January 26, 2022

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

Device:	COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)
EUA Number:	EUA200056
Company:	Healgen Scientific LLC
Indication:	Qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood (lithium heparin, dipotassium EDTA and sodium citrate), plasma (lithium heparin, dipotassium EDTA and sodium citrate), and serum. Intended for use as an aid in identifying individuals with an adaptive immune response 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, that meet requirements to perform moderate or high complexity tests.

Dear Ms. Pritchard:

On May 29, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing the use of the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) for the qualitative detection and differentiation of IgM and IgG antibodies against SARS-CoV-2 in human venous whole blood, plasma (Li+-heparin, K_2-EDTA and sodium-citrate), and serum, intended for use as an aid in identifying individuals with an adaptive immune response SARS-CoV-2, indicating recent or prior infection, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). 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 moderate or high complexity tests.

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Healgen Scientific LLC.

On September 23, 2021, FDA established additional Conditions of Authorization in response to the continued emergence of new variants of SARS-CoV-2.[2]

On November 17, 2021, FDA revised and reissued[3] your EUA to include new conditions that FDA determined were necessary to ensure that your product is distributed consistent with its authorization.

On July 1, 2020, you requested to amend your Emergency Use Authorization (EUA). Based on that request, and having concluded that revising the November 17, 2021 EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the November 17, 2021 letter in its entirety with the revisions incorporated.[4] Accordingly, your product[5] 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.[6]

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the "Healgen COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)" Instructions for Use (identified below).

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[2] The Viral Mutation Revision Letter – September 23, 2021, can be accessed at: https://www.fda.gov/media/152406/download.

[3] On November 17, 2021, the revisions to the May 29, 2020, letter and authorized labeling included: (i) revisions to the Letter of Authorization to include one new Condition of Authorization related to inclusion of Instructions for Use in each shipped kit, (Condition D), 11 new Conditions of Authorization related to authorized distributors (Conditions J and K, Conditions Y through GG), edits to two Conditions of Authorization related to positive and negative controls (Conditions I and T), and incorporate Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (Conditions U and V), (ii) revisions to the authorized labeling to fulfill Condition of Authorization (1) in the Viral Mutation Revision Letter – September 23, 2021, and (iii) revisions to reflect language used in more recent authorizations.

[4] The revisions to the November 17, 2021, letter and authorized labeling include: (1) revisions to the assay labeling to reflect the availability of external positive and negative controls with separate labeling per Condition T of the May 29, 2020 Letter of Authorization, (2) minor updates to the Fact Sheet for Recipients and Fact Sheet for Healthcare Providers to be consistent with language used in more recent authorizations, and (3) removal of Condition T that has been fulfilled and update to Condition I (below) concerning availability of the external positive and negative controls.

[5] 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) used for the indication identified above.

[6] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that your product may be effective in diagnosing COVID-19, and that the known and potential benefits of your product when used for diagnosing COVID-19, outweigh the known and potential risks of your product; and

3. There is no adequate, approved, and available alternative to the emergency use of your product.[7]

II. Scope of Authorization

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

Authorized Product Details

Your product is an immunoassay intended for qualitative test for the detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in venous whole blood (lithium heparin, dipotassium EDTA and sodium citrate), plasma (lithium heparin, dipotassium 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. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity.

Testing is limited to Laboratories CLIA, 42 U.S.C. §263a, that meet the requirements to perform moderate or high complexity tests.

To use your product, the clinical specimen is tested and the results interpreted according the test procedures described in the authorized labeling (described below). The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) includes the materials or other authorized materials (as may be requested under Condition N below) required to perform testing with your product as described in the authorized labeling (described below).

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

Your product requires the following procedural control, or other authorized control materials (as may be requested under Condition N below), that is processed along with the specimen on the device cassette. The procedural control must generate expected results in order for a test to be considered valid, as described in the authorized labeling (described below).

Your product also requires the use of external positive and negative controls (COVID-19 IgG/IgM CONTROL Kit) which are not included with the kit but are available from you with the "COVID-19 IgG/IgM CONTROL Kit" instructions for use, or other authorized controls (as may be requested under Condition N below), as described in the authorized labeling (described below).

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 "Healgen COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)" 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 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: Healgen Scientific LLC - COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)
- Fact Sheet for Recipients: Healgen Scientific LLC - COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)

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 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:

Healgen Scientific LLC (You) and Authorized Distributor(s)[8]

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).

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 Fact Sheet for Healthcare Providers and the Fact Sheet for Recipients.

D. You and authorized distributor(s) must include a physical copy of the "Healgen COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma)" Instructions for Use (described above) with each shipped product of the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) to authorized laboratories.

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.

[8] "Authorized Distributor(s)" are identified by you, Healgen Scientific LLC, in your EUA submission as an entity allowed to distribute your product.

F. 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.

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.

I. You and authorized distributor(s) must make available the control material (COVID-19 IgG/IgM CONTROL Kit) with the "COVID-19 IgG/IgM CONTROL Kit Package Insert" or other authorized control materials (as may be requested under Condition N below), at the same time as your product.

J. You and authorized distributor(s) must sign a quality agreement that includes all of the conditions for authorized distributors listed in this letter.

K. You and authorized distributor(s) must limit the distribution of the authorized product to at most a three-tier distribution model:
    a. Healgen to end user,
    b. Healgen to distributor to end user, or
    c. Healgen to distributor to distributor to end user.

Healgen Scientific LLC (You)

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

M. 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).

N. 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 DMD/OHT7-

OIR/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.

O. 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).

P. 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.

Q. 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.

R. You must evaluate the analytical limit of detection and assess traceability[9] 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.

S. You must have a process in place to track adverse events, including any occurrence of false results with your product and report to FDA pursuant to 21 CFR Part 803.

T. You must evaluate the impact of SARS-CoV-2 viral mutations on your product's performance. Such evaluations must occur on an ongoing basis and must include any additional data analysis that is requested by FDA in response to any performance concerns you or FDA identify during routine evaluation. Additionally, if requested by FDA, you must submit records of these evaluations for FDA review within 48 hours of the request. If your evaluation identifies viral mutations that affect the stated expected performance of your device, you must notify FDA immediately.

U. 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.

V. If requested by FDA, you must periodically submit new lots for testing at the National Cancer Institute, 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.

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

W. You must 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 must update your product labeling to reflect the additional testing. Such labeling updates must be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

X. You must follow the below listed procedures, which you provided to FDA by email on June 7, 2021:
   a. Q2-H00 – Product Requirement Determination and Contract Review, V4
   b. Q3-H01 – Order Processing Procedure, V5
   c. Q2-G00 – Quality Planning Control Procedure, V1.

   Changes to the above listed documents and procedures may only be made following FDA concurrence.

Y. You must define and document the requirements for your authorized distributors and must document that you have reviewed and evaluated each authorized distributor to ensure compliance with those requirements.

Z. You must review the marketing materials for all authorized distributors to ensure such materials are consistent with this authorization.

AA. You must review the websites of all authorized distributors on a monthly basis to ensure all information is consistent with this letter of authorization. You must document the results of these reviews and any action(s) taken to correct any materials that are not consistent with this authorization.

BB. You must notify authorized distributors about your procedure for disqualification as an authorized distributor.

Authorized Distributor(s)

CC. Authorized distributor(s) must implement Healgen's process for managing orders for the authorized product.

DD. All authorized distributor(s) must be approved by Healgen prior to receiving the authorized product for distribution and prior to accepting purchase orders from end users for the authorized product.

EE. Authorized distributor(s) must provide a report of all distribution of authorized product to Healgen on a monthly basis.

FF. As described in condition K above, authorized distributor(s) who receive the authorized product from Healgen may choose to ship product to other authorized distributors. Authorized distributors must control any such distribution of the authorized product by:

a. Sending a letter to each distributor outlining the responsibilities of authorized distributors, including a copy of this letter, and copy Healgen for verification that the information has been sent, received, and signed.
b. Training the distributor on the process of verifying that customers are authorized laboratories. Training records must be provided to Healgen no later than 10 days after approval of a distributor.
c. Monitoring all distributor websites for consistency with this letter.

Authorized Laboratories

GG. 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.

HH. Authorized laboratories using your product must use your product as outlined in the authorized labeling. 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.

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

JJ. 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.

KK. 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 Healgen Scientific LLC (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.

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

Healgen Scientific LLC (You), Authorized Distributor(s) and Authorized Laboratories

MM. You, authorized distributor(s), 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

NN. 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, as applicable, and FDA implementing regulations.

OO. 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.

PP. 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 detecting the presence of IgG and IgM antibodies to 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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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure