

April 14, 2022

John Redmond
InspectIR Systems LLC
8000 Warren Pkwy, Bldg 3, Suite 350
Frisco, TX 75034

Device: InspectIR COVID-19 Breathalyzer
EUA Number: EUA202006
Company: InspectIR Systems LLC
Indication: Detection of five Volatile Organic Compounds (VOCs) in the ketone and aldehyde families associated with SARS-CoV-2 infection in exhaled breath from individuals, aged 18 years and older, with or without symptoms or other epidemiological reasons to suspect COVID-19. Emergency use of this test is limited to authorized settings.
Authorized Settings: Testing is limited to use by a qualified, trained operator under the supervision of a healthcare provider licensed or authorized by state law¹ to prescribe tests in an environment where the patient specimen is both collected and analyzed.

Dear John Redmond:

This letter is in response to your² request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of your product,³ pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3).

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 Under section 201(a)(1) of the Act, the term “State” is defined to mean “any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.”

² For ease of reference, this letter will use the term “you” and related terms to refer to InspectIR Systems LLC.

³ For ease of reference, this letter will use the term “your product” to refer to the InspectIR COVID-19 Breathalyzer used for the indication identified above.

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.⁴

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 “InspectIR COVID-19 Breathalyzer (for use on PNY-1000)” Package Insert (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

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.⁵

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 a portable, rapid, gas chromatography-mass spectrometry (GC-MS) test for the in vitro qualitative detection of five Volatile Organic Compounds (VOCs) in the ketone and aldehyde families associated with SARS-CoV-2 infection in exhaled breath from individuals, aged 18 years and older, with or without symptoms or other epidemiological reasons to suspect COVID-19.

Results are for the detection and identification of VOCs in breath. Positive results indicate the

⁴ 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).

⁵ No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

presence of VOC markers associated with SARS-CoV-2 infection, but clinical correlation with patient history and other diagnostic information is necessary to determine SARS-CoV-2 infection status. Positive results should be treated as presumptive and confirmed with a molecular assay. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19 and should undergo follow up testing if necessary for patient management. Test results will be reported by the ordering healthcare provider to relevant public health authorities in accordance with local, state, and federal requirements.

Testing of exhaled breath using your product, as outlined in the “InspectIR COVID-19 Breathalyzer (for use on PNY-1000)” Package Insert, is limited to use by a qualified, trained operator under the supervision of a healthcare provider licensed or authorized by state law to prescribe tests in an environment where the patient specimen is both collected and analyzed (Authorized Settings).

The exhaled breath is tested with your product according to the “InspectIR COVID-19 Breathalyzer (for use on PNY-1000)” Package Insert. The InspectIR COVID-19 Breathalyzer includes the materials, or other authorized materials (as may be requested under Condition N. below), necessary to collect, process and test exhaled breath as described in the “InspectIR COVID-19 Breathalyzer (for use on PNY-1000)” Package Insert.

Your product requires use of an authorized control material (InspectIR COVID-19 Breathalyzer Control Material for use on the PNY-1000 instrument), or other authorized control materials (as may be requested under Condition N. below), which is not included with your product but is available from you with the “InspectIR COVID-19 Breathalyzer Control Material for use on the PNY-1000 instrument” Package Insert. The control material must generate expected results in order for a test to be considered valid, as outlined in the “InspectIR COVID-19 Breathalyzer (for use on PNY-1000)” Package Insert and the “InspectIR COVID-19 Breathalyzer Control Material for use on the PNY-1000 instrument” Package Insert.

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 “InspectIR COVID-19 Breathalyzer (for use on PNY-1000)” Package Insert.

The labeling entitled “InspectIR COVID-19 Breathalyzer (for use on PNY-1000)” Package Insert, the “InspectIR Systems, LLC – How to Perform a SARS-CoV-2 Breath Screening” Quick Reference Instructions the “InspectIR COVID-19 Breathalyzer Test for Use on PNY-1000 User Manual,” (available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas>), and the following fact sheets pertaining to the emergency use, are 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: InspectIR Systems LLC - InspectIR COVID-19 Breathalyzer
- Fact Sheet for Patients: InspectIR Systems LLC - InspectIR COVID-19 Breathalyzer

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), is authorized to be distributed and used by Authorized Settings as defined 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 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:

InspectIR Systems LLC (You)

- 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 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 must make your product available with the authorized labeling to Authorized Settings as defined under this EUA.
- C. You must make available on your website(s) the authorized labeling.
- D. You will include a physical copy of the authorized “InspectIR COVID-19 Breathalyzer (for use on PNY-1000)” Package Insert, the “InspectIR Systems, LLC – How to Perform a SARS-CoV-2 Breath Screening” Quick Reference Instructions and the “InspectIR COVID-19 Breathalyzer Test for Use on PNY-1000 User Manual,” with each shipped kit of your product, to Authorized Settings.
- E. You must inform Authorized Settings 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. You must have a process in place to ensure that your product is used only in Authorized Settings, as defined under this EUA, and its use is 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).
- G. Through a process of inventory control, you must maintain records of the Authorized Settings to which you distribute your product and number distributed.
- H. You must collect information on the performance of your product. You will 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 or false negative results and significant deviations from the established performance characteristics of the product of which you become aware.
- I. You 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.
- J. You must make available the InspectIR COVID-19 Breathalyzer Control Material for

use on the PNY-1000 instrument with the “InspectIR COVID-19 Breathalyzer Control Material for use on the PNY-1000 instrument” Package Insert or other authorized control materials (as may be requested under Condition N. below), at the same time as your product.

- K. You 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).
- 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 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. 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.
- O. 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.
- P. 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-EUAReporting@fda.hhs.gov).
- Q. 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.
- R. You must complete the additional software validation for your product in an FDA agreed upon post authorization study within 6 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH) and submit the validation results for review and concurrence by DMD/OHT7-OIR/OPEQ/CDRH.

- S. You must complete the additional analytical precision studies for your product in an FDA agreed upon post authorization study within 3 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized 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 complete the additional cross reactivity studies for your product in an FDA agreed upon post authorization study within 9 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- U. You must complete the additional clinical studies, focused on presumptive positive patients, for your product in an FDA agreed upon post authorization study within 9 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.
- V. You must complete the additional Omicron studies for your product in an FDA agreed upon post authorization study within 3 months of the date of this letter (unless otherwise agreed to with DMD/OHT7-OIR/OPEQ/CDRH). After submission to and concurrence with the data by FDA, you must update the authorized labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7-OIR/OPEQ/CDRH.

Authorized Settings

- W. Authorized Settings using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating this labeling may be used, which may include mass media.
- X. Authorized Settings using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including authorized instruments, authorized clinical specimen types, authorized control materials, authorized ancillary reagents and authorized materials required to use your product are not permitted.
- Y. Authorized Settings that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- Z. Authorized Settings using your product must have a process in place for reporting test results to relevant public health authorities, as appropriate.

AA. Authorized Settings 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 you (via email: techsupport@inspect-ir.com, or via phone by contacting InspectIR Systems Technical Support at 1-469-206-4555) 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.

BB. All operators using your product in Authorized Settings under the supervision of a healthcare provider must be appropriately qualified and trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

InspectIR Systems LLC (You) and Authorized Settings

CC. You and Authorized Settings 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

DD. 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.

EE. 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.

FF. 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 by FDA under an EUA for use in authorized settings;
- This product has been authorized only for the detection of volatile organic compounds (VOCs) in the ketone and aldehyde families associated with SARS-CoV-2 infection, 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