



August 18, 2021

Gary K. Price
Head of Regulatory Affairs and Quality Assurance
Infinity BiologiX LLC
30 Knightsbridge Road
Piscataway, NJ 08854

Device: Infinity BiologiX TaqPath SARS-CoV-2 Assay

EUA: EUA200090

Company: Infinity BiologiX LLC

Indication: This test is indicated for the following indications for use:

Qualitative detection of nucleic acid from Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in oropharyngeal (throat) swab, nasopharyngeal swab, anterior nasal swab, mid-turbinate nasal swab, and bronchoalveolar lavage (BAL) fluid from individuals suspected of COVID-19 by their healthcare provider.

When determined to be appropriate by a healthcare provider, this test is also for use with saliva specimens that are self-collected at home using the IBX Saliva Collection Kit or that are collected in a healthcare setting by individuals using the Spectrum Solutions SDNA-1000 Saliva Collection Device.

This test is also for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled saliva samples containing up to 5 individual saliva specimens that are self-collected at home using the IBX Saliva Collection Kit or that are collected in a healthcare setting by individuals using the Spectrum Solutions SDNA-1000 Saliva Collection Device, when determined to be appropriate by healthcare provider.

Authorized Laboratories: Testing is limited to Infinity BiologiX LLC laboratories, located at Nelson Biological Sciences, C-Wing, 604 Allison Road, Piscataway, NJ 08854 and 3510 Hopkins Place, Bldg 4, Oakdale, MN 55128, which are certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a and meet requirements to perform high-complexity tests.

Dear Mr. Price:

On April 10, 2020, based on a request from Rutgers Clinical Genomics Laboratory at RUCDR Infinite Biologics – Rutgers University (“Rutgers”), the Food and Drug Administration (FDA) issued a letter determining that the Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay met the criteria for issuance under section 564(c) of the Act to be eligible for authorization under the March 31, 2020, Emergency Use Authorization (EUA) for Molecular-based Laboratory Developed Tests for Detection of Nucleic Acid from SARS-CoV-2 (High Complexity LDT umbrella EUA) for the qualitative detection of nucleic acid from SARS-CoV-2 in respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). As authorized under the High Complexity LDT umbrella EUA, testing was limited to the single laboratory that developed the authorized test and that is certified under CLIA, 42 U.S.C. §263a, to perform high complexity tests pursuant to the Scope of Authorization and Conditions of Authorization of that EUA.¹ Based on your requests, on May 7, 2020,² September 18, 2020,³ and November 13, 2020.⁴ FDA authorized the use of the assay with revisions incorporated. FDA granted updates to the authorized labeling on November 30, 2020⁵, March 11, 2021⁶ and May 27, 2021.⁷

¹ In this case testing was limited to Rutgers Clinical Genomics Laboratory (RCGL) at RUCDR Infinite Biologics – Rutgers University, Piscataway, NJ, that is a CLIA, 42 U.S.C. §263a, certified high-complexity laboratory.

² On April 30, 2020, FDA received a request from Rutgers to revise the Scope of Authorization and thus, the test’s intended use as originally specified by the High Complexity LDT umbrella EUA, to include home collection of saliva specimens using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device when determined to be appropriate by a healthcare provider. In response to that request, because the requested revision to the test’s intended use was beyond the Scope of Authorization of the High Complexity LDT umbrella EUA, FDA authorized the use of the Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay, pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of the May 7, 2020 letter of authorization, for the qualitative detection of nucleic acid from SARS-CoV-2 in oropharyngeal (throat) swab, nasopharyngeal swab, anterior nasal swab, mid-turbinate nasal swab, and bronchoalveolar lavage (BAL) fluid from individuals suspected of COVID-19 by their healthcare provider. As part of the authorization, the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device could be used to self-collect saliva specimens at home or in a healthcare setting by individuals when determined to be appropriate by a healthcare provider. In the May 7, 2020, letter, testing was limited to Rutgers Clinical Genomics Laboratory (RCGL) at RUCDR Infinite Biologics – Rutgers University, Piscataway, NJ, that is a CLIA, 42 U.S.C. §263a, certified high-complexity laboratory.

³ On August 12 and 13, 2020, FDA received requests from Rutgers and Infinity BiologiX LLC, respectively, to amend the EUA for the Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay to transfer the EUA from Rutgers to Infinity BiologiX LLC and update the device name to Infinity BiologiX TaqPath SARS-CoV-2 Assay. On September 18, 2020, additional revisions to the May 7, 2020, letter included revisions to (1) update the authorized labeling, (2) revise the Conditions of Authorization to apply to Infinity BiologiX LLC, and (3) add appropriate Conditions of Authorization for authorized distributors.

⁴ On October 29, 2020, FDA received a request from Infinity BiologiX LLC to add a second Infinity BiologiX LLC authorized laboratory at 3510 Hopkins Place, Bldg 4, Oakdale, MN 55128.

⁵ On November 30, 2020, your request was granted to add an authorized distributor to distribute the IBX Saliva Collection Kit under the brand name AZOVA At-Home COVID-19 Test Collection Kit for use with the Infinity BiologiX TaqPath SARS-CoV-2 Assay.

⁶ On March 11, 2021, your request was granted to add an authorized distributor to distribute the IBX Saliva Collection Kit under the brand name Wellness 4 Humanity SDNA-1000 Saliva Collection Kit for use with the Infinity BiologiX TaqPath SARS-CoV-2 Assay.

⁷ On May 27, 2021, your supplement was acknowledged via email to update the EUA Summary of your product with results from testing with the FDA SARS-CoV-2 Reference Panel.

On June 23, 2021, you⁸ requested to further amend this EUA. Based on that request, and having concluded that revising the November 13, 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 November 13, 2020, letter in its entirety with the revisions incorporated.⁹ Accordingly, your product¹⁰ 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.¹¹

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 EUA Summary (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 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:

⁸ For ease of reference, this EUA will use the term “you” and related terms to refer to Infinity BiologiX LLC.

⁹ The revisions to the November 13, 2020, letter and authorized labeling include: (1) update the point of contact, (2) update the intended use to include a claim for the “*qualitative detection of nucleic acid from SARS-CoV-2 in pooled saliva samples containing up to 5 individual saliva specimens that are self-collected at home using the IBX Saliva Collection Kit or that are collected in a healthcare setting by individuals using the Spectrum Solutions SDNA-1000 Saliva Collection Device, when determined to be appropriate by healthcare provider*” and associated updates to the Healthcare Provider and Patient Fact Sheets, laboratory SOPs, EUA Summary and Letter of Authorization to reflect the updated indication, (3) updates to the Conditions of Authorization to add new Conditions related to circulating variants (Conditions K. and L.) and conditions associated with the updated intended use for pooling (Conditions U., V. and W.); (4) addition of new laboratory SOPs related to the new intended use and also updates to the previous laboratory SOPs, and (5) updates to the IFU, Conditions of Authorization, Healthcare Provider and Patient Fact Sheets to reflect language used in more recent authorizations.

¹⁰ For ease of reference, this EUA will use the term “your product” to refer to the entire test system – e.g., the Infinity BiologiX TaqPath SARS-CoV-2 Assay, controls, ancillary reagents, other materials, the Spectrum Solutions SDNA-1000 Saliva Collection Device, and the IBX Saliva Collection Kit – authorized under this EUA as outlined in the Scope of Authorization (Section II) and Conditions of Authorization (Section IV).

¹¹ 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).

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.¹²

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 test system that includes the Infinity BiologiX TaqPath SARS-CoV-2 Assay, controls, ancillary reagents, other materials, the Spectrum Solutions SDNA-1000 Saliva Collection Device, and the IBX Saliva Collection Kit. The product is authorized to be distributed and used as described in this letter, despite the fact that the product does not meet certain requirements otherwise required by applicable federal law.

The test is a qualitative test for the detection of nucleic acid from SARS-CoV-2 in oropharyngeal (throat) swab, nasopharyngeal swab, anterior nasal swab, mid-turbinate nasal swab, and bronchoalveolar lavage (BAL) fluid from individuals suspected of COVID-19 by their healthcare provider.

When determined to be appropriate by a healthcare provider, this test is also for use with saliva specimens that are self-collected at home using the IBX Saliva Collection Kit or that are collected in a healthcare setting by individuals using the Spectrum Solutions SDNA-1000 Saliva Collection Device.

This test is also for the qualitative detection of nucleic acid from SARS-CoV-2 in pooled saliva samples containing up to 5 individual saliva specimens that are self-collected at home using the IBX Saliva Collection Kit or that are collected in a healthcare setting by individuals using the Spectrum Solutions SDNA-1000 Saliva Collection Device, when determined to be appropriate by healthcare provider. Negative results from pooled testing should not be treated as definitive. If a patient's clinical signs and symptoms are inconsistent with a negative result or results are necessary for patient management, the patient should be considered for individual testing. Specimens included in pools with a positive and indeterminate result must be tested individually prior to reporting a result. Specimens with low viral loads may not be detected in sample pools due to decreased sensitivity in pooled testing.

¹² No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

Testing is limited to Infinity BiologiX, Nelson Biological Sciences, C-Wing, 604 Allison Road, Piscataway, NJ 08854, and 3510 Hopkins Place, Bldg 4, Oakdale, MN 55128, which are certified under CLIA, 42 U.S.C. §263a and meet requirements to perform high-complexity tests.

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 test, SARS-CoV-2 nucleic acid is first extracted, isolated and purified from in oropharyngeal (throat) swab, nasopharyngeal swab, anterior nasal swab, mid-turbinate nasal swab, saliva and BAL fluid. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using an authorized real-time (RT) PCR instrument. Your test uses all commercially sourced materials or other authorized materials and authorized ancillary reagents commonly used in clinical laboratories as described in the authorized labeling.

Your test requires the following control materials, or other authorized control materials (as may be requested under Condition I. below), that are to be run as outlined in the authorized labeling. All controls listed below must generate expected results in order for a test to be considered valid, as outlined in the authorized labeling (described below):

- Internal Control – MS2 Phage – added to each specimen and the negative control prior to extraction - controls for specimen quality and demonstrates that nucleic acid was generated by the extraction process.
- Positive Control - monitors the integrity of the RT-PCR reagents and process.
- Negative Control – monitors for cross-contamination during RNA extraction and RT-PCR.
- No Template (Negative) Control - Nuclease-free, molecular-grade water used to monitor non-specific amplification, cross-contamination during experimental setup, and nucleic acid contamination of reagents.

Your test also requires the use of additional authorized materials and authorized ancillary reagents that are not included with your product and which are described in the authorized labeling.

The above described test is authorized to be accompanied with the EUA Summary (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>), the Infinity BiologiX LLC Standard Operating Procedures (SOPs) bundle,¹³ and the following product-specific information

¹³ The SOP bundle consists of the following: 103-0010 Sample Registration and Accessioning in IBX LIMS, 503-

pertaining to the emergency use, which is required to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Infinity BiologiX LLC - Infinity BiologiX TaqPath SARS-CoV-2 Assay
- Fact Sheet for Patients: Infinity BiologiX LLC - Infinity BiologiX TaqPath SARS-CoV-2 Assay

The above described product, when accompanied by the Infinity BiologiX LLC Standard Operating Procedures (SOPs) bundle (see footnote 13) the EUA Summary (identified above) and the two Fact Sheets is authorized to be distributed to and used by the authorized laboratories (i.e., limited to Infinity BiologiX, Nelson Biological Sciences, C-Wing, 604 Allison Road, Piscataway, NJ 08854, and 3510 Hopkins Place, Bldg 4, Oakdale, MN 55128) under this EUA, despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

The IBX Saliva Collection Kit and Spectrum Solutions SDNA-1000 Saliva Collection Device when accompanied by the “Patient Self-collection Kit and Collection Process SOP – Telehealth” and “Patient Self-collection Kit and Collection Process SOP” instructions (for the IBX Saliva Collection Kit) and patient instructions that accompany the Spectrum Solutions SDNA-1000 Saliva Collection Device, are authorized to be distributed and used as part of the above described product for use with the test as set forth in this EUA.

“Authorized labeling” refers to the EUA Summary, Infinity BiologiX LLC SOPs bundle (see footnote 13), two Fact Sheets, “Patient Self-collection Kit and Collection Process SOP – Telehealth” and “Patient Self-collection Kit and Collection Process SOP” instructions (for the IBX Saliva Collection Kit) and patient instructions that accompany the Spectrum Solutions SDNA-1000 Saliva Collection Device.

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 the indication above, 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

0013 Infinity BiologiX Clinical Genomics Laboratory TaqPath SARS-CoV-2 Assay, 503-0017 Infinity BiologiX Taqpath SARS-CoV-2 Testing with Pooling Methodology, 2003-0360 Purification of Viral DNA-RNA Using the Chemagic 360 with the Thermo TaqPath COVID-19 Assay, 2003-0425 Purification of Viral DNA-RNA Using the Chemagic 360 with Pooled Source Samples, 2003-0426 Transfer of Saliva Samples to Intermediate Tubes and DWPs on Hamilton STAR and STARlet, 2003-0451 Saliva based pooling sample deconvolution for retesting and reporting in Project Destiny.

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.

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Infinity BiologiX LLC (You) and Authorized Distributor(s)¹⁴

- A. You and authorized distributors will make available all instructions related to the self-collection of saliva specimens using the IBX Saliva Collection Kit and Spectrum Solutions SDNA-1000 Saliva Collection Device, both in the shipped kit and on your website.
- B. Through a process of inventory control, you and authorized distributor(s) will maintain records of the numbers and locations to which the IBX Saliva Collection Kit and/or Spectrum Solutions SDNA-1000 Saliva Collection Device are distributed.
- C. You and authorized distributor(s) will maintain customer complaint files on record. You will report to FDA any significant complaints about usability or deviations from the established performance characteristics of which you become aware.
- D. 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.

Infinity BiologiX LLC (You)

¹⁴ “Authorized Distributor(s)” are identified by you, Infinity BiologiX LLC, in your EUA submission as an entity allowed to distribute the IBX Saliva Collection Kit and/or Spectrum Solutions SDNA-1000 Saliva Collection Device.

- E. Your product must comply with the following labeling requirements: 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).
- F. You will make available on your website(s) the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients.
- G. You will notify FDA of any authorized distributor(s) of the IBX Saliva Collection Kit and/or Spectrum Solutions SDNA-1000 Saliva Collection Device, including the name, address, and phone number of any authorized distributor(s).
- H. You will provide authorized distributor(s), relevant public health authorities, and the two authorized laboratories with a copy of this EUA and communicate to authorized distributor(s), relevant public health authorities, and the two authorized laboratories any subsequent amendments that might be made to this EUA and the authorized accompanying materials.
- I. 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 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) and require appropriate authorization from FDA prior to implementation.
- J. You will evaluate the analytical limit of detection and assess traceability of your test with any FDA-recommended reference material(s), if requested by FDA.¹⁵ After submission to and concurrence with the data by FDA, FDA will update the EUA Summary to reflect the additional testing.
- K. 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.

¹⁵ 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.

- L. 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.
- M. You will ensure authorized laboratories using your product have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
- N. You will have a process in place to track adverse events, including any occurrence of false results with your product, including with the IBX Saliva Collection Kit and Spectrum Solutions SDNA-1000 Saliva Collection Device, and report any such events to FDA pursuant to 21 CFR Part 803. Serious adverse events, especially unexpected biosafety concerns, should immediately be reported to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov).
- O. You 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.

Authorized Laboratories

- P. 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.
- Q. 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.
- R. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- S. 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.
- T. 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 (via email: IBX-COVID19@infinity-biologix.com or phone: 1-732-445-1498) 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.

- U. Authorized laboratories using specimen pooling strategies when testing patient specimens with your product must include with test result reports for specific patients whose specimen(s) were the subject of pooling, a notice that pooling was used during testing and that “Patient specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing.”
- V. Authorized laboratories implementing pooling strategies for testing patient specimens must use the “Specimen Pooling Implementation and Monitoring Guidelines” available in the authorized labeling to evaluate the appropriateness of continuing to use such strategies based on the recommendations in the protocol.
- W. Authorized laboratories must keep records of specimen pooling strategies implemented including type of strategy, date implemented, and quantities tested, and test result data generated as part of the Protocol for Monitoring of Specimen Pooling Testing Strategies. For the first 12 months from the date of their creation, such records will be made available to FDA within 48 business hours for inspection upon request, and will be made available within a reasonable time after 12 months from the date of their creation.
- X. All laboratory personnel using your product must be appropriately trained in molecular techniques and use appropriate laboratory and personal protective equipment when handling this product, and use your product in accordance with the authorized labeling.

Infinity BiologiX (You), Authorized Distributors and Authorized Laboratories

- Y. 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

- Z. 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.
- AA. 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.
- BB. 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