Emergency Use Authorization

Emergency Use Authorization (EUA) information, and list of all current EUAs

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Español (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/autorizacion-de-uso-de-emergencia)

About Emergency Use Authorizations (EUAs)

The Emergency Use Authorization (EUA) authority allows FDA to help strengthen the nation's public health protections against CBRN threats by facilitating the availability and use of MCMs needed during public health emergencies.

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act (/federal-food-drug-and-cosmetic-act-fdc-act)), the FDA Commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents when there are no adequate, approved, and available alternatives.

Section 564 of the FD&C Act was amended by the Project Bioshield Act of 2004 (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation#bioshield) and was further amended by the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-

framework/pandemic-and-all-hazards-preparedness-reauthorization-act-2013-pahpra) (PAHPRA), the 21st Century Cures Act (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation#21CC) of 2016, and Public Law 115-92 (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/mcm-related-counterterrorism-legislation#PL11592) of 2017.

Guidance

In January 2017, FDA finalized the guidance: Emergency Use Authorization of Medical Products and Related Authorities (/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities). For more information, please see the January 13, 2017 Federal Register notice (https://www.federalregister.gov/documents/2017/01/13/2017-00721/emergency-use-authorization-of-medical-products-and-related-authorities-guidance-for-industry-and).

Printable PDF (288 KB) (/media/97321/download)

In addition, in January 2014, FDA issued a question and answer document (/media/87718/download) (PDF, 762K) to respond to questions raised by public health stakeholders about PAHPRA's amendments to the EUA authority and establishment of new authorities related to the emergency use of MCMs during CBRN emergencies.

General Emergency Diagnostics Information

- Emergency Use Authorizations (/about-fda/page-not-found) (current device EUAs)
- How to Submit a Pre-EUA for *In vitro* Diagnostics (IVDs) to FDA (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/how-submit-pre-eua-vitro-diagnostics-fda) (for test manufacturers)
- Information for Laboratories Implementing IVD Tests Under EUA (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/information-laboratories-implementing-ivd-tests-under-eua)

Coronavirus Disease 2019 (COVID-19) EUA Information

- **Coronavirus Disease (COVID-19) updates from FDA** (/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19)
- **Overviews:**
  - **FDA Combating COVID-19 With Medical Devices (/media/136702/download)** (PDF, 708 KB)
  - **FDA Combating COVID-19 With Therapeutics** (/media/136832/download) (PDF, 610 KB)
  - **EUA Authorized Serology Test Performance (/medical-devices/emergency-situations-medical-devices/eua-authorized-serology-test-performance)**
- **Detailed Information for all COVID-19 EUAs, including authorizations and fact sheets**
  - In Vitro Diagnostic Products
  - High Complexity Molecular-Based Laboratory Developed Tests
  - SARS-CoV-2 Antibody Tests
  - Personal Protective Equipment and Related Devices
  - Ventilators and Other Medical Devices
  - Drug Products

In Vitro Diagnostic Products

On February 4, 2020, the HHS Secretary determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. On the basis of this determination, the Secretary then declared 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. The EUAs subsequently issued by FDA are listed in the table below this blue box.

- Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FD&C Act (https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency) (February 4, 2020)

In continuing response to the COVID-19 pandemic, on March 24, 2020, and based on the February 4, 2020 HHS EUA determination, the HHS Secretary declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 outbreak.

- Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FD&C Act (https://www.federalregister.gov/documents/2020/03/27/2020-06541/emergency-use-authorization-

declaration) (March 24, 2020)

On February 29, 2020, the FDA issued an immediately in effect guidance (/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised) with policy specific to development of in vitro diagnostic tests during this public health emergency. This guidance was updated on March 16, 2020, May 4, 2020, and May 11, 2020.

CDC has granted a right of reference to the performance data contained in CDC's EUA (FDA submission number EUA200001) to any entity seeking an FDA EUA for a COVID-19 diagnostic device.

Templates for these EUA submissions (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas) are available to help facilitate the preparation, submission, and authorization of an EUA.

If you need additional information, please refer to the FAQs on Diagnostic Testing for SARS-CoV-2 (/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2).

The HHS Secretary issued a Declaration pursuant to section 319F-3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures against COVID-19.

- Notice of Declaration under the Public Readiness and Emergency Preparedness Act for medical countermeasures against COVID-19 (https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures) (February 4, 2020)

Please note: a determination under section 319 of the Public Health Service Act that a public health emergency exists, such as the one issued on January 31, 2020 (https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx), does not enable FDA to issue EUAs. A separate determination and declaration are needed under section 564 of the Federal Food, Drug and Cosmetic Act to enable FDA to issue EUAs, provided other statutory criteria are met.

On June 16, 2020, based on FDA's continued review of the scientific evidence available for Chembio Diagnostic Systems, Inc.'s DPP COVID-19 IgM/IgG System for detection of IgM and IgG antibodies against SARS-CoV-2, including evidence from an NIH/NCI independent evaluation (https://www.accessdata.fda.gov/cdrh_docs/presentations/maf/maf3265-a001.pdf), FDA determined that the statutory criteria for issuing an EUA in Section 564(c)(2) of the Federal Food, Drug, and Cosmetic (FD&C) Act are no longer met. Specifically, FDA determined that it is not reasonable to believe the product may be effective in detecting antibodies against SARS-CoV-2 or that the known and potential benefits of the device when used for this purpose outweigh its known and potential risks. FDA also concluded that based on the risks to public health from false test results, revocation is appropriate to protect the public health or safety. Accordingly, the EUA was revoked (/media/139109/download) under Section 564(g)(2)(B) & (C) of the FD&C Act.

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Date EUA First Issued	Entity	Diagnostic (Most Recent Letter of Authorization) (PDF)	Technology[3]	Authorized Setting(s)[1] (ivdnote2)	Authorization Labeling[2] (PDF)
+ 07/06/2020	Laboratorio Clinico Toledo	Laboratorio Clinico Toledo SARS-CoV-2 Assay (/media/139785/download) (285KB)	Molecular	H	HCP (/media/139786/download) (105KB) Patients (/media/139787/download) (93KB) EUA Summary (/media/139788/download) (125KB)
+ 07/06/2020	Assure Tech. (Hangzhou Co., Ltd)	Assure COVID-19 IgG/IgM Rapid Test Device (/media/139789/download) (340KB)	Serology IgM and IgG, Lateral Flow	H, M	HCP (/media/139790/download) (81KB) Recipients (/media/139791/download) (131KB) IFU (/media/139792/download) (360KB)
+ 07/02/2020	Centers for Disease Control and Prevention (CDC)	Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay (/media/139744/download) (143KB)	Molecular	H	HCP (/media/139742/download) (153KB) Patients (/media/139745/download) (134KB) IFU (/media/139743/download) (1.47MB)
+ 07/02/2020	Becton, Dickinson and Company (BD)	BD Veritor System for Rapid Detection of SARS-CoV-2 (https://www.fda.gov/media/139752/download) (330KB)	Antigen	H, M, W	HCP (https://www.fda.gov/media/139753/download) (147KE Patients (https://www.fda.gov/media/139754/download) (162KE IFU (https://www.fda.gov/media/139755/download) (1.04M
+ 07/01/2020	CENTOGENE US, LLC	CentoFast-SARS-CoV-2 RT-PCR Assay (/media/139722/download) (106KB)	Molecular	H	HCP (/media/139723/download) (137KB) Patients (/media/139724/download) (125KB) EUA Summary (/media/139725/download) (178KB)
+ 06/30/2020	The Kroger Co.	Kroger Health COVID-19 Test Home Collection Kit (/media/139681/download) (311KB)	Molecular		IFU (/media/139682/download) (69KB) EUA Summary (/media/139683/download) (147KB)

Date EUA First Issued	Entity	Diagnostic (Most Recent Letter of Authorization) (PDF)	Technology[3]	Authorized Setting(s)[1] (ivdnote2)	Authorization Labeling[2] (PDF)
+ 06/30/2020	TNS Co., Ltd (Bio TNS)	COVID-19 RT-PCR Peptide Nucleic Acid (PNA) kit (/media/139677/download) (321KB)	Molecular	H	HCP (/media/139678/download) (143KB) Patients (/media/139679/download) (135KB) IFU (/media/139680/download) (1.20MB)
+ 06/30/2020	Psomagen, Inc.	Psoma COVID-19 RT Test (/media/139673/download) (284KB)	Molecular	H	HCP (/media/139674/download) (105KB) Patients (/media/139675/download) (94KB) EUA Summary (/media/139676/download) (118KB)
+ 06/30/2020	InBios International, Inc.	SCoV-2 Detect IgM ELISA (/media/139726/download) (115KB)	Serology IgM, ELISA	H	HCP (/media/139727/download) (166KB) Recipients (/media/139729/download) (158KB) IFU (/media/139730/download) (395KB)
+ 06/29/2020	LifeHope Labs	LifeHope 2019-nCoV Real-Time RT-PCR Diagnostic Panel (/media/139620/download) (282KB)	Molecular	H	HCP (/media/139621/download) (104KB) Patients (/media/139622/download) (94KB) EUA Summary (/media/139623/download) (128KB)

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[1] Settings for use include the following:

- H - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
- M - Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate complexity tests.
- W - Patient care settings operating under a CLIA Certificate of Waiver.

[2] Authorization Documents include the Healthcare Provider (HCP) and Patient Fact Sheets and either the Manufacture Instructions/Package Insert (abbreviated to IFU) or the EUA Summary.

[3] Abbreviations: CLIA = chemiluminescence immunoassay; ELISA = enzyme-linked immunosorbent assay; ECLIA = electrochemiluminescence immunoassay; FMIA = fluorescent microsphere Immunoassay, CMIA = chemiluminescent microparticle immunoassay

High Complexity Molecular-Based Laboratory Developed Tests

On March 31, 2020, the FDA concluded based on the totality of scientific evidence available that molecular-based laboratory developed tests (LDTs) that are authorized for use by the singular developing laboratory are appropriate to protect the public health or safety (as described under the Scope of Authorization (Section II)) under section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. Â§ 360bbb-3). Under this EUA, authorized tests are authorized for use in the single laboratory that developed the authorized test and that is certified under Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. Â§263a to perform high complexity tests.

- EUA Letter of Authorization - Laboratories Who Have Developed a Molecular-Based Test (LDTs) for Coronavirus Disease 2019 (COVID-19) (/media/136598/download) (144KB)
- Fact Sheet for Healthcare Providers (/media/136599/download) (134KB)
- Fact Sheet for Patients (/media/136600/download) (122KB)
- Authorization of Emergency Use of Certain Medical Devices During COVID-19 (https://www.federalregister.gov/documents/2020/06/05/2020-12117/authorization-of-emergency-use-of-certain-medical-devices-during-covid-19-availability) (*Federal Register* notice, June 5, 2020)
- See the table below for a current list of included laboratories and their LDTs

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Date of EUA Issuance	Laboratory	Letter Granting Inclusion Under EUA (PDF)	EUA Summary (PDF)
06/12/2020	Cormeum Laboratory Services	Cormeum SARS-CoV-2 Assay (/media/138933/download) (67KB)	EUA Summary (/media/138934/download) (117KB)
06/09/2020	Warrior Diagnostics, Inc.	Warrior Diagnostics SARS-CoV-2 Assay (/media/138791/download) (67KB)	EUA Summary (/media/138790/download) (90KB)
06/04/2020	Nebraska Medicine Clinical Laboratory	NEcov19 RT-PCR Assay (/media/138624/download) (120KB)	EUA Summary (/media/138625/download) (195KB)

Date of EUA Issuance	Laboratory	Letter Granting Inclusion Under EUA (PDF)	EUA Summary (PDF)
06/02/2020	CSI Laboratories	CSI SARS-CoV-2 RT PCR Test (/media/138529/download) (223KB)	EUA Summary (/media/138528/download) (385KB)
06/01/2020	Aspirus Reference Laboratory	Aspirus SARS-CoV-2 rRT Assay (/media/138527/download) (222KB)	EUA Summary (/media/138526/download) (368KB)
05/22/2020	Exact Sciences Laboratories	Exact Sciences SARS-CoV-2 (N gene detection) Test (/media/138327/download) (120KB)	EUA Summary (/media/138328/download) (191KB)
05/22/2020	Express Gene LLC (dba Molecular Diagnostics Laboratory)	Express Gene 2019-nCoV RT-PCR Diagnostic Panel (/media/138329/download) (120KB)	EUA Summary (/media/138330/download) (143KB)
05/22/2020	Avera Institute for Human Genetics	Avera Institute for Human Genetics SARS-CoV-2 Assay (/media/138331/download) (120KB)	EUA Summary (/media/138332/download) (143KB)
05/18/2020	Color Genomics, Inc.	Color SARS CoV-2 Diagnostic Assay (/media/138248/download) (223KB)	EUA Summary (/media/138249/download) (630KB)
05/13/2020	One Health Laboratories, LLC	SARS-CoV-2 Real-Time RT-PCR-Test (/media/138062/download) (222KB)	EUA Summary (/media/138063/download) (394KB

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SARS-CoV-2 Antibody Tests

On April 28, 2020, FDA issued an Emergency Use Authorization for SARS-CoV-2 Antibody Tests (Lateral flow or Enzyme-linked immunosorbent assay (ELISA) tests) that have been evaluated in an independent validation study performed at the National Institutes of Health's (NIH) National Cancer Institute (NCI), or by another government agency designated by FDA, and are confirmed by FDA to meet the criteria set forth in the Scope of Authorization (Section II) in the Letter of Authorization under section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360bbb-3). Under this EUA, authorized devices are intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, by detecting antibodies (IgG, or IgG and IgM, or total), as specified in each authorized device's instructions for use, to SARS-CoV-2 in human plasma and/or serum.

Emergency use of the authorized devices is limited to the authorized laboratories. Authorized Laboratories are laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. 263a, to perform moderate or high complexity tests. Authorized devices will be added to Appendix A (below) upon submission of the information set forth in the Scope of Authorization (Section II) and after confirmation that the applicable performance and labeling criteria set forth in the Scope of Authorization (Section II) have been met.

- Letter of Authorization – Serology IVD Umbrella (/media/137470/download) (PDF, 83KB)
- Fact Sheet for Healthcare Providers (/media/137468/download) (PDF, 79KB)
- Fact Sheet for Recipients (/media/137469/download) (PDF, 102KB)
- Appendix A Table (/media/137471/download) (PDF, 72KB)

Personal Protective Equipment and Related Devices

For information on the applicable HHS Secretary determination and declaration supporting a particular EUA in the table below, as well as a link to any applicable PREP Act declaration, please use the expansion buttons on the left hand side of the table.

For additional information, please see Recent Final Medical Device Guidance Documents (/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/recent-final-medical-device-guidance-documents) and Coronavirus (COVID-19) Update: FDA takes action to increase U.S. supplies through instructions for PPE and device manufacturers (/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-increase-us-supplies-through-instructions-ppe-and).

Please also see the Non-NIOSH Approved Respirator FAQ (/medical-devices/emergency-situations-medical-devices/non-niosh-approved-respirator-eua-faq) for additional information.

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Date of First EUA Issuance	Most Recent Letter of Authorization (PDF)	Appendix (PDF)	Authorized Labeling (PDF)

Date of First EUA Issuance	Most Recent Letter of Authorization (PDF)	Appendix (PDF)	Authorized Labeling (PDF)
+ 06/13/2020	Negative-pressure Respiratory System with Advanced Ventilation Return (NRSAVR-100) (/media/138955/download) (103KB)		• Fact Sheet for Healthcare Providers (/media/138956/download) (148KB) • Fact Sheet for Patients (/media/138957/download) (133KB) • Instructions for Healthcare Facilities (/media/138958/download) (381KB) • Instructions for Healthcare Personnel (/media/138959/download) (399KB)
+ 06/13/2020	Technical Safety Services VHP Decontamination System (/media/138954/download) (79KB)		• Fact Sheet for Healthcare Personnel (/media/138951/download) (152KB) • Instructions for Healthcare Facilities (/media/138952/download) (143KB) • Instructions for Healthcare Personnel (/media/138953/download) (135KB)
+ 05/27/2020	Stryker Sustainability Solutions VHP Decontamination System (/media/138394/download) (248KB) (Reissued June 6, 2020)		• Fact Sheet for Healthcare Personnel (/media/138395/download) (143KB) • Instructions for Healthcare Personnel and Healthcare Facilities (/media/138396/download) (113KB) • Collect and Ship Protocol (/media/138397/download) (219KB)
+ 05/22/2020	Gowns and Other Apparel (/media/138326/download) (310KB)		
+ 05/21/2020	STERIS STEAM Decon Cycle in AMSCO Medium Steam Sterilizers (/media/138282/download) (293KB)		• Fact Sheet for Healthcare Personnel (/media/138283/download) (147KB) • Instructions for Healthcare Facilities (/media/138284/download) (568KB) • Instructions for Healthcare Personnel (/media/138285/download) (206KB)
+ 05/19/2020	COVID-19 Airway Management Isolation Chamber (CAMIC) (/media/139391/download) (99KB) (Reissued June 22, 2020)		• Fact Sheet for Healthcare Providers (/media/139392/download) (154KB) • Fact Sheet for Patients (/media/139393/download) (134KB) • Instructions for Healthcare Facilities - Assembly, Disassembly and Disinfection of the CAMIC (/media/139394/download) (823KB) • Instructions for Healthcare Personnel - Use of the CAMIC (/media/139395/download) (247KB)
+ 05/07/2020	Duke Decontamination System (/media/137762/download) (284KB) (Reissued June 6, 2020)		• Fact Sheet for Healthcare Personnel (/media/137758/download) (296KB) • Instructions for Decontamination Facility (/media/137760/download) (410KB) • Instructions for Healthcare Facilities (/media/137763/download) (406KB) • Instructions for Healthcare Personnel (/media/137757/download) (583KB)
+ 05/01/2020	Protective Barrier Enclosures (/media/137584/download) (295KB)		• Fact Sheet for Healthcare Providers (/media/137585/download) (135KB) • Fact Sheet for Patients (/media/137586/download) (127KB)
+ 04/20/2020	Sterilucent, Inc. Sterilization System (/media/137167/download) (2477KB) (Reissued June 6, 2020)		• Fact Sheet for Healthcare Personnel (/media/137170/download) (85KB) • Instructions for Healthcare Facilities (/media/137169/download) (657KB) • Instructions for Healthcare Personnel (/media/137168/download) (261KB)

Date of First EUA Issuance	Most Recent Letter of Authorization (PDF)	Appendix (PDF)	Authorized Labeling (PDF)
+ 04/15/2020	Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle (/media/136976/download) (272KB) (Reissued June 6, 2020)		• Fact Sheet for Healthcare Personnel (/media/136977/download) (94KB) • Instructions for Healthcare Facilities (/media/136979/download) (182KB) • Instructions for Healthcare Personnel (/media/136980/download) (221KB)

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Ventilators and Other Medical Devices

In continuing response to the COVID-19 pandemic, on March 24, 2020, and based on the February 4, 2020 HHS EUA determination, the HHS Secretary declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 outbreak. The EUAs FDA subsequently authorized based on this determination and declaration are listed in the table below this blue box.

- Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FD&C Act (https://www.federalregister.gov/documents/2020/03/27/2020-06541/emergency-use-authorization-declaration) (March 24, 2020)

The HHS Secretary issued a Declaration pursuant to section 319F-3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures against COVID-19.

- Notice of Declaration under the Public Readiness and Emergency Preparedness Act for medical countermeasures against COVID-19 (https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures) (February 4, 2020)

Templates for these EUA submissions (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ventilators) are available to help facilitate the preparation, submission, and authorization of an EUA.

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Date EUA First Issued	Device Type	Most Recent Letter of Authorization (PDF)	Appendix to Letter and Other Documents (PDF)	Fact Sheets (PDF)
+ 05/29/2020	Right Ventricular Assist Catheter	Abiomed, Inc., Impella RP System (/media/138460/download) (142KB)	• Impella RP System Instructions for Use (/media/138463/download) (4.39MB)	• Healthcare Providers (/media/138461/download) (214KB) • Patients (/media/138462/download) (183KB)
+ 05/26/2020	Predictive Screening	CLEW Medical Ltd., CLEWICU System (/media/138369/download) (105KB)	• CLEWICU - IFU (/media/138372/download) (1.22MB) • Letter Granting EUA Amendment(s) (June 30, 2020) (/media/139801/download) (108KB)	• Healthcare Providers (/media/138370/download) (148KB) • Patients (/media/138371/download) (132KB)
+ 05/20/2020	CRRT Set	Baxter Healthcare Corporation, Prismaflex ST Set (/media/138254/download) (355KB)	• Prismaflex ST Set - IFU - Global (/media/138252/download) (6.12MB) • Prismaflex ST Set - IFU - South Korea (/media/138257/download) (4.82MB) • Prismaflex ST Set - IFU - China (/media/138255/download) (5.08MB)	• Healthcare Providers (/media/138256/download) (300KB) • Patients (/media/138253/download) (205KB)
+ 05/14/2020	Remote Patient QT Interval Monitor	G Medical Innovations, Ltd., VSMS Patch (/media/138105/download) (107KB)	• Professional User Guide, VSMS Patch (/media/138108/download) (2.07MB) • Quick Start Guide, VSMS Patch (/media/138109/download) (943KB)	• Healthcare Providers (/media/138104/download) (112KB) • Patients (/media/138107/download) (110KB)

Date EUA First Issued	Device Type	Most Recent Letter of Authorization (PDF)	Appendix to Letter and Other Documents (PDF)	Fact Sheets (PDF)
+ 05/13/2020	Infusion Pumps and Infusion Pump Accessories	Infusion Pumps and Infusion Pump Accessories (/media/138057/download) (471KB)	• Appendix A: Authorized Infusion Pumps and Infusion Pump Accessories (/media/138067/download) (227KB)	• Healthcare Providers (/media/138068/download) (246KB) • Patients (/media/138069/download) (202KB)
+ 05/11/2020	LVEF Screen	Eko Devices, Inc, ELEFT (/media/137932/download) (379KB)	• IFU (/media/137931/download) (249KB)	• Healthcare Providers (/media/137930/download) (248KB) • Patients (/media/137929/download) (179KB)
+ 05/11/2020	Nurse Call System	Ascom (US), Inc., teleCARE (/media/137943/download) (357KB)	• IFU (/media/137941/download) (578KB) • IFU - Installation Guide (/media/137945/download) (8.85MB)	• Healthcare Providers (/media/137942/download) (204KB) • Patients (/media/137944/download) (243KB)
+ 05/08/2020	Patient Isolation Transport Unit (PITU)	Patient Isolation Transport Unit (PITU) Device (/media/137856/download) (400KB)	• PITU Set Up and Operation Guide (/media/137859/download) (681KB) • PITU User Manual (/media/137860/download) (70KB)	• Healthcare Providers (/media/137857/download) (142KB) • Patients (/media/137858/download) (127KB)
+ 05/05/2020	Remote Patient QT Interval Monitor	PhysiolGuard, ECG-QT Analysis System (/media/137693/download) (109KB)	• Lay User Instructions for Use (/media/137692/download) (166KB) • MiCorA100 User Manual (/media/137694/download) (1.27MB) • Analysis Platform User Manua (/media/137696/download)l (1.15MB)	• Healthcare Providers (/media/137691/download) (207KB) • Patients (/media/137695/download) (201KB)
+ 05/01/2020	Respiratory Muscle Stimulator	Liberate Medical, LLC VentFree Respiratory Muscle Stimulator Device (/media/137587/download) (347KB)	• IFU - Model A (/media/137590/download) (3.73MB) • IFU - Model B (/media/137591/download) (3.79MB)	• Healthcare Providers (/media/137588/download) (91KB) • Patients (/media/137589/download) (93KB)

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[1] The multiBic/multiPlus Solutions include multiBic dialysate and replacement fluid and multiPlus dialysate. The multiFiltrate PRO System, multiBic dialysate and the multiPlus dialysate solutions are regulated as devices by CDRH. The multiBic replacement fluid is regulated as a drug by CDER.

Drug Products

On February 4, 2020, the HHS Secretary determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19. On the basis of this determination, the Secretary then declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564 of the FD&C Act, effective March 27, 2020. The EUAs subsequently issued by FDA are listed in the table below this blue box.

- Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the FD&C Act (https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency) (February 4, 2020)
- Emergency Use Authorization Declaration (https://www.federalregister.gov/documents/2020/04/01/2020-06905/emergency-use-authorization-declaration) (March 27, 2020)

On June 15, 2020, based on FDA's continued review of the scientific evidence available for hydroxychloroquine sulfate (HCQ) and chloroquine phosphate (CQ) to treat COVID-19, FDA has determined that the statutory criteria for EUA as outlined in Section 564(c)(2) of the Food, Drug, and Cosmetic Act are no longer met. Specifically, FDA has determined that CQ and HCQ are unlikely to be effective in treating COVID-19 for the authorized uses in the EUA. Additionally, in light of ongoing serious cardiac adverse events (/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or) and other serious side effects, the known and potential benefits of CQ and HCQ no longer outweigh the known and potential risks for the authorized use. This warrants revocation of the EUA (/media/138945/download) for HCQ and CQ for the treatment of COVID-19.

- Frequently Asked Questions on the Revocation of the Emergency Use Authorization for Hydroxychloroquine Sulfate and Chloroquine Phosphate (PDF, 125 KB) (/media/138946/download)

- Español (/media/139648/download) (PDF-159KB); 简体中文 (/media/139647/download) (PDF-264KB); 한국어 (/media/139646/download) (PDF-440KB); Tagalog (/media/139649/download) (PDF-118KB); Việt (/media/139650/download) (PDF-245KB)

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Date of First EUA Issuance	Most Recent Letter of Authorization (PDF)	Authorized Use [1]	Fact Sheets and Manufacturer Instructions/ Package Insert (PDF)
+ 05/08/2020	Fresenius Kabi Propoven 2% (/media/137888/download) (209KB)	To maintain sedation via continuous infusion in patients older than age 16 with suspected or confirmed COVID-19 who require mechanical ventilation in an ICU setting [2]	Healthcare Providers (/media/137889/download) (288KB) Patients and Parent/Caregivers (/media/137890/download) (39KB) Propoven 2% Wall Chart (/media/137891/download) (2.4MB)
+ 05/01/2020	Remdesivir for Certain Hospitalized COVID-19 Patients (/media/137564/download) (365KB)	To only treat adults and children with suspected or laboratory confirmed COVID-19 and severe disease defined as SpO2 94% on room air, requiring supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation (ECMO)	Healthcare Providers (/media/137566/download) (408KB) Patients and Parent/ Caregivers (/media/137565/download) (63KB) • Spanish (/media/139460/download) (109KB) Frequently Asked Questions on the EUA for Remdesivir for Certain Hospitalized Patients (/media/137574/download) (235KB) • Spanish (/media/138804/download) (222KB)
+ 04/30/2020	Fresenius Medical, multiFiltrate PRO System and multiBic/multiPlus Solutions (/media/137520/download) (171KB) [3] *[also listed under Medical Device EUAs]*	To provide continuous renal replacement therapy (CRRT) to treat patients in an acute care environment during the COVID-19 pandemic.	Healthcare Providers (/media/137522/download) (135KB) Patients (/media/137521/download) (125KB) Instructions for Use, Bloodline/ Tubing (/media/137523/download) (83KB) Instructions for Use, UltraFlux (/media/137527/download) (147KB) Instructions for Use, multiFiltratePRO (/media/137528/download) (15.07MB) Summary of Product Characteristics (SmPC) (/media/137524/download) (308KB) Instructions for Use, MultiPlus (/media/137526/download) (110KB)

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[1] The virus that causes COVID-19 has led to an increased number of patients requiring critical care, such as with severe respiratory illness. As a result, there is a shortage of adequate, FDA-approved drugs used for their treatment, such as propofol for sedation of mechanically ventilated patients.

[2] In the circumstances of this public health emergency, it would not be feasible to require healthcare providers to seek to limit Fresenius Propoven 2% Emulsion only to be used for patients with suspected or confirmed COVID-19; therefore, this authorization does not limit use to such patients.

[3] The multiBic/multiPlus Solutions include multiBic dialysate and replacement fluid and multiPlus dialysate. The multiBic replacement fluid is regulated as a drug by CDER. The multiFiltrate PRO System, multiBic dialysate and the multiPlus dialysate solutions are regulated as devices by CDRH.

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Other Current EUAs

The tables below provide information on current EUAs:

- Anthrax EUAs
- Ebola Virus EUA Information

- Enterovirus D68 (EV-D68) EUA Information
- Freeze Dried Plasma Information
- H7N9 Influenza EUA Information
- Middle East Respiratory Syndrome Coronavirus (MERS-CoV) EUA Information
- Nerve Agent EUA Information
- Zika Virus EUA Information

Information about EUAs that are no longer in effect is available on our EUA archive page (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information).

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Anthrax EUAs

The 2016 FDA Doxycycline Emergency Dispensing Order (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-dispensing-orders#doxy) and CDC Doxycycline Emergency Use Instructions (EUI) (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-dispensing-orders#doxy) together replace the need for the doxycycline mass dispensing EUA (issued on July 21, 2011). Therefore, the doxycycline emergency dispensing order and EUI should be used by stakeholders for anthrax preparedness and response instead of the mass dispensing EUA.

The July 21, 2011, doxycycline mass dispensing EUA, and the October 14, 2011, National Postal Model anthrax EUA will be terminated by FDA, and notice of such termination will be published in the *Federal Register*. For additional information, see Emergency Use Authorization--Archived Information (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information).

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Ebola Virus EUA Information

Ebola preparedness and response updates from FDA (/emergency-preparedness-and-response/mcm-issues/ebola-preparedness-and-response-updates-fda) (all agency activities)

For more information about the diagnostics below, also see Emergency Use Authorizations (/about-fda/page-not-found) **(current device EUAs).**

Ebola Diagnostic Tests with De Novo, 510(k) or PMA

- **OraQuickEbola Rapid Antigen Test** (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?ID=DEN190025)- On October 10, 2019, FDA allowed marketing (https://www.accessdata.fda.gov/cdrh_docs/pdf19/DEN190025.pdf) (PDF, 255 KB) of a rapid diagnostic test (RDT) to detect Ebola virus antigens (proteins) in human blood from certain living individuals and samples from certain recently deceased individuals suspected to have died from Ebola (cadaveric oral fluid). The OraQuick Ebola Rapid Antigen Test is the first rapid diagnostic test the FDA has allowed to be marketed in the U.S. for Ebola virus disease (EVD). The test provides a rapid, presumptive diagnosis that must be confirmed. *Also see the FDA news release: FDA allows marketing of first rapid diagnostic test for detecting Ebola virus antigens (/news-events/press-announcements/fda-allows-marketing-first-rapid-diagnostic-test-detecting-ebola-virus-antigens)*

  The OraQuick Ebola Test was reviewed under the De Novo premarket review pathway (/medical-devices/premarket-submissions/de-novo-classification-request), a regulatory pathway for low-to-moderate-risk devices of a new type. Along with this marketing authorization, the FDA is establishing criteria, called special controls, that determine the requirements for demonstrating accuracy, reliability and effectiveness of tests intended to identify Ebola virus antigens. These special controls, when met along with general controls, provide a reasonable assurance of safety and effectiveness for tests of this type. This action also creates a new regulatory classification, which means that subsequent devices of the same type with the same intended use may go through the FDA's 510(k) pathway, whereby devices can obtain clearance by demonstrating substantial equivalence to a predicate device.

Medical Product	Date of EUA Issuance	Letter of Authorization	Federal Register Notice for EUA	Fact Sheets and Manufacturer Instructions/Package Insert

EZ1 Real-time RT-PCR Assay (DoD)	August 5, 2014 (initial issuance) October 10, 2014 (reissuance)	Authorization (/media/89984/download) (PDF, 61 KB)	FR notice (https://www.federalregister.gov/articles/2014/09/17/2014-22086/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-ebola-zaire-virus)	• Healthcare (/media/89986/download) (PDF, 58 KB) • Patients (/media/89988/download) (PDF, 59 KB) • Instruction Booklet (/media/89989/download) (PDF, 1.1 MB)
CDC Ebola Virus NP Real-time RT-PCR Assay (CDC)	October 10, 2014 (initial issuance) March 2, 2015 (reissuance) October 8, 2019 (amended)	Authorization (/media/91083/download) (PDF, 282 KB) Letter granting EUA amendment(s) (PDF, 134 KB) (/media/131606/download)	FR notice (https://www.federalregister.gov/articles/2014/12/24/2014-30108/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-zaire-virus)	• Healthcare (/media/91087/download) (PDF, 207 KB) • Patients (/media/91092/download) (PDF, 149 KB) • Instructions for Use (/media/91097/download) (PDF, 496 KB)
CDC Ebola Virus VP40 Real-time RT-PCR Assay (CDC)	October 10, 2014 (initial issuance) March 2, 2015 (reissuance) October 8, 2019 (amended)	Authorization (/media/91105/download) (PDF, 285 KB) Letter granting EUA amendment(s) (PDF, 135 KB) (/media/131605/download)	FR notice (https://www.federalregister.gov/articles/2014/12/24/2014-30108/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-zaire-virus)	• Healthcare (/media/91111/download) (PDF, 207 KB) • Patients (/media/91118/download) (PDF, 149 KB) • Instructions for Use (/media/91142/download) (PDF, 494 KB)
FilmArray NGDS BT-E Assay (Biofire Defense, LLC)	October 25, 2014 (initial issuance) March 2, 2015 (reissuance)	Authorization (/media/91070/download) (PDF, 326 KB)	FR notice (https://www.federalregister.gov/articles/2015/02/09/2015-02467/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus)	• Healthcare (/media/91149/download) (PDF, 40 KB) • Patients (/media/91153/download) (PDF, 40 KB) • Instructions for Use (/media/91077/download) (PDF, 740 KB)
FilmArray Biothreat-E test (Biofire Defense, LLC)	October 25, 2014 November 12, 2019 (amended)	Authorization (/media/89580/download) (PDF, 73 KB) Letter granting EUA amendment(s) (PDF, 152 KB) (/media/132517/download)	FR notice (https://www.federalregister.gov/articles/2015/02/09/2015-02467/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus)	• Healthcare (/media/89585/download) (PDF, 227 KB) • Patients (/media/89604/download) (PDF, 191 KB) • Instructions for Use (/media/89614/download) (PDF, 1.6 MB)
RealStar Ebolavirus RT-PCR Kit 1.0 (altona Diagnostics, GmbH)	November 10, 2014 (initial issuance) November 26, 2014 (reissuance)	Authorization (/media/123410/download) (PDF, 263 KB)	FR notice (https://www.federalregister.gov/articles/2015/02/09/2015-02467/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus)	• Healthcare (/media/120428/download) (PDF, 81 KB) • Patients (/media/120429/download) (PDF, 92 KB) • Instructions for Use (/media/120430/download) (PDF, 79 KB)
LightMix Ebola Zaire rRT-PCR Test (Roche Molecular Systems, Inc.)	December 23, 2014	Authorization (/media/120431/download) (PDF, 2.2 MB)	FR notice (https://www.federalregister.gov/articles/2015/03/17/2015-06039/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-ebola-zaire-virus)	• Healthcare (/media/120432/download) (PDF, 59 KB) • Patients (/media/120433/download) (PDF, 60 KB) • Instructions for Use (/about-fda/page-not-found) (PDF, 328 KB)

Xpert Ebola Assay (Cepheid)	March 23, 2015	Authorization (/media/91315/download) (PDF, 240 KB)	FR notice (https://www.federalregister.gov/articles/2015/06/05/2015-13699/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus)	• Healthcare (/media/91934/download) (PDF, 310 KB) • Patients (/media/91939/download) (PDF, 211 KB) • Instructions for Use (/media/91944/download) (PDF, 625 KB)
Idylla Ebola Virus Triage Test (Biocartis NV)	May 26, 2016	Authorization (/media/98460/download) (PDF, 321 KB)	FR notice (https://www.federalregister.gov/articles/2016/07/08/2016-16176/authorizations-of-emergency-use-in-vitro-diagnostic-device-for-detection-of-ebola-zaire-virus)	• Healthcare (/media/98451/download)(PDF, 203 KB) • Patients (/media/98442/download) (PDF, 163 KB) • Instructions for Use (/media/98434/download) (PDF, 2.1 MB)
DPP Ebola Antigen System (Chembio Diagnostic Systems, Inc.)	November 9, 2018 April 2, 2019 (amended)	Authorization (/media/117735/download) (PDF, 103 KB) Letter Granting EUA Amendment(s) (/media/122553/download) (PDF, 87 KB)	FR notice (https://www.federalregister.gov/documents/2019/02/13/2019-02134/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-ebola-virus)	• Healthcare (/media/117736/download)(PDF, 12 KB) • Patients (/media/117737/download (PDF, 119 KB) • Instructions for Use (/media/117738/download) (PDF, 2 MB)

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Enterovirus D68 (EV-D68) EUA Information

For more information about the diagnostics below, also see Emergency Use Authorizations (/about-fda/page-not-found) **(current device EUAs).**

Medical Product	Date of EUA Issuance	Letter of Authorization	Federal Register Notice for EUA	Fact Sheets and Manufacturer Instructions/Package Insert	EUA Determination a
CDC Enterovirus D68 2014 Real-time RT-PCR Assay (EV-D68 2014 rRT-PCR)	May 12, 2015	Authorization (/media/120425/download) (PDF, 229 KB)	FR notice (https://www.federalregister.gov/articles/2015/07/01/2015-16125/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-enterovirus-d68)	• Healthcare (/media/92008/download) (PDF, 214 KB) • Patients (/media/120426/download) (PDF, 150 KB) • Instructions for Use (/media/120427/download)(PDF, 531 KB)	Determination and D New *In Vitro* Diagnos (https://www.federal 04121/determinatior use-of-new-in-vitro-d 2015)

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Freeze Dried Plasma Information

Also see FDA News Release: FDA takes action to support American military personnel by granting an authorization for freeze-dried plasma product to enable broader access while the agency works toward approval of the product (/news-events/press-announcements/fda-takes-action-support-american-military-personnel-granting-authorization-freeze-dried-plasma) (July 10, 2018)

Medical Product	Date of EUA Issuance	Letter of Authorization	Federal Register Notice for EUA	Fact Sheets and Manufacturer Instructions/Package Insert	EUA Determinatio

Pathogen-Reduced Leukocyte-Depleted Freeze Dried Plasma (Centre de Transfusion Sanguine des Armées)	July 9, 2018 (initial issuance) May 8, 2020 (amendment)	Authorization (/media/114282/download) (PDF, 203 KB) Letter granting EUA amendments (/media/137970/download) (PDF, 60 KB)	FR notice (https://www.federalregister.gov/documents/2018/08/13/2018-17303/authorization-of-emergency-use-of-a-freeze-dried-plasma-treatment-for-hemorrhage-or-coagulopathy)	• Fact Sheet for U.S. Military Medical Personnel (/media/119949/download) (PDF, 132 KB) • Fact Sheet for Recipients (/media/119948/download) (PDF, 101 KB)	Determination by Declaration Rega Hemorrhage or C Agents of Military (https://www.fed 16331/emergenc hemorrhage-due- 9, 2018)

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H7N9 Influenza EUA Information

For more information about the diagnostics below, also see Emergency Use Authorizations (/about-fda/page-not-found) **(current device EUAs).**

Medical Product	Date of EUA Issuance	Letter of Authorization	Federal Register Notice for EUA	Fact Sheet and Manufacturer Instructions/Package Insert	EUA Determination and D
CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay	April 22, 2013 (initial issuance) March 27, 2018 (reissuance)	Authorization (/media/85910/download) (PDF, 301 KB), re-issued March 27, 2018	FR notice (https://www.federalregister.gov/articles/2013/06/25/2013-15096/authorization-of-emergency-use-of-an-in-vitro-diagnostic-for-detection-of-the-novel-avian-influenza)	• Healthcare (/media/85915/download) (PDF, 46 KB) • Patients (/media/85446/download) (PDF, 32 KB) • Instructions for Use (/media/85454/download) (PDF, 433 KB)	Determination and Declara Diagnostics for Detection (https://www.federalregis 10055/determination-and- vitro-diagnostics-for-detec Additional information fro (http://www.phe.gov/eme influenza-virus.aspx)
Quidel Lyra Influenza A Subtype H7N9 Assay	February 14, 2014	Authorization (/media/87767/download) (PDF, 57 KB)	FR notice (https://www.federalregister.gov/articles/2014/04/17/2014-08706/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-novel-influenza-a)	• Healthcare (/media/87775/download) (PDF, 42 KB) • Patients (/media/87780/download) (PDF, 40 KB)	Determination and Declara Diagnostics for Detection (https://www.federalregis 10055/determination-and- vitro-diagnostics-for-detec Additional information fro (http://www.phe.gov/eme influenza-virus.aspx)
A/H7N9 Influenza Rapid Test	April 25, 2014	Authorization (/medical-devices/emergency-situations-medical-devices/ah7n9-influenza-rapid-test-letter-authorization)	FR notice (https://www.federalregister.gov/articles/2014/06/23/2014-14547/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-novel-influenza-a)	• Healthcare (/medical-devices/emergency-situations-medical-devices/fact-sheet-health-care-providers-interpreting-ah7n9-influenza-rapid-test-results) • Patients (/medical-devices/emergency-situations-medical-devices/fact-sheet-patients-understanding-results-ah7n9-influenza-rapid-test)	Determination and Declara Diagnostics for Detection (https://www.federalregis 10055/determination-and- vitro-diagnostics-for-detec Additional information fro (http://www.phe.gov/eme influenza-virus.aspx)

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Middle East Respiratory Syndrome Coronavirus (MERS-CoV) EUA Information

For more information about the diagnostics below, also see Emergency Use Authorizations (/about-fda/page-not-found) **(current device EUAs).**

Medical Product	Date of EUA Issuance	Letter of Authorization	Federal Register Notice for EUA	Fact Sheets and Manufacturer Instructions/Package Insert	EUA Determin
CDC Novel Coronavirus 2012 Real-time RT-PCR Assay	June 5, 2013 (initial issuance) June 10, 2014 (reissuance)	Authorization (/media/88518/download) (PDF, 2.2 MB)	FR notice (https://www.federalregister.gov/documents/2013/07/17/2013-17103/authorization-of-emergency-use-of-an-in-vitro-diagnostic-for-detection-of-middle-east-respiratory)	• Healthcare (/medical-devices/emergency-situations-medical-devices/fact-sheet-health-care-professionals-interpreting-cdc-novel-coronavirus-2012-real-time-rt-pcr-assay) • Patients (/medical-devices/emergency-situations-medical-devices/fact-sheet-patients-understanding-results-cdc-novel-coronavirus-2012-real-time-rt-pcr-assay) • Contacts (/media/88505/download) (PDF, 1.2 MB) • Instructions for Use (/media/85951/download) (PDF, 743 KB)	Determinatio Diagnostics f Coronavirus ((https://www. 13333/determ vitro-diagnost Additional inf (http://www.p cov.aspx)
RealStar MERS-CoV RT-PCR Kit U.S.	July 17, 2015 (initial issuance) February 12, 2016 (reissuance)	Authorization (/media/93040/download) (PDF, 238 KB)	FR notice (https://www.federalregister.gov/documents/2015/09/01/2015-21585/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-middle-east)	• Healthcare (/media/93048/download) (PDF, 269 KB) • Patients (/media/93056/download) (PDF, 241 KB) • Instructions for Use (/media/120434/download) (PDF, 1.28 MB) • Fact Sheet for Asymptomatic Individuals Suspected of Exposure to MERS-CoV Cases (/media/95614/download) (PDF, 285 KB)	Determinatio Diagnostics f Coronavirus ((https://www. 13333/determ vitro-diagnost Additional inf (http://www.p cov.aspx)

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Nerve Agent EUA Information

On July 9, 2018, FDA approved (https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2018/212319Orig1s000ltr.pdf) (PDF, 49 KB) the 2 mg Atropine Auto-Injector manufactured by Rafa Laboratories, Ltd., for the treatment of poisoning by susceptible organophosphorous nerve agents having cholinesterase activity as well as organophosphorous or carbamate insecticides in adults and pediatric patients weighing over 90 lbs [41 kg] (generally over 10 years of age). For more information about the approved 2 mg Rafa Atropine Auto-Injector, see the product label (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/212319s000lbl.pdf) (PDF, 482 KB). The EUA detailed in the table below is still in effect.

Medical Product	Date of EUA Issuance	Letter of Authorization	Federal Register Notice for EUA	Fact Sheets and Manufacturer Instructions/Package Insert	EUA Determination

Atropine Auto-Injector (Rafa Laboratories Ltd.)	April 11, 2017 (initial issuance) May 23, 2017 (amended) January 24, 2018 (amended) March 6, 2018 (amended) May 15, 2018 (amended)	Letter of Authorization (/media/104550/download) (PDF, 514 KB) Letter granting EUA amendment(s) (/media/105590/download) (PDF, 28 KB) 2nd letter granting EUA amendment(s) (/media/110881/download) (PDF, 33 KB) 3rd letter granting EUA amendment(s) (/media/111656/download) (PDF, 85 KB) 4th letter granting EUA amendment(s) (/media/113102/download) (PDF, 42 KB)	FR notice (https://www.federalregister.gov/documents/2017/06/30/2017-13664/emergency-use-authorizations-injectable-treatment-for-nerve-agent-or-certain-insecticide)	• Healthcare (/media/104559/download) (PDF, 531 KB) • Patients and Caregivers (/media/104564/download) (PDF, 675 KB)	Determination and Certain Insecticide Poisoning (https://www.federa 07685/determinatic of-injectable-treatm

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Zika Virus EUA Information

Zika virus response updates from FDA (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda)

Zika virus diagnostic development information (/emergency-preparedness-and-response/mcm-issues/zika-virus-diagnostic-development)

For more information about the diagnostics below, also see Emergency Use Authorizations (/about-fda/page-not-found) (current device EUAs).

Draft EUA review templates for Zika are available by email request to: CDRH-ZIKA-Templates@fda.hhs.gov (mailto:CDRH-ZIKA-Templates@fda.hhs.gov?Subject=EUA template request)

Laboratory personnel using Zika diagnostic assays under EUA are encouraged to report performance concerns directly to FDA at CDRH-EUA-Reporting@fda.hhs.gov (mailto:CDRH-EUA-Reporting@fda.hhs.gov), in addition to reporting concerns to the manufacturer.

Zika Diagnostic Tests with De Novo, 510(k), or PMA

- **ZIKV Detect 2.0 IgM Capture ELISA (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/denovo.cfm?ID=DEN180069)** - On May 23, 2019, FDA authorized marketing (https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180069.pdf) (PDF, 175 KB) of the ZIKV Detect 2.0 IgM Capture ELISA to detect Zika virus immunoglobulin (IgM) antibodies in human blood. The ZIKV Detect 2.0 IgM Capture ELISA is the first Zika diagnostic test the FDA has allowed to be marketed in the U.S.; previously, tests for detecting Zika virus IgM antibodies—including the ZIKV Detect 2.0 IgM Capture ELISA—had been authorized only for emergency use under the FDA's EUA authority. *Also see the FDA news release: FDA authorizes marketing of first diagnostic test for detecting Zika virus antibodies (/news-events/press-announcements/fda-authorizes-marketing-first-diagnostic-test-detecting-zika-virus-antibodies)*
- **ADVIA Centaur Zika test** (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K191578) – On July 17, 2019, FDA cleared the ADVIA Centaur Zika test. This is the second Zika diagnostic test FDA has allowed to be marketed in the U.S. for detecting Zika virus IgM antibodies. Previously, the test had been authorized only for emergency use under FDA's EUA authority.
- **LIAISON XL Zika Capture IgM Assay II** (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K192046) – On October 28, 2019, FDA cleared the LIAISON XL Zika Capture IgM Assay II for detecting Zika virus IgM antibodies. Previously, the test had been authorized only for emergency use under FDA's EUA authority.
- DPP Zika IgM Assay System (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K192046) – On June 3, 2020, FDA cleared a similar DPP Zika IgM System for detecting Zika virus IgM antibodies. Previously, the test had been authorized only for emergency use under FDA's EUA authority.

Medical Product	Date of EUA Issuance	Letters	Federal Register Notice for EUA	Fact S Instru
CDC Zika Immunoglobulin M (IgM) Antibody Capture Enzyme-Linked Immunosorbent Assay *CDC statement on this EUA (http://www.cdc.gov/media/releases/2016/s0226-laboratory-test-for-zika-virus.html)*	February 26, 2016 (initial issuance) June 29, 2016 (amended) November 15, 2016 (amended) December 6, 2016 (amended) May 3, 2017 (amended) July 31, 2017 (amended) April 16, 2018 (amended) September 26, 2018 (amended)	Letter granting EUA amendment(s) (/media/101616/download) (PDF, 155 KB) Letter granting EUA amendment(s) (/media/101586/download) (PDF, 123 KB) Letter granting EUA amendment(s) (/media/120186/download) (PDF, 110 KB) Letter granting EUA amendment(s) (/media/120187/download) (PDF, 113 KB) Letter granting EUA amendment(s) (/media/120188/download) (PDF, 131 KB) Letter granting EUA amendment(s) (/media/120189/download) (PDF, 131 KB)	FR notice (https://www.federalregister.gov/articles/2016/03/28/2016-06888/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-diagnosis-of-zika-virus)	• • •
CDC Trioplex Real-time RT-PCR Assay (Trioplex rRT-PCR) *CDC statement on this EUA (http://www.cdc.gov/media/releases/2016/s0318-zika-lab-test.html)*	March 17, 2016 (initial issuance) September 21, 2016 (amended) January 12, 2017 (amended) February 28, 2017 (amended) April 6, 2017 (amended)	Authorization (/media/96683/download) (PDF, 82 KB) Letter granting EUA amendment(s) (/media/100200/download) (PDF, 223 KB) Letter granting EUA amendment(s) (/media/102439/download) (PDF, 223 KB) Letter granting EUA amendment(s) (/media/103400/download) (PDF, 223 KB) Letter granting EUA amendment(s) (/media/120192/download) (PDF, 126 KB)	FR notice (https://www.federalregister.gov/articles/2016/04/22/2016-09370/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-zika-virus)	• • •
Zika Virus RNA Qualitative Real-Time RT-PCR (Quest Diagnostics Infectious Disease, Inc.)	April 28, 2016 (initial issuance) October 7, 2016 (reissuance) April 11, 2017 (amended)	Authorization (/media/122435/download) (PDF, 339 KB) Letter granting EUA amendment(s) (/media/120127/download) (PDF, 126 KB)	FR notice (https://www.federalregister.gov/articles/2016/06/17/2016-14380/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)	• • •
RealStar Zika Virus RT-PCR Kit U.S. (altona Diagnostics GmbH)	May 13, 2016 (initial issuance) October 31, 2016 (amended) March 6, 2017 (amended)	Authorization (/media/120121/download) (PDF, 342 KB) Letter Granting EUA Amendment(s) (/media/120122/download) (PDF, 130 KB) Letter Granting EUA Amendment(s) (/media/120123/download) (PDF, 130 KB)	FR notice (https://www.federalregister.gov/articles/2016/06/17/2016-14380/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)	• • •

Aptima Zika Virus assay (Hologic, Inc.)	June 17, 2016 (initial issuance) September 7, 2016 (amended) April 12, 2017 (amended) March 8, 2018 (amended)	Authorization (/media/120114/download) (PDF, 305 KB) Letter granting EUA amendment(s) (/media/122434/download) (PDF, 126 KB) Letter granting EUA amendment(s) (/media/120116/download)(PDF, 124 KB) Letter granting EUA amendment(s) (/media/120117/download)(PDF, 130 KB)	FR notice (https://www.federalregister.gov/articles/2016/07/08/2016-16177/authorizations-of-emergency-use-in-vitro-diagnostic-device-for-detection-of-zika-virus)	
Zika Virus Real-time RT-PCR Test (Viracor Eurofins)	July 19, 2016 (initial issuance) February 28, 2017 (amended)	Authorization (/media/120033/download) (PDF, 334 KB) Letter granting EUA amendment(s) (/media/120034/download) (PDF, 124 KB)	FR notice (https://www.federalregister.gov/articles/2016/09/07/2016-21353/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-zika-virus#h-6)	
VERSANT Zika RNA 1.0 Assay (kPCR) Kit (Siemens Healthcare Diagnostics Inc.)	July 29, 2016 (initial issuance) December 19, 2016 (amended)	Authorization (/media/99444/download) (PDF, 78 KB) Letter granting EUA amendment(s) (/media/120030/download) (PDF, 124 KB)	FR notice (https://www.federalregister.gov/documents/2016/10/28/2016-26066/emergency-use-authorizations-in-vitro-diagnostic-devices-for-detection-andor-diagnosis-of-zika-virus)	
Sentosa SA ZIKV RT-PCR Test (Vela Diagnostics USA, Inc.)	September 23, 2016	Authorization (/media/120017/download) (PDF, 355 KB)	FR notice (https://www.federalregister.gov/documents/2016/11/03/2016-26532/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)	
Zika Virus Detection by RT-PCR Test (ARUP Laboratories)	September 28, 2016	Authorization (/media/120014/download) (PDF, 98 KB)	FR notice (https://www.federalregister.gov/documents/2016/11/03/2016-26532/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)	
Abbott RealTi*m*e ZIKA (Abbott Molecular Inc.)	November 21, 2016 (initial issuance) January 6, 2017 (amended)	Authorization (/media/101657/download) (PDF, 84 KB) Letter granting EUA amendment(s) (/media/120010/download) (PDF, 150 KB)	FR notice (https://www.federalregister.gov/documents/2016/12/20/2016-30532/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-zika-virus)	

Zika ELITe MGB Kit U.S. (ELITechGroup Inc. Molecular Diagnostics)	December 9, 2016	Authorization (/media/119919/download) (PDF, 312 KB)	FR notice (https://www.federalregister.gov/documents/2017/01/09/2017-00084/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-zika-virus)	• • •
Gene-RADAR Zika Virus Test (Nanobiosym Diagnostics, Inc.)	March 20, 2017	Authorization (/media/119915/download)(PDF, 313 KB)	FR notice (https://www.federalregister.gov/documents/2017/06/30/2017-13720/emergency-use-authorizations-in-vitro-diagnostic-devices-for-detection-of-zika-virus)	• • •
TaqPath Zika Virus Kit (Thermo Fisher Scientific)	August 2, 2017	Authorization (/media/119906/download)(PDF, 292 KB)	FR notice (https://www.federalregister.gov/documents/2017/10/26/2017-23224/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)	• • •
CII-ArboViroPlex rRT-PCR Assay (Columbia University)	August 11, 2017	Authorization (/media/107073/download) (PDF, 377 KB)	FR notice (https://www.federalregister.gov/documents/2017/10/26/2017-23224/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)	• • •

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- Process for Publishing Emergency Use Authorizations for Medical Devices During Coronavirus Disease 2019 (https://www.federalregister.gov/documents/2020/06/02/2020-11898/process-for-publishing-emergency-use-authorizations-for-medical-devices-during-coronavirus-disease) (June 2, 2020)
- Emergency Use Authorization--Archived Information (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information)
- Emergency Dispensing Orders (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-dispensing-orders)
- 21st Century Cures Act: MCM-Related Cures Provisions (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions)
- Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA) (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/pandemic-and-all-hazards-preparedness-reauthorization-act-2013-pahpra)
- Public Readiness and Emergency Preparedness (PREP) Act (https://www.phe.gov/preparedness/legal/prepact/pages/default.aspx)
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- Ebola Preparedness and Response Updates from FDA (/emergency-preparedness-and-response/mcm-issues/ebola-preparedness-and-response-updates-fda)
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