FDA COMBATING COVID-19 WITH MEDICAL DEVICES

Since the beginning of the COVID-19 pandemic, FDA has been working to facilitate the development and availability of medical products and equipment for use by patients, physicians and healthcare systems as expeditiously and safely as possible. All of FDA’s latest actions around COVID-19 are available on our website.

During public health emergencies, FDA can use emergency authorities, including Emergency Use Authorizations (EUAs), to help make medical products available as quickly as possible by allowing unapproved medical products to reach patients in need when there are no adequate, FDA-approved and available alternatives. These products may include tests to help diagnose diseases, critical medical devices needed by patients or healthcare personnel in the context of a public health crisis, and drugs to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions.

During this pandemic, there have been a number of supply issues that have made it challenging to obtain access to diagnostic tests and test supplies (like swabs), and medical equipment. We are updating FAQs on our webpage regularly to provide information on diagnostic testing, including alternative test supplies and ways to conduct testing when necessary. If test developers or labs are having any issues developing or running tests, and for difficulties obtaining medical devices such as personal protective equipment (PPE) and other medical equipment shortages, we have a toll-free phone line that is open 24 hours a day: 1-888-INFO-FDA (1-888-463-6332), then press star (*).

Below is a list and descriptions and key information for all the molecular diagnostic and serological (antibody) tests and medical devices that have been authorized for emergency use (under an EUA).

The molecular diagnostic tests are generally authorized for qualitative detection of nucleic acid from SARS-CoV-2 in specific upper and lower respiratory specimens from individuals suspected of COVID-19 by their healthcare provider. The specific specimen types for each test can be found in the authorization letter. Some molecular diagnostic tests may require a highly trained operator to manually perform the test (e.g., perform an RNA extraction step usually using specific extraction platforms and kits), while other tests are automated and require only limited training to perform. Typically, manually performed tests are authorized for use by laboratories certified to perform high-complexity tests, while automated tests are authorized for use by laboratories certified to perform moderate complexity tests and/or at the point-of-care by facilities operating under a CLIA Certificate of Waiver.
The serological (antibody) tests are generally authorized for the qualitative detection of antibodies to SARS-CoV-2 in blood, serum, and/or plasma, and are intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The specific specimen types for each test can be found in the authorization letter.

<table>
<thead>
<tr>
<th>SPONSOR</th>
<th>PRODUCT (link to authorization letter)</th>
<th>DESCRIPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DIAGNOSTICS</strong></td>
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</tbody>
</table>
| Center for Disease Control and Prevention              | CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel        | • Developed by CDC and initially distributed to public health labs across the country  
• Can only be run in high complexity labs                |
| Wadsworth – New York State Public Health               | New York SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel | • Developed by Wadsworth based on CDC’s published protocol  
• Run in qualified labs across New York State  
• Can only be run in high complexity labs |
| Roche Molecular Systems, Inc.                         | cobas® SARS-CoV-2 for use on the cobas® 6800/8800 Systems | • Commercially distributed as a kit to labs  
• Can be run in moderate and high complexity labs         |
| Life Technologies (a part of Thermo Fisher Scientific, Inc.) | TaqPath™ COVID-19 Combo Kit, 100 Rxn, TaqPath™ COVID-19 Combo Kit, 1,000 Rxn | • Commercially distributed as a kit to labs  
• Can only be run in high complexity labs                |
| Laboratory Corporation of America Amended 4/20/20      | COVID-19 RT-PCR Test, COVID-19 RT-PCR Amendment         | • Developed and run in high complexity LabCorp labs only; not for broader lab distribution  
• Amendment permits use of the Pixel by LabCorp COVID-19 test home collection kit allowing patients to self-collect nasal swab specimens at home  
• The kit provides specimen collection materials and materials to safely mail specimens to an authorized laboratory |
| Hologic, Inc.                                          | Panther Fusion SARS-CoV-2 Assay                        | • Reagents commercially distributed as a kit to labs  
• Can only be run in high complexity labs               |
| Quest Diagnostics Infectious Disease, Inc.            | SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR           | • Developed and run in Quest labs only; not a kit for distribution.  
• Can only be run in high complexity labs               |
| Quidel Corporation                                     | Lyra® SARS-CoV-2 Assay                                | • Reagents commercially distributed as a kit to labs  
• Can only be run in high complexity labs               |
<p>| Abbott Molecular, Inc.                                | Abbott RealTime SARS-CoV-2 assay                       | • Reagents commercially distributed as a kit to labs                        |</p>
<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Test Name</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>GenMark Diagnostics, Inc.</td>
<td>ePlex SARS-CoV-2 Test</td>
<td>• Can only be run in high complexity labs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Reagents commercially distributed as a kit to labs</td>
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<tr>
<td></td>
<td></td>
<td>• Can run up to 24 specimens at the same time</td>
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<tr>
<td></td>
<td></td>
<td>• Can be run in a moderate or high complexity lab</td>
</tr>
<tr>
<td>DiaSorin Molecular LLC</td>
<td>Simplexa COVID-19 Direct</td>
<td>• Reagents commercially distributed as a kit to labs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can run 1 specimen at a time</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can be run in moderate and high complexity labs</td>
</tr>
<tr>
<td>Primerdesign Ltd.</td>
<td>Primerdesign Ltd COVID-19 genesig Real-Time PCR</td>
<td>• Reagents commercially distributed as a kit to labs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can only be run in high complexity labs</td>
</tr>
<tr>
<td>Cepheid</td>
<td>Xpert Xpress SARS-CoV-2 test</td>
<td>• Reagents commercially distributed as a kit to labs</td>
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<tr>
<td></td>
<td></td>
<td>• Can run up to 2,000 samples per day</td>
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<tr>
<td></td>
<td></td>
<td>• Can be run in a high or moderate complexity lab or at the Point of Care (POC) near the patient (deemed CLIA waived)</td>
</tr>
<tr>
<td>Mesa Biotech Inc.</td>
<td>Accula SARS-CoV-2 Test</td>
<td>• Reagents commercially distributed as a kit to labs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Runs one specimen at a time</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can be run in a high or moderate complexity lab or at the Point of Care (POC) near the patient (deemed CLIA waived)</td>
</tr>
<tr>
<td>BioFire Defense, LLC</td>
<td>BioFire COVID-19 Test</td>
<td>• Reagents commercially distributed as a kit to labs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can run up to 264 tests per day</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can be run in moderate or high complexity labs</td>
</tr>
<tr>
<td>PerkinElmer, Inc.</td>
<td>PerkinElmer New Coronavirus Nucleic Acid Detection kit</td>
<td>• Reagents commercially distributed as a kit to labs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can only be run in high complexity labs</td>
</tr>
<tr>
<td>Avellino Labs USA</td>
<td>AvellinoCoV2 test</td>
<td>• Developed and run in Avellino labs; not distributed to other labs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• High complexity test limited to authorized laboratories</td>
</tr>
<tr>
<td>BGI Genomics Co. Ltd.</td>
<td>Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV</td>
<td>• Reagents commercially distributed as a kit to labs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can only be run in high complexity labs</td>
</tr>
<tr>
<td>Luminex Molecular Diagnostics, Inc.</td>
<td>NxTAG CoV Extended Panel Assay</td>
<td>• Reagents commercially distributed as a kit to labs</td>
</tr>
<tr>
<td>Company</td>
<td>Product Name</td>
<td>Details</td>
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<tr>
<td>-------------------------</td>
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</tr>
<tr>
<td>Abbott Diagnostics</td>
<td>ID NOW™ COVID-19</td>
<td>Can only be run in high complexity labs</td>
</tr>
</tbody>
</table>
| Scarborough, Inc.       |                                     | Reagents commercially distributed as a kit  
|                         |                                     | Requires a specific platform (ID NOW), of which there are 18,000 installed across the US  
|                         |                                     | Runs one specimen at a time; each takes <13 minutes  
|                         |                                     | Can be run in a high or moderate complexity lab or at the Point of Care (POC) near the patient (deemed CLIA waived) |
| NeuMoDx Molecular, Inc. | NeuMoDx SARS-CoV-2 Assay           | Reagents commercially distributed as a kit  
|                         |                                     | Can run 288 or 96 samples at once, depending on the instrument, and takes 80 minutes per sample  
|                         |                                     | Can be run in high and moderate complexity labs |
| QIAGEN GmbH             | QIAsstat-Dx Respiratory SARS-CoV-2 Panel | Detects multiple other respiratory viral (17) and bacterial (3) organisms  
|                         |                                     | Reagents commercially distributed as a kit to labs  
|                         |                                     | Runs one specimen at a time and takes one hour  
|                         |                                     | Can be run in high and moderate complexity labs |
| EUA for COVID-19 LDTs   | Laboratory developed tests that are authorized are listed below and hyper link to letter granting inclusion under EUA | Authorizes the use of LDTs that meet certain criteria  
|                         |                                     | Authorized tests can be used in the high complexity CLIA-certified lab that developed the test |

- **AIT Laboratories**
- **CirrusDx SARS-CoV-2 Assay**
- **Diagnostic Molecular Laboratory-Northwestern Medicine**
- **Diatherix Eurofins Laboratory**
- **Exact Sciences Laboratories**
- **Hackensack University Medical Center (HUMC) Molecular Pathology Laboratory**
- **Infectious Diseases Diagnostics Laboratory (IDDL), Boston Children’s Hospital**
- **Infectious Disease Diagnostics Laboratory-Children’s Hospital of Philadelphia**
- **Integrity Laboratories**
- **Massachusetts General Hospital (Mass Gen)**
- **Mayo Clinic Laboratories, Rochester, MN**
- **Nationwide Children’s Hospital**
- **Orig3n, Inc.**
- **Pathology/Laboratory Medicine Lab of Baptist Hospital Miami**
- **Rutgers Clinical Genomics Laboratory-Rutgers University**
<table>
<thead>
<tr>
<th>Organization</th>
<th>Test Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ipsum Diagnostics</td>
<td><strong>COV-19 IDx assay</strong></td>
</tr>
<tr>
<td><strong>Newest authorizations are in bold</strong></td>
<td></td>
</tr>
<tr>
<td>Becton, Dickinson &amp; Company (BD)</td>
<td><strong>BioGX SARS-CoV-2 Reagents for BD MAX System</strong></td>
</tr>
<tr>
<td>Luminex Corporation</td>
<td><strong>ARIES SARS-CoV-2 Assay</strong></td>
</tr>
<tr>
<td>ScienCell Research Laboratories</td>
<td><strong>ScienCell SARS-CoV-2 Coronavirus Real-time RT-PCR (RT-qPCR) Detection Kit</strong></td>
</tr>
<tr>
<td>Co-Diagnostics, Inc.</td>
<td><strong>Logix Smart Coronavirus Disease 2019 (COVID-19) kit</strong></td>
</tr>
<tr>
<td>Gnomegen LLC</td>
<td><strong>Gnomegen COVID-19 RT-Digital PCR Detection Kit</strong></td>
</tr>
<tr>
<td>InBios International, Inc</td>
<td><strong>Smart Detect SARS-CoV-2 rRT-PCR Kit</strong></td>
</tr>
<tr>
<td>Becton, Dickinson &amp; Company (BD)</td>
<td><strong>BD SARS-CoV Reagents for BD MAX System</strong></td>
</tr>
<tr>
<td>DiaCarta, Inc.</td>
<td><strong>QuantiVirus SARS-CoV-2 Test Kit</strong></td>
</tr>
<tr>
<td>Atila BioSystems, Inc.</td>
<td><strong>iAMP COVID-19 Detection Kit</strong></td>
</tr>
</tbody>
</table>

- Uses commercially available reagents
- Can only be run in high complexity labs by Ipsum
- Reagents commercially distributed as a kit to labs
- Fully automated, 8 samples per hour
- Can be run in moderate and high complexity labs
- Reagents commercially distributed as a kit to labs
- Can be run in moderate and high complexity labs
- Reagents commercially distributed as a kit to labs
- Can only be run in high complexity labs
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<table>
<thead>
<tr>
<th>Company</th>
<th>Kit Name</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maccura Biotechnology (USA) LLC</td>
<td><strong>SARS-CoV-2 Fluorescent PCR Kit</strong></td>
<td>• Reagents commercially distributed as a kit to labs</td>
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<td>• Can only be run in high complexity labs</td>
</tr>
<tr>
<td>GenoSensor, LLC.</td>
<td><strong>GS™ COVID-19 RT-PCR KIT</strong></td>
<td>• Reagents commercially distributed as a kit to labs</td>
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<td>• Can only be run in high complexity labs</td>
</tr>
<tr>
<td>KorvaLabs Inc.</td>
<td><strong>Curative-Korva SARS-CoV-2 Assay</strong></td>
<td>• Laboratory Developed Test</td>
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<tr>
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<td>• High complexity test limited to KorvaLabs, Inc., a certified high complexity laboratory</td>
</tr>
<tr>
<td>Fosum Pharma USA Inc.</td>
<td><strong>Fosun COVID-19 RT-PCR Detection Kit</strong></td>
<td>• Reagents commercially distributed as a kit to labs</td>
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<td></td>
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<td>• Can only be run in high complexity labs</td>
</tr>
<tr>
<td>OSANG Healthcare</td>
<td><strong>GeneFinder COVID-19 Plus RealAmp Kit</strong></td>
<td>• Reagents commercially distributed as a kit to labs</td>
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<td></td>
<td></td>
<td>• Can only be run in high complexity labs</td>
</tr>
<tr>
<td>Trax Management Services Inc.</td>
<td><strong>PhoenixDx 2019-CoV</strong></td>
<td>• Reagents commercially distributed as a kit to labs</td>
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<td></td>
<td></td>
<td>• Can only be run in high complexity labs</td>
</tr>
<tr>
<td>Seegene, Inc.</td>
<td><strong>Allplex 2019-nCoV Assay</strong></td>
<td>• Reagents commercially distributed as a kit to labs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can only be run in high complexity labs</td>
</tr>
<tr>
<td>altona Diagnostics GmbH</td>
<td><strong>RealStar SARS-CoV02 RT-PCR Kits U.S.</strong></td>
<td>• Reagents commercially distributed as a kit to labs</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can only be run in high complexity labs</td>
</tr>
<tr>
<td>SD Biosensor, Inc.</td>
<td><strong>STANDARD M nCoV Real-Time Detection Kit</strong></td>
<td>• Reagents commercially distributed as a kit to labs</td>
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<td></td>
<td></td>
<td>• Can only be run in high complexity labs</td>
</tr>
<tr>
<td>SEASUN BIOMATERIALS</td>
<td><strong>U-TOP COVID-19 Detection Kit</strong></td>
<td>• Reagents commercially distributed as a kit to labs</td>
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<td></td>
<td></td>
<td>• Can only be run in high complexity labs</td>
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</tbody>
</table>

**SEROLOGY TESTS**
<table>
<thead>
<tr>
<th>Company</th>
<th>Test Description</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellex Inc.</td>
<td>Serology Test qSARS-CoV-2 IgG/IgM Rapid Test</td>
<td>• The first serological test authorized under EUA.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Detects SARS-CoV-2 antibodies in blood and differentiates between IgG and IgM antibodies.</td>
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<tr>
<td></td>
<td></td>
<td>• Rapid test provides results in 15-20 minutes.</td>
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<td></td>
<td></td>
<td>• Can be run in high and moderate complexity labs</td>
</tr>
<tr>
<td>Ortho Clinical Diagnostics, Inc.</td>
<td>VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack</td>
<td>• Detects total antibodies in serum and plasma.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can be run in high and moderate complexity labs</td>
</tr>
<tr>
<td>Chembio Diagnostic Systems, Inc.</td>
<td>DPP COVID-19 IgM/IgG System</td>
<td>• Detects and differentiates IgM and IgG antibodies in whole blood, fingerstick whole blood, serum and plasma.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can be run in high and moderate complexity labs</td>
</tr>
<tr>
<td>Mount Sinai Laboratory</td>
<td>COVID-19 ELISA IgG Antibody Test</td>
<td>• Detects IgG antibodies in serum and plasma.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Test is limited to Mount Sinai Laboratory.</td>
</tr>
<tr>
<td>Autobio Diagnostics Co. Ltd.</td>
<td>Anti-SARS-CoV-2 Rapid Test</td>
<td>• Detects and differentiates IgM and IgG antibodies in serum and plasma</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can be run in high and moderate complexity labs</td>
</tr>
<tr>
<td>Ortho Clinical Diagnostics, Inc.</td>
<td>VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack</td>
<td>• Detects IgG antibodies in serum.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can be run in high and moderate complexity labs</td>
</tr>
<tr>
<td>DiaSorin Inc.</td>
<td>LIAISON SARS-CoV-2 S1/S2 IgG</td>
<td>• Detects IgG antibodies in serum and plasma.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can be run in high and moderate complexity labs</td>
</tr>
<tr>
<td>Abbott Laboratories Inc.</td>
<td>SARS-CoV-2 IgG assay</td>
<td>• Detects IgG antibodies in serum and plasma.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Can be run in high and moderate complexity labs</td>
</tr>
</tbody>
</table>

**Devices**

<table>
<thead>
<tr>
<th>Company</th>
<th>Test Description</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced Sterilization Products, Inc.</td>
<td>Advanced Sterilization Products (ASP) STERRAD Sterilization System</td>
<td>Decontaminates compatible N95 or N95-equivalent respirators for single user reuse by healthcare personnel to prevent exposure to airborne particulates when there are insufficient supplies of N95 respirators.</td>
</tr>
<tr>
<td>Battelle</td>
<td>Battelle Decontamination System</td>
<td>A single compatible respirator to be recycled and reused up to 20 times using the Battelle Decontamination System.</td>
</tr>
</tbody>
</table>
Battelle is authorized to scale up their operations to decontaminate about 120,000 respirators daily by using all 12 of their satellite facilities once they submit data to FDA.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>B.Braun</td>
<td>Space and Outlook Pumps (Infusion Pump)</td>
<td>An infusion pump for delivery of medications into a nebulizer to treat COVID-19 patients of all ages.</td>
</tr>
<tr>
<td>CytoSorbents, Inc.</td>
<td>CytoSorb Device (Extracorporeal Blood Purification (EBP) Device)</td>
<td>Blood purification system to treat patients 18 years older with confirmed COVID-19 diagnosis admitted to the intensive care unit with confirmed or imminent respiratory failure.</td>
</tr>
<tr>
<td>ExThera Medical Corporation</td>
<td>Seraph 100 Microbind Affinity Blood Filter Device</td>
<td>Blood purification system to treat patients 18 years older with confirmed COVID-19 diagnosis admitted to the intensive care unit with confirmed or imminent respiratory failure.</td>
</tr>
<tr>
<td>Lungpacer Medical, Inc.</td>
<td>Lungpacer Medical, Inc. Diaphragm Pacing Therapy System (DPTS)</td>
<td>A device that assists in weaning patients that are at risk of weaning failure off breathing assistance machines requiring patient intubation.</td>
</tr>
<tr>
<td>Sterilucent, Inc.</td>
<td>Sterilucent, Inc. Sterilization System</td>
<td>Decontaminates compatible N95 or N95 equivalent respirators (compatible N95 respirators) for single-user reuse by healthcare personnel.</td>
</tr>
<tr>
<td>STERIS</td>
<td>STERIS V-PRO 1 Plus, maX, and maX2 Lower Temperature Systems (STERIS Sterilization Systems)</td>
<td>Decontaminates compatible N95 or N95 equivalent respirators (compatible N95 respirators) for single-user reuse by healthcare personnel.</td>
</tr>
<tr>
<td>Stryker</td>
<td>STERIZONE VP4 N95 Respirator Decontamination Cycle</td>
<td>Decontaminates compatible N95 or N95 equivalent respirators (compatible N95 respirators) for single-user reuse by healthcare personnel.</td>
</tr>
<tr>
<td>Synapse Biomedical, Inc.</td>
<td>Synapse Biomedical, Inc. TransAeris Diaphragmatic Pacing Therapy System (DPTS)</td>
<td>A device that assists in weaning patients that are at risk of weaning failure off breathing assistance machines.</td>
</tr>
<tr>
<td>Terumo BCT Inc. and Market Therapeutics AG</td>
<td>Spectra Optia Apheresis System with the Depuro D2000 Adsorption Cartridge</td>
<td>Blood purification system to treat patients 18 years older with confirmed COVID-19 diagnosis admitted to the intensive care unit with confirmed or imminent respiratory failure.</td>
</tr>
</tbody>
</table>

Manufacturers of Face Masks (non-surgical) | Face masks are authorized under this umbrella authorization when they are intended for use by members of the general public, which includes HCP (refers to all paid and unpaid persons serving in healthcare settings), to cover their noses and mouths in accordance with CDC recommendations. Authorized face masks must meet the following requirements: |
1. The product is labeled accurately to describe the product as a face mask and includes a list of the body contacting materials (which does not include any drugs or biologics);

2. The product is labeled accurately so that it does not claim to be intended for use as a surgical mask or to provide liquid barrier protection, and includes recommendations that would reduce the risk of such use; for example, the labeling might include recommendations against: use in any surgical setting or where significant exposure to liquid, bodily or other hazardous fluids, may be expected; use in a clinical setting where the infection risk level through inhalation exposure is high; and use in the presence of a high intensity heat source or flammable gas; or as an alternative example, recommendations for use only by the general public; and

3. The product is not labeled in such a manner that would misrepresent the product’s intended use; for example, the labeling should not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction, nor should it be used for particulate filtration.

For conditions of authorization for manufacturers and distributors, including conditions related to advertising and promotion, see pages 4-6 of Letter of Authorization.

<table>
<thead>
<tr>
<th>Manufacturers of Face Shields</th>
<th>Face shields for use by HCP as PPE are authorized under this EUA when they are intended for use by HCP as PPE in healthcare settings in accordance with CDC recommendations to cover the front and sides of the face and provide barrier protection and meet the following requirements:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A.</td>
<td>The product is labeled accurately to describe the product as a face shield for medical purposes and includes a list of the body contacting materials (which does not include any drugs or biologics);</td>
</tr>
<tr>
<td>B.</td>
<td>The product is not integrated with any other article of PPE such as a face mask, but rather is for use as a standalone face shield.</td>
</tr>
<tr>
<td>C.</td>
<td>The product includes labeling that describes the product as intended for either a single-user, single use, or for multiple uses by the same user, and includes instructions for recommended cleaning and/or disinfection materials and processes, if applicable.</td>
</tr>
<tr>
<td>D.</td>
<td>The face shield does not contain any materials that will cause flammability, or the product meets Class I or Class II flammability requirement per 16 CFR 1610 (unless labeled with a recommendation against use in the presence of high intensity heat source or flammable gas);</td>
</tr>
<tr>
<td>E.</td>
<td>The product is not intended for any use that would create an undue risk in light of the public health emergency; for example, the labeling does not state that use of the authorized face shield alone will prevent infection from microbes or viruses, or that it is effective against radiation protection. As indicated in Section I, face shields authorized by this EUA may be effective at preventing HCP exposure to certain particulates during face shield shortages by providing minimal or low barrier HCP protection to the wearer during COVID-19. All</td>
</tr>
</tbody>
</table>
Manufacturers are reminded that they must comply with all Conditions of Authorization, including those relating to advertising and promotion in Section IV of this letter. Manufacturers of authorized face shields do not need to take any action, other than complying with the Conditions of Authorization (Section IV) in this letter of authorization to be an authorized face shield under this EUA if they are within the Scope of Authorization (Section II) of this EUA.

**RESPIRATORS**

| CDC | National Institute for Occupational Safety and Health (NIOSH)-Approved Air Purifying Respirators for Use in Health Care Settings During Response to the COVID-19 Public Health Emergency | Decontaminates compatible N95 or N95-equivalent respirators for single user reuse by healthcare personnel to prevent exposure to airborne particulates when there are insufficient supplies of N95 respirators. |

- Non-powered air-purifying particulate Filtering facepiece respirators (FFRs) and reusable respirators such as elastomeric half and full faced facepiece respirators, approved by NIOSH and listed on the NIOSH Certified Equipment list (CEL) for non-powered air purifying respirators with particulate protection;
- Other powered air purifying respirators (PAPRs) approved by NIOSH, and that are listed on the NIOSH CEL for PAPRs with particulate protection;
- FFRs that were NIOSH-approved but have since passed the manufacturers’ recommended shelf-life, are not damaged, and have been held in accordance with manufacturers’ storage conditions in strategic stockpiles; and,
- Any authorized respirator that has been decontaminated pursuant to the terms and conditions of an authorized decontamination system.

**Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators**

- Products from the following countries: Australia, Brazil, Europe, Japan, South Korea, and Mexico; and/or
- Products authorized in the following regulatory jurisdictions: European CE Mark, Australia Register of Therapeutic Goods (ARTG) Certificate of Inclusion, Health Canada License, or Japan Pharmaceuticals and Medical Device (PMDA)/Ministry of Health and Labour and Welfare (MHLW)

**Authorized Imported, Non-NIOSH Approved Respirators**

- 3M, Model 8205, Manufactured in Japan

This EUA authorizes certain respirators, including ones that have used a specific decontamination system, to be used in health care settings by healthcare personnel in accordance with CDC’s recommendations. Authorized Respirators are listed in Exhibit 1 and listed below.
This EUA allows disposable non-NIOSH-approved respirators manufactured in China that meet one of the following criteria to be eligible for authorization after completing a verification process:

1. Manufactured by an entity that holds one or more NIOSH approvals for other models of FFRs produced in accordance with the applicable standards of authorization in other countries that can be verified by FDA; or
2. It has a regulatory authorization under a jurisdiction other than China that can be authenticated and verified by FDA; or
3. It demonstrates acceptable performance to applicable testing standards as documented by test reports from a recognized independent test laboratory that can be verified by FDA.

The EUA also authorizes respirators listed in Appendix A (also listed below) that have been decontaminated pursuant to the terms and conditions of an authorized decontamination system.

### Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China

- 3M, 9001, 9002, 9501, 9501+, 9501V+, 9502, 9502+, 9502V+, 9505+, 9541, 9541V, 9542, 9542V, 9552, 9552V, Made in China.
- Allmed, KN95 Particulate Respirator LP220002, Made in China.
- AOK Tooling Ltd. (aka Shenzhonghai Medical), 20130040, 20130045A, 20180021, 20130038, 20190019, Made in China.
- Bei Bei Safety Co Ltd., B702, B702V, B704, B704V, Made in China.
- BYD Precision Manufacture Co. Ltd., BYD KN95 Particulate Respirator (Model Number DG3101), Made in China.
- Changsha JNEYL Medical Equipment Co., Ltd., BYD Kn95 Particulate Respirator (Model Number: DG3101), Made in China.
- Changzhou Wedream Medical Device Co., Ltd. KN95. Made in China.
- Chengde Technology Co., KN95 (PM 2.5) Protective Mask, Made in China.
- China Nano Technology Co., Ltd., ZN6005, ZN8005, Made in China.
- Chongqing China Nano Technology Co., Ltd. KN95, ZN6005. Made in China.
- Creative Concepts Manufacturing Ltd., 02669, 02676, KN95, Made in China.
- CTT Co. Ltd., KN95, Made in China.
- Daddybaby Co. Ltd., KN95 FFP2, Made in China.
- Dongguan Huagang Communication Technology Co., Ltd., KN950A; KN95-B. Made in China.
- Dongguan Huagang Communication Technology Co. Ltd., KN95-A; KN95-B. Made in China.
- Dongguan Leihuo Medical Device Co. LTD., CPFM-100, CPFM-101, LH-KN95. Made in China.
- Dongguan Sengtor Plastics Products Co., Ltd., KN95, Made in China.
- Dongguan Xianda Medical Equipment Co., Ltd, KN95, Made in China.
- Foshan Nanhai Weijian Sanbang Protective Equipment Technology Co., Ltd. KN95 Model 9051A. Made in China.
- Fujian Pageone Garment Co, Ltd. K95, Made in China.
- Fujian Yongtai Sanlian Garment Co., Ltd., N95. Made in China.
- Guangdong Fei Fan MStar Technology Ltd., KN95, Made in China.
- Guangdong Golden Leaves Technology Development Co., Ltd., 8862, KN95, Made in China.
- Guangdong Kaper Protection Technology Co., Ltd, KP0K02 (N95), Made in China.
- Guangdong Nuokang Medical Technology Co., Ltd., KN95, Made in China.
- Guangdong ZhiZhen Biological Medicine Biological Medicine Co., Ltd., KN95, Made in China.
- Guangzhou Aiyinmei Co., Ltd., A&F KN95, Made in China.
- Guangzhou Harley Commodity Company Limited, L-103V, KN95, Made in China.
- Guangzhou Nan Qi Xing Nonwoven Co. Ltd., KN95, Made in China.
- Guangzhou Powecom Labor Insurance Supplies Co., LTD. KN95, Made in China.
- Guangzhou Sunjoy Auto Supplies Co., Ltd., Earhook Folding type K1-K100, Headband folding type K1-K100, Made in China.
- Guangzhou Yihere Medical Technology Development Co., Ltd., YH-MFK-B95, YH-MFK-Z95, Made in China.
- Guizhou Bocai Medical Device Co., Ltd., Bocai KN95, Made in China.
- HeiQ Materials AG, HVP-FFP2-01, Made in China.
- Henan Fengzhihuang Industrial Co., Ltd. HF/KN95-3, Made in China.
- Henan Youmansi Health Technology Co. LTD., YMS-AN95, Made in China.
- Huizhou Jiahe Cubic Technology Co., Ltd., KN95, Made in China.
- Huizhou Lexulsance Technology Co., Ltd., LK-003, Made in China.
- Jiangsu Weichuangli New Materials Co., Ltd., WCL-0075, Made in China.
- Jiangsu Yimao Filter Media Co., Ltd. 9570K, Made in China.
• Jiangxi Hornet Industrial Co. Ltd., S-KN95, Made in China.
• Jiangxi Yifengyuan Biological Engineering Co., LTD., N95, KN95, Made in China.
• Jinhua Jiadaifu Medical Supplies, Co., Ltd., KN95, FFP2, Made in China.
• Jinan Vhold Co., Ltd., VH-95. Made in China.
• Lanshan Shendun Technology Co. SD-KN95-01, SD-KN95-02, SD-KN95-CO1, SDKN95-CO2. Made in China.
• Panzhihua Gangchen Group Yasheng Industrial Co., Ltd., KN95, Made in China.
• Qingyuan Leite Technology Development Co., GV-0095A, GVHKN95, Made in China.
• Raxwell Industrial Technology (Shanghai) Co., Ltd., RX9501. Made in China.
• Rizhao Sanqi Medical & Health Articles Co., Ltd. RIZ100CVb, 3Q KN95, 3Q FFP2 NR, RIZQ100Sb, 3Q KN95 9505, Made in China.
• Shandong Daddy’s Choice Health Science and Technology Co., Ltd. Purism KN95. Made in China.
• Shandong Huishoutang Pharmaceutical Co., KN95, Made in China.
• Shandong Shengquan New Material Co., Ltd., SNN70370B (Willow leaf form valveless), Made in China.
• Shanghai Dasheng Health Products Manufacture Company, Ltd., DTC3X-1, DTC3C-2, DTC3X-3, DTC3B-1, Made in China.
• Shanghai Yunqing Industrial Co., Ltd., YQD95, KN95, Made in China.
• Shuaguan Taije Protection Technology Col, Ltd., KN95, Made in China.
• Shenzhen Horb Technology Corp., Ltd., 1.7.02.02.0001, Made in China.
• Shenzhen Missadola Technology Col, Ltd. Dba 1AK Medical Supplies, 2323-1 KN95, Made in China.
• Sunright Medical Technology (GuangDong) Co., LTD., KN95-C3, Made in China
• Suzhou Bolisi Medical Technology Co., Ltd., BS-9501L, BS-9501FL, BS-9502C, BS-9502FC, Made in China.
• Tianjin Benmo Medical Equipment Co., Ltd., KN95, Made in China.
• Weini Technology Development Co., Ltd. FFP2 NR E-300, FFP NR E-680, FFP2 NR 952, FFP2 NR F-820, Made in China.
• Winner Medical Co. Ltd., WN-N95FW, WN-N95FG, WN-N95FGIN, Made in China.
• Yiwu Henghao household products Co., Ltd., HH-KN95-01, Made in China.
• Yiwu Yifan Knitting Co., Ltd., KN95, Made in China.
• Zhanghou Easepal Industrial Corp., MASK-104, Made in China.
• Zhejiang Baiyi Intelligent Garment Co. Ltd., KN95, Made in China.
• Zhejiang Shengtai Baby Products Co. Ltd., KN95, Made in China.
• Zhende Medical Co., LTD., N9501F, Made in China.
• Zhengzhou QBS New Material Co., LTD. KN95, Made in China.
• Zhengzhou Ripe Medical Technology Co., LTD, Disposable Protective Mask KN95, Made in China.
• Zhengzhou Ruipu Medical Technology Co., Ltd., KN95, Made in China.
• Zhengzhou Wanshenshan Healthcare PPE Co., Ltd., KN95, Made in China.
• ZhongKang protective equipment technology (Guangzhou) Co., Ltd. ZK601, Made in China.

**VENTILATORS**

<table>
<thead>
<tr>
<th>Manufacturers and other stakeholders</th>
<th>Eligible products are new/modified ventilators, anesthesia gas machines modified for use as ventilators</th>
<th>Authorizes the use of these products if they meet specific criteria for safety performance, and labeling, (listed in Appendix A) and available here and listed below:</th>
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Newest authorizations are in bold
and positive pressure breathing devices modified for use as ventilators (collectively referred to as “ventilators”), ventilator tubing connectors, and ventilator accessories.

Authorized Ventilators:

- **Beijing Aeonmed Co, Ltd. VG70 ventilator**
  Critical care ventilator for mechanical ventilation of patients in ICU
- **Shenzen Mindray Biomedical Electronics, Mindray SV300/SV600/S800 ventilators**
  Critical care ventilator intended to provide ventilation assistance and breaking support for adult, pediatric and infant patients
- **Vyaire Medical Inc. LTV2 model 2150**
  Critical care ventilator that are intended to provide continuous or intermittent ventilatory support for the care of the individuals who require mechanical ventilation
- **RESMED, Stellar 150**
  Ventilator, Continuous, Minimal Ventilatory Support, Facility Use. The Stellar 150 is intended to provide ventilation for non-dependent spontaneously breathing adult and pediatric patients (30 lb/13 kg and above) with respiratory insufficiency, or respiratory failure, with or without obstructive sleep apnea. The device is for invasive use (with the use of the ResMed Leak Valve)
- **RESMED, Lumis 150 VPAP ST**
  Ventilator, Continuous, Minimal Ventilatory Support, Facility Use. The ResMed Lumis 150 VPAP ST devices are indicated to provide non-invasive ventilation for patients weighing more than 30 lbs (13 kg), or more than 66 lbs (30kg) in iVAPS mode, with respiratory insufficiency or obstructive sleep apnea (OSA). They are intended for home and hospital use
- **RESMED, GA ST**
  Ventilator, Continuous, Minimal Ventilatory Support for patients weighing more than 44lbs., Facility Use
- **RESMED, Flexo Bi Level ST**
  Ventilator, Continuous, Minimal Ventilatory Support, Facility Use
- **RESMED, AirCurve ST**
  Ventilatory, Continuous, Minimal Ventilatory Support for patients weighing more than 66lbs, Facility Use
- **Amsino, YUWELL YH-730 Bi-level PAP and YH-830 Bi-level PAP**
  Ventilator for patients weighing more than 66lbs, Non-Continuous
- **Inovytec, Ventway Sparrow,**
  Ventilator, Continuous for pediatric and adult patients
- **Philips Respironics, VX850 Ventilator**
  Critical Care Ventilator for pediatric (infants) and adults
- **BMC Medical CO. LTD. Luna G3 BPAP 25A-LG3700**
  Ventilator, continuous, minimal ventilatory support for adult use, facility use
- **BMC Medical CO. LTD. Y-30 T**
  Ventilator, continuous, minimal ventilatory support for adult patients, facility use
- **Dragerwerk AG & CO. KGaA, Evita V800 and Evita V600**
  Critical Care Ventilator for adults, adolescents, children, infants and neonates
- **Dragerwerk AG & CO. KGaA, Babylog VN800 and VN600.**
  Critical Care Ventilator intended for neonates and pediatric patients

Newest authorizations are in bold
- GE Healthcare, pNeuton Model, A-E Ventilator
  *
  *Ventilator, Continuous, Facility Use*
- Covidien LLC, Puritan Bennett 560 Ventilator System
  *
  *Ventilator, Continuous for adult and pediatric patients*
- CoLabs. COVID Ventilator
  *
  *Emergency Ventilator for adult patients*
- MEKICS Co., Ltd., MTV1000 Ventilator
  *
  *Ventilator, Continuous for use on pediatric and adult patients*
- Dragerwerk AG & Co. KGaA, Atlan A350 and Atlan A350XL
  *
  *Gas-Machine, Anesthesia intended for anesthetizing adults, pediatric patients and neonates*
- VenTec Life Systems, V+Pro Emergency Ventilator
  *
  *Ventilator for pediatric and adult patients, continuous*
- Ambulancetech Co., Ltd. Models 600S, T5, T7
  *
  *Ventilator for infants, children and adults*
- Philips Respironics, E30 ventilator
  *
  *Ventilator, Continuous, Minimal Ventilatory Support, facility use*
- Incoba, LLC., Apogee
  *
  *Oxygen Conserver intended as a delivery device for medical grade oxygen from high-pressure oxygen cylinders. Ambulatory device for use in hospital, healthcare facilities, or home care environments.*
- SecondBreath LLC, Pneumatic Resuscitator device
  *
  *Emergency Resuscitator*
- University of Minnesota Medical School and Boston Scientific Corporation, Coventor Adult Manual Resuscitator Compressor
  *
  *Emergency Resuscitator*
- Umbulizer, UMV-001 EUA
  *
  *Emergency Resuscitator*
- Hillrom, MetaNeb 4
  *
  *Intermittent Positive Pressure Breathing Device for patients 5 years old and above whom can follow verbal instructions in hospitals, subacute and nursing facilities, physician offices, clinics and home settings.*
- Spiro Devices, LLC. Spiro Wave
  *
  *Emergency Resuscitator to support adults when Positive Pressure Ventilation (PPV) is required to manage Acute Respiratory Failure*
- RESMED. AirCurve 10 ST-A
  *
  *Ventilator, Continuous, minimal ventilatory support for facility use in patients weighting more than 30lbs*
- PVA, PREVENT.
  *
  *Emergency Resuscitator for emergency resuscitation with appropriate critical care monitoring on adult patients weighing more than 66 lbs*
- 3B Medical Inc. Luna G3 B30VT
  *
  *Ventilator, Continuous Minimal Ventilatory Support*
- Resvent, iBreeze PAP
  *
  *Ventilator, Continuous, Minimal Ventilatory Support, Facility Use*
- Virgin Orbit, Virgin Orbit Resuscitator
  *
  *Emergency Resuscitator*
- Amisino International Inc’s, YUESELL YH-725
  *
  *Ventilator, Non-Continuous*
- AutoMedX Inc., SAVe II Series Ventilator
  *Powered emergency Ventilator*
- SLS Medical Technology Corp. Ltd., CP101/CP101S Series Ventilator, Non-Continuous
- Resvent Medical Technology CO., Ltd’s, iBreeze 20STA device
  *Ventilator, Non-Continuous*

**Authorized Ventilator Tubing Connectors**
- Prisma Health, Ventilation Expansion Splitter (VESper)
  *VESper allows multiple patients to be treated by a single ventilator*
- Vent Multiplexor, LLC., Vent Multiplexor
  *Dual patient circuit connector that is intended to provide temporary rescue mechanical ventilation for dual patient ventilation until an additional ventilator is available*
- MakeMedical, VentMI
  *Dual Patient Circuit Connector*

**Authorized Ventilator Accessories**
- SMD Manufacturing, LLC. ReddyPort Mini NIV Access Elbow
  *Mini NIV Access Elbow is intended to provide an interface for application of CPAP or bi-level therapy. The elbow is for single patient use in the hospital/institutional environment*

**Elbow connector for mask**
- 3B Medical, Inc., 3B Hi-Flow H80, Respiratory Humidifier
  *H-80 series humidifier is for the treatment of spontaneously breathing patients who would benefit from receiving high flow warmed and humidified respiratory gases. This device is for patients by prescription in the home or hospital/institutional environment*