



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-1584]

Authorization of Emergency Use of Certain Medical Devices During COVID-19;

Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of Emergency Use Authorizations (EUAs) (the Authorizations) for certain medical devices related to the Coronavirus Disease 2019 (COVID-19) public health emergency. FDA has issued the Authorizations listed in this document under the Federal Food, Drug, and Cosmetic Act (FD&C Act). These Authorizations contain, among other things, conditions on the emergency use of the authorized products. The Authorizations follow the February 4, 2020, determination by the Secretary of Health and Human Services (HHS) that there is a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad, and that involves the virus that causes COVID-19, and the subsequent declarations on February 4, 2020, March 2, 2020, and March 24, 2020, 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, personal respiratory protective devices, and medical devices, including alternative products used as medical devices, respectively, subject to the terms of any authorization issued under the FD&C Act. These Authorizations, which include an explanation of the reasons for issuance, are listed in this document, and can be accessed on FDA's website from the links indicated.

DATES: These Authorizations are effective on their date of issuance.

ADDRESSES: Submit written requests for single copies of an EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the Authorization.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) allows FDA to strengthen the public health protections against biological, chemical, radiological, or nuclear agent or agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help ensure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by a biological, chemical, radiological, or nuclear agent or agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces, including

personnel operating under the authority of title 10 or title 50 of the U.S. Code, of attack with (A) a biological, chemical, radiological, or nuclear agent or agents; or (B) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to U.S. military forces¹; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. 247d-6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the *Federal Register* a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Under section 564(h)(1) of the FD&C Act, revisions to an authorization shall be made available on the internet website of the FDA. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under section 505, 510(k), 512, or 515 of the FD&C Act (21 U.S.C. 355, 360(k), 360b, or 360e) or

¹ In the case of a determination by the Secretary of Defense, the Secretary of HHS shall determine within 45 calendar days of such determination, whether to make a declaration under section 564(b)(1) of the FD&C Act, and, if appropriate, shall promptly make such a declaration.

section 351 of the PHS Act (42 U.S.C. 262), or conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (CDC) (to the extent feasible and appropriate given the applicable circumstances), FDA² concludes: (1) that an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that (A) the product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; (4) in the case of a determination described in section 564(b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and (5) that such other criteria as may be prescribed by regulation are satisfied. No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act.

II. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet and can be accessed from <https://www.fda.gov/emergency->

² The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

III. The Authorizations

Having concluded that the criteria for the issuance of the following Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of the following products for diagnosing, treating, or preventing COVID-19 subject to the terms of each Authorization. The Authorizations in their entirety, including any authorized fact sheets and other written materials, can be accessed from the FDA web page entitled “Emergency Use Authorization,” available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>. The lists that follow include Authorizations issued from February 16, 2021, through May 31, 2021, and we have included explanations of the reasons for their issuance, as required by section 564(h)(1) of the FD&C Act. In addition, the EUAs that have been reissued can be accessed from FDA’s web page: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

FDA is hereby announcing the following Authorizations for molecular diagnostic and antigen tests for COVID-19, excluding multianalyte tests:³

- University of Illinois Office of the Vice President for Economic Development and Innovation’s covidSHIELD, issued February 24, 2021;
- Viracor Eurofins Clinical Diagnostics’s Viracor SARS-CoV-2 Assay DTC, issued February 26, 2021;
- Quidel Corporation’s QuickVue At-Home COVID-19 Test, issued March 1, 2021;

³ As set forth in the EUAs for these products, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, 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 the products may be effective in diagnosing COVID-19, and that the known and potential benefits of the products, when used for diagnosing COVID-19, outweigh the known and potential risks of such products; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

- Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of the Massachusetts Institute of Technology and Harvard's CRSP SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Assay (Version 3), issued March 5, 2021;
- Cue Health Inc.'s Cue COVID-19 Test for Home and Over The Counter (OTC) Use, issued March 5, 2021;
- Color Health, Inc.'s Color SARS-CoV-2 RT-LAMP Diagnostic Assay DTC, issued March 19, 2021;
- Twist Bioscience Corporation's SARS-CoV-2 NGS Assay, issued March 23, 2021;
- STS Lab Holdco's (a subsidiary of Amazon.com Services LLC), Amazon Real-Time RT-PCR Test for Detecting SARS-CoV-2, issued March 25, 2021;
- DiaSorin, Inc.'s LIAISON SARS-CoV-2 Ag, issued March 26, 2021;
- Abbott Diagnostics Scarborough, Inc.'s BinaxNOW COVID-19 Ag 2 Card, issued March 31, 2021;
- Quidel Corporation's QuickVue At-Home OTC COVID-19 Test, issued March 31, 2021;
- Abbott Diagnostics Scarborough, Inc.'s BinaxNOW COVID-19 Antigen Self Test, issued March 31, 2021;
- Abbott Diagnostics Scarborough, Inc.'s BinaxNOW COVID-19 Ag Card 2 Home Test, issued March 31, 2021;
- Thermo Fisher Scientific's Amplitude Solution with the TaqPath COVID-19 High-Throughput Combo Kit, issued April 9, 2021;
- Lucira Health, Inc.'s Lucira CHECK√IT COVID-19 Test Kit, issued April 9, 2021;
- PerkinElmer Genomics's PerkinElmer SARS-CoV-2 RT-qPCR Reagent Kit, issued April 12, 2021;
- Qorvo Biotechnologies, LLC.'s Omnia SARS-CoV-2 Antigen Test, issued April 13, 2021;

- Clinical Enterprise, Inc.’s Clinical Enterprise SARS-CoV-2 RT-PCR Assay DTC, issued April 13, 2021;
- Clinical Enterprise, Inc.’s Clinical Enterprise SARS-CoV-2 RT-PCR Assay, issued April 13, 2021;
- LGC, Biosearch Technologies’ Biosearch Technologies SARS-CoV-2 Real-Time and End-Point RT-PCR Test, issued April 15, 2021;
- Synergy Diagnostic Laboratory, Inc.’s (DBA SynergyDx), SynergyDx SARS-CoV-2 RNA Test, issued April 16, 2021;
- Synergy Diagnostic Laboratory, Inc.’s (DBA SynergyDx), SynergyDx SARS-CoV-2 RNA Test DTC, issued April 16, 2021;
- Celltrion USA, Inc.’s Celltrion DiaTrust COVID-19 Ag Rapid Test, issued April 16, 2021;
- Southern California Permanente Medical Group’s Kaiser Permanente High Throughput SARS-CoV-2 Assay, issued April 19, 2021;
- PathogenDx, Inc.’s DetectX-Rv, issued April 20, 2021;
- InBios International, Inc.’s SCoV-2 Ag Detect Rapid Test, issued May 6, 2021;
- Phosphorus Diagnostics LLC’s Phosphorous COVID19 RT-qPCR Test DTC, issued May 17, 2021;
- Salofa Oy’s Sienna-Clarity COVID-19 Antigen Rapid Test Cassette, issued May 20, 2021;
- Harvard University Clinical Laboratory’s Quaeris SARS-CoV-2 Assay, issued May 21, 2021;
- Thermo Fisher Scientific Inc.’s TaqPath COVID-19 Pooling Kit, issued May 25, 2021.

FDA is hereby announcing the following Authorizations for serology tests⁴:

⁴ As set forth in the EUAs for these products, FDA has concluded that: (1) 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

- Abbott Laboratories Inc.'s AdviseDx SARS-CoV-2 IgG II, issued March 1, 2021;
- Beckman Coulter, Inc.'s Access SARS-CoV-2 IgG II, issued March 22, 2021;
- Siemens Healthcare Diagnostics Inc.'s Atellica IM SARS-CoV-2 IgG (sCOVG), issued March 23, 2021;
- Symbiotica, Inc.'s COVID-19 Self-Collected Antibody Test System, issued April 5, 2021;
- Inova Diagnostics, Inc.'s QUANTA Flash SARS-CoV-2 IgG, issued April 19, 2021;
- QIAGEN, GmbH's QIAreach Anti-SARS-CoV-2 Total Test, issued May 11, 2021;
- ZEUS Scientific, Inc.'s ZEUS ELISA SARS-CoV-2 Total Antibody Test System, issued May 11, 2021;
- DiaSorin, Inc.'s LIAISON SARS-CoV-2 TrimericS IgG, issued May 19, 2021;
- NOWDiagnostics, Inc.'s ADEXUSDx COVID-19 Test, issued May 24, 2021.

FDA is hereby announcing the following Authorization for a T-cell immune response test:

- Adaptive Biotechnologies Corporation's T-Detect COVID Test, issued March 5, 2021.⁵

FDA is hereby announcing the following Authorizations for multianalyte in vitro diagnostics⁶:

the totality of scientific evidence available to FDA, it is reasonable to believe that the products may be effective in diagnosing recent or prior infection with SARS-CoV-2 by identifying individuals with an adaptive immune response to the virus that causes COVID-19, and that the known and potential benefits of the products when used for such use, outweigh the known and potential risks of the products; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

⁵ As set forth in the EUA, FDA has concluded that: (1) 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 the T-Detect COVID Test may be effective in diagnosing recent or prior infection with SARS-CoV-2 by identifying individuals with a T-cell immune response to the virus that causes COVID-19, and that the known and potential benefits of your product when used for such use, outweigh the known and potential risks of the T-Detect COVID Test; and (3) there is no adequate, approved, and available alternative to the emergency use of the T-Detect COVID Test.

⁶ There are FDA-approved/cleared tests for Influenza A virus (with subtype differentiation), and other organisms, such as Influenza B virus, Respiratory Syncytial virus (RSV) A and RSV B, Coronaviruses 229E, OC43, NL63 and HKU1, Human Metapneumovirus, Rhinovirus/Enterovirus, Adenovirus, Parainfluenza virus Types 1, 2, 3, and 4, Human Bocavirus, *Chlamydomonas pneumoniae*, and *Mycoplasma pneumoniae* but there are no FDA approved/cleared multiplexed tests for simultaneous qualitative detection and differentiation of SARS-CoV-2, and these additional pathogens targeted by the products (see individual EUAs for specific other pathogens). Respiratory infections caused by the aforementioned pathogens and SARS-CoV-2 can have similar clinical presentation and

- Luminex Molecular Diagnostics, Inc.'s NxTAG Respiratory Pathogen Panel + SARS-CoV-2, issued March 3, 2021;⁷
- Abbott Molecular Inc.'s Alinity m Resp-4-Plex, issued March 4, 2021;⁸
- Becton, Dickinson and Company's (BD's) BD Veritor System for Rapid Detection of SARS-CoV-2 & Flu A+B, issued March 24, 2021;⁹
- NeuMoDx Molecular, Inc.'s NeuMoDx Flu A-B/RSV/SARS-CoV-2 Vantage Assay, issued March 25, 2021.¹⁰

FDA is hereby announcing the following Authorizations for other medical devices:

diagnostic considerations. Thus, to differentially detect SARS-CoV-2, information from a test that detects and differentiates the virus that causes COVID-19 and other respiratory pathogens is needed. For example, the common influenza viruses that cause seasonal epidemics of flu, influenza A and B, is needed during the flu season that coincides with the COVID-19 pandemic.

⁷ As set forth in the EUA, FDA has concluded that: (1) 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 the product may be effective in diagnosing COVID-19, through the simultaneous detection and differentiation of nucleic acids from SARS-CoV-2 and other respiratory viral and bacterial organisms and that the known and potential benefits of the product when used for diagnosing COVID-19, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product. The NxTAG Respiratory Pathogen Panel + SARS-CoV-2 is intended for the simultaneous detection and differentiation of nucleic acid from SARS-CoV-2 and the following organism types and subtypes: Influenza A, Influenza A H1, Influenza A H3, Influenza B, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, Coronavirus 229E, Coronavirus OC43, Coronavirus NL63, Coronavirus HKU1, Human Metapneumovirus, Rhinovirus/Enterovirus, Adenovirus, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Human Bocavirus, *Chlamydomphila pneumoniae*, and/or *Mycoplasma pneumoniae*.

⁸ As set forth in the EUA, FDA has concluded that: (1) 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 the product may be effective in diagnosing COVID-19 through the simultaneous detection and differentiation of SARS-CoV-2, influenza A virus, influenza B virus and/or RSV nucleic acids and that the known and potential benefits of the product when used for diagnosing COVID-19, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

⁹ As set forth in the EUA, FDA has concluded that: (1) 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 the product may be effective in diagnosing COVID-19 through the simultaneous detection and differentiation of SARS-CoV-2, and/or influenza A virus and influenza B virus protein antigens and that the known and potential benefits of the product when used for such a use, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

¹⁰ As set forth in the EUA, FDA has concluded that: (1) 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 the product may be effective in diagnosing COVID-19 and that the known and potential benefits of the product when used for diagnosing COVID-19, outweigh the known and potential risks of the product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

- GetMyDNA’s GetMyDNA COVID-19 Test Home Collection Kit, issued March 9, 2021;¹¹
- Color Health, Inc.’s Color COVID-19 Self-Swab Collection Kit DTC, issued March 19, 2021;¹²
- Tiger Tech Solutions, Inc.’s Tiger Tech COVID Plus Monitor, issued March 19, 2021.¹³
- Inspire Rx, LLC’s Inspire Rx, LLC Portable Negative Pressure Isolation & Procedural Tent System, (referred to as the “AerosolVE Device”), issued March 29, 2021;¹⁴

¹¹ As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, 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 the GetMyDNA COVID-19 Test Home Collection Kit may be effective in diagnosing COVID-19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the home-collected human specimen, and that the known and potential benefits of the GetMyDNA COVID-19 Test Home Collection Kit when used for diagnosing COVID-19, outweigh the known and potential risks of the GetMyDNA COVID-19 Test Home Collection Kit; and (3) there is no adequate, approved, and available alternative to the emergency use of the GetMyDNA COVID-19 Test Home Collection Kit.

¹² As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, 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 the Color COVID-19 Self-Swab Collection Kit DTC may be effective in diagnosing COVID-19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the home-collected human specimen, and that the known and potential benefits of the Color COVID-19 Self-Swab Collection Kit DTC when used for diagnosing COVID-19, outweigh the known and potential risks of the Color COVID-19 Self-Swab Collection Kit DTC; and (3) there is no adequate, approved, and available alternative to the emergency use of the Color COVID-19 Self-Swab Collection Kit DTC.

¹³ As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, 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 the Tiger Tech COVID Plus Monitor, when used by trained personnel, may be effective at preventing exposure to and spread of SARS-CoV-2 by identifying certain biomarkers in asymptomatic individuals over the age of 5, when performed following a temperature reading that does not meet the criteria for fever in settings where temperature check is being conducted in accordance with CDC and local institutional infection prevention and control guidelines, and that the known and potential benefits of such product, when used as described in the Scope of Authorization of the authorization letter, outweigh the known and potential risks; and (3) there are no adequate, approved, and available alternatives to the emergency use of the Tiger Tech COVID Plus Monitor.

¹⁴ As set forth in the EUA, FDA has concluded that: (1) 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 the AerosolVE Device may be effective in preventing healthcare provider exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment, at the time of definitive airway management, or when performing airway-related medical procedures, or during certain transport (when end-tidal CO₂ monitoring is not available) for a maximum duration of use of 30 minutes, of patients with suspected or confirmed diagnosis of COVID-19 and that the known and potential benefits of the AerosolVE Device for such use outweigh its known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the AerosolVE Device. During the public health emergency, it would not be feasible to require healthcare providers to limit use of the AerosolVE Device to patients with suspected or confirmed COVID-19; therefore, the authorization does not restrict use to such patients.

- J. Peter Rubin, MD, MBA, FACS at the University of Pittsburgh’s Individual Biocontainment Unit (“IBU”), issued April 1, 2021;¹⁵
- Yale School of Public Health, Department of Epidemiology of Microbial Diseases’ SalivaDirect At-Home Collection Kit, issued April 9, 2021;¹⁶
- Color Health, Inc.’s Color COVID-19 Self-Swab Collection Kit with Saline, issued April 14, 2021;¹⁷
- Prep Tech, LLC’s ISOCUBE SS and ISOCUBE ONE (“ISOCUBE”), issued May 4, 2021;¹⁸

¹⁵ As set forth in the EUA, FDA has concluded that: (1) 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 the IBU may be effective in preventing healthcare provider exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment, at the time of definitive airway management, or when performing medical procedures, or during transport of patients with suspected or confirmed diagnosis of COVID-19 and that the known and potential benefits of the IBU for such use outweigh its known and potential risks; and (3) there are no adequate, approved, and available alternatives to the emergency use of the IBU. During the public health emergency, it would not be feasible to require healthcare providers to limit the IBU use for patients with suspected or confirmed COVID-19; therefore, the authorization does not restrict use to such patients.

¹⁶ As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, 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 the SalivaDirect At-Home Collection Kit may be effective in diagnosing COVID-19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the self-collected human specimen, and that the known and potential benefits of the SalivaDirect At-Home Collection Kit when used for diagnosing COVID-19, outweigh the known and potential risks of the SalivaDirect At-Home Collection Kit; and (3) there is no adequate, approved, and available alternative to the emergency use of the SalivaDirect At-Home Collection Kit.

¹⁷ As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, 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 the Color COVID-19 Self-Swab Collection Kit with Saline may be effective in diagnosing COVID-19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the self-collected human specimen, and that the known and potential benefits of the Color COVID-19 Self-Swab Collection Kit with Saline when used for diagnosing COVID-19, outweigh the known and potential risks of the Color COVID-19 Self-Swab Collection Kit with Saline; and (3) there is no adequate, approved, and available alternative to the emergency use of the Color COVID-19 Self-Swab Collection Kit with Saline.

¹⁸ As set forth in the EUA, FDA has concluded: (1) 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 ISOCUBE may be effective in preventing healthcare provider exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment, at the time of definitive airway management, or when performing airway-related medical procedures, or during certain transport of patients with suspected or confirmed diagnosis of COVID-19 and that the known and potential benefits of ISOCUBE for such use outweigh its known and potential risks; and (3) there are no adequate, approved, and available alternatives to the emergency use of the ISOCUBE. During the public health emergency, it would not be feasible to require healthcare providers to limit the ISOCUBE use for patients with suspected or confirmed COVID-19; therefore, the authorization does not restrict use to such patients.

- Breegi Scientific, Inc.’s Negative Pressure SteriDome (NPS), issued May 6, 2021;¹⁹
- Phosphorus Diagnostics LLC’s Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC, issued May 17, 2021.²⁰

Finally, FDA is hereby announcing an amendment to certain EUAs to allow certain authorized molecular diagnostic SARS-CoV-2 tests to be distributed and used to pool anterior nasal respiratory specimens from asymptomatic individuals as part of a serial testing program after developers submit a complete notification, including meeting required validation data, as set forth in the amendment letter. The amendment “Amending Certain EUAs for RT-PCR Molecular-Based Diagnostic Tests to Authorize the Detection of Nucleic Acid from SARS-CoV-2 from Pooled Anterior Nasal Respiratory Specimens for Screening When Used as Part of a Serial Testing Program,” was issued to “Developers of Molecular-Based Diagnostic Tests Authorized for Emergency Use for Coronavirus Disease 2019 (COVID-19) as of Today’s Date” on April 20, 2021.²¹

¹⁹ As set forth in the EUA, FDA has concluded: (1) 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 the NPS may be effective in preventing healthcare provider exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to personal protective equipment, at the time of definitive airway management, when performing airway-related medical procedures, or during certain transport for a maximum duration of use of 1 hour, of patients with suspected or confirmed diagnosis of COVID-19 and that the known and potential benefits of the NPS for such use outweigh its known and potential risks; and (3) there are no adequate, approved, and available alternatives to the emergency use of the NPS. During the public health emergency, it would not be feasible to require healthcare providers to limit use of the NPS to patients with suspected or confirmed COVID-19; therefore, the authorization does not restrict use to such patients.

²⁰ As set forth in the EUA, FDA has concluded that: (1) SARS-CoV-2, the virus that causes COVID-19, 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 the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC may be effective in diagnosing COVID-19, by serving as an appropriate means to collect and transport human specimens so that an authorized laboratory can detect SARS-CoV-2 RNA from the self-collected human specimen, and that the known and potential benefits of the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC when used for diagnosing COVID-19, outweigh the known and potential risks of the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC; and (3) there is no adequate, approved, and available alternative to the emergency use of the Pinpoint by Phosphorus COVID-19 Test Home Collection Kit DTC.

²¹ As set forth in the amendment, FDA has concluded (1) 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 the authorized tests may be effective in diagnosing COVID-19 for the indications set forth in the appendices of the amendment letter, and that the known and potential benefits of the authorized tests when used for such use, outweigh the known and potential risks of the authorized tests included in the amendment; and (3) there are no adequate, approved, and available alternatives to the emergency use of the authorized tests included in the amendment.

Dated: July 16, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021-15680 Filed: 7/22/2021 8:45 am; Publication Date: 7/23/2021]