November 30, 2021

Paul Isabelli
Chief Operating Officer
Audere
1191 2nd Avenue, Suite 450
Seattle, WA 98101

Device:	HealthPulse@home
EUA Number:	EUA210353
Company:	Audere
Indication:	Collection kit for use by any individual aged 16 years and older (self-collected) or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19, for collection of anterior nares (nasal) swab specimens at home or in a healthcare setting when determined to be appropriate by a healthcare provider. Anterior nasal swab specimens collected using HealthPulse@home (i.e., a collection kit that is assembled and conforms with the specifications outlined by the HealthPulse@home Emergency Use Authorization (EUA)) can be transported at ambient temperature for testing at an authorized laboratory. SARS-CoV-2 RNA from the anterior nasal swabs specimen is maintained in the specimen packaging and suitable for use in molecular diagnostic testing performed using an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 RNA that is indicated for use with HealthPulse@home.
Authorized Laboratories:	Testing is limited to laboratories designated by Audere that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests when such laboratories assemble and use a collection kit that conforms with the HealthPulse@home Emergency Use Authorization (EUA) with an in vitro diagnostic (IVD) molecular test that is indicated for use with the HealthPulse@home when used consistent with its authorization.

Dear Mr. Isabelli:

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).

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.[3] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices during the COVID-19 outbreak, 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 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 by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the collected human specimen, and that the known and potential benefits of your product when used for such use, outweigh the known and potential risks of your product; and

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Audere.
[2] For ease of reference, this letter will use the term "your product" to refer to the HealthPulse@home used for the indication identified above.
[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] U.S. Department of Health and Human Services, *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 17335 (March 27, 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 collection kit intended for use by any individual aged 16 years and older (self-collected) or 2 years and older (collected with adult assistance), including individuals without symptoms or other reasons to suspect COVID-19, for collection of anterior nares (nasal) swab specimens at home or in a healthcare setting when determined to be appropriate by a healthcare provider.

Testing is limited to laboratories designated by you that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests when such laboratories assemble and use a collection kit that conforms with this EUA.

Anterior nasal swab specimens collected using the authorized product (i.e., a collection kit that is assembled and conforms with the specifications outlined in this EUA) can be transported at ambient temperature for testing at an authorized laboratory. SARS-CoV-2 RNA from the anterior nasal swab specimen is maintained in the specimen packaging and suitable for use in molecular diagnostic testing preformed using an in vitro diagnostic (IVD) test for the detection of SARS-CoV-2 RNA that is indicated for use with your product.

Your product contains instructions, according to the authorized kit assembly operating procedure (see authorized labeling below), that authorized laboratories, designated by you through the "Laboratory Approval Process" and the License Agreement, must utilize to assemble the authorized product with specified components that can be purchased as general purpose laboratory equipment to facilitate human specimen collection consistent with this authorization. Specimens collected using your product are for testing with molecular SARS-CoV-2 tests indicated for use with your product. Your product also contains instructions for use (IFU) templates with customizable sections where authorized laboratories, designated by you, can add laboratory-specific information and branding.

Authorized laboratories, designated by you, can either assemble the collection kits themselves or via sub-contracted kit suppliers. After assembly, your product is provided to individuals when determined to be appropriate by a healthcare provider either through pickup from a central location or delivery via a delivery service, as defined by the authorized laboratory. Individuals then register the kit and collect the specimen according to the provided authorized sample collection instructions (see authorized labeling below) before returning the specimen either via a drop-off location or shipment to the authorized laboratory, according to the specimen return instructions.

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

Anterior nasal swab specimens collected using your product are transported at ambient temperature. Once received at the authorized laboratory samples are accessioned according to the authorized accessioning operating procedure (see authorized labeling below), rehydrated according to the authorized swab rehydration operating procedure (see authorized labeling below) and tested using an IVD test for the detection of SARS-CoV-2 RNA that is indicated for use with your product. Test results are returned to the ordering healthcare provider, who is ultimately responsible for releasing results to the patient verbally and/or electronically.

The specimen collection kits conforming with the HealthPulse@home EUA include the following materials or other authorized materials (as may be requested under Condition K. below):

Nasal swab
Dry collection tube
Outer enclosure for specimen collection kit – Kit Box for collection kits shipped and returned via shipping or Kit Zip Bag for kits picked-up/dropped-off by an individual
Barcode labels (as applicable)
Tube Label
Specimen transport bag - with biohazard symbol (included or separate absorbent pad)
Return shipping bag (as applicable)
Prepaid return shipping label (for shipped kits)
Instructions for Use

The labeling entitled "HealthPulse@home Nasal Specimen Collection Kit Instructions" - Drop-off, "HealthPulse@home Nasal Specimen Collection Kit Instructions" - Ship Back, 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), the following operating procedures: "Operating Procedure HealthPulse@home Kit Assembly," "Operating Procedure HealthPulse@home Laboratory Accessioning," "Operating Procedure HealthPulse@home Laboratory Swab Rehydration Process" provided to authorized laboratories as part of the license agreement with Audere are required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling."

The above described product, when accompanied by the authorized labeling as set forth in the Conditions of Authorization (Section IV) is authorized to be distributed and used under this EUA, 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 by serving as an appropriate means to collect and transport human

specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the collected human specimen 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, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

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

Audere (You) and Authorized Laboratories[6]

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 and authorized laboratories 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.

[6] "Authorized Laboratories" are designated by you, Audere, in your EUA submission as an entity allowed to assemble and distribute specimen collection kits that conform to the HealthPulse@home EUA.

C. Through a process of inventory control, you and authorized laboratories must maintain records of the numbers and locations to which your product is distributed.

D. You and authorized laboratories 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.

E. You and authorized laboratories 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.

F. 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.

Audere (You)

G. You must notify FDA of any authorized laboratories designated by Audere to use your product, including details of any brand names used, and any in vitro diagnostic (IVD) molecular test manufacturers interested in seeking an indication for use with your product, including their test and contact name, address, and phone number.

H. You must have a process in place to designate authorized laboratories that use your product and to ensure the use of your product by the authorized laboratories under this EUA is consistent with, and does not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV).

I. You must provide authorized laboratories 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 provide authorized laboratories using your product with copies of the authorized labeling as part of the License Agreement between you and the authorized laboratory.

K. 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 requests 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.

L. You must have a process in place to track adverse events associated with your product (i.e., collection kits that are assembled and conform with the specifications outlined by

this EUA), including any occurrences of false results with your product, and report any such events 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-EUAReporting@fda.hhs.gov).

M. You must submit to FDA summary report(s) summarizing the results of testing performed using anterior nasal swab specimens collected with collection kits conforming with your product using the reporting parameters agreed upon by FDA. The summary report should be stratified by age group, authorized laboratory, EUA test used, and include how many collection kits were requested and sent for specimen collection to individuals, how many collection kits were distributed and returned to the laboratory according to the instructions, how many specimens had to be rejected during accession and the main reasons for rejection, and the positivity rate.

Authorized Laboratories

N. Authorized laboratories using your product must have processes in place and oversee use of your product to ensure that your product is used as outlined in the authorized labeling and in the laboratory's signed License Agreement with Audere.

O. Authorized laboratories using your product must keep records of any subcontractors they enter into agreements with regarding the manufacture or distribution of your product and, upon request, must make such records available to FDA within 5 business days for inspection.

P. Authorized laboratories and subcontractors assembling collection kits in accordance with this EUA must follow the "Operating Procedure HealthPulse@home Kit Assembly" and the requirements outlined in the laboratory's signed License Agreement with Audere.

Q. Authorized laboratories and subcontractors assembling collection kits in accordance with this EUA must make available the appropriate instructions related to the collection and return (drop-off or shipment) of anterior nasal swab specimens (e.g., "HealthPulse@home Nasal Specimen Collection Kit Instructions" - Drop-off or "HealthPulse@home Nasal Specimen Collection Kit Instructions" - Ship Back) in the distributed kit and make available all such instructions on your website(s).

R. Authorized laboratories and subcontractors assembling collection kits in accordance with this EUA must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the collection kits released for distribution have the performance claimed in the authorized labeling.

S. If requested by FDA, authorized laboratories and subcontractors assembling collection kits in accordance with this EUA must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of the collection kits for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.

T. Authorized laboratories and subcontractors assembling collection kits in accordance with this EUA must comply with the following requirements under FDA regulations: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

U. Authorized laboratories must report significant customer complaints about the usability of your product of which they become aware to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (support@healthpulsenow.org).

V. Authorized laboratories testing anterior nasal swab specimens collected using your product must follow and/or develop an accessioning standard operating procedure (SOP) in accordance with the "Operating Procedure HealthPulse@home Laboratory Accessioning" and must follow the "Operating Procedure HealthPulse@home Laboratory Swab Rehydration Process" when accepting and rehydrating specimens for testing.

W. Authorized laboratories using your product must use it only in conjunction with COVID-19 in vitro diagnostic (IVD) molecular tests that are indicated for use with your product.

X. Authorized laboratories must collect information on the performance collection kits conforming with your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (support@healthpulsenow.org) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.

Conditions Related to Printed Materials, Advertising and Promotion

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

Z. 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.

AA. All descriptive printed matter, advertising and promotional materials (with the exception of information provided in the generic sections of a patient portal associated with the kit activation) 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;

- This product has been authorized only for the collection and maintenance of anterior nasal swab specimens as an aid in 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 medical devices 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 medical devices during the COVID-19 outbreak 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