



November 13, 2020

Andrew Brooks, Ph.D.
Chief Executive Officer
Infinity BiologiX LLC
604 Allison Road
Piscataway, NJ 08854

Device: Infinity BiologiX TaqPath SARS-CoV-2 Assay
Company: Infinity BiologiX LLC
Indication: 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.

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 Dr. Brooks:

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 On May 7, 2020² and September 18, 2020,³ FDA authorized the use of the assay with revisions incorporated.

On October 29, 2020, you⁴ requested to further revise this EUA. Based on that request, and having concluded that revising the September 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 September 18, 2020, letter in its entirety with the revisions incorporated.⁵ Accordingly, your product⁶ 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

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, saliva specimens could be collected for use with the test using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device 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 For ease of reference, this EUA will use the term “you” and related terms to refer to Infinity BiologiX LLC.

⁵ 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.

⁶ 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).

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.⁷

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:

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.⁸

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.

⁷ 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).

⁸ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

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.

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 are described in the authorized labeling.

The above described test is authorized to be accompanied with the labeling entitled, EUA Summary (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid->

[19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas](#)), Standard Operating Procedures (SOPs) for the Infinity BiologiX TaqPath SARS-CoV-2 Assay, Purification of Viral DNA-RNA Using the Chemagic 360 with the Thermo TaqPath COVID-19 Assay, the Sample Registration and Accessioning in StarLIMS, and Collection Process SOP, 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: 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 IBX Saliva Collection Kit and 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, Standard Operating Procedures (SOPs) for the Infinity BiologiX TaqPath SARS-CoV-2 Assay, Purification of Viral DNA-RNA Using the Chemagic 360 with the Thermo TaqPath COVID-19 Assay, the Sample Registration and Accessioning in StarLIMS, and Collection Process SOP, two Fact Sheets, Patient Self-collection Kit and Collection Process instructions (for the IBX Saliva Collection Kit) and patient instructions for 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 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)⁹

- 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)

- 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.

⁹ “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.

- 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.¹⁰ After submission to and concurrence with the data by FDA, FDA will update the EUA Summary to reflect the additional testing.
- K. 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.
- L. 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).
- M. 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

¹⁰ 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.

- N. 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.
- O. 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.
- P. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Q. 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.
- R. 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.
- S. 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

- T. 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

- U. All descriptive printed matter, including advertising and promotional materials, relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.
- V. 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.
- W. All descriptive printed matter, including 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;
- This product has been authorized 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
- 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 authorization is terminated or 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