



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 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. 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

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.

for Disease Control and Prevention (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.

III. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

IV. The Authorizations

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.

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(h)(1) of the FD&C Act. FDA is hereby announcing the following Authorizations for molecular diagnostic 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;

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.

- Exact Sciences Laboratories' SARS-CoV-2 (N gene detection) Test, issued May 22, 2020, and reissued August 3, 2020;
- dba SpectronRx's Hymon 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 SARS-CoV-2 RNA Test, issued June 5, 2020;
- Euroimmun US Inc.'s EURORealTime SARS-CoV-2, issued June 8, 2020;
- ChromaCode Inc.'s HDPCR SARS-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 SARS-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 SARS-CoV-2 Real-Time PCR Kit, issued June 12, 2020;
- Kaiser Permanente Mid-Atlantic States's KPMAS COVID-19 Test, issued June 13, 2020, and reissued September 9, 2020;
- Applied BioCode, Inc.'s BioCode SARS-CoV-2 Assay, issued June 15, 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 Biopurfectus 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 SARS-CoV-2 Kit, issued June 18, 2020;
- HealthQuest Esoterics's HealthQuest Esoterics TaqPath SARS-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 SARS-CoV-2 Test, issued June 23, 2020;
- University of Texas MD Anderson Cancer Center, Molecular Diagnostics Laboratory's MD Anderson High-throughput SARS-CoV-2 RT-PCR Assay, issued June 24, 2020;
- Diagnostic Solutions Laboratory, LLC's DSL COVID-19 Assay, issued June 25, 2020;
- PreciGenome LLC's FastPlex Triplex SARS-CoV-2 detection kit (RT-Digital PCR), issued June 25, 2020;
- PlexBio Co., Ltd.'s IntelliPlex SARS-CoV-2 Detection Kit, issued June 25, 2020;
- Inform Diagnostics, Inc.'s Inform Diagnostics SARS-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;
- Psomagen, Inc.'s Psoma 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-SARS-CoV-2 RT-PCR Assay, issued July 1, 2020;
- Becton, Dickinson and Co.'s BD Veritor System for Rapid Detection of SARS-CoV-2, issued July 2, 2020;
- Laboratorio Clinico Toledo's Laboratorio Clinico Toledo SARS-CoV-2 Assay, issued July 6, 2020;
- Gene By Gene's Gene By Gene SARS-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 SARS-CoV-2 Test System, issued July 7, 2020;
- Clinical Research Sequencing Platform (CRSP), LLC at the Broad Institute of MIT and Harvard's CRSP SARS-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 SARS-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 SARS-CoV-2 Multiplex, issued July 13, 2020;
- Compass Laboratory Services, LLC's Compass Laboratory Services SARS-CoV2 Assay, issued July 13, 2020;
- Quest Diagnostics Infectious Disease, Inc.'s Quest Diagnostics PF SARS-CoV-2 Assay, issued July 15, 2020, and reissued August 21, 2020;
- Quest Diagnostics Infectious Disease, Inc.'s Quest Diagnostics RC SARS-CoV-2 Assay, issued July 15, 2020, and reissued August 21, 2020;

- Quest Diagnostics Infectious Disease, Inc.'s Quest Diagnostics HA SARS-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 OraRisk COVID-19 RT-PCR, issued July 17, 2020;
- DiaCarta, Inc.'s QuantiVirus SARS-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 (SARS-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 SARS-CoV-2 Assay, issued July 27, 2020;
- Sandia National Laboratories' SNL-NM 2019 nCoV Real-Time RT-PCR Diagnostic 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 SARS-CoV-2 Assay, issued July 31, 2020;
- Xiamen Zeesan Biotech Co., Ltd.'s SARS-CoV-2 Test Kit (Real-time PCR), issued July 31, 2020;
- ISPM Labs, LLC dba Capstone Healthcare's Genus SARS-CoV-2 Assay, issued August 3, 2020;
- Poplar Healthcare's Poplar SARS-CoV-2 TMA Pooling assay, issued August 3, 2020;
- Cleveland Clinic Robert J. Tomsich Pathology and Laboratory Medicine Institute's Cleveland Clinic SARS-CoV-2 Assay, issued August 3, 2020;
- Ethos Laboratories' Ethos Laboratories SARS-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 SARS-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 SARS-CoV-2 RT-PCR Test, issued August 7, 2020;
- Quest Diagnostics Infectious Disease, Inc.'s SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR, reissued August 7, 2020 (original issuance March 17, 2020);
- Alpha Genomix Laboratories' Alpha Genomix TaqPath SARS-CoV-2 Combo Assay, issued August 10, 2020;
- Solaris Diagnostics' Solaris Multiplex SARS-CoV-2 Assay, issued August 10, 2020;
- Biomeme, Inc.'s Biomeme SARS-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 SARS-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;
- ZhuHai Sinochips Bioscience Co., Ltd.'s COVID-19 Nucleic Acid RT-PCR Test Kit, issued August 17, 2020;
- LumiraDx UK Ltd.'s LumiraDx SARS-CoV-2 Ag Test, issued August 18, 2020;
- Assurance Scientific Laboratories' Assurance SARS-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 SARS-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 SARS-CoV-2 Assay, issued August 21, 2020;
- Fluidigm Corp.'s Advanta Dx SARS-CoV-2 RT-PCR Assay, issued August 25, 2020;
- QDx Pathology Services' QDX SARS-CoV-2 Assay, issued August 25, 2020;
- Cuur Diagnostics' Cuur Diagnostics SARS-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 SARS-CoV-2 Real-Time RT-PCR Assay, issued August 28, 2020;
- DxTerity Diagnostics, Inc.'s DxTerity SARS-CoV-2 RT PCR CE Test, issued August 28, 2020;
- T2 Biosystems, Inc.'s T2SARS-CoV-2 Panel, issued August 31, 2020;
- MiraDx's MiraDx SARS-CoV-2 RT-PCR assay, issued August 31, 2020;
- Mammoth Biosciences, Inc.'s SARS-CoV-2 DETECTR Reagent Kit, issued August 31, 2020;
- BayCare Laboratories, LLC's BayCare SARS-CoV-2 RT PCR Assay, issued August 31, 2020;
- Detectachem 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 SARS-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

- Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.'s Wantai SARS-CoV-2 RT-PCR Kit, issued September 9, 2020.

FDA is hereby announcing the following Authorizations for serology tests⁴:

- Healgen Scientific LLC's COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma), issued May 29, 2020;
- Siemens Healthcare Diagnostics Inc.'s Atellica IM SARS-CoV-2 Total (COV2T), issued May 29, 2020;
- Siemens Healthcare Diagnostics Inc.'s ADVIA Centaur SARS-CoV-2 Total (COV2T), issued May 29, 2020;
- Hangzhou Biotest Biotech Co., Ltd.'s RightSign COVID-19 IgG/IgM Rapid Test Cassette, issued June 4, 2020;
- Vibrant America Clinical Labs' Vibrant COVID-19 Ab Assay, issued June 4, 2020;
- Siemens Healthcare Diagnostics Inc.'s Dimension Vista SARS-CoV-2 Total antibody assay (COV2T), issued June 8, 2020;
- Siemens Healthcare Diagnostics Inc.'s Dimension EXL SARS-CoV-2 Total antibody assay (CV2T), issued June 8, 2020;
- InBios International, Inc.'s SCoV-2 Detect IgG ELISA [enzyme-linked immunosorbent assay], issued June 10, 2020;
- Cellex Inc.'s qSARS-CoV-2 IgG/IgM Rapid Test, reissued June 12, 2020 (original issuance April 1, 2020);
- Emory Medical Laboratories' SARS-CoV-2 RBD IgG test, issued June 15, 2020;

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 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.

- Biohit Healthcare (Hefei) Co. Ltd.'s Biohit SARS-CoV-2 IgM/IgG Antibody Test Kit, issued June 18, 2020;
- Hangzhou Laihe Biotech Co., Ltd.'s LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold), issued June 19, 2020;
- Babson Diagnostics, Inc.'s Babson Diagnostics aC19G1, issued June 23, 2020;
- Beckman Coulter, Inc.'s Access SARS-CoV-2 IgG, issued June 26, 2020;
- InBios International, Inc.'s SCoV-2 Detect IgM ELISA, issued June 30, 2020;
- Assure Tech.'s (Hangzhou Co., Ltd) Assure COVID-19 IgG/IgM Rapid Test Device, issued July 6, 2020;
- Diazyme Laboratories, Inc.'s Diazyme DZ-Lite SARS-CoV-2 IgG CLIA Kit, issued July 8, 2020;
- Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.'s WANTAI SARS-CoV-2 Ab Rapid Test, July 10, 2020;
- Salofa Oy's Sienna-Clarity COVIBLOCK COVID-19 IgG/IgM Rapid Test Cassette, issued July 13, 2020;
- Luminex Corp.'s xMAP SARS-CoV-2 Multi-Antigen IgG Assay, issued July 16, 2020;
- Megna Health, Inc.'s Rapid COVID-19 IgM/IgG Combo Test Kit, issued July 17, 2020;
- Access Bio, Inc.'s CareStart COVID-19 IgM/IgG, issued July 24, 2020;
- Xiamen Biotime Biotechnology Co., Ltd.'s BIOTIME SARS-CoV-2 IgG/IgM Rapid Qualitative Test, issued July 24, 2020;
- Siemens Healthcare Diagnostics Inc.'s ADVIA Centaur SARS-CoV-2 IgG (COV2G), issued July 31, 2020;
- Siemens Healthcare Diagnostics Inc.'s Atellica IM SARS-CoV-2 IgG (COV2G), issued July 31, 2020;
- Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.'s WANTAI SARS-CoV-2 Ab ELISA, issued August 5, 2020;

- bioMérieux SA’s VIDAS SARS-CoV-2 IgM, issued August 6, 2020;
- bioMérieux SA’s VIDAS SARS-CoV-2 IgG, issued August 6, 2020;
- Diazyme Laboratories, Inc.’s Diazyme DZ-Lite SARS-CoV-2 IgM CLIA Kit, issued August 17, 2020;
- BioCheck, Inc.’s BioCheck SARS-CoV-2 IgG and IgM Combo Test, issued August 17, 2020;
- Biocan Diagnostics Inc.’s Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test, issued August 25, 2020;
- TBG Biotechnology Corp.’s TBG SARS-CoV-2 IgG / IgM Rapid Test Kit, issued August 31, 2020;
- University of Arizona Genetics Core for Clinical Services’ COVID-19 ELISA pan-Ig Antibody Test, issued August 31, 2020;
- Sugentech, Inc.’s SGTi-flex COVID-19 IgG, issued September 3, 2020;
- BioCheck, Inc.’s BioCheck SARS-CoV-2 IgG Antibody Test Kit, issued September 9, 2020;
- BioCheck, Inc.’s BioCheck SARS-CoV-2 IgM Antibody Test Kit, issued September 9, 2020; and
- Shenzhen New Industries Biomedical Engineering Co., Ltd.’s MAGLUMI 2019-nCoV IgM/IgG, issued September 14, 2020.

FDA is hereby announcing the following Authorizations for multianalyte in vitro diagnostics⁵:

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.

- Centers for Disease Control and Prevention’s Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay, issued July 2, 2020;
- Roche Molecular Systems, Inc.’s cobas SARS-CoV-2 & Influenza A/B, issued September 3, 2020; and
- Roche Molecular Systems, Inc.’s cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System, issued September 14, 2020.

FDA is hereby announcing the following Authorizations for personal respiratory protective devices⁶:

- Certain Non-National Institute of Industrial and Occupational Safety (NIOSH)-Approved Disposable Filtering Facepiece Respirators Manufactured in China, reissued June 6, 2020 (original issuance April 3, 2020). A current list of respirator models authorized by this EUA is available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#appendixa>; and
- Certain Imported, Non-NIOSH Approved Disposable Filtering Facepiece Respirators, reissued June 6, 2020 (original issuance March 24, 2020). A current list of respirator models authorized by this EUA is available at <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#exhibit1>.

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

- Baxter Healthcare Corp.’s Prismaflex ST Set, issued May 20, 2020;⁷

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 in preventing healthcare personnel (HCP) exposure to pathogenic biological airborne particulates during Filtering Facepiece Respirator (FFR) shortages, and that the known and potential benefits of the authorized respirators, when used to prevent HCP exposure to such particulates during FFR shortages during 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 this 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;

- STERIS Corp.'s AMSCO Medium Steam Sterilizers + the STERIS STEAM Decon Cycle, issued May 21, 2020⁸;
- Certain Gowns and Other Apparel, issued May 22, 2020⁹;
- CLEW Medical Ltd.'s CLEWICU System, issued May 26, 2020¹⁰;
- Abiomed, Inc.'s Impella RP System, issued May 29, 2020¹¹;
- Roche Diagnostics' Elecsys IL-6, issued on June 2, 2020¹²;

(2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Prismaflex ST Set 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 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 STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers may be effective at decontaminating compatible N95 respirators for single-user reuse by HCPs to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates for a maximum of 10 decontamination cycles per respirator, and that the known and potential benefits of this product, when used as described, outweigh the known and potential risks of the use of such 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, 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 gowns and other apparel worn by HCPs may be effective at preventing the transfer of microorganisms, bodily fluids, and particulate material in low or minimal risk situations by providing minimal-to-low barrier protection to HCP and patients to prevent the spread of COVID-19, and that the known and potential benefits of gowns and other apparel for such use, outweigh the known and potential risks of such products; and (3) there is no adequate, approved, and available alternative to the emergency use of these products.

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 CLEWICU System may be effective in treating COVID-19, when used by HCP in the intensive care unit (ICU) as a diagnostic aid to assist with the early identification of adult patients who are likely to be diagnosed with respiratory failure or hemodynamic instability which are common complications associated with COVID-19, and that the known and potential benefits of the CLEWICU System, for such use, outweigh the known and potential risks; 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 Impella RP may be effective in providing temporary right 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 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 ; 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 product may be effective in treating COVID-19, by assisting in identifying severe inflammatory response in patients with confirmed COVID-19 illness to aid in determining the risk of intubation with mechanical ventilation, and that the known and potential benefits of this 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.

- Battelle Memorial Institute’s Battelle CCDS Critical Care Decontamination System (“Batelle Decontamination System”), reissued June 6, 2020¹³ (original issuance March 29, 2020);
- STERIS Corp.’s STERIS Sterilization System, reissued June 6, 2020¹⁴ (original issuance April 9, 2020);
- Stryker Instruments’ STERIZONE VP4 N95 Respirator Decontamination Cycle, reissued June 6, 2020¹⁵ (original issuance on April 14, 2020);
- Advanced Sterilization Products, Inc.’s (ASP) STERRAD 100S, NX, and 100NX Sterilization Systems (“ASP STERRAD Sterilization Systems”), reissued June 6, 2020¹⁶ (original issuance April 11, 2020);
- Stryker Sustainability Solutions’ (SSS) SSS VHP N95 Respirator Decontamination System, issued May 27, 2020, reissued June 6, 2020¹⁷;

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 Battelle Decontamination System may be effective at decontaminating compatible N95 respirators for multiple-user reuse by HCPs to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

¹⁴ 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 STERIS Sterilization Systems may be effective at decontaminating compatible N95 respirators for single-user reuse by HCPs to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

¹⁵ 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 STERIZONE VP4 N95 Respirator Decontamination Cycle may be effective at preventing exposure to pathogenic biological airborne particulates by decontaminating, for a maximum of 2 decontamination cycles per respirator, comparable N95 respirators that are contaminated with SARS-CoV-2 or other pathogenic microorganisms, and that the known and potential benefits of this product, when used as described, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

¹⁶ As set forth in this 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 ASP STERRAD Sterilization Systems may be effective at decontaminating, for a maximum of 2 decontamination cycles per respirator, compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates, and that the known and potential benefits of the ASP STERRAD Sterilization Systems, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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;

- Sterilucent, Inc.’s Sterilucent HC 80TT Hydrogen Peroxide Sterilizer (“Sterilucent Sterilization System”), reissued June 6, 2020¹⁸ (original issuance April 20, 2020);
- Duke University Health System’s Duke Decontamination System for Decontamination and Reuse of N95 Respirators with Hydrogen Peroxide Vapor (“Duke Decontamination System”), reissued June 6, 2020¹⁹ (original issuance May 7, 2020);
- Technical Safety Services LLC’s 20-CS Decontamination System, issued June 13, 2020²⁰;
- Oceanetics, Inc.’s Negative-pressure Respiratory System with Advanced Ventilation Return (“NRS AVR-100”), issued June 13, 2020²¹;

(2) based on the totality of scientific evidence available to FDA, it is reasonable to believe that the SSS VHP N95 Respirator Decontamination may be effective at decontaminating compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used as described, outweigh the known and potential risks; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

¹⁸ 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 Sterilucent Sterilization System may be effective at decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to pathogenic biological airborne particulates, and that the known and potential benefits of this device, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

¹⁹ 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 Duke Decontamination System may be effective at decontaminating compatible N95 respirators for multiple-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

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 20-CS Decontamination System may be effective at decontaminating compatible N95 respirators for multiple-user reuse by HCPs to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used as described, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

²¹ 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 NRS AVR-100 may be effective in preventing HCP exposure to pathogenic biological airborne particulates by providing an extra layer of barrier protection in addition to PPE, 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 NRS AVR-100 for such use outweigh its known and potential risks; and (3) there is no adequate, approved available alternative to the emergency use of this product.

- US Army and MHS’s COVID-19 Airway Management Isolation Chamber (CAMIC), issued May 19, 2020 and reissued to US Army Medical Research Development Command June 22, 2020²²;
- electroCore, Inc.’s gammaCore Sapphire CV, issued July 10, 2020²³;
- Michigan State University Animal Care Program’s MSU Decontamination System, issued July 24, 2020²⁴;
- IkonX, Inc.’s Airway Dome, issued July 24, 2020²⁵;
- Abiomed, Inc.’s Impella Left Ventricular (LV) Support Systems, issued August 3, 2020²⁶;

²² 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 CAMIC 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 CAMIC for such use outweigh its known and potential risks; and (3) there is no adequate, approved available alternative to the emergency use of the product.

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 gammaCore 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 for such use 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.

²⁴ 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 Decontamination System may be effective at decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

²⁵ 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, at the time of definitive airway management, 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 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.

²⁶ 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 Systems may be effective when used by HCP in the hospital setting for providing temporary LV unloading and support to treat critical care patients with confirmed COVID-19 infection who are undergoing ECMO treatment and who develop pulmonary edema while on V-A ECMO support or late cardiac decompensation from myocarditis while on V-V ECMO support, and that the known and potential benefits of the Impella LV Support System, for such

- Disposable, single-use surgical masks, issued August 5, 2020.²⁷ A current list of surgical masks authorized by this EUA is available here: <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas#appendixasurgicalmasks>;
- Baxter Healthcare Corp.'s Prismaflex HF20 Set, issued August 10, 2020²⁸;
- NovaSterilis, Inc.'s Nova2200 using the NovaClean decontamination process for decontaminating compatible N95 respirators, issued August 20, 2020²⁹; and
- Color Genomics, Inc.'s Color COVID-19 Self-Swab Collection Kit, issued August 31, 2020.³⁰

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

²⁷ 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 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.

²⁸ 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 and multiple organ failure, including acute kidney injury, to humans infected by this virus; (2) Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Prismaflex HF20 Set (cartridge, including hemodialyzer plus tubing set) may be effective at providing continuous renal replacement therapy (CRRT) to treat low weight patients who have low blood volume and who have acute renal failure, fluid overload, or both, and who cannot tolerate a larger extracorporeal circuit volume in an acute care environment during the COVID-19 emergency and that the known and potential benefits of the Prismaflex HF20 Set, when used for such use, outweigh the known and potential risks of the Prismaflex HF20 Set; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

²⁹ 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 Nova2200 may be effective at decontaminating compatible N95 respirators for single-user reuse by HCP to prevent exposure to SARS-CoV-2 and other pathogenic biological airborne particulates, and that the known and potential benefits of this product, when used for such use, outweigh the known and potential risks of the use of such product; and (3) there is no adequate, approved, and available alternative to the emergency use of the product.

³⁰ 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 this product 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 this 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.

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