December 16, 2021

Michael Lau
Director of Corporate Strategy
GenScript USA Inc.
860 Centennial Ave
Piscataway, NJ 08854

Device:	cPass SARS-CoV-2 Neutralization Antibody Detection Kit
EUA Number	EUA201427
Company:	GenScript USA Inc.
Indication:	Qualitative and semi-quantitative direct detection of total neutralizing antibodies to SARS-CoV-2 in human serum and dipotassium EDTA plasma. 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, that meet requirements to perform high complexity tests.

Dear Mr. Lau:

On November 6, 2020, based on your request[1] the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the cPass SARS-CoV-2 Neutralization Antibody Detection Kit for the qualitative detection of total neutralizing antibodies to SARS-CoV-2 in human serum and K_2-EDTA plasma, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). The cPass SARS-CoV-2 Neutralization Antibody Detection Kit was intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. 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 high complexity tests. FDA established additional Conditions of Authorization in response to the continued emergence of

[1] For ease of reference, this letter will use the term "you" and related terms to refer to GenScript USA Inc., a subsidiary of Genscript Biotech Corporation.

new variants of SARS-CoV-2 on September 23, 2021.[2] Based on your request, FDA reissued the letter in its entirety on November 12, 2021.[3]

On November 19, 2021, you requested to revise your Emergency Use Authorization (EUA). Based on this request, and having concluded that revising the November 12, 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 12, 2021, letter in its entirety with the revisions incorporated.[4] Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product[5] is authorized for use consistent with the indication described above.

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 included in the "cPass SARS-CoV-2 Neutralization Antibody Detection Kit" 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] The revisions to the November 6, 2020, letter and authorized labeling included: 1) modification of the intended use to include semi-quantitative detection and additions to the authorized labeling reflecting this claim, 2) addition of a limitation in the Instructions for Use (IFU) related to performance for individuals who have received a COVID-19 vaccine, 3) extension of kit stability to nine months when stored at 2 – 8 ℃, 4) addition of the "SARS-CoV-2 Neutralizing Antibody Calibrator" Instructions for Use, and addition of Product Information Cards (PICs) for both the assay and calibrator kits, 5) updating the Conditions of Authorization to add new Condition L, below, related to periodic testing at the National Cancer Institute and incorporation of Conditions of Authorization (2) and (3) from the Viral Mutation Revision Letter – September 23, 2021 (Conditions T and U, below), and 6) updates to the assay IFU, the Conditions of Authorization and Fact Sheets for Healthcare Providers and Recipients to reflect language used in more recent authorizations and 7) updates to the authorized labeling to fulfill Condition of Authorization (1) in the Viral Mutation Revision Letter – September 23, 2021.

[4] The revisions to the November 12, 2021, letter and authorized labeling include: 1) add a new business unit, Nanjing GenScript Diagnostics Technology Co., Ltd., who will be fully responsible for the manufacturing, supply and business-related decisions of the cPass SARS-CoV-2 Neutralization Antibody Detection Kit, 2) corrections to the IFU related to calibrator volume and test procedures, and 3) updates to the IFU, Fact Sheets for Healthcare Providers and Recipients and Letter of Authorization to include the new business unit.

[5] For ease of reference, this letter will use the term "your product" to refer to the cPass SARS-CoV-2 Neutralization Antibody Detection Kit, manufactured at Nanjing GenScript Diagnostics Technology Co., Ltd., a subsidiary of GenScript Biotech Corporation, 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 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.[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 a blocking Enzyme-Linked Immunosorbent Assay (ELISA) intended for the qualitative and semi-quantitative direct detection of total neutralizing antibodies to SARS-CoV-2 in human serum and dipotassium EDTA plasma. 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. Semi-quantitative results from your product should not be interpreted as an indication or degree of immunity or protection from infection. Testing is limited to laboratories certified under CLIA, 42 U.S.C. §263a, that meet the requirements to perform high complexity tests.

The test mimics the virus neutralization process. The kit contains two key components: Horseradish peroxidase (HRP) conjugated recombinant SARS-CoV-2 RBD fragment (HRP-RBD) and the human ACE2 receptor protein (hACE2). If the neutralizing antibodies against SARS-CoV-2 RBD are sufficient in the serum or plasma, the protein-protein interaction between HRP-RBD and hACE2 can be blocked.

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

First, the samples or controls are pre-incubated with the HRP-RBD to allow the binding of the circulating neutralization antibodies to HRP-RBD forming HRP-RBD/neutralizing antibodies complexes. The mixture of unbound HRP-RBD and HRP-RBD/neutralizing antibodies complexes is then added to the capture plate, which is pre-coated with the hACE2 protein, the SARS-CoV-2 receptor. The unbound HRP-RBD will be captured on the plate, while the complexes of circulating neutralization antibodies to HRP-RBD remain in the supernatant and get removed during washing. After washing steps, 3,3′,5,5′-Tetramethylbenzidine TMB solution is added, making the color blue. By adding Stop Solution, the reaction is quenched, and the color turns yellow. The Optical Density (OD) of the final solution is read at 450 nm in a microtiter plate reader. Inhibition is defined as [1- (OD value of Sample)/(OD value of Negative Control)]100%. When Inhibition is ≥ 30%, the sample is positive for neutralizing antibodies. When Inhibition is < 30%, the sample is negative for neutralizing antibodies. The test is calibrated by use of the SARS-CoV-2 Neutralizing Antibody Calibrator. The semi-quantitative results are expressed in Units/mL.

The cPass SARS-CoV-2 Neutralization Antibody Detection Kit includes the following materials or other authorized materials: pre-coated 96 well microplates, positive control, negative control, conjugate, conjugate dilution buffer, sample dilution buffer, wash solution, TMB solution, stop solution.

Your product requires the use of the SARS-CoV-2 Neutralizing Antibody Calibrator which is not included with the kit but is available from you with the "SARS-CoV-2 Neutralizing Antibody Calibrator" Instruction for Use. The SARS-CoV-2 Neutralizing Antibody Calibrator consists of one vial of SARS-CoV-2 neutralizing monoclonal antibody in phosphate buffer with 2% BSA, 0.1% Proclin-300.

Your product requires the following authorized external positive and negative controls, or other authorized controls (as may be requested under Condition O below):

- Negative Control - The Negative Control must have an OD reading > 1.0 – used to assure the validity of the results.
- Positive Control - The Positive Control contains SARS-CoV-2 neutralizing antibodies and must have an OD reading < 0.3 – used to assure the validity of the results.

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 "cPass SARS-CoV-2 Neutralization Antibody Detection Kit" Instructions for Use.

The labeling entitled "cPass SARS-CoV-2 Neutralization Antibody Detection Kit" Instructions for Use, "SARS-CoV-2 Neutralizing Antibody Calibrator" 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), the two Product Information Cards (PICs) 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 "authorized labeling":

- Fact Sheet for Healthcare Providers: GenScript USA Inc. – cPass SARS-CoV-2 Neutralization Antibody Detection Kit
- Fact Sheet for Recipients: GenScript USA Inc. – cPass SARS-CoV-2 Neutralization Antibody Detection Kit

The above described product, when accompanied by the authorized labeling as set forth in the Conditions of Authorization, 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 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 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:

GenScript USA Inc. (You) and Authorized Distributor(s)[8]

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) 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 applicable PIC card with each shipped cPass SARS-CoV-2 Neutralization Antibody Detection Kit, and SARS-CoV-2 Neutralizing Antibody Calibrator to authorized laboratories, and will make the "cPass SARS-CoV-2 Neutralization Antibody Detection Kit" Instructions for Use and "SARS-CoV-2 Neutralizing Antibody Calibrator" Instructions for Use electronically available with the opportunity to request a copy in paper form, and after such request, you must promptly provide the requested information without additional cost.

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.

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 must 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) (via email: CDRH-EUA-Reporting@fda.hhs.gov) 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

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

information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

GenScript USA Inc. (You) and Nanjing GenScript Diagnostics Technology Co., Ltd.

I. You and Nanjing GenScript Diagnostics Technology Co., Ltd., 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).

J. You and Nanjing GenScript Diagnostics Technology Co., Ltd., 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.

K. If requested by FDA, you and Nanjing GenScript Diagnostics Technology Co., Ltd., 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.

L. If requested by FDA, you and Nanjing GenScript Diagnostics Technology Co., Ltd., 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.

GenScript USA Inc. (You)

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

N. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).

O. 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.

P. You must evaluate the performance and assess traceability[9] of your product with any FDA-recommended reference material(s) or established panel(s) of characterized clinical specimens. 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.

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

R. You must complete the agreed upon real-time stability studies for your product. 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. If requested by FDA, you must participate in a National Institutes of Health independent evaluation of your product. After submission to and concurrence with the data by FDA, you must 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 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 (via email: CDRH-EUA-Reporting@fda.hhs.gov).

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

Authorized Laboratories

V. 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.

W. Authorized laboratories must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other

[9] Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material. FDA may request, for example, that you perform this study in the event that we receive reports of adverse events concerning your product.

ancillary reagents and authorized materials required to use your product are not permitted.

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

Y. 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.

Z. 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 to you (at qa@genscript.com) 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.

AA. 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.

GenScript Inc. (You), Nanjing GenScript Diagnostics Technology Co., Ltd., Authorized Distributor(s) and Authorized Laboratories

BB. You, Nanjing GenScript Diagnostics Technology Co., Ltd., authorized distributor(s), 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

CC. 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.

DD. 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.

EE. 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 total neutralizing 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,

_____
Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Enclosure
cc: Daniel F. Simpson, RAC, Sr. Director, Clinical and Regulatory Affairs, Corgenix Inc. (representing GenScript USA Inc.)