March 31, 2021

Angela Drysdale
VP, Regulatory Affairs
Abbott Diagnostics Scarborough, Inc.
10 Southgate Road
Scarborough, ME 04074

Device:	BinaxNOW COVID-19 Ag Card 2 Home Test
EUA Number:	EUA210272
Company:	Abbott Diagnostics Scarborough, Inc.
Indication:	Qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in direct anterior nasal (nares) swabs from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested twice over three days with at least 36 hours between tests. This test is authorized for non-prescription home use with self-collected observed direct anterior nasal (nares) swab samples from individuals aged 15 years or older or adult collected anterior nasal swab samples from individuals aged two years or older. The BinaxNOW COVID-19 Ag Card Home Test is to be performed only with the supervision of a telehealth proctor.

Dear Ms. Drysdale:

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. 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

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Abbott Diagnostics Scarborough, Inc.
[2] For ease of reference, this letter will use the term "your product" to refer to the BinaxNOWCOVID-19 Ag Card 2 Home Test used for the indication identified above.

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 included in the Instructions for Use (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.[4]

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 lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 from SARS-CoV-2 in direct anterior nasal (nares) swabs from individuals with or without symptoms or other epidemiological reasons to suspect COVID-19 infection when tested twice over three days with at least 36 hours between tests. This test is authorized for non-prescription home use with self-collected observed direct anterior nasal (nares) swab samples from individuals aged 15 years or older or adult collected anterior nasal swab samples from individuals aged two years or older. The BinaxNOW COVID-19 Ag Card 2 Home Test is to be performed only with the supervision of a telehealth proctor.[5]

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[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.

[5] For purposes of this EUA, a telehealth proctor is someone who has been trained to observe sample collection and

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nasal (nares) swabs during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19. For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of COVID-19, such as, an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. Additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Individuals who test negative and continue to experience COVID-like symptoms of fever, cough, and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care from their healthcare provider.

To use your product the individual must first log into the NAVICA software application (App) and selects, "I Already Have a Test Kit." Next they visit the telehealth provider website to start testing and wait in queue to connect to the telehealth proctor.

Your product is performed with the supervision of a telehealth proctor. First, the patient opens the test kit when instructed and scans the QR code on the test card with a compatible smart phone or computer using the NAVICA App. Next, 6 drops of extraction reagent from a dropper bottle are added to the top hole of the swab well. A nasal swab specimen is then self-collected or adult-collected under observation of the telehealth proctor. The patient sample is inserted into the test card through the bottom hole of the swab well, and firmly pushed upwards until the swab tip is visible through the top hole. The swab is rotated 3 times clockwise and the card is closed, bringing the extracted sample into contact with the test strip. Test results are interpreted visually after 15 minutes based on the presence or absence of visually detectable pink/purple colored lines. Results should not be read after 30 minutes. The patient scans the QR code again on the test card before showing the test card to the telehealth proctor who instructs the patient on how to read the test card result. Upon completion of the test and result interpretation by the user, the telehealth proctor will send the results to the user via the NAVICA App. The user will then be notified by email and on their mobile device that their results are ready and can go to the results screen in the NAVICA App to view their result. The telehealth proctor will also send the "BinaxNOW COVID-19 Ag Card 2 Home Test Kit Procedure Card" to the patient at the conclusion of the test. Reporting to appropriate public health authorities will be handled by a healthcare provider, based on the information submitted to the NAVICA App by the telehealth proctor.

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provide instructions and result interpretation assistance to patients using your product. In general, the telehealth proctor that will observe testing through the NAVICA App is **not** a healthcare provider.

The BinaxNOW COVID-19 Ag Card 2 Home Test includes the following materials or other authorized materials: two Test Cards, two Extraction Reagent bottles, and two Nasal Swabs.

Your product includes an internal control test line that must generate the expected result for a test to be considered valid, as outlined in the "BinaxNOW COVID-19 Ag Card 2 Home Test Healthcare Provider Instructions for Use" and the "BinaxNOW COVID-19 Ag Card 2 Home Test Kit Procedure Card."

The labeling entitled "BinaxNOW COVID-19 Ag Card 2 Home Test Kit Procedure Card" and the "BinaxNOW COVID-19 Ag Card 2 Home Test Healthcare Provider Instructions for Use" (available at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas), and the "BinaxNOW COVID-19 Ag CARD 2 HOME TEST Kit" box label, NAVICA App, and the following fact sheets pertaining to the emergency use, is required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as "authorized labeling":

- Fact Sheet for Healthcare Professionals: Abbott Diagnostics Scarborough, Inc.- BinaxNOW COVID-19 Ag Card 2 Home Test Kit
- Fact Sheet for Individuals: Abbott Diagnostics Scarborough, Inc. - BinaxNOW COVID-19 Ag Card 2 Home Test Kit

The above described product, with 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, 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:

Abbott Diagnostics Scarborough, Inc. (You) and Authorized Distributor(s)[6]

A. Your product must comply with the following labeling requirements: the intended use statement in 21 CFR 809.10(a)(2), (b)(2); adequate directions for use in 21 U.S.C. 352(f) and 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 the "BinaxNOW COVID-19 Ag Card 2 Home Test Kit Procedure Card" and the "Fact Sheet for Individuals" for your product electronically available on your website.

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

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

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the locations (e.g., pharmacies, doctor's offices, etc.) to which your product is distributed and the number of tests distributed to each location.

F. You and authorized distributor(s) must collect information on the performance of your

[6] "Authorized Distributor(s)" are identified by you, Abbott Diagnostics Scarborough, Inc., in your EUA submission as an entity allowed to distribute your product.

product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any such events to FDA 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).

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.

H. You and authorized distributors 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.

Abbott Diagnostics Scarborough, Inc. (You)

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

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

K. You must provide an electronic copy of the "BinaxNOW COVID-19 Ag Card 2 Home Test Kit Procedure Card" at the conclusion of the telehealth service to each patient, and must make the authorized "BinaxNOW COVID-19 Ag Card 2 Home Test Healthcare Provider Instructions for Use" and "Fact Sheet for Healthcare Professionals" electronically available on your website. Additionally, you must provide healthcare providers the opportunity to request a copy of the Instructions for Use and Fact Sheet for Healthcare Professionals in paper form, and after such request, promptly provide the requested labeling without additional cost.

L. 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 shall 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.

M. 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).

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

O. If requested by FDA, you must submit your 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 them within 48 hours of the request.

P. You must evaluate the analytical limit of detection and assess traceability[7] 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.

Q. You must evaluate the clinical performance of your product to support the serial screening claim in an FDA agreed upon post authorization clinical evaluation study within 6 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 must update the 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.

R. You must evaluate software validation of the NAVICA App, including cybersecurity in an FDA agreed upon post authorization study within 2 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 the authorized labeling to reflect the additional testing and complete any necessary software modification. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

S. You must implement the FDA agreed upon software updates to the NAVICA App software to further facilitate result reporting within 2 months of this letter (unless otherwise agreed to with DMD/OHT7- OIR/OPEQ/CDRH) and submit the updates to DMD/OHT7-OIR/OPEQ/CDRH and receive DMD/OHT7-OIR/OPEQ/CDRH's concurrence prior to implementation.

T. You must ensure that any telehealth proctor, whether hired by you or a third-party, is appropriately trained with training materials as agreed to with DMD/OHT7-OIR/OPEQ/CDRH, on the processes for providing instructions and documenting results in the NAVICA App with respect to use of your product.

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

U. You must ensure that any telehealth provider that provides services related to use of your product has healthcare providers with prescribing privileges available to answer patient questions, provide patients with additional information about their results, and report patient test results as appropriate to public health authorities.

V. You must ensure that any telehealth provider that provides services related to use of your product has processes in place to track and promptly report any adverse events or other performance concerns about the use of your product to you. You must ensure that such telehealth provider adequately trains appropriate personnel about such processes.

Conditions Related to Printed Materials, Advertising and Promotion

W. 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 and FDA implementing regulations.

X. 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.

Y. 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;
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,
- 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