June 24, 2024

Mandy K. Cohen, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Rd., MS D-14
Atlanta, GA 30333

Device:	Novel Coronavirus 2012 Real-time RT- PCR Assay
EUA Number:	EUA140004
Company:	Centers for Disease Control and Prevention (CDC)
Indication:	This assay is authorized for the *in vitro* qualitative detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) RNA in nasopharyngeal or oropharyngeal swabs, sputa, and lower respiratory aspirates/washes from individuals meeting MERS clinical and/or epidemiological criteria (for example, clinical signs and symptoms associated with MERS-CoV infection, contact with a presumptive or confirmed MERS case, or history of travel to geographic locations where MERS cases were detected). Emergency use of this assay is limited to authorized laboratories.
Authorized Laboratories:	Testing is limited to Centers for Disease Control and Prevention designated laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity testing.

Dear Dr. Cohen:

On June 5, 2013, based on your[1], the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the Novel Coronavirus 2012 Real-time RT- PCR Assay, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for the indication stated in the letter.[2] Based on your requests,

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Centers for Disease Control and Prevention (CDC).

[2] The June 5, 2013, letter authorized the Novel Coronavirus 2012 Real-time RT- PCR Assay for the *in vitro* qualitative detection of MERS-CoV RNA in respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, sputa, lower respiratory aspirates/washes), sera and stool from patients with signs and symptoms of MERS-CoV infection in conjunction with clinical and epidemiological risk factors. Results were for the presumptive identification of MERS-CoV. Use within the United States was limited to qualified laboratories with training, facilities and equipment appropriate for specimen handling, testing and interpretation of the results of this real-time RT-PCR assay.

FDA reissued the letter in its entirety with revisions incorporated on June 10, 2014,[3] and granted updates on February 17, 2023.[4]

On December 22, 2023, you requested that FDA amend your EUA. Based on that request, and having concluded that revising the June 10, 2014, 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 June 10, 2014, letter in its entirety with the revisions incorporated.[5] 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[6] is now authorized for use consistent with the indication described above.

On May 29, 2013, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb- 3(b)(1)(C), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for 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 a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such an agent or agents -in this case, MERS-CoV.[7] Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of MERS-CoV, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).[8]

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[3] On June 10, 2014, the revisions to the June 5, 2013, letter and authorized labeling included: (1) expanding use of the CDC Novel Coronavirus 2012 Realtime RT -PCR Assay to include the in vitro qualitative detection of genomic RNA from MERS-CoV in clinical specimens collected from individuals meeting certain epidemiological criteria (e.g., contact with a probable or confirmed MERS-CoV case, history of travel to geographic locations where MERS-CoV cases were detected, or other epidemiologic links for which MERS-CoV testing may be indicated as part of a public health investigation) who may or may not exhibit clinical signs and symptoms associated with MERS-CoV infection; (2) creating a new Fact Sheet for Contacts of MERS-CoV Cases; and (3) updates to the Instructions for Use, product insert, and Fact Sheets for Health Care Professionals and Patients to incorporate the requested updates, where applicable.

[4] On February 17, 2023, your request was granted to make some minor updates to the Instructions for Use (IFU) for the CDC Novel Coronavirus 2012 Real-time RT-PCR Assay.

[5] The revisions to the June 10, 2014, letter and authorized labeling include: (1) updates to the intended use to remove stool and serum as specimen claims, (2) updates to the intended use for consistency with language used in more recent authorizations, (3) remove use of one of the primer/probes sets used as part of the product and update the testing algorithm accordingly, (4) remove the MagNA Pure Compact as an authorized extraction method, (5) add the QIAGEN QIAamp MinElute Virus Spin (manual) kit and QIAGEN DSP virus kit used with QIAGEN EZ1 Advanced XL platform (automated) as authorized extraction method options, (6) add the TaqPath 1-step multiplex master mix as a master mix option, (7) update the inclusivity, cross reactivity and clinical performance data, (8) include the addition of a Human Specimen Control (HSC) as an external extraction control, (9) combine the Patient and Contacts Fact Sheets into one Fact Sheet for Patients and Contacts, and (10) updating the authorized Fact Sheets and the Letter of Authorization to reflect the updates made and for consistency with language used in more recent authorizations.

[6] For ease of reference, this letter will use the term "your product" to refer to the Novel Coronavirus 2012 Real-time RT- PCR Assay for the indication identified above.

[7] As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act, the Secretary may make a determination of a public health emergency, or of a significant potential for a public health emergency.

[8] U.S. Department of Health and Human Services. *Determination and Declaration Regarding Emergency Use of In Vitro Diagnostics for Detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV).* 78 Fed. Reg. 33842 (June *5,* 2013).

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 Instructions for Use (identified below). There are FDA-cleared tests for the qualitative detection of MERS-CoV nucleic acid, but these are not adequate and available alternatives to your product.[9]

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. MERS-CoV 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 MERS-CoV, and that the known and potential benefits of your product, when used for diagnosing MERS-CoV infection, 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.[10]

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 RT-PCR test intended for the *in vitro* qualitative detection of MERS-CoV nucleic acid in nasopharyngeal or oropharyngeal swabs, sputa, and lower respiratory aspirates/washes from individuals meeting MERS clinical and/or epidemiological criteria (for example, clinical signs and symptoms associated with MERS-CoV infection, contact with a presumptive or confirmed MERS case, or history of travel to geographic locations where MERS cases were detected). Testing is limited to Centers for Disease Control and Prevention designated laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform high complexity testing.

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[9] To date, the FDA-granted FilmArray Respiratory Panel 2 Plus (Product Code: PZF; DEN170017) and the FDA-cleared FilmArray Pneumonia Panel plus (Product Code: QDS; K181324 and K222601) are available with FDA clearance for the qualitative detection of MERS-CoV nucleic acid in various clinical specimens for the presumptive identification of MERS-CoV. Available information indicates that these are not adequate and available alternatives to your product.

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

Testing with your product should not be performed unless the patient meets clinical and/or epidemiologic criteria for testing suspect specimens.

Results are for the presumptive identification of MERS-CoV RNA. MERS-CoV RNA is generally detectable in upper and lower respiratory specimens during the acute phase of infection. Positive results are indicative of active infection with MERS-CoV but do not rule out bacterial infection or co-infection with other viruses; clinical correlation with patient history, signs, symptoms, exposure likelihood, and other laboratory evidence and diagnostic information is necessary to determine patient infection status. Laboratories are required to report results to CDC. The definitive identification of MERS-CoV requires additional testing and confirmation to be performed by CDC.

Negative results with your product do not preclude MERS-CoV 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/or epidemiological information. In asymptomatic individuals, a negative result does not exclude the possibility of future illness and does not demonstrate that an individual is not infectious.

To use your product, nucleic acid is first extracted, isolated and purified from nasopharyngeal or oropharyngeal swabs, sputa, and lower respiratory aspirates/washes. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument described in the Instructions for Use. The Novel Coronavirus 2012 Real-time RT- PCR Assay includes the materials (or other authorized materials and authorized ancillary reagents as may be requested under Condition P. below) described in the Instructions for Use.

Your product requires control materials including the external quality controls, available from you separately as the "NCV-2012 rRT-PCR Assay Positive Control" with the "Novel Coronavirus 2012 Real-time RT-PCR Positive Control – Package Insert," (or other authorized control materials as may be requested under Condition P. below) to be run as outlined in the Instructions for Use.

The labeling entitled "Novel Coronavirus 2012 Real-time RT- PCR Assay Instructions for Use," the "Novel Coronavirus 2012 Real-time RT-PCR Primer and Probe Set – Package Insert," the "Novel Coronavirus 2012 Real-time RT-PCR Positive Control – Package Insert," (available at Emergency Use Authorizations for Medical Devices | FDA or at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices#coronavirus2013, and the following fact sheets pertaining to the emergency use, are 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: Centers for Disease Control and Prevention (CDC) – Novel Coronavirus 2012 Real-time RT- PCR Assay
- Fact Sheet for Patients and Contacts: Centers for Disease Control and Prevention (CDC) – Novel Coronavirus 2012 Real-time RT- PCR Assay

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), 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 consistently 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 the diagnosis of infection with MERS-CoV, 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), Subpart O (Statistical Techniques, 21 CFR 820.250) and Subpart M (Complaint Files, 21 CFR 820.198).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Centers for Disease Control and Prevention (CDC) (You) and Authorized Distributor(s)[11]

A. Your product must comply with the following labeling requirements: 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).

B. Your product must comply with the following quality system 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), Subpart O (Statistical Techniques, 21 CFR 820.250), and Subpart M (Complaint Files, 21 CFR 820.198).

C. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.

D. You and authorized distributor(s) must make available on your website(s) the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients and Contacts.

E. You and authorized distributor(s) must include a physical copy of the "Novel Coronavirus 2012 Real-time RT-PCR Primer and Probe Set – Package Insert" with each shipped product to authorized laboratories.

F. 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.

G. 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 of your product they distribute.

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.

I. You and authorized distributor(s) must make available the control material "NCV-2012 rRT-PCR Assay Positive Control" with the "Novel Coronavirus 2012 Real-time RT-PCR Positive Control – Package Insert," or other authorized control materials (as may be requested under Condition P. below), at the same time as your product.

[11] "Authorized Distributor(s)" are identified by you, Centers for Disease Control and Prevention (CDC), in your EUA submission as an entity allowed to distribute your product.

Centers for Disease Control and Prevention (CDC)

J. You must register and list consistent with 21 CFR Part 807 within one month of this letter.

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

L. You must have a signed agreement with each authorized distributor that distribution of the authorized product must be consistent with this Letter of Authorization.

M. You must maintain records of the laboratories you designate as authorized laboratories, and you must also maintain records of test usage by all such authorized laboratories.

N. If requested by FDA, you must submit associated documents and records related to your quality system for FDA review within 48 hours of the request.

O. 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).

P. You may request modifications 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 modification to this EUA should be submitted to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and requires appropriate authorization from FDA.

Q. 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.

R. 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.

S. You must evaluate the analytical limit of detection and assess traceability[12] 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/OPEQ/CDRH.

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

T. You must have a process in place to track adverse events and report to FDA pursuant to 21 CFR Part 803.

U. You must evaluate the impact of MERS-CoV 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 (via email: CDRH-EUA-Reporting@fda.hhs.gov).

V. If requested by FDA, you must update your labeling within 7 calendar days to include any additional labeling risk mitigations identified by FDA regarding the impact of viral mutations on test performance. Such updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

Authorized Laboratories

W. 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.

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

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

Z. Authorized laboratories using your product must have a process in place for reporting test results to health care providers and relevant public health authorities, as appropriate.

AA. Authorized laboratories must have a process in place to track adverse events and report to you (via email: LRN@cdc.gov) and to FDA pursuant to 21 CFR Part 803.

BB. 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.

Centers for Disease Control and Prevention (CDC), Authorized Distributor(s) and Authorized Laboratories

CC. You, authorized distributor(s), and authorized laboratories must collect information on the performance of your product and must report any significant deviations from the established performance characteristics of your product of which you or they become aware to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov). In addition, authorized distributor(s) and authorized laboratories must report to you those deviations (via email: LRN@cdc.gov).

DD. You, authorized distributor(s) and authorized laboratories 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

EE. 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.

FF. 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 diagnosis of MERS-CoV infection.

GG. 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 MERS-CoV and not for any other viruses or pathogens; and
- The EUA for this product will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection of MERS-CoV is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

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 diagnostic tests for detection of MERS-CoV 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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Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure