June 12, 2020

James X. Li, Ph.D.
Chief Executive Officer
76 TW Alexander Drive
Research Triangle Park, NC 27709

Device:	qSARS-CoV-2 IgG/IgM Rapid Test
Company:	Cellex Inc.
Indication:	Qualitative detection of IgM and IgG antibodies against SARS-CoV-2 in serum, plasma (EDTA or citrate), or venipuncture whole blood from individuals suspected of COVID-19 by their healthcare provider. 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 and high complexity tests.

Dear Dr. Li:

On April 1, 2020, based on your[1] request, the Food and Drug Administration (FDA) issued a letter authorizing 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) for the indication identified above, for use by authorized laboratories.

FDA has received multiple signals of EUA-authorized tests with variable or poorer performance than expected, including instances where independent testing shows different performance than was submitted to FDA to support Emergency Use Authorizations (EUA). Thus, FDA is reissuing the April 1, 2020, letter in its entirety with revisions incorporated[3] to authorize the emergency use of your product for the indication identified above, by authorized laboratories, having concluded that revising the April 1, 2020, letter of authorization 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)).

[1] For ease of reference, this letter will use the term "you" and related terms to refer to the Cellex Inc..
[2] For ease of reference, this letter will use the term "your product" to refer to the qSARS-CoV-2 IgG/IgM Rapid Test used for the indication identified above.
[3] The revisions to the April 1, 2020, letter include: (1) revison of the Section III Waiver of Certain Requirements to exclude waiver of some requirements, (2) addition of Conditions of Authorization under Section IV concerning good manufacturing practices, lot release procedures, and post-authorization review of test performance to ensure consistent final product is distributed that meets labeled performance, and (3) addition of a specified a period of time in Condition U, Conditions of Authorization under Section IV, and (4) minor revisions to incorporate updated language consistent with more recent EUAs.

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.[4] 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.[5]

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 Section 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.[6]

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 of IgM and IgG antibodies against SARS-CoV-2 in serum and plasma (EDTA or citrate) blood specimens and venipuncture whole blood specimens collected from individuals suspected of COVID-19 by their healthcare provider.

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[4] On February 11, 2020, the virus tentatively named 2019-nCoV was formally designated as Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Also on February 11, 2020, the disease caused by SARS-CoV-2 was formally designated as Coronavirus Disease 2019 (COVID-19). This document uses the updated names.

[5] 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).

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

Results are for the detection of SARS-CoV-2 antibodies, IgM and IgG that are generated as part of the human immune response to the virus. IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although levels over the course of infection are not well characterized. IgG antibodies to SARS-CoV-2 become detectable later following infection. Positive results for both IgG and IgM could occur after infection and can be indicative of acute or recent infection.

To use your product, the device cassette, specimen, and buffer solution are allowed to equilibrate to room temperature. Specimen (10 µL) is transferred to the center of the sample well. After the sample well is free of liquid, two drops of Sample Diluent are then added to the sample well. Wait for fifteen to twenty minutes and read the test results. Results are not to be read after twenty minutes. An IgM Positive Result occurs when a colored band appears at both the M Test Line (M) and Control Line (C) and indicates that IgM against SARS-CoV-2 is present. An IgG Positive Result occurs when a colored band appears at both the G Test Line (G) and Control Line (C) and indicates that IgG against SARS-CoV-2 is present. A positive result for IgM and IgG occurs when colored bands occur at both M and G as well as at C. A Negative Result occurs when a colored band appears at C only and indicates that IgM and IgG antibodies against SARS-CoV-2 were not detected. An Invalid Result occurs when no colored band occurs at C and the test should be repeated.

Your product requires the following internal control, that are processed along with the patient sample 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 should appear for every test and checks that flow of reagents is satisfactory.

Your product also includes external positive and negative controls, or other authorized controls, to be run as outlined in the Instructions for Use:

- Positive Control – Spiked, chemically inactivated, human serum containing IgM and IgG antibodies against SARS-CoV-2 close to the cutoff of the test. The M, G, and C lines should all appear. The positive control is used to monitor for failures of antibody detection reagents and reaction conditions.
- Negative Control – Previously characterized, chemically inactivated, negative human serum.

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, when labeled consistently with the labeling authorized by FDA, entitled “Cellex qSARS-CoV-2 IgG/IgM Rapid Test” (available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations), which may be revised in consultation with, and with concurrence of, the Division of Microbiology Devices (DMD)/Office of Health Technology 7 Office of In Vitro Diagnostics and Radiological Health (OHT7-OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH), 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.

Your product is authorized to be accompanied by the following product-specific information pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: qSARS-CoV-2 IgG/IgM Rapid Test
- Fact Sheet for Patients: qSARS-CoV-2 IgG/IgM Rapid Test

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 of IgM and IgG against SARS-CoV-2 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 for the indication above, 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.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

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 the Cellex qSARS-CoV-2 IgG/IgM Rapid Test, 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:

Cellex Inc. (You) and Authorized Distributor(s)[7]

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 provide to authorized laboratories the Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients. You may request changes to the authorized Fact Sheets. Such requests will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

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

E. 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, authorized labeling and authorized Fact Sheets.

F. 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.

G. 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.

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) will make available the control material or other

[7] "Authorized Distributor(s)" are identified by you, Cellex Inc., in your EUA submission as an entity allowed to distribute your device.

authorized control materials for purchase at the same time as your product.

Cellex Inc. (You)

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

K. You will provide its 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).

L. 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.

M. 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.

N. 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.

O. 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.

P. 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.

Q. You will evaluate the performance and assess traceability[8] 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.

R. You will track adverse events, including any occurrence of false results and report to FDA under 21 CFR Part 803.

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

S. You will complete the agreed upon capillary fingerstick whole blood study. After submission to FDA and DMD/OHT7-OIR/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

T. You will complete the agreed upon real-time stability study for your product. After submission to FDA and DMD/OHT7-OIR/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.

U. You will evaluate different transfer pipettes capable of consistently delivering 10 µL to mitigate possible operator error and submit the results to FDA within 1 month of the date of this letter. After submission to FDA and DMD/OHT7-OIR/CDRH's review of and concurrence with the data, you will update your product labeling to reflect the additional testing and the recommendation for inclusion of acceptable pipettes for use with your device. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7- OIR/OPEQ/CDRH.

V. You will comply with the following requirements under FDA regulations: 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).

W. 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.

X. Within 48 hours following this re-authorization, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of Cellex qSARS-CoV-2 IgG/IgM Rapid Test for distribution in the US.

Y. If requested by FDA, you 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.

Authorized Laboratories

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

AA. Authorized laboratories using your product will use your product as outlined in the Instructions for Use. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.

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

CC. 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.

DD. 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 (tech@cellex.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.

EE. 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. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.

Cellex Inc. (You), Authorized Distributors and Authorized Laboratories

FF. 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 Matter, Advertising and Promotion

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

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.

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.

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

Enclosures