates the virus that causes COVID-19 and the common influenza viruses that cause seasonal epidemics of flu is needed.

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 through the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus RNA, 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]

[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).

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

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 real-time reverse transcription polymerase chain reaction (rRT-PCR) test intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus RNA in anterior nasal swab specimens that are self-collected at home using the SelfCheck Nasal Swabbing Kit, by individuals (18 years of age or older) who are suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider based on either a telemedicine visit or an in-person visit with a healthcare provider. The SelfCheck cobas SARS-CoV-2 + Flu Assay is intended for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A, and influenza B in humans and is not intended to detect influenza C.

RNA from SARS-CoV-2, influenza A, and influenza B 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, influenza A, and/or influenza B 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, influenza A, and/or influenza B 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.

The SelfCheck Nasal Swabbing Kit provides specimen collection materials and materials to safely mail specimens to the authorized laboratory for testing. Individuals should follow all specimen collection and mailing instructions provided in the kit.

To use your product, SARS-CoV-2, influenza A, and/or influenza B nucleic acids are first extracted, isolated and purified from anterior nasal 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. 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 (described below).

Your product requires control materials (or other authorized control materials as may be requested under Condition O. below) that are described in the authorized labeling (described below).

The above described product is authorized to be accompanied by 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 the "Accessioning the SelfCheck COVID-19 Swabbing kit or the SelfCheck Nasal Swabbing Kit" SOP, the laboratory's "Roche cobas 6800/8800 System SARS-CoV-2 & Influenza A/B" SOP, and the following fact sheets pertaining to the emergency use, which are required to be made available to

healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute - SelfCheck cobas SARS-CoV-2 + Flu Assay
- Fact Sheet for Patients: Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute - SelfCheck cobas SARS-CoV-2 + Flu Assay

The above described product, when accompanied by the EUA Summary, "Accessioning the SelfCheck COVID-19 Swabbing kit or the SelfCheck Nasal Swabbing Kit" SOP, the laboratory's "Roche cobas 6800/8800 System SARS-CoV-2 & Influenza A/B" SOP, and the two Fact Sheets 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 SelfCheck Nasal Swabbing Kit with the "SelfCheck Nasal Swabbing Kit" collection instructions and "SelfCheck Nasal Swabbing Kit" outer label 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 "Accessioning the SelfCheck COVID-19 Swabbing kit or the SelfCheck Nasal Swabbing Kit" SOP, the laboratory's "Roche cobas 6800/8800 System SARS-CoV-2 & Influenza A/B" SOP, the two Fact Sheets, the "SelfCheck Nasal Swabbing Kit" collection instructions, and the "SelfCheck Nasal Swabbing Kit" outer label.

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:

Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute (You) and Authorized Distributor(s)[5]

A. Your product must comply with the following labeling requirements pursuant to 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 and authorized distributor(s) must make available on your website(s), if applicable, the Fact Sheet for Healthcare Providers and the 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 SelfCheck Nasal Swabbing Kit, both in the shipped kit and on your website.

D. Through a process of inventory control, you and authorized distributor(s) must maintain records of the numbers and locations to which the SelfCheck Nasal Swabbing Kit is distributed.

E. You and authorized distributor(s) 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.

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) 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.

[5] "Authorized Distributor(s)" are identified by you, Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute, in your EUA submission as an entity allowed to distribute the SelfCheck Nasal Swabbing Kit.

Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute (You)

H. You must notify FDA of any authorized distributor(s) of the SelfCheck Nasal Swabbing Kit, 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 to authorized distributor(s) any subsequent amendments 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 and 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 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. You 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 other ancillary reagents and authorized materials required to use your product are not permitted. When testing self-collected specimens using your product, you must have in place a suitable specimen receipt and accessioning SOP.

O. 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, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. 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.

P. 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. [6] After submission to and concurrence with the data by FDA, DMD/OHT7-

[6] 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.

OIR/OPEQ/CDRH will update the EUA Summary to reflect the additional testing.

Q. You must have a process in place to track adverse events, including any occurrence of false results with your product, including the SelfCheck Nasal Swabbing Kit, and report to FDA pursuant to 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).

R. You 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) 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.

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

T. You must evaluate the impact of SARS-CoV-2 viral mutations and all other target analytes 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 (via email: CDRH-EUA-Reporting@fda.hhs.gov).

U. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding 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.

Conditions Related to Printed Materials, Advertising and Promotion

V. 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.

W. 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.

X. 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 the authorized laboratory;

- This product has been authorized only for the detection and differentiation of nucleic acid of SARS-CoV-2 from influenza A and/or influenza B, 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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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure