

December 17, 2020

Aditi Luthra
Genophyll Enterprises, LLC
Representing: 3B Blackbio Biotech India Ltd, a subsidiary of Kilpest India Ltd.
100 Davidson Avenue, Suite 109
Somerset, NJ, 08873

Device: TRUPCR SARS-CoV-2 Kit

Company: 3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd.
("3B Blackbio Biotech India Ltd.")

Indication: Qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal and oropharyngeal swabs, anterior nasal swab and mid-turbinate nasal swabs, nasopharyngeal aspirate/wash or nasal aspirates, and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider (HCP).

Qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens that are collected with the assistance of a HCP in a healthcare setting using the OMNIgene-ORAL OM-505/OME-505 saliva collection device by individuals suspected of COVID-19 by their HCP.

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 Aditi Luthra:

On June 18, 2020, based on your¹ request, the Food and Drug Administration (FDA) issued a letter authorizing the emergency use of the TRUPCR SARS-CoV-2 Kit for the qualitative detection of nucleic acid from SARS-CoV-2 nasopharyngeal and oropharyngeal swabs, anterior nasal swab and mid-turbinate nasal swabs, nasopharyngeal aspirate/wash or nasal aspirates, and bronchoalveolar lavage (BAL) specimens from individuals suspected of COVID-19 by their healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the

¹ For ease of reference, this letter will use the term "you" and related terms to refer to 3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd.

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 high complexity tests. Based on your request, FDA granted updates to the Instructions for Use (IFU) on July 21, 2020.²

On October 28, 2020, you requested to further revise your Emergency Use Authorization (EUA). Based on these requests, and having concluded that revising the June 18, 2020, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the June 18, 2020, letter in its entirety with the revisions incorporated.³ 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 product⁴ is now 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.⁵

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 Instructions for Use (identified below).

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

I. Criteria for Issuance of Authorization

² On July 21, 2020, your request was granted to update the Instructions for Use (IFU) to (1) add two alternative workflows to help conserve resources of the TRUPCR SARS-CoV-2 Detection Kit, and (2) include minor updates to the IFU for clarification.

³ The revisions to the June 18, 2020, letter include: (1) addition of the qualitative detection of nucleic acid from SARS-CoV-2 in saliva specimens that are collected with the assistance of a healthcare provider (HCP) in a healthcare setting using the OMNIgene·ORAL OM-505/OME-505 saliva collection device by individuals suspected of COVID-19 by their HCP; (2) add use of the Applied Biosystems QuantStudio 5 Real-Time PCR instrument with software version 1.5.0 to the IFU; (3) inclusion of additional analytical and clinical data to the IFU; (4) new conditions of authorization specific to the saliva collection device; (5) update and consolidation of conditions to reflect more recent authorizations; and (6) associated revisions to IFU, healthcare provider fact sheet, and patient fact sheet to reflect addition of saliva.

⁴ For ease of reference, this letter will use the term “your product” to refer to the TRUPCR SARS-CoV-2 Kit used for the indication identified above.

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).

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 nucleic acid from SARS-CoV-2 in nasopharyngeal and oropharyngeal swabs, anterior nasal swab and mid-turbinate nasal swabs, nasopharyngeal aspirate/wash or nasal aspirates, and bronchoalveolar lavage (BAL) specimens collected from individuals suspected of COVID-19 by their healthcare provider (HCP). Your product is also for use with saliva specimens that are collected with the assistance of a HCP in a healthcare setting using the OMNIgene·ORAL OM-505/OME-505 saliva collection device by individuals suspected of COVID-19 by their HCP.

The SARS-CoV-2 nucleic acid is generally detectable in respiratory and saliva specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2 nucleic acid; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information. Negative results for SARS-CoV-2 RNA from saliva should be confirmed by testing of an alternative specimen type if clinically indicated.

To use your product, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from nasopharyngeal and oropharyngeal swabs, anterior nasal swab and mid-turbinate nasal swabs, nasopharyngeal aspirate/wash or nasal aspirates, bronchoalveolar lavage (BAL), and saliva specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument. The TRUPCR SARS-CoV-2 Kit includes the following materials or other authorized materials: Master Mix,

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

Enzyme Mix, Primer Probe Mix-1, Primer Probe Mix-2, Water (RNase free), Negative Control, High Positive Control, and Low Positive Control.

Your product requires the following control materials, or other authorized control materials (as may be requested under Condition J. below), that are processed in the same way as the specimens and are required to be included with each batch of specimens tested with your product. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Instructions for Use:

- Internal Control – The RNase P primer and probe set is included in both assay tubes to test for human RNase P in clinical samples. The internal control monitors for specimen quality and demonstrates that nucleic acid was generated by the extraction process.
- Positive Control (PC) – The high and low positive controls consist of DNA plasmids harboring RdRP, E, and N genes mixed in equal concentrations to monitor for failures of rRT-PCR reagents and reaction conditions.
- Negative Control (No Template Control, NTC) – RNase-free water used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.

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 “TRUPCR SARS-CoV-2 Kit Instructions for Use” (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>), and 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: 3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd. - TRUPCR SARS-CoV-2 Kit
- Fact Sheet for Patients: 3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd. - TRUPCR SARS-CoV-2 Kit

The above described product, when accompanied by the Instructions for Use (identified above), the “TRUPCR Viral RNA Extraction Kit Instructions for Use” 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 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 for

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:

3B Blackbio Biotech India Ltd. (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.
- C. You and authorized distributor(s) will make available on your website(s) the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.

⁷ “Authorized Distributor(s)” are identified in your EUA submission as an entity allowed to distribute your device.

- 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/or 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 or 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.

3B Blackbio Biotech India Ltd. (You)

- H. You will notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).
- I. 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).
- J. You may request changes to this EUA, 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 Division of Microbiology (DMD)/Office of Health Technology 7 (OHT&)_Office of In Vitro Diagnostics and Radiological Health (OIR)/Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) and require appropriate authorization from FDA prior to implementation.
- K. 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).
- L. 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.

- M. 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.
- N. You will evaluate the analytical limit of detection and assess traceability⁸ of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, 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.
- O. You will have a process in place to track adverse events, including any occurrence of false results and report to FDA in accordance with 21 CFR Part 803.
- P. You will submit to FDA a summary report within 30 calendar days of authorization summarizing the results of any testing performed using saliva specimens collected with the OMNIgene·ORAL OM-505/OME-505 during that timeframe, including the positivity rate for saliva specimens.

Authorized Laboratories

- Q. 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.
- R. Authorized laboratories using your product will use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- S. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- T. 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.
- U. 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 (mail@genophyll.com and info@3bblackbio.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.

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

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

3B Blackbio Biotech India Ltd. (You), Authorized Distributors and Authorized Laboratories

- W. 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

- X. 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 and FDA implementing regulations.
- Y. 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.
- Z. All descriptive printed matter, advertising, and promotional materials relating to the use of your product shall clearly and conspicuously state that:
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
 - This product has been authorized only for the detection of nucleic acid from 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,

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosure