

May 29, 2020

Jinjie Hu, Ph.D.
Axteria BioMed Consulting Inc.
Representing: Healgen Scientific LLC
8040 Cobble Creek Circle
Potomac, MD 20854

Device: COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)

Company: Healgen Scientific LLC

Indication: Qualitative detection and differentiation of IgM and IgG antibodies against SARS-CoV-2 in human venous whole blood, plasma (Li+-heparin, K₂-EDTA and sodium-citrate), and serum. Intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. 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, to perform moderate or high complexity tests.

Dear Dr. Hu:

This letter is in response to your¹ request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,² pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

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

¹ For ease of reference, this letter will use the term “you” and related terms to refer to Healgen Scientific LLC

² For ease of reference, this letter will use the term “your product” to refer to the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) for the indication identified above.

vitro diagnostics for detection and/or diagnosis of the virus that causes COVID-19 subject to the terms of any authorization issued under Section 564(a) of the Act.³

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 recent or prior infection with SARS-CoV-2 by identifying individuals with an adaptive immune response to the virus that causes COVID-19, and that the known and potential benefits of your product when used for such 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.⁴

II. Scope of Authorization

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

Authorized Product Details

Your product is a qualitative test for the detection and differentiation of IgM and IgG antibodies against SARS-CoV-2 in venous whole blood, plasma (Li⁺-heparin, K₂-EDTA and sodium-citrate), and serum. The product is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

To use your product, the device cassette, specimen, and sample buffer are allowed to equilibrate to room temperature. Serum and plasma (5 µL) or one drop of venous whole blood (10 µL) is transferred to the specimen well. Then 2 drops of sample buffer are added to the buffer well. Wait for 10 minutes and read the test results. Results are not to be read after 15 minutes. An IgM Positive Result occurs when a colored line appears at the M Test Line (M) region and the colored

³ 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).

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

line changes from blue to red in the Control Line (C); this indicates that IgM against SARS-CoV-2 is present. An IgG Positive Result occurs when a colored line appears at the G Test Line (G) region and the colored line changes from blue to red in the Control Line (C); this indicates that IgG against SARS-CoV-2 is present. A positive result for IgM and IgG occurs when colored lines occur at both M and G as well as the change in color at C. A Negative Result occurs when the change in color occurs at C only and indicates that IgM and IgG antibodies against SARS-CoV-2 were not detected. An Invalid Result occurs when the line at C remains completely or partially blue and fails to completely change to red; the test should then be repeated.

Your product requires the following internal control, that is processed along with the specimen on the device cassette. The internal control listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use.

- Internal Control – The C line color change from blue to red should appear for every test and checks that flow of reagents is satisfactory.

You also recommend use of external positive and negative controls, or other authorized controls, to be 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 “COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) Instructions for Use” (available at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>), and the following product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and recipients:

- Fact Sheet for Healthcare Providers: COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)
- Fact Sheet for Recipients: COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)

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 authorized product, when used to diagnose recent or prior infection with SARS-CoV-2 by identifying individuals with an adaptive immune response to the virus and 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 diagnosing recent or prior infection with SARS-CoV-2 by identifying individuals with an adaptive immune response to the virus that causes COVID-19, when used consistently 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) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), 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:

Healgen Scientific LLC (You) and Authorized Distributor(s)⁵

- 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 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. You and authorized distributor(s) will make your product available with the authorized labeling to authorized laboratories. You may request changes to the authorized labeling. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- C. You and authorized distributor(s) will make available on your website(s) the Fact

⁵ “Authorized Distributor(s)” are identified by you, Healgen Scientific LLC, in your EUA submission as an entity allowed to distribute your device.

Sheet for Healthcare Providers and the Fact Sheet for Recipients.

- D. You and authorized distributor(s) will 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) will maintain records of the authorized laboratories to which they distribute the test and number of tests they distribute.
- F. You and authorized distributor(s) will collect information on the performance of your product. You will report to FDA any suspected occurrence of false positive and 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.
- H. You and authorized distributor(s) will make available your SARS-CoV-2 IgM and IgG Positive Control(s) and a Negative Control by June 26, 2020, and, when available, refer to condition T.

Healgen Scientific LLC (You)

- I. You will notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- J. You will 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 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. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- L. You will comply with the following requirements under FDA regulations: acceptance activities (21 CFR 820.80 and 21 CFR 820.86), nonconforming product (21 CFR 820.90), and statistical techniques (21 CFR 820.250).
- M. You may request changes to the Scope of Authorization (Section II in this letter) of your product. Such requests will be made in consultation with DMD/OHT7-OIR/OPEQ/CDRH, and require concurrence of, Office of Counterterrorism and

Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OHT7-OIR/OPEQ/CDRH.

- N. You may request the addition of other ancillary methods for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- O. You may request the addition of other specimen types for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- P. You may request the addition and/or substitution of control materials for use with your product. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- Q. You may request substitution for or changes to the authorized materials used in the detection process of human antibodies against SARS-CoV-2. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- R. You will evaluate the performance and assess traceability⁶ of your product with any FDA-recommended reference material(s) or established panel(s) of characterized clinical specimens. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, you will update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- S. You will track adverse events, including any occurrence of false results and report to FDA under 21 CFR Part 803.
- T. You recommend use of external positive and negative controls, to be run as outlined in the Instructions for Use. You will develop SARS-CoV-2 IgM and IgG Positive Control(s) and a Negative Control and submit data demonstrating reactivity levels sufficient to serve as proper control for the performance of your product. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence, you will update your labeling with the information on these external controls by June 26, 2020.
- U. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must assure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.
- V. Within 48 hours following authorization, 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 US.

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

- W. If requested by FDA, manufacturers will periodically submit new lots for testing at the National Cancer Institute (NCI), or by another government agency designated by FDA, to confirm continued performance characteristics across lots. In addition, FDA may request records regarding lot release data for tests to be distributed or already distributed. If such lot release data are requested by FDA, you must provide it within 48 hours of the request.
- X. You will complete the agreed upon real-time stability study for your product. After submission to FDA and DMD/OHT7-OIR/OPEQ/CDRH's review of and concurrence with the data, you will update your product labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

Authorized Laboratories

- Y. Authorized laboratories using your product will 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.
- Z. Authorized laboratories will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- AA. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- BB. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- CC. Authorized laboratories will 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 (info@healgen.us) 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.
- DD. All laboratory personnel using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.

Healgen Scientific LLC (You), Authorized Distributors and Authorized Laboratories

- EE. 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

FF. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product shall be consistent with authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

GG. No descriptive printed matter, including 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.

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

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the presence of IgM and IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens; and
- This test 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 authorization is terminated or 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,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures