Additional Draft Q&As on Biosimilar Development and the BPCI Act. The Q&A format is intended to inform prospective applicants and facilitate the development of proposed biosimilars and proposed interchangeable biosimilars, as well as to describe FDA’s interpretation of certain statutory requirements added by the BPCI Act. The BPCI Act created an abbreviated licensure pathway in section 351(k) of the PHS Act (42 U.S.C. 262(k)) for biological products shown to be biosimilar to, or interchangeable with, an FDA-licensed biological reference product (see sections 7001 through 7003 of the Patient Protection and Affordable Care Act (Pub. L. 111–148)). FDA believes that guidance for industry that provides answers to commonly asked questions regarding FDA’s interpretation of the BPCI Act will enhance transparency and facilitate the development and approval of biosimilar and interchangeable products. FDA has been using the format of Q&A guidance to describe the Agency’s thinking on and update certain information and recommendations relevant to the development of biosimilar and interchangeable products. This draft guidance document contains only Q&As that are in draft form. After FDA has considered any comments on the Q&As contained in this draft guidance received during the relevant comment period and, as appropriate, incorporated suggested changes to the Q&A, individual Q&As will be finalized and moved to the final guidance document “Questions and Answers on Biosimilar Development and the BPCI Act,” which is updated as appropriate. The final guidance contains Q&As that have been through the public comment process and reflects FDA’s current thinking on the topics described. A Q&A may be withdrawn and removed from the Q&A guidance documents if, for instance, the issue addressed in the Q&A has been addressed in another FDA guidance document. No such changes to currently issued draft or final guidance documents are being made in connection with the issuance of this draft guidance.

FDA has maintained the original numbering of the Q&As used in the December 2018 final guidance “Questions and Answers on Biosimilar Development and the BPCI Act” and the December 2018 draft guidance “New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2).” This draft guidance document provides new Q&As. It does not replace the draft guidance document entitled “New and Revised Draft Q&As on Biosimilar Development and the BPCI Act (Revision 2),” issued December 12, 2018.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The Q&As in this draft guidance, when finalized, will appear in the final guidance, and the final guidance will represent the current thinking of FDA on the Q&As posed in the “Biosimilarity and Interchangeability: Additional Draft Q&As on Biosimilar Development and the BPCI Act.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for submission of an investigational new drug application have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 314.50 for submission of a new drug application have been approved under OMB control number 0910–0001. The collections of information in section 351(a) of the PHS Act and 21 CFR part 601 for submission of a biologics license application (BLA) have been approved under OMB control number 0910–0338. The collections of information in section 351(k) of the PHS Act and 21 CFR part 601 for submission of a BLA have been approved under OMB control number 0910–0719.

III. Electronic Access


Lauren K. Roth,
Acting Principal Associate Commissioner for Policy.

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 and reissuance 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, and in some cases reissued, 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 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 and reissuance, are listed in this document, and are available on FDA’s website at the links indicated.

DATES: These Authorizations are applicable on their date of issuance/reissuance.

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 approved 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 forces;1 (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. 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 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 (to the extent feasible and appropriate given the applicable circumstances), FDA 2 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.

III. Electronic Access


IV. The Authorizations

Having concluded that the criteria for the issuance and, in some cases reissuance, 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, are available on the internet 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, in some cases reissued, from May 16, 2020, through September 14, 2020, and we have included explanations of the reasons for their issuance, as required by section 564(b)(1) of the FD&C Act. FDA is hereby announcing the following Authorizations for molecular diagnostic

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.

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.
and antigen tests for COVID–19, excluding multianalyte tests: 3
• Color Genomics, Inc.'s Color SARS–CoV–2 LAMP Diagnostic Assay, issued May 18, 2020, and reissued July 24, 2020;
• Quidel Corp.'s Lyra Direct SARS–CoV–2 Assay, issued May 18, 2020;
• P23 Labs, LLC's P23 Labs TaqPath SARS–CoV–2 Assay, issued May 21, 2020, and reissued July 10, 2020;
• SEASUN BIOMATERIALS, Inc.'s AQ–TOP COVID–19 Rapid Detection Kit, issued May 21, 2020;
• SolGent Co., Ltd.'s DiaPlexQ Novel Coronavirus (2019–nCoV) Detection Kit, issued May 21, 2020;
• BioCore Co., Ltd.'s BioCore 2019–nCoV Real Time PCR Kit, issued May 21, 2020;
• Exact Sciences Laboratories’ SARSd–CoV–2 (N gene detection) Test, issued May 22, 2020, and reissued August 3, 2020;
• dba SpectronRx's Hymol SARS–CoV–2 Test Kit, issued May 22, 2020;
• PrivaPath Diagnostics, Inc.'s LetsGetChecked Coronavirus (COVID–19) Test, issued May 28, 2020, and reissued August 14, 2020;
• Gravity Diagnostics, LLC’s Gravity Diagnostics COVID–19 Assay, issued June 1, 2020;
• Phosphorus Diagnostics LLC’s Phosphorus COVID–19 RT–qPCR Test, issued June 4, 2020;
• Genetron Health (Beijing) Co., Ltd.'s Genetron SARSd–CoV–2 RNA Test, issued June 5, 2020;
• Euroimmun US Inc.’s EUIRORealTime SARSd–CoV–2, issued June 8, 2020;
• ChromaCode Inc.’s HDPCR SARSd–CoV–2 Assay, issued June 9, 2020;
• illumina, Inc.’s illumina COVIDSeq Test, issued June 9, 2020;
• Tide Laboratories, LLC’s DTPM COVID–19 RT–PCR Test, issued June 10, 2020;
• TBG Biotechnology Corp.’s ExProbe SARSd–CoV–2 Testing Kit, issued June 10, 2020;
• Cue Health, Inc.’s Cue COVID–19 Test, issued June 10, 2020;
• RTA Laboratories Biological Products Pharmaceutical and Machinery Industry’s Diagnovital SARSd–CoV–2 Real–Time PCR Kit, issued June 12, 2020;
• Kaiser Permanente Mid–Atlantic States’s KMPAS COVID–19 Test, issued June 13, 2020, and reissued September 9, 2020;
• The Ohio State University Wexner Medical Center’s OSUWMC COVID–19 RT–PCR test, issued June 17, 2020;
• Omnipathology Solutions Medical Corp’s Omni COVID–19 assay by RT–PCR, issued June 17, 2020;
• Jiangsu Bioperfectus Technologies Co., Ltd.’s COVID–19 Coronavirus Real Time PCR Kit, issued June 18, 2020;
• 3B Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd.’s TRUPCR SARSd–CoV–2 Kit, issued June 18, 2020;
• HealthQuest Esoterics’s HealthQuest Esoterics TaqPath SARSd–CoV–2 Assay, issued June 23, 2020;
• University of Alabama at Birmingham Fungal Reference Lab’s FRL SARS CoV–2 Test, issued June 23, 2020;
• Gencurix, Inc.’s GenePro SARSd–CoV–2 Test, issued June 23, 2020;
• University of Texas MD Anderson Cancer Center, Molecular Diagnostics Laboratory’s MD Anderson High–throughput SARSd–CoV–2 RT–PCR Assay, issued June 24, 2020;
• Diagnostic Solutions Laboratory, LLC’s DSL COVID–19 Assay, issued June 25, 2020;
• P3 Blackbio Biotech India Ltd., a subsidiary of Kilpest India Ltd.’s TRUPCR SARSd–CoV–2 Kit, issued June 18, 2020;
• HealthQuest Esoterics’s HealthQuest Esoterics TaqPath SARSd–CoV–2 Assay, issued June 23, 2020;
• University of Texas MD Anderson Cancer Center, Molecular Diagnostics Laboratory’s MD Anderson High–throughput SARSd–CoV–2 RT–PCR Assay, issued June 24, 2020;
• Diagnostic Solutions Laboratory, LLC’s DSL COVID–19 Assay, issued June 25, 2020;
• Inform Diagnostics, Inc.’s Inform Diagnostics SARSd–CoV–2 RT–PCR Assay, issued June 26, 2020;
• Acupath Laboratories, Inc.’s Acupath COVID–19 Real–Time (RT–PCR) Assay, issued June 29, 2020;
• LifeHope Labs’ LifeHope 2019–nCoV Real–Time RT–PCR Diagnostic Panel, issued June 29, 2020;
• Psmogenc, Inc.’s Psmogenc COVID–19 RT Test, issued June 30, 2020;
• TNS Co., Ltd.’s (Bio TNS) COVID–19 RT–PCR Peptide Nucleic Acid (PNA) kit, issued June 30, 2020;
• The Kroger Co.’s Kroger Health COVID–19 Test Home Collection Kit, issued June 30, 2020;
• CENTOGENE US, LLC’s CentoFast–SARSd–CoV–2 RT–PCR Assay, issued July 1, 2020;
• Beston. Dickinson and Co.’s BD Veritor System for Rapid Detection of SARS–CoV–2, issued July 2, 2020;

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.

• Laboratorio Clínico Toledo’s Laboratorio Clínico Toledo SARSd–CoV–2 Assay, issued July 6, 2020;
• Gene By Gene’s Gene By Gene SARSd–CoV–2 Detection Test, issued July 7, 2020;
• Access Bio, Inc.’s CareStart COVID–19 MDx RT–PCR, issued July 7, 2020;
• Enzo Life Sciences, Inc.’s AMPIPROBE SARSd–CoV–2 Test System, issued July 7, 2020;
• Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard’s CRSP SARSd–CoV–2 Real–time Reverse Transcriptase (RT–PCR) Diagnostic Assay, issued July 8, 2020;
• BioSewoom, Inc.’s Real–Q 2019–nCoV Detection Kit, issued July 9, 2020;
• UCSF Health Clinical Laboratories, UCSF Clinical Labs at China basin’s SARSd–CoV–2 RNA DETECTR Assay, issued July 9, 2020;
• Boston Medical Center’s BMC–CREM COVID–19 Test, issued July 10, 2020;
• KoGeneBiotech Co., Ltd.’s PowerChek 2019–nCoV Real–time PCR Kit, issued July 13, 2020;
• Trax Management Services Inc.’s PhoenixDx SARSd–CoV–2 Multiplex, issued July 13, 2020;
• Compass Laboratory Services, LLC’s Compass Laboratory Services SARSd–CoV2 Assay, issued July 13, 2020;
• Quest Diagnostics Infectious Disease, Inc.’s Quest Diagnostics PF SARSd–CoV–2 Assay, issued July 15, 2020, and reissued August 21, 2020;
• Quest Diagnostics Infectious Disease, Inc.’s Quest Diagnostics RC SARSd–CoV–2 Assay, issued July 15, 2020, and reissued August 21, 2020;
• Quest Diagnostics Infectious Disease, Inc.’s Quest Diagnostics HA SARSd–CoV–2 Assay, issued July 15, 2020, and reissued August 21, 2020;
• Boston Heart Diagnostics’ Boston Heart COVID–19 RT–PCR Test, issued July 16, 2020;
• Access Genetics, LLC’s OnaRisk COVID–19 RT–PCR, issued July 17, 2020;
• DiaCarta, Inc.’s QuantiVirus SARSd–CoV–2 Multiplex Test Kit, issued July 21, 2020;
• Helix OpCo LLC’s (dba Helix’s) Helix COVID–19 Test, issued July 23, 2020;
• Jiangsu CoWin Biotech Co., Ltd.’s Novel Coronavirus (SARSd–CoV–2) Fast Nucleic Acid Detection Kit (PCR–Fluorescence Probing), issued July 24, 2020;
• LabCorp’s COVID–19 RT–PCR Test, reissued July 24, 2020 (original issuance March 16, 2020);
• Eli Lilly and Co.’s Lilly SARSd–CoV–2 Assay, issued July 27, 2020;
• Clinical Reference Laboratory, Inc.’s CRL Rapid Response, issued July 30, 2020;  
• University of California San Diego Health’s UCSD RC SARSd–CoV–2 Assay, issued July 31, 2020;  
• Xiamen Zeesan Biotech Co., Ltd.’s SARSd–CoV–2 Test Kit (Real-time PCR), issued July 31, 2020;  
• ISFM Labs, LLC dba Capstone Healthcare’s Genus SARSd–CoV–2 Assay, issued August 3, 2020;  
• Poplar Healthcare’s Poplar SARSd–CoV–2 TMA Pooling assay, issued August 3, 2020;  
• Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute’s Cleveland Clinic SARSd–CoV–2 Assay, issued August 3, 2020;  
• Ethos Laboratories’ Ethos Laboratories SARSd–CoV–2 MALDI–TOF Assay, issued August 3, 2020;  
• Wren Laboratories LLC’s Wren Laboratories COVID–19 PCR Test, issued August 3, 2020;  
• Vela Operations Singapore Pte Ltd.’s ViroKey SARSd–CoV–2 RT–PCR Test, issued August 5, 2020;  
• Helix OpCo LLC’s (dba Helix) Helix COVID–19 NGS Test, issued August 6, 2020;  
• George Washington University Public Health Laboratory’s GWU SARSd–CoV–2 RT–PCR Test, issued August 7, 2020;  
• Quest Diagnostics Infectious Disease, Inc.’s SARSd–CoV–2 RNA, Qualitative Real–Time RT–PCR, reissued August 7, 2020 (original issuance March 17, 2020);  
• Alpha Genomix Laboratories’ Alpha Genomix TaqPath SARSd–CoV–2 Combo Assay, issued August 10, 2020;  
• Solaris Diagnostics’ Solaris Multiplex SARSd–CoV–2 Assay, issued August 10, 2020;  
• Biomeone, Inc.’s Biomeone SARSd–CoV–2 Real–Time RT–PCR Test, issued August 11, 2020;  
• LumiraDx UK Ltd.’s LumiraDx SARS–CoV–2 RNA STAR, issued August 11, 2020;  
• Pro–Lab Diagnostics’ Pro–AmpRT SARSd–CoV–2 Test, issued August 13, 2020;  
• Yale School of Public Health, Department of Epidemiology of Microbial Diseases’ SalivaDirect, issued August 15, 2020, and reissued August 28, 2020;  
• ZhuHui Sinochips Bioscience Co., Ltd.’s COVID–19 Nucleic Acid RT–PCR Test Kit, issued August 17, 2020;  
• LumiraDx UK Ltd.’s LumiraDx SARSd–CoV–2 Ag Test, issued August 18, 2020;  
• Assurance Scientific Laboratories’ Assurance SARSd–CoV–2 Panel, reissued August 19, 2020 (original issuance May 15, 2020);  
• Guardant Health, Inc.’s Guardant–19, issued August 21, 2020;  
• DxTerity Diagnostics, Inc.’s DxTerity SARSd–CoV–2 RT–PCR Test, issued August 21, 2020;  
• Texas Department of State Health Services, Laboratory Services Section’s Texas Department of State Health Services SARSd–CoV–2 Assay, issued August 21, 2020;  
• Fluidigm Corp.’s Advanta Dx SARSd–CoV–2 RT–PCR Assay, issued August 25, 2020;  
• QDX Pathology Services’ QDX SARSd–CoV–2 Assay, issued August 25, 2020;  
• Cuur Diagnostics’ Cuur Diagnostics SARSd–CoV–2 Molecular Assay, issued August 26, 2020;  
• Abbott Diagnostics Scarborough, Inc.’s BinaxNOW COVID–19 Ag Card, issued August 26, 2020;  
• Patients Choice Laboratories, LLC’s PCL SARSd–CoV–2 Real–Time RT–PCR Assay, issued August 28, 2020;  
• DxTerity Diagnostics, Inc.’s DxTerity SARSd–CoV–2 RT PCR CE Test, issued August 28, 2020;  
• T2 Biosystems, Inc.’s T2SARSd–CoV–2 Panel, issued August 31, 2020;  
• MiraDx’s MiraDx SARSd–CoV–2 RT–PCR assay, issued August 31, 2020;  
• Mammoth Biosciences, Inc.’s SARSd–CoV–2 DETECTR Reagent Kit, issued August 31, 2020;  
• BayCare Laboratories, LLC’s BayCare SARSd–CoV–2 RT PCR Assay, issued August 31, 2020;  
• Detectachen Inc.’s MobileDetect Bio BCC19 (MD–Bio BCC19) Test Kit, issued September 1, 2020;  
• OPTOLANE Technologies, Inc.’s Kaira 2019–nCoV Detection Kit, issued September 1, 2020;  
• Bioeksen R&D Technologies Ltd.’s Bio–Speedy Direct RT–qPCR SARSd–CoV–2, issued September 2, 2020;  
• BillionToOne, Inc.’s qSanger–COVID–19 Assay, issued September 4, 2020;  
• Verily Life Sciences’ Verily COVID–19 RT–PCR Test, issued September 8, 2020;  
• and  

FDA is hereby announcing the following Authorizations for serology tests:  

As set forth in the EUAs for these products, FDA has concluded that: (1) SARSd–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 products may be effective in diagnosing recent or prior infection with SARSd–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 EUAs, 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 products may be effective in diagnosing COVID-19 through the simultaneous detection and differentiation of SARS-CoV-2, influenza A virus, and/or influenza B virus nucleic acids and that the known and potential benefits of the products when used for such a 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.

6 As set forth in the EUAs, 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 authorized respirators may be effective to treat patients in an acute care environment during the COVID-19 pandemic, and that the known and potential benefits of the Prismaflex ST Set, when used for such use, outweigh the known and potential risks of the Prismaflex ST Set; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

7 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 authorized respirators may be effective to treat patients in an acute care environment during the COVID-19 pandemic, and that the known and potential benefits of the Prismaflex ST Set, when used for such use, outweigh the known and potential risks of the Prismaflex ST Set; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

8 As set forth in the EUAs, 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 authorized respirators may be effective to treat patients in an acute care environment during the COVID-19 pandemic, and that the known and potential benefits of the Prismaflex ST Set, when used for such use, outweigh the known and potential risks of the Prismaflex ST Set; 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, 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 authorized respirators may be effective to treat patients in an acute care environment during the COVID-19 pandemic, and that the known and potential benefits of the Prismaflex ST Set, when used for such use, outweigh the known and potential risks of the Prismaflex ST Set; 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, 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 authorized respirators may be effective to treat patients in an acute care environment during the COVID-19 pandemic, and that the known and potential benefits of the Prismaflex ST Set, when used for such use, outweigh the known and potential risks of the Prismaflex ST Set; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 authorized respirators may be effective to treat patients in an acute care environment during the COVID-19 pandemic, and that the known and potential benefits of the Prismaflex ST Set, when used for such use, outweigh the known and potential risks of the Prismaflex ST Set; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 authorized respirators may be effective to treat patients in an acute care environment during the COVID-19 pandemic, and that the known and potential benefits of the Prismaflex ST Set, when used for such use, outweigh the known and potential risks of the Prismaflex ST Set; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.
ventricular support for up to 14 days in critical care patients with a body surface area ≥1.5 m², for the treatment of acute right heart failure or decompensation caused by complications related to COVID–19, including pulmonary embolism, and that the known and potential benefits of the Impella RP, for such use, outweigh the known and potential risks; (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 product when used for such use, outweigh the known and potential risks of this product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.
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 MSU Sapphire CV may be effective for acute emergency use at home or in a healthcare setting to treat adult patients with known or suspected COVID–19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their HCP, by using non-invasive Vagus Nerve Stimulation (nVNS) on either side of the patients neck, and that the known and potential benefits of this product outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 IMPAACT Sapphire CV, issued July 10, 2020; 23 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 NoveSterilis, Inc.’s Nova2200 using the NovaClean decontamination process for decontaminating compatible N95 respirators, issued August 20, 2020; 29 and 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 Impella LV Support System, issued August 10, 2020, 20 and that the known and potential benefits of the authorized surgical masks may be effective for use in healthcare settings by HCPs as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID–19 pandemic, and that the known and potential benefits of the authorized surgical masks, when used consistent with the scope of the authorization, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

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 Impella LV Support System, issued August 10, 2020, 20 and that the known and potential benefits of the authorized surgical masks may be effective for use in healthcare settings by HCPs as PPE to provide a physical barrier to fluids and particulate materials to prevent HCP exposure to respiratory droplets and large particles during surgical mask shortages resulting from the COVID–19 pandemic, and that the known and potential benefits of the authorized surgical masks, when used consistent with the scope of the authorization, outweigh the known and potential risks of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the products.

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 Airway Dome may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE when transporting or performing medical procedures on patients who are known or suspected to have COVID–19, and that the known and potential benefits of the Airway Dome 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 product.

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 IkonX, Inc.’s Airway Dome, issued July 24, 2020; 25 and (3) there is no adequate, approved available alternative to the emergency use of the product.

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 Abiomed, Inc.’s Abiomed Impella Left Ventricular (LV) Support Systems, issued August 3, 2020; 26 and (3) there is no adequate, approved available alternative to the emergency use of the product.

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 Michigan State University Animal Care Program’s MSU Decontamination System, issued July 24, 2020; 24 and (3) there is no adequate, approved available alternative to the emergency use of the product.