

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 your¹ 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 product⁵ 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).

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 as 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 traceability⁹ 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,

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure