May 6, 2021

Richard Uhlig
Chief Executive Officer
Quadrant Biosciences Inc.
505 Irving Ave, Suite 3100AB
Syracuse, NY 13210

Device:	Clarifi COVID-19 Test Kit
EUA Number:	EUA202168
Company:	Quadrant Biosciences Inc.
Indication:	This test is authorized for the following indications for use: Qualitative detection of RNA from SARS-CoV-2 in saliva specimens collected in a healthcare setting using the ORAcollect•RNA (OR-100/ORE-100) or the OMNIgene•ORAL (OM-505/OME-505) collection device from individuals who are suspected of COVID-19 by their healthcare provider. Qualitative detection of nucleic acid from the SARS-CoV-2 in pooled samples containing up to twelve (12) individually collected saliva specimens. 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 requirements to perform high complexity tests.

Dear Mr. Uhlig:

On September 22, 2020, based on your[1] request the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the Clarifi COVID-19 Test Kit for the qualitative detection of RNA from SARS-CoV-2 in saliva swab specimens collected from individuals suspected of COVID-19 by their healthcare provider (HCP), pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). This test was for use with saliva swab specimens that are collected by a HCP in a healthcare setting using the ORAcollect•RNA (OR-100) saliva collection device. Testing was limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

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

On March 9, 2021, you requested to amend your Emergency Use Authorization (EUA). Based on that request and having concluded that revising the September 22, 2020, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the September 22, 2020, letter in its entirety with the revisions incorporated.[2] 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[3] is now intended for 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.[4]

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 contained in the "Clarifi COVID-19 Test Kit" 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:

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[2] The revisions to the September 22, 2020, letter and authorized labeling include: (1) update to the intended use to include the addition of the OMNIgene•ORAL (OM-505/OME-505) collection device as an authorized collection device for saliva specimens, addition of pooling of up to twelve (12) individually-collected saliva specimens, and minor updates to reflect language used in more recent authorizations, (2) update the Instructions for Use to include two additional RT-PCR instruments, addition of revised procedures and result interpretations related to sample pooling, addition of a limitation related to the performance with circulating variants, addition of results of FDA SARS-CoV-2 Reference Panel Testing, extension of specimen stability from 48 hours to 6 days and update of the name of the extraction kit, (3) update to the healthcare provider and patient fact sheets accordingly, and (4) revise the Letter of Authorization to reflect language used in more recent authorizations, update indication, update Conditions O and Q to include the OMNIgene•ORAL (OM-505/OME-505) collection device, add Conditions of Authorization related to specimen pooling (X, Y and Z), delete Condition S from the September 22, 2020 letter (fulfilled) and combine O and P from the Septebmer 22, 2020 letter in Condition O below.

[3] For ease of reference, this letter will use the term "your product" to refer to the Clarifi COVID-19 Test Kit used for the indication identified above.

[4] 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).

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.[5]

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 real-time qRT-PCR test for the qualitative detection of RNA from SARS-CoV-2 in saliva specimens collected in a healthcare setting using the ORAcollect•RNA (OR-100/ORE-100) or the OMNIgene•ORAL (OM-505/OME-505) collection device from individuals who are suspected of COVID-19 by their healthcare provider.

This test is also for the qualitative detection of nucleic acid from the SARS-CoV-2 in pooled samples containing up to twelve (12) individually collected saliva specimens. Negative results from pooled testing should not be treated as definitive. If a patient's clinical signs and symptoms are inconsistent with a negative result or results are necessary for patient management, the patient should be considered for individual testing. Specimens included in pools with a positive, presumptive positive, or invalid result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to decreased sensitivity in pooled testing.

Testing is limited to laboratories certified under CLIA, 42 U.S.C. §263a, that meet the requirements to perform high complexity tests.

The SARS-CoV-2 RNA is generally detectable in saliva specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from saliva specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by

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

PCR amplification and detection using an authorized real-time (RT) PCR instrument. The Clarifi COVID-19 Test Kit includes the following materials or other authorized materials: Quick RNA Viral 96 Kit extraction kit, 4x Reliance One-Step Multiplex Supermix, Positive Control, primers and probes and one of the two authorized saliva collection devices.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition J below), that are processed in the same way as the patient specimens and are required to be included with each batch of specimens tested with your product. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use:

- Negative Control (processing blank) - contains PCR Grade RNase-Free Water; needed to monitor contamination of reagents with amplifiable material and is included in each extraction run.
- Positive Control - needed to monitor integrity of reagents, screen for improper assay set up and RT-PCR reagent failure. The positive Control is run at least once per qRT-PCR batch of specimens.
- No template Control - contains PCR Grade RNase-Free Water; needed to monitor the RT-PCR reagents and process for contamination with amplifiable material. The control is run once per RT-PCR plate.
- Internal (Sample) Control – a primer/probe set directed towards human RNA; used to monitor for improper assay set up and reagent failure including the reverse-transcriptase reaction. This internal control is also used to screen for poor specimen collection, extraction failure, and PCR inhibition. Failure to amplify the human gene indicates a failed test.

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 the labeling entitled "Clarifi COVID-19 Test Kit" Instructions for use" (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: Quadrant Biosciences - Clarifi COVID-19 Test Kit
- Fact Sheet for Patients: Quadrant Biosciences - Clarifi COVID-19 Test Kit

The above described product, when accompanied by the Instructions for Use (identified above) and the two Fact Sheets (collectively referenced 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:

Quadrant Biosciences Inc. (You) and Authorized Distributor(s)[6]

A. Your product must comply with the following labeling requirements pursuant to FDA regulations: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

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

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 they distribute.

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

Quadrant Biosciences Inc. (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 amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

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

K. 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).

L. 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.

M. 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.

N. You must evaluate the analytical limit of detection and assess traceability[7] of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you must 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.

O. You must have a process in place to track adverse events, including any occurrence of false results with your product (including with the ORAcollect•RNA (OR-100/ORE-100) or the OMNIgene•ORAL (OM-505/OME-505) collection devices) and report to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, must be immediately reported to DMD/OHT-7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).

P. Upon request, you must conduct post-authorization studies and/or data analysis concerning the performance of saliva specimens with your authorized test. Such studies and/or data analysis must be agreed upon between you and FDA. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of the data, FDA will consider whether additional action is appropriate, such as revision or revocation of the EUA.

Q. You must submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using saliva specimens collected with the OMNIgene•ORAL (OM-505/OME-505) during that timeframe, including the positivity rate for saliva specimens.

Authorized Laboratories

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

S. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen

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

types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

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

U. 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.

V. 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 operations@quadrantbiosciences.com or by phone: 1-866-205-7336) 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.

W. All laboratory personnel using your product must be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

X. Authorized laboratories using specimen pooling strategies when testing patient specimens with your product must include with test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing and that "Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing."

Y. Authorized laboratories implementing pooling strategies for testing patient specimens must use the "Laboratory Monitoring Plan for Pooling" available in the authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.

Z. Authorized laboratories must keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the Protocol for Monitoring of Specimen Pooling Testing Strategies. For the first 12 months from the date of their creation, such records must be made available to FDA within 48 business hours for inspection upon request, and must be made available within a reasonable time after 12 months from the date of their creation.

Quadrant Biosciences Inc. (You), Authorized Distributors and Authorized Laboratories

AA. You, authorized distributors, and authorized laboratories using your product will 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, including 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.

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 for emergency use by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the detection of nucleic acid 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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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure