March 2, 2021

Marc Jones
Chief Operating Officer and CFO
binx health, Inc.
77 N. Washington Street
Boston, MA 02114

Device:	binx health At-Home Nasal Swab COVID-19 Sample Collection Kit
EUA Number:	EUA202509
Company:	binx health, Inc.
Indication:	For self-collection of anterior nasal (nasal) swab specimens at home, (which includes in a community-based setting) from individuals 18 years and older suspected of COVID-19 by a healthcare provider.
Authorized Laboratories:	Testing is limited to laboratories designated by binx health, Inc. 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 and that run the specimens collected from the binx health At-Home Nasal Swab COVID-19 Sample Collection Kit on an in vitro diagnostic (IVD) molecular test that is indicated for use with the binx health At-Home Nasal Swab COVID-19 Sample Collection Kit for self-collection of nasal swabs.

Dear Mr. Jones:

On October 20, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the binx health At-Home Nasal Swab COVID-19 Sample Collection Kit, for use by individuals for self-collection of nasal swab specimens at home when determined by a healthcare provider to be appropriate based on the results of an online COVID-19 questionnaire and for use only with an in vitro diagnostic (IVD) molecular test for the detection of SARS-CoV-2 that is indicated for use with the binx health At-Home Nasal Swab COVID-19 Sample Collection Kit pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). Testing was limited to laboratories designated by binx health, Inc. that are certified under the Clinical Laboratory Improvement

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

Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet requirements to perform high complexity tests and that run the specimens collected from the binx health At-Home Nasal Swab COVID-19 Sample Collection Kit on an in vitro diagnostic (IVD) molecular test that is indicated for use with the binx health At-Home Nasal Swab COVID-19 Sample Collection Kit for self-collection of nasal swabs. FDA reissued the October 20, 2020, letter in its entirety on December 4, 2020.[2]

On January 29, 2021, you requested to revise your Emergency Use Authorization (EUA). Based on that request, and having concluded that revising the December 4, 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 December 4, 2020, letter in its entirety with the revisions incorporated.[3] 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[4] 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.[5] 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.[6]

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).

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[2] The revisions to the October 20, 2020, letter include: (1) modification of the Intended Use to refer to use of the self-collection kit in a community-based setting and (2) update the Instructions for Use (IFU) of the binx health At-home Nasal Swab COVID-19 Sample Collection Kit to clarify instructions for kit activation and to modify the instructions for tube labeling and (3) additional IFUs to address two types of specimen collection packaging due to the addition of an individually wrapped nasal swab and to add instructions for returning kits for specimens shipped individually or dropped off in a community-based setting and (4) add Binx Dry Nasal Swab Accessioning Criteria to authorized labeling and (5) clarifying revisions to the conditions of authorization.

[3] Revisions to the December 4, 2020 EUA include: (1) modification of the self-collection IFU to clarify instructions for activation, to clarify the format of the sample identification label and to update the checklist for collection completion; (2) update the intended use to remove reference to the online COVID-19 questionnaire and other changes to reflect more recent authorizations, (3) remove the COVID-19 At-Home Test Questionnaire as a component of the authorized labeling defined in this letter, and (4) update conditions of authorization consistent with recent authorizations and removal of conditions O., P. and Q.

[4] For ease of reference, this letter will use the term "your product" to refer to the binx health At-Home Nasal Swab COVID-19 Sample Collection Kit used for the indication described above.

[5] 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).

[6] 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)

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 nasal swab specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the self-collected specimen, 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.[7]

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 self-collection of anterior nasal (nasal) swab specimens at home (which includes in a community-based setting) from individuals 18 years and older suspected of COVID-19 by a healthcare provider. Once collected at home or in a community-based setting, the dry human anterior nasal swab specimen, which may include SARS-CoV-2 RNA, is maintained in the authorized product packaging and transported at ambient temperature to an authorized laboratory. The authorized laboratory then runs the specimen using an IVD molecular test that is indicated for use with nasal swab specimens collected with the binx health At-home Nasal Swab COVID-19 Sample Collection Kit. When using your product, individuals must follow all specimen collection and mailing instructions provided with the kit. The binx health At-home Nasal Swab COVID-19 Sample Collection Kit includes the following materials or other authorized materials: cardboard shipping box, sterile swab either in a plastic transport tube or in separate peel pouch packaging, instructions for collection/shipping or collection/drop-off, sample bag with absorbent pad, a sample identification label and either a pre-paid return envelope (for shipping) or a return envelope (for kit drop-off).

The above described product is authorized to be accompanied with authorized labeling (available

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

at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas). Authorized labeling includes the following documents: the EUA Summary, the binx health Collection Kit patient instructions "binx health At-home Nasal Swab COVID-19 Sample Collection Kit – for return at a drop-off location Instructions for Use," (bundle for both individual swab packaging and swab/tube combination packaging), the "binx health At-home Nasal Swab COVID-19 Sample Collection Kit – for individual shipping Instructions for Use," (bundle for both individual swab packaging and swab/tube combination packaging), and the "Binx Dry Nasal Swab Accessioning Criteria."

The above described product, when accompanied by the authorized labeling (identified above) is authorized to be distributed and used by individuals (accompanied only by binx health At-home Nasal Swab COVID-19 Sample Collection Kit instructions for return at a drop-off location or shipping) and authorized laboratories (accompanied by all authorized labeling) as set forth in this letter and pursuant to the conditions in the 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 nasal swab specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the self-collected 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:

binx health, Inc. (You) and Authorized Distributor(s)[8]

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 distributor(s) must make available with the shipped product (including community-based distributed product) the appropriate the binx health Collection Kit patient instructions ("binx health At-home Nasal Swab COVID-19 Sample Collection Kit – for return at a drop-off location Instructions for Use," or the "binx health At-home Nasal Swab COVID-19 Sample Collection Kit – for individual shipping Instructions for Use").

C. You and authorized distributor(s) must make all patient instructions available on your website(s).

D. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product, or the authorized labeling.

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

F. 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.

G. 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.

[8] "Authorized distributors" are identified by you (binx health, Inc.) in your EUA submission as an entity allowed to distribute your device. By agreement with FDA, conditions C, D and F do not apply to Expeditors International and United Parcel Service (UPS).

binx health, Inc. (You)

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

I. You must notify FDA of any authorized laboratories designated by binx health, Inc. to use your product, including the name, address, and phone number of any authorized laboratories.

J. You must provide authorized distributor(s) and 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.

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, 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.

L. You must comply with the following requirements pursuant to FDA regulations: 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).

M. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the kits released for distribution have the clinical and analytical performance claimed in the authorized labeling.

N. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product 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.

O. You must have a process in place to track adverse events, including any occurrence of false results with your product and report to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should also be immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email:CDRH-EUAReporting@fda.hhs.gov).

Authorized Laboratories

P. Authorized laboratories testing nasal swab specimens self-collected using your product must have in place a suitable specimen receipt and accessioning SOP when accepting specimens for testing, such as the Binx Dry Nasal Swab Accessioning Criteria.

Q. 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.

R. 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 (www.mybinxhealth.com) 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.

binx health, Inc. (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 the applicable requirements set forth in section 501(a), (q)(1), and (r) of the Act 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, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This self-collection kit 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 self-collection kit has been authorized only for the self-collection and maintenance of nasal swab specimens as an aid in the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and

- The emergency use of this self-collection kit in combination with the authorized test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of medical devices 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 medical devices 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