HENRY SCHEIN®

COVID-19 TEST KIT
CUSTOMER NOTICE

PLEASE READ THIS COVID-19 TEST KIT NOTICE CAREFULLY BEFORE PURCHASING ANY TEST KITS (DEFINED BELOW). THE TEST KITS HAVE BEEN AUTHORIZED BY THE FDA UNDER AN EMERGENCY USE AUTHORIZATION (THE "EUA"). THE EUA AND THIS NOTICE CONTAINS VERY IMPORTANT INFORMATION ABOUT CUSTOMER'S OBLIGATIONS, INCLUDING WITH RESPECT TO THE CLINICAL ADMINISTRATION OF THE TEST KITS.

Information Relating to the Test Kits and Conditions of Use

a. The QuickVue SARS Antigen Test ("Test Kits"), manufactured by Quidel Corporation, are indicated for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nares (NS) swab specimens directly from (1) individuals who are suspected of COVID-19 by their healthcare provider when used serially, at least twice over three days with at least 48 hours between tests, or (2) individuals without symptoms or other epidemiological reasons to suspect COVID-19 when used serially, at least three times over five days with at least 48 hours between tests. Negative results are presumptive. A copy of the emergency use authorization (EUA) for the Test Kits (with related revisions) is attached hereto as **Exhibit A**. **The Test Kits are not returnable**.

b. The Test Kits are only for in vitro diagnostic use, by Authorized Laboratories, under the Food and Drug Administration's EUA authority, and they have not been FDA cleared or approved. "*Authorized Laboratories*" means laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high, moderate, or waived complexity tests. These Test Kits are authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. Negative results are presumptive.

c. Emergency use of these Test Kits is limited to Authorized Laboratories, and 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner. The Test Kits have been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.

d. Please be sure to read the EUA carefully, as it includes specific obligations that apply to you, including obligations requiring you to collect and report information on the performance of the Test Kits, including any suspected occurrence of false positive results, false negative results, and significant deviations from the established performance characteristics of the Test Kits. Please notify HSI of any complaints about the Test Kits via telephone at 1-800-472-4346.

e. Please note that the EUA also lists materials authorized to be used with the Test Kits.

f. Please keep all records associated with the Test Kits as required by the EUA until otherwise notified by the FDA.

g. Please carefully read the Fact Sheet for Healthcare Providers for the Test Kits attached hereto as **Exhibit B**, and provide it to your Healthcare Providers.

h. Please carefully read the Fact Sheet for Patients attached hereto as **Exhibit C**, and use it as instructed by the EUA.

i. Updated copies of the EUA and related Test Kit documentation, including the "QuickVue SARS Antigen Test" Instructions for Use, the "QuickVue SARS Antigen Test Quick Reference Instructions", and the Fact Sheets for Healthcare Providers and Patients, are available on Henry Schein's website at www.henryschein.com/QuickvueSarsPro.

EXHIBIT A

Emergency Use Authorization

(Starts on Following Page)

November 9, 2021

Ronald H. Lollar
VP, Clinical and Regulatory Affairs – Infectious Disease Quidel Corporation
9975 Summers Ridge Road San Diego, CA
92121

Device:	QuickVue SARS Antigen Test
Company:	Quidel Corporation
EUA Number:	EUA203086
Indication:	Qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nares (NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests. Emergency use of this test is limited to authorized laboratories.
Authorized Laboratories:	Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, that meet the requirements to perform moderate, high or waived complexity tests. This product is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Dear Mr. Lollar:

On December 18, 2020, based on your[1] request the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the QuickVue SARS Antigen Test, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3 for

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

the indications stated in the letter.[2] Based on your request, the December 18, 2020, letter was revised and reissued by FDA on July 26, 2021.[3]

On October 12, 2021, you requested to amend the authorized labeling. Based on that request, and additional minor labeling changes recommended by the FDA, the Agency has concluded that revising the July 26, 2021, 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 July 26, 2021, letter in its entirety with the revisions incorporated.[4] 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[5] is now authorized for use consistent with the indication 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.[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 Instructions for Use (identified below).

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[2] The December 18, 2020, letter authorized your product for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nares (NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms. Emergency use of this test is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate complexity, high complexity, or waived tests. This test was also authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

[3] On July 26, 2021, the revisions to the December 18, 2020, letter and authorized labeling included: (1) revisions to the intended use and authorized labeling documents, including the Fact Sheet for Healthcare Providers and Fact Sheet for Patients to reflect current information known about serial testing as outlined in the March 16, 2021, FDA "Supplemental Template for Developers of Molecular and Antigen Diagnostic COVID-19 Tests for Screening with Serial Testing" (https://www.fda.gov/media/146695/download), which includes testing of individuals without symptoms or other epidemiological reasons to suspect COVID-19, (2) updates to the Conditions of Authorization to add new Conditions related to circulating variants (Conditions T. and U.), and (3) updates to the Conditions of Authorization to require a post-authorization clinical study to support the serial testing claim (Condition S.), and to use language consistent with recent authorizations.

[4] The revisions to the July 26, 2021, letter and authorized labeling include: (1) revisions to the intended use and authorized labeling documents, including the Fact Sheet for Healthcare Providers, to allow "*no more than 48 hours between tests*" for serial testing (updated from 36 hours), (2) updates to the Conditions of Authorization to remove two conditions (Conditions P. and Q. in the July 26, 2021 letter) that were fulfilled through data submission to the FDA, and (3) update Condition of Authorization Q. below to give a 6 month extension.

[5] For ease of reference, this letter will use the term "your product" to refer to the QuickVue SARS Antigen Test used for the indication identified above.

[6] 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).

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.[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 lateral flow immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nares (NS) swab specimens directly from individuals suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested twice over two or three days with at least 24 hours and no more than 48 hours between tests.

Your product does not differentiate between SARS-CoV and SARS-CoV-2. The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nares swab specimens 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, 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, and confirmed with a molecular assay, if necessary, for patient management.

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

For serial testing programs, additional confirmatory testing with a molecular test for negative results may be necessary, if there is a high likelihood of SARS-CoV-2 infection, such in an individual with as 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 SARS-CoV-2 infection, such as in individuals without known exposures to SARS-CoV-2 or residing in communities with low prevalence of infection.

Testing of anterior nares swab specimens using your product, as outlined in the "QuickVue SARS Antigen Test," Instructions for Use, is limited to laboratories certified under CLIA that meet the requirements to perform high, moderate, or waived complexity tests. This product is authorized for use at the POC, i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

To use your product, an anterior nares swab specimen is collected from the individual. To begin the test, a lyophilized reagent must be rehydrated in the Reagent Tube. This reagent facilitates exposure of the appropriate viral antigens to the antibodies used in the test. The Reagent is first rehydrated with the provided Reagent Solution, and the swab specimen is then inserted into the Reagent Tube. This Reagent interacts with the specimen and facilitates exposure of the appropriate viral antigens to the antibodies used in the test. The Test Strip is added to the Reagent Tube containing the specimen and Reagent Solution. If the extracted specimen contains SARS-CoV or SARS-CoV-2 antigens, a pink-to-red Test Line, along with a blue procedural Control Line will appear on the Test Strip indicating a positive result. If SARS-CoV or SARS-CoV-2 is not present, or is present at very low levels, only a blue procedural Control Line will appear.

The QuickVue SARS Antigen Test includes the following materials or other authorized materials: Individually Packaged Test Strips, Reagent Tubes, Reagent Solution, Sterile Nasal Swabs, SARS Positive Control Swab, and Negative Control Swab.

Your product requires use of the SARS Positive Control Swab and Negative Control Swab or other authorized controls (refer to Condition M. below), that are run as outlined in the Instructions for Use. Your product also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and are described in the Instructions for Use.

The above described product is authorized to be accompanied with labeling entitled "QuickVue SARS Antigen Test" Instructions for Use and the "QuickVue SARS Antigen Test Quick Reference Instructions" (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 product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Quidel Corporation - QuickVue SARS Antigen Test
- Fact Sheet for Patients: Quidel Corporation - QuickVue SARS Antigen Test

The above described product, when accompanied by the "QuickVue SARS Antigen Test"

Instructions for Use and the "QuickVue SARS Antigen Test Quick Reference Instructions," and the two Fact Sheets (collectively referred to as "authorized labeling") is authorized to be distributed to and used by authorized laboratories 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:

Quidel Corporation (You) and Authorized Distributor(s)[8]

[8] "Authorized Distributor(s)" are identified by you, Quidel Corporation, in your EUA submission as an entity allowed to distribute your product.

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 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 your product available with the authorized labeling to authorized laboratories.

C. You and authorized distributor(s) must make available on your website(s) the authorized labeling.

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 and authorized labeling.

E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute your product and number distributed.

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

Quidel Corporation (You)

H. You must notify FDA of any authorized distributor(s) of your product, 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 revisions that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

J. You must comply with the following requirements pursuant to 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).

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

L. 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.

M. 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 DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

N. You must evaluate the analytical limit of detection and assess traceability[9] of your product with any FDA-recommended reference material(s). After submission to and review and concurrence with the data by FDA, you must update labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

O. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results as they become available until completion of the study. After submission of the study data, and review and concurrence with the data by FDA, you must update your product labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

P. You must work with FDA and implement any agreed upon software solutions to further facilitate result reporting within 4 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.

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

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

updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

R. 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.

S. 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.

T. 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.

Authorized Laboratories

U. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.

V. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.

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

X. 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.

Y. 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 (via email: QDL.COV2.test.event.report@quidel.com, or via phone by contacting Quidel Customer Support Services at 800.874.1517 (in the U.S.) or 858.552.1100) 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.

Z. All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment

when handling this kit, and use your product in accordance with the authorized labeling.

Quidel Corporation (You), Authorized Distributor(s) and Authorized Laboratories

AA. You, authorized distributors, 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

BB. 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.

CC. 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.

DD. 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 for use by authorized laboratories;
- This product has been authorized only for the detection of proteins 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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Jacqueline A. O'Shaughnessy, Ph.D. Acting Chief Scientist
Food and Drug Administration

Enclosure

November 1, 2022

To: Developers of Antigen In Vitro Diagnostics (IVDs) Authorized for Emergency Use for Coronavirus Disease 2019 (COVID-19) as of Today's Date

Re: Revisions Related to Serial (Repeat) Testing for the EUAs of Antigen IVDs

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3(b)(1)(C)), 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.[1] FDA subsequently authorized the emergency use of numerous in vitro diagnostics (IVDs) for detection and/or diagnosis of SARS-CoV-2, the virus that causes COVID-19. [2]

Pursuant to Section 564 of the Act, and in response to new data regarding performance of antigen tests from a study assessing at-home COVID-19 antigen test performance ("the antigen

[1] 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)

[2] In Vitro Diagnostics EUAs: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas, includes links to tables of currently authorized IVD EUAs for SARS-CoV-2.

study"),[3] FDA is revising the authorized uses[4] and requiring updates to product labeling of all tests that are within the scope of this letter. This revision also establishes one additional Condition of Authorization, and eliminates one Condition of Authorization, on EUAs that are within the scope of this revision (Section I).

The additional condition of authorization established by this revision concerns updates to the authorized labeling[5] to reflect the revised authorized use for tests that are within the scope of this revision. FDA's determination that the Condition of Authorization established by this revision is necessary or appropriate to protect the public health is based on the available scientific evidence and FDA's continuing efforts to evaluate the performance of authorized antigen IVDs with respect to the use of serial testing. The eliminated condition of authorization concerns the collection of additional data to evaluate the performance of authorized antigen IVDs with respect to the use of serial testing. FDA's determination that the Condition of Authorization eliminated by this revision is no longer necessary or appropriate to protect the public health in light of the antigen study.

Having concluded that the revisions to the EUAs of tests that are within the scope of this letter (section I) are appropriate to protect the public health or safety, I am hereby revising all such EUAs pursuant to Section 564(g)(2)(C), including to revise the authorized use and to establish the additional condition set forth in this letter as permitted by Section 564(e) of the Act. This

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[3] COVID-19 antigen tests are less likely to detect the SARS-CoV-2 virus than molecular tests, such as polymerase chain reaction (PCR) tests. However, repeat, or serial, antigen testing has been shown to improve the ability of an antigen test to detect the virus in time for an individual to take actions to contain the spread of disease. To investigate the performance of SARS-CoV-2 antigen serial testing and generate data to support regulatory decisions, FDA collaborated with the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School to design and implement a study (*Finding a Needle in the Haystack: Design and Implementation of a Digital Site-less Clinical Study of Serial Rapid Antigen Testing to Identify Asymptomatic SARS-CoV-2 Infection* - https://www.medrxiv.org/content/10.1101/2022.08.04.22278274v1, referred to as "the antigen study" in this letter) to assess at-home COVID-19 antigen test performance. Results from the antigen study (*Performance of Screening for SARS-CoV-2 using Rapid Antigen Tests to Detect Incidence of Symptomatic and Asymptomatic SARS-CoV-2 Infection: findings from the Test Us at Home prospective cohort study* - https://www.medrxiv.org/content/10.1101/2022.08.05.22278466v1) show that repeat testing over multiple days improves test performance and increases the likelihood that an at-home COVID-19 antigen test will accurately detect an infection. These results have informed the FDA's general understanding that repeat testing after a negative result with an at-home COVID-19 antigen test reduces the risk of a false negative result. On August 11, 2022, based on the results of the antigen study, FDA advised individuals to perform repeat, or serial, testing following a negative result on any at-home COVID-19 antigen test, to reduce the risk an infection may be missed (false negative result) and to help prevent individuals from unknowingly spreading the SARS-CoV-2 virus to others. The FDA recommended repeat testing following a negative result whether or not an individual has COVID-19 symptoms. (https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-fda-safety-communication).

[4] Generally, the authorized uses of antigen tests are described in, among other locations, the "indication" discussion and "authorized product detail" section in the letters of authorization, and in an "intended use" section in the authorized labeling.

[5] Authorized labeling impacted by the additional condition of authorization established by this letter includes some combination of the following documents: Instructions for Use (IFU), Quick Reference Instructions (QRI), laboratory Standard Operating Procedures (SOPs), electronic labeling and applications, and Fact Sheets. Note that the Fact Sheets are generated by FDA who will update the documents after it receives the supplement request to update the test's other labeling consistent with this revision.

action is based on the available scientific evidence[6] on the impact of serial testing on the performance of SARS-CoV-2 antigen tests.

I. Scope of this Revision

This letter revises all current EUAs for antigen SARS-CoV-2 IVD devices[7] as of today's date by:

(1) revising the authorized use to be for serial testing at least twice over three days for individuals with symptoms of COVID-19 and, for tests previously authorized for testing individuals without symptoms, revising the authorized use to be for serial testing at least three times over five days for individuals without symptoms of COVID-19, as set forth in Appendix A of this letter,
(2) establishing a new condition of authorization, as set forth in Section III of this letter, on such authorizations, and
(3) eliminating a condition of authorization, as set forth in Section III of this letter, on such authorizations.

This revision does not apply to EUAs for non-antigen based authorized assays (e.g., molecular, serology), EUAs for authorized IL-6 assays, EUAs for standalone specimen collection devices, or EUAs for standalone home collection kits.

All updated labeling will be added to FDA's webpage and posted with the EUA after it is submitted to FDA as required by Condition of Authorization (1) of this letter.

II. Waiver of Certain Requirements

This revision does not change the waiver of any requirements included in the EUAs being revised.

III. Revisions to Conditions of Authorization

A. Pursuant to Section 564(e) of the Act, I am establishing the additional condition below with respect to repeat testing on all authorized tests within this letter's scope.

Developer (You)

(1) You must update your authorized labeling to reflect the revised authorized use in Appendix A and as set forth in Appendix B of this letter by submitting your proposed updated labeling to FDA as a supplement to your EUA within 10 business days of today's date, unless otherwise agreed to by the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics

[6] *Performance of Screening for SARS-CoV-2 using Rapid Antigen Tests to Detect Incidence of Symptomatic and Asymptomatic SARS-CoV-2 Infection: findings from the Test Us at Home prospective cohort study* - https://www.medrxiv.org/content/10.1101/2022.08.05.22278466v1

[7] Please see the following link for currently authorized Antigen IVD devices for SARS-CoV-2: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2.

/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH). Following FDA's concurrence with the supplement, you must update your electronic labeling and electronic/mobile applications (apps) within 20 business days. You must update your paper labeling within 30 business days of FDA's concurrence and all tests distributed subsequently must be accompanied by the updated paper labeling.

B. Pursuant to section 564(g)(2)(C) of the Act, and in consideration of the establishment of Condition of Authorization (1) above, I am eliminating the following condition (or similar condition) from EUAs within the scope (section I above):

Developer (You)

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 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7/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/OPEQ/CDRH.

Sincerely,

_____

Namandjé N. Bumpus, Ph.D.
Chief Scientist
Food and Drug Administration

Enclosure

Appendix A
Revised Authorized Uses

The authorized uses for tests that are within the scope (Section I) of this letter are revised as follows:

1) Where a test was previously authorized for testing of symptomatic individuals (e.g., within the first [*number specific to each test*] days of symptom onset), the test is now authorized for use at least twice over three days with at least 48 hours between tests.
2) Where a test was previously authorized for testing of asymptomatic individuals (e.g., individuals without symptoms or other epidemiological reasons to suspect COVID-19), the test is now authorized for use at least three times over five days with at least 48 hours between tests.

Appendix B
Required Changes to Authorized Labeling

As required by Condition of Authorization (1), you must update your authorized labeling to include the labeling elements, sections, and statements below:

1. **Intended Use:**[8]

   In addition to name, technology, analyte specific information and other validated claims, the Intended Use must include the updated frequency of testing for symptomatic and asymptomatic individuals (as applicable).

   - For tests referenced in Appendix A, #1, this means including language that the test is for serial testing for use at least twice over three days with at least 48 hours between tests;
   - For tests referenced in Appendix A, #2, this means including language that the test is for serial testing for use at least three times over five days with at least 48 hours between tests and removing language regarding testing at least twice over two or three days with at least 24 and no more than 36 hours between tests.

   In addition, the Intended Use must include the following statements:

   - "negative results are presumptive"
   - "The [*Test Name*] is only for in vitro diagnostic use under the Food and Drug Administration's Emergency Use Authorization. This product has not been FDA cleared or approved."

2. **Outer Box and Subassembly Labeling (as applicable):**

   - Expiration date (sticker): Based on component of kit with the earliest expiration date
   - Summary of box contents
   - Items necessary to use the test but not provided in the test kit: *[e.g., access to computer/smartphone, internet, email account]*
   - Storage temperature
   - Summary of how the kit works

   Statements that must be present on the outer box:

   - For Emergency Use Authorization (EUA) only
   - For in vitro diagnostic use
   - In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an EUA.

[8] As discussed in footnote 4, generally the authorized uses of antigen tests are described in, among other locations, an "intended use" section in the authorized labeling. If such uses are discussed elsewhere in the authorized labeling, you must also make appropriate updates to that labeling to reflect the revised authorized uses.

- This product has been authorized only for the detection of proteins from SARS-CoV-2 [*for multi-analyte tests please insert the additional on-panel analytes, e.g., influenza A/B]*, not for any other viruses or pathogens.
- 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.
- Determining a negative result requires multiple tests. You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

3. Instructions for Use

a. <u>Lay User Labeling (applicable only to tests authorized for home use)</u>

i. Test Interpretation

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

Status on First Day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

<u>COVID-19 Positive (+)</u>

If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible [*color*] test (T) line with the control line (C) should be read as positive.

You do not need to perform repeat testing if you have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in your sample and it is very likely you have COVID-19 and are contagious. Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

COVID-19 Negative (-)

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if you have symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if you do not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in your sample. A negative result is presumptive, meaning it is not certain that you do not have COVID-19. You may still have COVID-19 and you may still be contagious. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR. If you test negative and continue to experience COVID-19-like symptoms, (e.g., fever, cough, and/or shortness of breath) you should seek follow up care with your health care provider.

Invalid

If the control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

ii. How to Use This Test

The Lay User labeling must include a specific section "How to Use this Test" with the following information:

- Serial testing should be performed in all individuals with negative results; individuals with symptoms of COVID-19 and initial negative results should be tested again after 48 hours. Individuals without symptoms of COVID-19, and with initial negative results, should be tested again after 48 hours and, if the 2nd test is also negative, a 3rd time after an additional 48 hours. You may need to purchase additional tests to perform this serial (repeat) testing.
- If you test negative but continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with your healthcare provider.
- If your test is positive, then proteins from the virus that causes COVID-19 have been found in your sample and you likely have COVID-19.

iii. Warnings, Precautions, and Safety Information

The Lay User labeling must include the following warnings, precautions and/or safety information:

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
- An anterior nasal swab sample can be self-collected by an individual age [*X*] years and older. Children age 2 to [*X*] years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test card should be used within [*X*] minutes.
- Do not read test results before [*X*] minutes or after [*Y*] minutes. Results read before [*X*] minutes or after [*Y*] minutes may lead to a false positive, false negative, or invalid result.
- If applicable: Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your [e.g., *skin, eyes, nose, or mouth*]. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your [e.g., *e.g., skin, eyes, nose, or mouth]*, flush with large amounts of water.

  If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222. *[Note: Please do not use the following website in your labeling: https://www.poison.org/contact-us. Also, please populate the following table as appropriate for your device and per FDA toxicological assessment of your device:*]

Chemical Name	GHS Code for each Ingredient	Concentrations
e.g., Microcide III	H315, skin irritation	0.2%

- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

iv. Limitations

- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between [*month, year and month, year*]. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and you likely have COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.

v. Frequently Asked Questions (FAQ):

The following FAQ section should be added to the Lay User IFU (and, if applicable, the QRI) for those Lay User IFUs that also contain the information typically found in a Patient Fact Sheet for OTC tests:

WHAT ARE THE KNOWN AND POTENTIAL RISKS AND BENEFITS OF THE TEST?

Potential risks include:

- Possible discomfort during sample collection.
- Possible incorrect test result (see Warnings and Result Interpretation sections for more information).

Potential benefits include:

- The results, along with other information, can help you and your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the potential spread of COVID-19 to your family and others in your community.

For more information on EUAs go here: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

WHAT IS THE DIFFERENCE BETWEEN AN ANTIGEN AND MOLECULAR TEST?

There are different kinds of tests for the SARS-CoV-2 virus that causes COVID-19. Molecular tests detect genetic material from the virus. Antigen tests, such as the [*Test Name*], detect proteins from the virus. Due to the lower sensitivity of antigen tests, there is a higher chance this test will give you a false negative result when you have COVID-19 than a molecular test would.

HOW ACCURATE IS THIS TEST?

Clinical studies have shown that antigen tests more accurately determine whether you are infected with the virus that causes COVID-19 when taken multiple times across several days. Repeat testing improves test accuracy. This serial testing approach is recommended to minimize the risk of incorrect results. For more information on the performance of the test and how the performance may apply to you, please refer to the performance data in the Healthcare Provider Instructions for Use (IFU), available at [***insert developer's website's address***].

WHAT IF I HAVE A POSITIVE TEST RESULT?

A positive result means that it is very likely you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. You should self-isolate from others and contact a healthcare provider for medical advice about your positive result.

WHAT IF I HAVE A NEGATIVE TEST RESULT?

A negative test result indicates that antigens from the virus that causes COVID-19 were not detected in your sample. However, if you have symptoms of COVID-19, and your first test is negative, you should test again in 48 hours since antigen tests are not as sensitive as molecular tests. If you do not have symptoms and received a negative result, you should test at least two more times with 48 hours in between tests for a total of three tests. If you have a negative result, it does not rule out SARS-CoV-2 infection; you may still be infected and you may still infect others. It is important that you work with your healthcare provider to help you understand the next steps you should take.

WHAT DOES AN INVALID TEST RESULT MEAN?

An invalid result means the test was not able to tell if you have COVID-19 or not. If the test is invalid, a new swab should be used to collect a new nasal specimen and you should test again with a new test.

IMPORTANT

Do not use this test as the only guide to manage your illness. Consult your healthcare provider if your symptoms persist or become more severe.

Individuals should provide all results obtained with this product to their healthcare provider.

b. HCP Labeling

i. Test Interpretation

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

Status on first day of Testing	First Result Day 1	Second Result Day 3	Third Result Day 5	Interpretation
With Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	N/A	Negative for COVID-19
Without Symptoms	Positive	N/A	N/A	Positive for COVID-19
	Negative	Positive	N/A	Positive for COVID-19
	Negative	Negative	Positive	Positive for COVID-19
	Negative	Negative	Negative	Negative for COVID-19

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

COVID-19 Positive (+)

If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible [*color*] test (T) line with the control line (C) should be read as positive.

Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient's doctor/primary care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-

isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the [*Test Name*] should self-isolate and seek follow up care with their physician or healthcare provider as 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.

COVID-19 Negative (-)

If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.

To increase the chance that the negative result for COVID-19 is accurate, you should:

- **Test again in 48 hours if the individual has symptoms on the first day of testing.**
- **Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.**

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection. 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.

Invalid

If the control (C) line is not visible, the test is invalid. Re-test with a new swab and new test device.

ii. Warnings, Precautions, and Safety Information

The following Warnings, Precautions, and Safety Information should be included in the full HCP IFU; in addition, the warning statements of the first three bullet points below should also be included in the Quick Reference Guide (QRI) of all tests authorized for point-of-care (PoC) use.

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2 [*for multi-analyte tests please insert the additional on-panel analytes, e.g., influenza A/B*], not for any other viruses or pathogens. 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.
- **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing**.
- An anterior nasal swab sample can be self-collected by an individual age [*X*] years and older. Children age 2 to [*X*] years should be tested by an adult.
- Do not use on anyone under 2 years of age.
- Wear a safety mask or other face-covering when collecting a specimen from a child or another individual.
- Do not use if any of the test kit contents or packaging is damaged.
- Test components are single-use. Do not re-use.
- Do not use kit past its expiration date.
- Do not touch the swab tip.
- Once opened, the test card should be used within [*X*] minutes.
- **Do not read test results before [X] minutes or after [Y] minutes. Results read before [X] minutes or after [Y] minutes may lead to a false positive, false negative, or invalid result.**
- **Keep testing kit and kit components away from children and pets before and after use. Avoid contact with your [*e.g., skin, eyes, nose, or mouth]*. Do not ingest any kit components. The reagent solution contains harmful chemicals (see table below). If the solution contacts your [e.g., *skin, eyes, nose, or mouth]*, flush with large amounts of water. If irritation persists, seek medical advice: https://www.poisonhelp.org or 1-800-222-1222**.

  [Note: Please do not use the following website in your labeling: https://www.poison.org/contact-us. Also, please populate the following table as appropriate for your device and per FDA toxicological assessment of your device:]

Chemical Name	GHS Code for each Ingredient	Concentrations
e.g., Microcide III	H315, skin irritation	0.2%

- For more information on EUAs please visit: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- For the most up to date information on COVID-19, please visit: www.cdc.gov/COVID19

iii. Limitations

- The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between [*month, year and month, year*]. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary.
- If the patient continues to have symptoms of COVID-19, and both the patient's first and second tests are negative, the patient may not have COVID-19, however additional follow-up may be needed.
- If the test is positive, then proteins from the virus that causes COVID-19 have been found in the sample and the individual likely has COVID-19.
- This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- Incorrect test results may occur if a specimen is incorrectly collected or handled.
- This test detects both viable (live) and nonviable SARS-CoV-2. Test performance depends on the amount of virus (antigens) in the sample and may or may not correlate with viral culture results performed on the same sample.

iv. Performance Section of HCP labeling

A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule.

Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 - 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in Table YYY.

Table YYY: Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

DAYS AFTER FIRST PCR POSITIVE TEST RESULT	ASYMPTOMATIC ON FIRST DAY OF TESTING			SYMPTOMATIC ON FIRST DAY OF TESTING		
	Ag Positive / PCR Positive (Antigen Test Performance % PPA)					
	1 Test	2 Tests	3 Tests	1 Test	2 Tests	3 Tests
0	9/97 (9.3%)	35/89 (39.3%)	44/78 (56.4%)	34/57 (59.6%)	47/51 (92.2%)	44/47 (93.6%)
2	17/34 (50.0%)	23/34 (67.6%)	25/32 (78.1%)	58/62 (93.5%)	59/60 (98.3%)	43/43 (100%)
4	16/21 (76.2%)	15/20 (75.0%)	13/15 (86.7%)	55/58 (94.8%)	53/54 (98.1%)	39/40 (97.5%)
6	20/28 (71.4%)	21/27 (77.8%)	16/18 (88.9%)	27/34 (79.4%)	26/33 (78.8%)	22/27 (81.5%)
8	13/23 (56.5%)	13/22 (59.1%)	4/11 (36.4%)	12/17 (70.6%)	12/17 (70.6%)	7/11 (63.6%)
10	5/9 (55.6%)	5/8 (62.5%)		4/9 (44.4%)	3/7 (42.9%)	

1 Test = one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.

2 Tests = two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests = three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

4. Fact Sheets

The Fact Sheet for Healthcare Providers (HCPs) and Fact Sheet for Patients and Fact Sheet for Individuals will be updated by FDA consistent with this revision, and FDA will provide them to you.

5. Electronic Applications (e.g., Cell Phone Apps)

Electronic applications (apps) should include a prominently placed warning for the requirement of repeat testing after a negative test result. App related software should be updated to accommodate the following minimal information:

- Test interpretation as outlined in section 3. a. i. above.
- How to Use This Test as outlined in section 3. a. ii. above
- Warning Statements:
  - In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. 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.
  - **Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.**
  - There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.
  - All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of

COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.
  - This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.
- A link to an FAQ document as described in section 3. a. v. above.

April 4, 2023

Ronald Lollar
VP, Clinical and Regulatory Affairs – Infectious Disease
Quidel Corporation
9975 Summers Ridge Road San
Diego, CA 92121

Re: EUA203086/S003
Trade/Device Name: QuickVue SARS Antigen Test
Dated: November 21, 2022
Received: November 21, 2022 Dear

Mr. Lollar:

This is to notify you that your request to update the authorized labeling of the QuickVue SARS Antigen Test; (1) in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A, and make various updates to the authorized labeling as required and described in Appendix B of the letter, (2) include results of additional reactivity studies, and (3) other minor updates that are clarifying in nature, is granted. Upon review, we concur that the information submitted in EUA203086/S003 supports the requested updates for use with the QuickVue SARS Antigen Test and fulfills Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022. The Fact Sheet for Healthcare Providers (HCPs) and Fact Sheet for Patients have been updated by FDA consistent with this revision and are included along with this letter.

By submitting this supplemental request for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 and complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the QuickVue SARS Antigen Test re-issued on November 9, 2021.

Sincerely yours,

Uwe Scherf, M.Sc., Ph.D.

Director, Division of Microbiology Devices OHT7:
Office of In Vitro Diagnostics Office of Product Evaluation and Quality

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903
www.fda.gov

EXHIBIT B

Fact Sheet for Healthcare Providers

(Starts on Following Page)

QUICKVUE® SARS ANTIGEN TEST

Quidel Corporation

April 4, 2023

All individuals whose specimens are tested with this product will receive the Fact Sheet for Patients for the product.

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the QuickVue SARS Antigen Test.

WHERE CAN I GO FOR GENERAL INFORMATION ON COVID-19?

For general information on COVID-19, including the symptoms of COVID-19, infection control precautions, and other information please check the CDC COVID-19 webpage (see links provided in "*Where can I go for updates and more information?*" section at the end of this document) or your local jurisdiction's website for the most up to date information.

WHAT DO I NEED TO KNOW ABOUT COVID-19 TESTING WITH THIS PRODUCT?

- The QuickVue SARS Antigen Test can be used to test direct anterior nasal (nares) swab specimens.
- The QuickVue SARS Antigen Test should be ordered for the detection of SARS-CoV-2 antigens by a healthcare provider.
- The QuickVue SARS Antigen Test is authorized for individuals who are suspected of COVID-19 by their healthcare provider within the first five days of the onset of symptoms when tested at least twice over three days with at least 48 hours between tests, or from individuals without symptoms or other epidemiological reasons to suspect COVID-19 when tested at least three times over five days with at least 48 hours between tests.
- The QuickVue SARS Antigen Test is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate, high or waived complexity tests.
- The QuickVue SARS Antigen Test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
- Please refer to the QuickVue SARS Antigen Test Instructions for Use for additional information.
- There is a higher chance of false negative results with antigen tests than with laboratory-based molecular tests due to the lower sensitivity of the test technology. This means that there is a higher chance this test will give a false negative result in an individual with COVID-19 as compared to a molecular test, especially in samples with low viral load.

Specimens should be collected with appropriate infection control precautions. When collecting and handling specimens from individuals suspected of being infected with the virus that causes COVID-19, appropriate personal protective equipment should be used as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19)*. For additional information, refer to CDC *Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing.*

WHAT DOES IT MEAN IF THE SPECIMEN TESTS POSITIVE FOR THE VIRUS THAT CAUSES COVID-19?

A positive test result for COVID-19 indicates that antigens from SARS-CoV-2 were detected, and therefore the individual being tested is infected with the virus and presumed to be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in determining individual diagnosis and patient management decisions and should follow current CDC guidelines.

The QuickVue SARS Antigen Test has been designed to minimize the likelihood of false positive test results. However, in the event of a false positive result, risks could include the following: a needless recommendation for the patient to isolate that might limit contact with family or friends and the ability to work, delayed diagnosis and treatment for the true infection causing the patient's symptoms, potentially increased likelihood that the patient could contract COVID-19 from other potentially COVID-19 positive patients isolated in the same areas, unnecessary prescription of a treatment or therapy, needless monitoring of close contacts for symptoms, or other unintended adverse effects.

All laboratories using this test must follow the standard testing and reporting guidelines according to their appropriate public health authorities.

WHAT DOES IT MEAN IF THE SPECIMEN TESTS NEGATIVE FOR THE VIRUS THAT CAUSES COVID-19?

A negative serial test result for this test means that SARS-CoV-2 antigens was not present in the specimen above the limit of detection. All negative results are presumptive and confirmation with a molecular assay, if necessary for patient management, may be performed. However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions (such as discontinuation of isolation precautions). Antigen tests are known to be less sensitive than molecular tests that detect viral nucleic acids.

The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day five (5) of illness may be more likely to be negative compared to a RT-PCR assay. Therefore, negative results from patients with symptom onset beyond five (5) days should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.

It is possible to test a person too early or too late during SARS-CoV-2 infection to make an accurate diagnosis via the QuickVue SARS Antigen Test.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of an individual's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. The possibility of a false negative result should especially be considered if the individual's recent exposures or clinical presentation indicate that COVID-19 is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If COVID-19 is still suspected based on exposure history together with other clinical findings, re-testing or testing with molecular methods should be considered by healthcare

providers in consultation with public health authorities. Additional testing may be helpful to ensure testing was not conducted too early.

Risks to a patient of a false negative test result include delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of COVID-19 spread within the community, or other unintended adverse events.

For additional recommendations regarding infection control, refer to CDC's *Ending Isolation and Precautions for People with COVID-19: Interim Guidance* (see links provided in "*Where can I go for updates and more information*?" section).

The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between August 2020 and December 2020. The clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

WHAT DO I NEED TO KNOW ABOUT SERIAL TESTING?

Serial testing of individuals whose initial test result is negative assists in identifying infected individuals earlier and facilitate timely infection control practices. A negative test result does not rule out infection but repeat testing over three days for symptomatic individuals or five days for asymptomatic individuals with at least 48 hours between tests may decrease the risks of false negative results.

An initial negative test result should be the first of a minimum of two tests. An asymptomatic individual undergoing serial testing who obtained two or more negative test results may require ongoing serial testing or confirmatory testing, depending on patient history and potential exposures. An asymptomatic individual undergoing serial testing who obtained one or more positive results indicates that SARS-CoV-2 antigen is present in the patient's sample but does not rule out coinfection with other pathogens.

For additional recommendations regarding confirmation of antigen test results, please refer to the CDC's *Guidance for Antigen Testing for SARS-CoV-2 for Healthcare Providers Testing Individuals in the Community* (see links provided in "*Where can I go for updates and more information*" section).

WHAT IS AN EUA?

The U.S. FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for the detection and/or diagnosis of the virus that causes COVID-19.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific

evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless the declaration is terminated or authorization is revoked sooner.

WHAT ARE THE APPROVED AVAILABLE ALTERNATIVES?

Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

WHERE DO I REPORT ADVERSE EVENTS?

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling **1-800-FDA-1088**

WHERE CAN I GO FOR UPDATES AND MORE INFORMATION?

CDC WEBPAGES:

General: https://www.cdc.gov/coronavirus/2019-ncov/index.html

Symptoms: https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html

Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html

Information for Laboratories: https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html

Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html

Isolation Precautions in Healthcare Settings: https://www.cdc.gov/infectioncontrol/guidelines/isolation/index.html

Specimen Collection: https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html

Infection Control: https://www.cdc.gov/coronavirus/2019-ncov/php/infection-control.html

Discontinuation of Isolation: https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

Antigen Testing: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

FDA WEBPAGES:

General: www.fda.gov/novelcoronavirus

EUAs: (includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas

Serial Testing: https://www.fda.gov/medical-devices/safety-communications/home-covid-19-antigen-tests-take-steps-reduce-your-risk-false-negative-results-fda-safety

QUIDEL CORPORATION:

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Technical Support:

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EXHIBIT C

Fact Sheet for Patients

(Starts on Following Page)

QUICKVUE® SARS ANTIGEN TEST

Quidel Corporation

March 31, 2023

For the most up to date COVID-19 information, including symptoms, please visit Coronavirus Disease 2019 (COVID-19) | CDC

Your sample(s) was tested for COVID-19 using the QuickVue SARS Antigen Test.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of COVID-19. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

WHAT IS COVID-19 (CORONAVIRUS DISEASE 2019)?

COVID-19 is a disease caused by the SARS-CoV-2 virus.

WHAT IS THE QUICKVUE SARS ANTIGEN TEST?

The QuickVue SARS Antigen Test is a type of test called an antigen test. Antigen tests are designed to detect proteins from the virus that causes COVID-19 in anterior nasal (nares) swab specimens.

WHY WAS MY SPECIMEN TESTED?

Testing of your specimen(s) will help find out if you may have COVID-19.

WHAT ARE THE KNOWN AND POTENTIAL RISK AND BENEFITS OF THE TEST?

Potential risks include:

- Possible discomfort or other complications that can happen during specimen collection.
- Possible incorrect test result (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of COVID-19 to your family and those you come in contact with.

WHAT DOES A POSITIVE TEST RESULT MEAN?

If you have a positive test result with the QuickVue SARS Antigen Test, it is very likely that you have COVID-19 because proteins from the virus that causes COVID-19 were found in your sample. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. You should follow CDC guidance to reduce the potential transmission of disease.

There is a chance that this test can give a positive result that is wrong (a false positive result) particularly when used in a population without many cases of COVID-19. Your healthcare provider will work with you to determine how best to care for you based on the test results along

with medical history, and your symptoms. Your healthcare provider may recommend a confirmatory test, depending on your clinical history and risk factors.

WHAT DOES A NEGATIVE TEST RESULT MEAN?

If your initial test result was negative, you should have serial testing performed (see below) and if after serial testing your test result is negative this means that antigens of the virus that causes COVID-19 were not found in your sample.

However, due to the sensitivity of antigen tests compared to molecular COVID-19 tests, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. For example, if you are tested too early during your infection. This means that you could possibly still have COVID-19 even though the test result is negative. If your test is negative, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. The amount of antigen in a sample may decrease the longer you have symptoms of infection. Specimens collected after you have had symptoms for more than five (5) days may be more likely to be negative compared to a molecular assay. It is important that you work with your healthcare provider to help you understand the next steps you should take.

WHAT IS SERIAL TESTING?

Serial testing is when a single person is tested for COVID-19 more than once using the same test. Because the amount of antigen in your sample may change over time and COVID-19 antigen tests have lower sensitivity than COVID-19 molecular tests, false results may occur. Therefore, repeated testing can identify more individuals with COVID-19 than testing a single time. By repeating testing, it may be possible to more quickly identify cases of COVID-19 and reduce spread of infection. Additional testing with a molecular COVID-19 test may be necessary, depending on your individual risk factors and test results.

WHAT ARE THE DIFFERENCES BETWEEN ANTIGEN TESTS AND OTHER COVID-19 TESTS?

There are different kinds of tests for diagnosing COVID-19. Molecular tests (also known as PCR tests) detect genetic material from the virus. Antigen tests detect proteins from the virus. Antigen tests are very specific for the virus, but are not as sensitive as molecular tests. This means that a positive result is highly accurate, but a negative result does not rule out infection. If your test result is negative, you should discuss with your healthcare provider whether an additional molecular test would help with your care, and when you should discontinue home isolation. If you do not have an additional test to determine if you are infected and may spread the infection to others, the CDC currently recommends that you should stay home until three things have happened:

- You have had no fever for at least 24 hours (that is one full day of no fever without the use of medicine that reduces fevers); **AND**
- Other symptoms have improved (for example, when your cough or shortness of breath has improved) **Loss of taste and smell may persist for weeks or months after recovery and need not delay the end of isolation; **AND**
- At least 5 days have passed since your symptoms first appeared.

For more information, the CDC has provided guidelines on how to prevent the spread of COVID- 19 if you are sick: https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/index.html

WHAT IS AN EUA?

This test has been issued an Emergency Use Authorization (EUA) by the U.S. FDA. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the emergency use of in vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect (meaning this test can be used) for the duration of the COVID-19 declaration justifying the emergency use of in vitro diagnostics, unless the declaration is terminated or authorization is revoked sooner.). An EUA is NOT an FDA-approval or clearance.

WHAT ARE THE APPROVED AVAILABLE ALTERNATIVES?

Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy- framework/emergency-use-authorization.