March 1, 2021

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

Device:	QuickVue At-Home COVID-19 Test
EUA Number:	EUA210133
Company:	Quidel Corporation
Indication:	Qualitative detection of nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for prescription home use with self-collected (unobserved) anterior nares (NS) swab specimens directly from individuals aged 14 years and older who are suspected of COVID-19 by their healthcare provider within the first six days of the onset of symptoms. This test is also authorized for prescription home use with adult-collected anterior NS samples directly from individuals aged 8 years or older who are suspected of COVID-19 by their healthcare provider within the first six days of the onset of symptoms.

Dear Mr. Lollar:

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

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.[3]

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Quidel Corporation.
[2] For ease of reference, this letter will use the term "your product" to refer to the QuickVue At-Home COVID-19 Test used for the indication identified above.
[3] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration*

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 "QuickVue At-Home COVID-19 Test Kit Healthcare Provider Instructions for Use" (identified below).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[4]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the indication above.

Authorized Product Details

Your product is a lateral flow immunoassay intended for prescription home use for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2, in anterior nares (NS) swab specimens that are self-collected directly by individuals age 14 years or older who are suspected of COVID-19 by their healthcare provider and are within the first six days of the onset of symptoms. This test is also intended for prescription home use with anterior NS samples in individuals age 8 years and older when the sample is collected by an adult. The QuickVue At-Home COVID-19 Test does not differentiate between SARS-CoV and SARS-CoV-2. Persons who test positive with the QuickVue At-Home COVID-19 Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary and for public health reporting.

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that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § *360bbb-3*. 85 FR 7316 (February 7, 2020).

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

The SARS-CoV-2 nucleocapsid protein antigen is generally detectable in anterior nares 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 and the agent detected may not be the definite cause of disease. Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out COVID-19 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. Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

Your product is performed by the individual, who upon opening the test kit performs the test as outlined in the instruction sheet included in the kit. The individual must first remove the cap from the pre-filled tube before removing the anterior nares swab from its wrapper. An anterior nasal swab specimen is then self-collected or adult-collected and then immediately placed into the open pre-filled tube. After stirring or twirling, the swab is left in the tube for at least one minute before being removed, according to the instructions, and then the Test Strip is inserted into the pre-filled tube. After 10 minutes the Test Strip is removed and test results are interpreted visually based on the presence or absence of visually detectable pink/purple colored lines.

The QuickVue At-Home COVID-19 Test includes the following materials or other authorized materials (as may be requested under Condition L. below): Swabs, Test Strips, Pre-filled Tubes, Tube Holder, instruction sheet and Fact Sheet for Patients.

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

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

- Fact Sheet for Healthcare Providers: Quidel Corporation - QuickVue At-Home COVID-19 Test
- Fact Sheet for Patients: Quidel Corporation - QuickVue At-Home COVID-19 Test

The above described product, when accompanied by the authorized labeling as set forth in the Conditions of Authorization (Section IV) is authorized to be distributed and used under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable

federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of your product, when used consistent with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your product.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that your product may be effective in diagnosing COVID-19, 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)[5]

A. Your product must comply with the following labeling requirements: the intended use statement in 21 CFR 809.10(a)(2), (b)(2); adequate directions for use in 21 U.S.C. 352(f) and 21 CFR 809.10(b)(5), (7), and (8); appropriate limitations on the use of the device

[5] "Authorized Distributor(s)" are identified by you, Quidel Corporation, in your EUA submission as an entity allowed to distribute the QuickVue At-Home COVID-19 Test.

including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

B. You and authorized distributor(s) must make available the "QuickVue At-Home COVID-19 Test User Instructions" and the "Fact Sheet for Patients" for your product in the shipped kit.

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

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

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

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

G. You and authorized distributor(s) must collect information on the performance of your product and have a process in place to track adverse events, including any occurrence of false positive or false negative results and significant deviations from the established performance characteristics of the product of which you become aware and report any such events to FDA in accordance with 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUAReporting@fda.hhs.gov).

H. 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)

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

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

K. For test kits prescribed by a telehealth service, you must ensure that the telehealth service provides individuals an electronic copy of the "QuickVue At-Home COVID-19 Test User Instructions" at the conclusion of the telehealth service. Additionally, you must provide healthcare providers the opportunity to request a copy of the "QuickVue At-Home COVID-19 Test Kit Healthcare Provider Instructions for Use" in paper form, and after such request, promptly provide the requested labeling without additional cost.

L. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and shall not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)-Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.

M. You must comply with the following requirements pursuant to FDA regulations: Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

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

O. If requested by FDA, you must submit your lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide them within 48 hours of the request.

P. You must evaluate the analytical limit of detection and assess traceability[6] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Q. You must complete the agreed upon real-time stability study for your product and notify DMD/OHT7-OIR/OPEQ/CDRH of the testing results. 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 if requested by FDA. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

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

R. You must develop a mobile phone application or website to further facilitate results reporting by both the healthcare provider and the individual using your product, and submit to FDA such application or website within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission of the mobile phone application or website to, and review of and concurrence with the developed mobile phone application or website by FDA, you must update the authorized labeling. Such labeling updates will be made in consultation with, and require concurrence of, FDA.

S. You must evaluate software validation for your future mobile application or website, including cybersecurity, in an FDA agreed upon post authorization study within 4 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the information by FDA, you will update the authorized labeling to reflect use of the App with your product (as outlined in Condition L.) prior to implementation.

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

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

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

W. You must submit to FDA a summary report within 90 calendar days of authorization summarizing the results of any testing performed using your product during that timeframe, including how many products were distributed, the positivity rate for specimens tested with your product, and how many individuals reported results to their healthcare provider as encouraged by the "QuickVue At-Home COVID-19 Test User Instructions," along with any proposed corrective action, as necessary.

Healthcare Providers

X. All prescribing healthcare providers must collect information on the performance of your product in the ordinary course of business 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.

Y. All prescribing healthcare providers must report all test results they receive from patients who use your product to relevant public health authorities in accordance with local, state, and federal requirements, using appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by the Centers for Disease Control and Prevention (available at: https://www.cdc.gov/csels/dls/sars-cov-2-livd-codes.html). Healthcare providers will also report to Quidel Corporation, when requested by Quidel, how many individuals reported test results compared to how many tests they prescribed.

Quidel Corporation (You), Authorized Distributor(s), and Healthcare Providers

Z. You, authorized distributor(s), and healthcare providers 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

AA. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act and FDA implementing regulations.

BB. 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.

CC. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved; but has been authorized by FDA under an EUA;
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens; and,
- This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.

The emergency use of your product as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure