



August 5, 2021

Rochelle P. Walensky, MD, MPH Director  
Centers for Disease Control and Prevention  
1600 Clifton Rd., MS H21-10  
Atlanta, GA 30333

Device: Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay  
EUA: EUA201781  
Company: Centers for Disease Control and Prevention (CDC)  
Indication: A multiplexed nucleic acid test intended for simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus nucleic acids in upper or lower respiratory specimens (such as nasopharyngeal, oropharyngeal and nasal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider.<sup>1</sup> 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 Dr. Walensky:

On July 2, 2020, based on your<sup>2</sup> request that the Food and Drug Administration (FDA) issued a letter authorizing use of the Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus nucleic acids in upper or lower respiratory specimens (such as nasopharyngeal, oropharyngeal and nasal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider (refer to footnote 1) pursuant to Section 564 of the Federal Food, Drug, and Cosmetic

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<sup>1</sup> For this EUA, a healthcare provider includes, but is not limited to, physicians, nurses, pharmacists, technologists, laboratory directors, epidemiologists, or any other practitioners or allied health professionals.

<sup>2</sup> For ease of reference, this letter will use the term “you” and related terms to refer to Centers for Disease Control and Prevention (CDC).

Act (the Act) (21 U.S.C. §360bbb-3). Based on your requests, FDA granted updates to the authorized labeling on November 20, 2020<sup>3</sup> and January 8, 2021<sup>4</sup>

On July 20, 2021, you requested to revise this EUA. Based on that request, and having concluded that revising the July 2, 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 July 2, 2020, letter in its entirety with the revisions incorporated.<sup>5</sup> Accordingly, your product<sup>6</sup> is hereby authorized pursuant to section 564 of the Act when used pursuant to the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter.

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.<sup>7</sup>

There is an FDA-approved/cleared test for the qualitative detection and identification of SARS-CoV-2, influenza A virus and influenza B virus, along with some other organism types and subtypes not targeted by this test, but this is not an adequate and available alternative to your

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<sup>3</sup> On November 20, 2020, your request was granted to update the Instructions for Use (IFU) of the Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay to: (1) add the Roche MagNA Pure Compact, QIAGEN QIAcube HT, ThermoFisher KingFisher Flex Purification System, and bioMérieux NucliSENS easyMAG extraction methods as authorized extraction options for use with the test; (2) to offer the Influenza SARS-CoV-2 Multiplex Assay reagents either as the original full kit (Catalog # Flu-SC2-EUA) or split into two separate kits: one that contains the primers and probes entitled Influenza SARS-CoV-2 Multiplex Assay Primer and Probe Kit (Catalog # Flu-SC2PP-EUA) and one that contains the positive controls entitled Influenza SARS-CoV-2 Multiplex Assay Positive Controls Kit (Catalog # Flu-SC2PC-EUA); and (3) minor updates to advise use of the JOE filter instead of the VIC filter when using the alternative filter calibrations option and other general clarifications.

<sup>4</sup> On January 8, 2021, your request was granted to update the Instructions for Use (IFU) of the Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay to: (1) add the Maxwell RSC Viral Total Nucleic Acid Purification Kit used with either the Maxwell CSC 48 or Maxwell RSC 48 Instruments as an authorized extraction option for use with the test; (2) to offer an additional Influenza SARS-CoV-2 Multiplex Assay Primers and Probes Kit; and (3) minor updates and other general clarifications. In addition, FDA also concurred with the updated manufacturer information for SC2PC reagent used with the Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay and made minor updates to the IFU to reflect more recent reporting requirements for SARS-CoV-2.

<sup>5</sup> The revisions to the July 2, 2020 letter and authorized labeling include: (1) updates to the inclusivity *in silico* analysis in the performance section; (2) update the limitation section to include general variant limitation; (3) updates to the Conditions of Authorization to add new Conditions related to circulating variants (Conditions P. and Q.); (4) updates to the letter to include the additional Product Information Sheets granted January 8, 2021; and (5) updates to the IFU, Conditions of Authorization (including consolidation of several conditions in new Condition K.), Healthcare Provider and Patient Fact Sheets to reflect language used in more recent authorizations.

<sup>6</sup> For ease of reference, this EUA will use the term “your product” to refer to the Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay used for the indication identified above.

<sup>7</sup> 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).

product.. Respiratory viral infections caused by the influenza A and B viruses and SARS-CoV-2 can have similar clinical presentation and diagnostic considerations. Thus, to differentially detect SARS-CoV-2, information from a test that detects and differentiates the virus that causes COVID-19 and the common influenza viruses that cause seasonal epidemics of flu, influenza A and B (not influenza C) is needed during the flu season that coincides with the COVID-19 pandemic. 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).

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 through the simultaneous detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus nucleic acids and that the known and potential benefits of your product when used for such a use, 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.<sup>8</sup>

### **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 multiplexed nucleic acid test intended for simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus nucleic acids in upper or lower respiratory specimens (such as nasopharyngeal, oropharyngeal and nasal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate) collected from individuals suspected of respiratory viral infection consistent with COVID-19 by a healthcare provider. Symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar.

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<sup>8</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

Your product is intended for use in the detection and differentiation of SARS-CoV-2, influenza A, and/or influenza B viral Ribonucleic acid (RNA) in patient specimens, and is not intended to detect influenza C. RNA from influenza A, influenza B, and/or SARS-CoV-2 viruses is generally detectable in upper and/or lower respiratory specimens during infection. Positive results are indicative of active infection but do not rule out bacterial infection or co-infection with other viruses; 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, influenza A, and/or influenza B infection and should not be used as the sole basis for diagnosis, treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and/or epidemiological information.

To use your product, SARS-CoV-2, influenza A, and/or influenza B nucleic acids are first extracted, isolated and purified from upper or lower respiratory specimens (such as nasopharyngeal, oropharyngeal and nasal swabs, sputum, lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate). The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument. The Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay includes the following materials or other authorized materials: FluSC2 Combined Primer Mix, FluSC2 Combined Probe Mix, SIPC Seasonal Influenza Positive Control (non-infectious), SC2PC Positive Control (non-infectious).

Your product requires the following control materials, or other authorized control materials (as specified under Condition K. below), that are processed in the same way as the 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:

- Human Specimen Control (HSC): A human cell culture preparation, negative human specimen material, or an alternative commercially manufactured and distributed extraction control identified as acceptable in the Instructions for Use, used as an extraction control and positive control for the RNase P primer and probe set that is extracted and tested concurrently with each specimen extraction run.
- Positive Control: Prepared from the SIPC Seasonal Influenza Positive Control (non-infectious) and SC2PC Positive Control (non-infectious) materials provided with your product, as described in the Instructions for Use. Run with each batch of specimens. Monitors for failures of RT-PCR reagents and reaction conditions.
- No Template Control (NTC): Sterile, molecular-grade nuclease-free water included in each run. Monitors for reagent and system contamination.
- RNase P (Internal Specimen Control): The RP primer and probe set is included in each run to test for human RNase P, which controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.

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 labeling entitled “CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay Instructions for

Use,” the “Influenza SARS-CoV-2 Multiplex Assay Product Information Sheet,” the “Influenza SARS-CoV-2 Multiplex Assay Primers and Probes Kit Product Information Sheet,”<sup>9</sup> (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 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 the “authorized labeling”:

- Fact Sheet for Healthcare Providers: Centers for Disease Control and Prevention (CDC) - Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay
- Fact Sheet for Patients: Centers for Disease Control and Prevention (CDC) - Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay

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 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 authorized product, when used for the qualitative detection and differentiation of SARS-CoV-2 from influenza A, and/or influenza B and 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, through the simultaneous detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus nucleic acid, 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.

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<sup>9</sup> Influenza SARS-CoV-2 Multiplex Assay Primers and Probes Kit Product Information Sheet for CATALOG: FluSC2PP-EUA and Influenza SARS-CoV-2 Multiplex Assay Primers and Probes Kit Product Information Sheet for CATALOG: FluSC2PPB-EUA.

### **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:

#### **Centers for Disease Control and Prevention (You) and Authorized Distributor(s)<sup>10</sup>**

- 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 include a physical copy (copies) of the authorized Product Information Sheets (described above) and Fact Sheets with your product to authorized laboratories, and must make the authorized Instructions for Use electronically available with the opportunity to request a copy in paper form, and after such request, promptly provide the requested information without additional cost.
- 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 authorized labeling.
- E. 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.

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<sup>10</sup> “Authorized Distributor(s)” are identified by you, in your EUA submission as an entity allowed to distribute your device.

- F. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.
- G. You and authorized distributor(s) must collect information on the performance of your product. You will report 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) 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.
- 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.

**Centers for Disease Control and Prevention (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 amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).
- K. 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 DMD/OHT7-OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.
- L. You must comply with the following requirements under 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).
- M. 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.
- N. 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.

- O. You will evaluate the analytical limit of detection and assess traceability<sup>11</sup> of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you will update labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- P. You must evaluate the impact of viral mutations for your target analytes 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.
- Q. 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.
- R. You must have a process in place to track adverse events, including any occurrence of false results and report to FDA under 21 CFR Part 803.

### **Authorized Laboratories**

- S. Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these this labeling may be used, which may include mass media.
- T. 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 authorized under this EUA.
- U. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- V. 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.
- W. Authorized laboratories must collect information on the performance of your product and

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<sup>11</sup> Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.



report to DMD/OHT7-OIR/OPEQ/CDRH (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)) and you ([CDCSARS2FluAB@cdc.gov](mailto:CDCSARS2FluAB@cdc.gov)) 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.

- X. Authorized laboratories must report adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling 1-800-FDA-1088.
- Y. 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.

**Centers for Disease Control and Prevention (You), Authorized Distributors and Authorized Laboratories**

- Z. 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**

- 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, as applicable, 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 for emergency use by FDA under an EUA for use by authorized laboratories;
  - This product has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acids from SARS-CoV-2, influenza A virus, and influenza B virus, and 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 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