Emergency Use Authorization

On this page:

- About Emergency Use Authorizations (EUAs)
- PREP Act
- EUA Guidance
- COVID-19 EUAs
  - Vaccines
  - Drugs and Non-Vaccine Biological Products
  - Information About COVID-19 EUAs for Medical Devices
- Other Current EUAs
- Related Links

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 chemical, biological, radiological, and nuclear (CBRN) threats including infectious diseases, by facilitating the availability and use of medical countermeasures (/emergency-preparedness-and-response/about-mcmi/what-are-medical-countermeasures) (MCMs) needed during public health emergencies.

What is an EUA?

Under section 564 of the Federal Food, Drug, and Cosmetic Act (FD&C Act (/federal-food-drug-and-cosmetic-act-fdc-act)), when the Secretary of HHS declares that an emergency use authorization is appropriate, FDA may authorize 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 certain criteria are met, including there are no adequate, approved, and available alternatives. The HHS declaration to support such use must be based on one of four types of determinations of threats or potential threats by the Secretary of HHS, Homeland Security, or Defense.

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. 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. Subsequent HHS declarations supporting use of EUAs and based on this determination are described in the blue boxes below.

Information on terminated and revoked EUAs can be found in archived information (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information).

Public Readiness and Emergency Preparedness Act (PREP Act)

Information on the PREP Act can be found here (https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx).

The PREP Act amended the Public Health Service Act (PHS Act) to add section 319F-3 (42 U.S.C. 247d-6d). The HHS Secretary has issued several Declarations pursuant to section 319F-3 of the PHS Act to provide liability immunity for activities related to medical countermeasures against COVID-19.

PREP Act - COVID-19 Related Information

- 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)
- COVID-19 PREP Act Declarations and Amendments (HHS) (https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx)
- Advisory Opinion 02-02 on the PREP Act and the Secretary's Declaration under the Act (https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf) (PDF, 278 KB, May 19, 2020)

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.

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)
- **Detailed Information for all COVID-19 EUAs, including authorizations and fact sheets**
  - Vaccines
  - Drugs and Non-Vaccine Biological Products
  - COVID-19 EUAs for Medical Devices (/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices), including:
    - Blood Purification Devices EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/blood-purification-devices-euas)
    - Continuous Renal Replacement Therapy and Hemodialysis Devices EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/continuous-renal-replacement-therapy-and-hemodialysis-devices-euas)
    - In Vitro Diagnostics EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas)
    - Decontamination Systems for Personal Protective Equipment EUAs (/about-fda/page-not-found)
    - Infusion Pump EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/infusion-pump-euas)
    - Personal Protective Equipment EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas)
    - Remote or Wearable Patient Monitoring Devices EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/remote-or-wearable-patient-monitoring-devices-euas)
    - Respiratory Assist Devices EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/respiratory-assist-devices-euas)
    - Ventilators and Ventilator Accessories EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas)
    - Other Medical Device EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/other-medical-device-euas)
  - Information About COVID-19 EUAs for Medical Devices

Vaccines

The HHS Secretary 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)

For additional information about COVID-19 vaccines, see:

- COVID-19 Vaccines (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines)
- Emergency Use Authorization for Vaccines Explained (/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained)
- Infographic: The Path for a COVID-19 Vaccine From Research to Emergency Use Authorization (https://www.fda.gov/media/143890/download) (PDF, 723 KB)
- Vaccine EUA Questions and Answers for Stakeholders (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/vaccine-eua-questions-and-answers-stakeholders)

Federal Register notices:

- Authorizations of Emergency Use of Two Biological Products During the COVID-19 Pandemic; Availability (https://www.federalregister.gov/documents/2021/01/19/2021-01022/authorizations-of-emergency-use-of-two-biological-products-during-the-covid-19-pandemic-availability)
  - On December 11, 2020, FDA issued an EUA to Pfizer, Inc. for the Pfizer-BioNTech COVID-19 Vaccine, subject to the terms of the Authorization. On December 18, 2020, FDA issued an EUA to ModernaTX, Inc. for the Moderna COVID-19 Vaccine, subject to the terms of the Authorization.
- Authorizations of Emergency Use of Certain Biological Products During the COVID-19 Pandemic; Availability (https://www.federalregister.gov/documents/2021/05/27/2021-11234/authorizations-of-emergency-use-of-certain-biological-products-during-the-covid-19-pandemic) (May 27, 2021)
  - On February 27, 2021, FDA issued an EUA to Janssen Biotech, Inc. for the Janssen COVID-19 Vaccine, subject to the terms of the authorization.

Search: Show 10 entries

Date of First EUA Issuance	Most Recent Letter of Authorization (PDF)	Authorized Use	Fact Sheets and Manufacturer Instructions/Package Insert (PDF)	Additional Information and Decision Memoranda (PDF)

Date of First EUA Issuance	Most Recent Letter of Authorization (PDF)	Authorized Use	Fact Sheets and Manufacturer Instructions/Package Insert (PDF)	Additional Information and Decision Memoranda (PDF)
+ 02/27/2021	Janssen COVID-19 Vaccine (https://www.fda.gov/media/146303/download) (299KB) (Reissued June 10, October 20 and November 19, 2021, and May 5, 2022) Letter Granting EUA Amendment (March 29, 2021) (/media/147194/download) (152KB) Letter Granting EUA Amendment (April 23, 2021) (/media/147865/download) (229KB) Concurrence Letter (/media/150064/download) (June 10, 2021) (26KB) Concurrence Letter (/media/150136/download) (June 15, 2021) (57KB) Concurrence Letter (/media/150163/download) (June 16, 2021) (70KB) Concurrence Letter (/media/150567/download) (July 2, 2021) (317.7KB) Letter Granting EUA Amendment (July 12, 2021) (/media/150723/download) (210KB) Concurrence Letter (/media/150743/download) (July 13, 2021) (213KB) Concurrence Letter (/media/151141/download) (July 28, 2021) (63KB) Letter Granting EUA Amendment (August 30, 2021) (/media/151868/download) (80KB) Concurrence Letter (/media/152046/download) (September 8, 2021) (353KB) Concurrence Letter (/media/152171/download) (September 14, 2021) (253KB) Concurrence Letter (/media/152547/download) (September 29, 2021) (28KB) Concurrence Letter (/media/153931/download) (November 5, 2021) (212KB) Letter Granting EUA Amendment (/media/154870/download) (December 14, 2021) (253KB) Letter Granting EUA Amendment (/media/155391/download) (January 11, 2022) (439KB) Letter Granting EUA Amendment (/media/155862/download) (January 31, 2022) (393KB) Concurrence Letter (/media/156787/download) (March 4, 2022) (33KB) Concurrence Letter (/media/157554/download) (April 7, 2022) (136KB)	For the prevention of Coronavirus Disease 2019 (COVID-19) for individuals 18 years of age and older for whom other FDA-authorized or approved COVID-19 vaccines are not accessible or clinically appropriate, and in individuals 18 years of age and older who elect to receive the Janssen COVID-19 Vaccine because they would otherwise not receive a COVID-19 vaccine	Healthcare Providers (https://www.fda.gov/media/146304/download) (715 KB) Recipients and Caregivers (https://www.fda.gov/media/146305/download) (362 KB) • View the Fact Sheet for Recipients and Caregivers in multiple additional languages (https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine#translated)	More information about the Janssen COVID-19 Vaccine (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine) Frequently Asked Questions on the Janssen COVID-19 Vaccine (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine-frequently-asked-questions) COVID-19 Vaccine Expiration Dating Extensions (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-dating-extension#covidvaccines) Decision Memorandum (/media/146338/download) (974KB, February 2021 initial EUA issuance) Decision Memorandum (/media/150081/download) (362KB, June 2021 EUA reissuance) Decision Memorandum Addendum (/media/150139/download) (59KB, June 2021 EUA reissuance) Decision Memorandum Addendum (/media/150571/download)(61KB, July 1, 2021 Assessment of Certain Janssen COVID-19 Vaccine Batches) Decision Memorandum Addendum (/media/150745/download) (58KB, July 13, 2021 Assessment of Certain Janssen COVID-19 Vaccine Batches) Decision Memorandum Addendum (/media/152100/download) (60KB, September 8, 2021 Assessment of Certain Janssen COVID-19 Vaccine Batches) Decision Memorandum Addendum (/media/152170/download) (55KB, September 14, 2021 Assessment of Certain Janssen COVID-19 Vaccine Batches) Decision Memorandum Addendum (/media/152567/download) (57KB, September 29, 2021 Assessment of Certain Janssen COVID-19 Vaccine Batches) Decision Memorandum (/media/153441/download) (605KB, October 20, 2021 EUA reissuance) Memorandum to the File (/media/153439/download) (940KB, October 20, 2021 EUA amendment to support use of a Janssen COVID-19 Vaccine heterologous booster dose following primary vaccination with other authorized COVID-19 vaccines) Decision Memorandum Addendum (/media/153944/download) (59KB, November 5, 2021 Assessment of Certain Janssen COVID-19 Vaccine Batches) Decision Memorandum Addendum (/media/154359/download) (64KB, November 18, 2021) Review Memorandum (/media/155670/download) (86KB, December 22, 2021) Addendum to Dec. 22, 2021 Review Memorandum (/media/155671/download) (398KB, December 22, 2021) Decision Memorandum Addendum (/media/155236/download) (87KB, December 30, 2021) Decision Memorandum Addendum (/media/155547/download) (87KB, January 6, 2022) Review Memorandum (/media/155466/download) (84KB, January 7, 2022) Addendum to Jan 7, 2022 Review Memorandum (/media/155467/download) (81KB, January 7, 2022) Decision Memorandum (/media/158318/download) (257KB, May 5, 2022)

Date of First EUA Issuance	Most Recent Letter of Authorization (PDF)	Authorized Use	Fact Sheets and Manufacturer Instructions/Package Insert (PDF)	Additional Information and Decision Memoranda (PDF)
+ 12/18/2020	Moderna COVID-19 Vaccine (/media/144636/download) (1.02MB) (Reissued February 25, July 7, August 12, October 20, and November 19, 2021, January 7, January 31, March 15, March 29, and June 17, 2022) Letter Granting EUA Amendment (April 1, 2021) (/media/147284/download) (193KB) Letter Granting EUA Amendment (June 25, 2021) (/media/150387/download) (90KB) Letter Granting EUA Amendment (August 30, 2021) (/media/151855/download) (58KB) Letter Granting EUA Amendment (December 9, 2021) (/media/154746/download) (192KB)	For the prevention of 2019 coronavirus disease (COVID-19) in individuals 6 months and older On January 31, 2022, FDA approved the Moderna COVID-19 Vaccine, now known as Spikevax (/vaccines-blood-biologics/spikevax), for the prevention of COVID-19.	• Important prescribing information for vaccine providers on booster dose volume (0.25mL) and vial presentation (/media/153354/download) (230KB) (October 21, 2021) Healthcare Providers (/media/159307/download) (1.65MB) – labels with magenta borders - 6 months through 5 years of age Healthcare Providers (/media/159308/download) (1.70MB) – labels with purple and light blue borders - 6 years through 11 years of age Healthcare Providers (/media/157233/download) (1.76MB) – labels with light blue borders Healthcare Providers (/media/157232/download) (1.73MB) – labels with purple borders Recipients and Caregivers (/media/159309/download) (742KB) – labels with magenta borders - 6 months through 5 years of age Recipients and Caregivers (/media/159310/download) (743KB) - labels with purple and light blue borders - 6 years through 11 years of age Recipients and Caregivers (/media/144638/download) (943KB) - labels with black borders – For 12 years of age and older • View the Fact Sheet for Recipients and Caregivers in multiple additional languages (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine#translated) Important Prescribing Information for Vaccine Providers on Vial Presentation Available to Provide Doses for Ages 6 Years Through 11 Years (/media/159305/download) (708KB, June 17, 2022) Moderna COVID-19 Vaccine Presentations Wall Chart (/media/159306/download) (900KB, June 17, 2022)	More information about the Moderna COVID-19 Vaccine (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine) Frequently Asked Questions on the Moderna COVID-19 Vaccine (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine-frequently-asked-questions) Decision Memorandum (/media/144673/download) (769KB) Decision Memorandum (/media/151611/download) (65KB, August 12, 2021 EUA reissuance) Decision Memorandum (/media/153911/download) (606KB, October 20, 2021 EUA reissuance) Memorandum to the File (/media/153912/download) (605KB, October 20, 2021 EUA amendment to support use of a Moderna COVID-19 Vaccine heterologous booster dose following primary vaccination with other authorized COVID-19 vaccines) Decision Memorandum Addendum (/media/154407/download) (89KB, November 18, 2021) Decision Memorandum (/media/154405/download) (85KB, November 19, 2021) Decision Memorandum Addendum (/media/154406/download) (101KB, November 19, 2021) Decision Memorandum Addendum (/media/155235/download) (92KB, December 30, 2021) Decision Memorandum (/media/155548/download) (112KB, January 6, 2022) Decision Memorandum (/media/157368/download) (278KB, March 28, 2022) Decision Memorandum (/media/159611/download) (2.48MB, June 17, 2022)
+ 12/11/2020	Pfizer-BioNTech COVID-19 Vaccine (/media/150386/download) (484KB) (Reissued February 25, May 10, June 25, August 12, August 23, September 22, October 20, October 29, November 19, December 9, and December 16, 2021, January 3, March 29, May 17, and June 17, 2022) Letter Granting EUA Amendment (/media/144955/download)(January 6, 2021) (164KB) Letter Granting EUA Amendment (/media/145493/download)(January 22, 2021) (190KB) Letter Granting EUA Amendment (/media/147390/download)(April 6, 2021) (166KB) Letter Granting EUA Amendment (/media/148877/download)(May 19, 2021) (184KB) Concurrence Letter (/media/151731/download) (August 22, 2021) (68KB) Letter Granting EUA Amendment (/media/155676/download)(September 1, 2021) (98KB) Letter Granting EUA Amendment (/media/155863/download) (January 31, 2022) (170KB) Letter Granting EUA Amendment (/media/157684/download) (April 13, 2022) (375KB) Letter Granting EUA Amendment (/media/157977/download) (April 26, 2022) (179KB) Letter Granting EUA Amendment (/media/158909/download) (June 1, 2022) (164KB) Letter Granting EUA Amendment (/media/159558/download) (June 28, 2022)(128KB)	For the prevention of 2019 coronavirus disease (COVID-19) in individuals 6 months and older On August 23, 2021, FDA approved the Pfizer-BioNTech COVID-19 Vaccine, now known as Comirnaty (/vaccines-blood-biologics/comirnaty), for the prevention of COVID-19.	Healthcare Providers (/media/159312/download) (2.43MB) – for-6 months through 4 years of age, maroon cap (must dilute) Healthcare Providers (/media/153714/download) (1.33MB) – for 5-11 years of age, orange cap (must dilute) Healthcare Providers (/media/153713/download) (1.34MB) – for 12 years of age and older, purple cap (must dilute) Healthcare Providers (/media/153715/download) (1.06MB) – for 12 years of age and older, gray cap (no dilution) Recipients and Caregivers (/media/159313/download) (632KB) –for-6 months through 4 years of age Recipients and Caregivers (/media/153717/download) (646KB) – 5-11 years of age Recipients and Caregivers (/media/153716/download) (204KB) –12 years of age and older • View the Fact Sheet for Recipients and Caregivers in multiple additional languages (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine#translated) Pfizer Dear Healthcare Provider Letter (/media/159303/download) (200KB, June 17, 2022) Pfizer-BioNTech COVID-19 Vaccine Presentations Wall Chart (/media/159304/download) (820KB, June 17, 2022)	More information about the Pfizer-BioNTech COVID-19 Vaccine (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine) Frequently Asked Questions on the Pfizer-BioNTech COVID-19 Vaccine (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine-frequently-asked-questions) COVID-19 Vaccine Expiration Dating Extensions (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-dating-extension#covidvaccines) Decision Memorandum (/media/144416/download) (709KB, December 2020 initial EUA issuance) Decision Memorandum (/media/148542/download) (868KB, May 2021 EUA reissuance) Decision Memorandum (/media/151613/download) (93KB, August 12, 2021 EUA reissuance) Decision Memorandum (/media/152432/download) (362KB, September 24, 2021) Decision Memorandum (/media/153482/download) (630KB, October 20, 2021 EUA reissuance) Decision Memorandum (/media/153947/download) (508KB, October 29, 2021) Decision Memorandum (/media/154357/download) (135KB, November 19, 2021) Decision Memorandum Addendum (/media/154358/download) (96KB, November 19, 2021) Decision Memorandum (/media/154869/download) (135KB, December 8, 2021) Decision Memorandum (/media/155234/download) (140KB, December 30, 2021) Decision Memorandum Addendum (/media/155549/download) (87KB, January 6, 2022) Decision Memorandum (/media/157364/download) (279KB, March 28, 2022) Decision Memorandum (/media/158575/download) (481KB, May 17, 2022 Decision Memorandum (/media/159393/download) (973KB, June 17, 2022)

Showing 1 to 3 of 3 entries

Previous 1 Next

Drugs and Non-Vaccine Biological Products

The HHS Secretary 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)

COVID-19 EUA FAERS Public Dashboard

The dashboard provides weekly updates of adverse event reports submitted to FAERS for drugs and therapeutic biological products used under EUA during the COVID-19 public health emergency. After launching the FAERS Public Dashboard (/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard), click on the COVID-19 EUA link at the top of the home page to open the COVID-19 EUA FAERS Public Dashboard.

Federal Register notices:

- Authorizations and Revocation of Emergency Use of Drugs During the COVID-19 Pandemic; Availability (https://www.federalregister.gov/documents/2020/09/11/2020-20041/authorizations-and-revocation-of-emergency-use-of-drugs-during-the-covid-19-pandemic-availability) (September 11, 2020)
  - FDA announced issuance of four authorizations for the emergency use of drugs during the COVID-19 pandemic and one revocation. On March 28, 2020, FDA issued an EUA to BARDA for oral formulations of chloroquine phosphate and hydroxychloroquine sulfate, subject to the terms of the Authorization. On April 30, 2020, FDA issued an EUA to Fresenius Medical Care for multiFiltrate PRO System and multiBic/multiPlus Solutions, subject to the terms of the authorization. On May 1, 2020, FDA issued an EUA to Gilead Sciences, Inc. for remdesivir, subject to the terms of the authorization. On May 8, 2020, FDA issued an EUA to Fresenius Kabi USA, LLC for Fresenius Propoven 2% Emulsion, subject to the terms of the authorization. FDA revoked the EUA for BARDA's oral formulations of chloroquine phosphate and hydroxychloroquine sulfate on March 28, 2020.
- Authorizations of Emergency Use of Certain Drug and Biological Products During the COVID-19 Pandemic; Availability (https://www.federalregister.gov/documents/2021/02/19/2021-03429/authorizations-of-emergency-use-of-certain-drug-and-biological-products-during-the-covid-19-pandemic) (February 19, 2021)
  - FDA announced issuance of five authorizations for the emergency use of drug and biological products during the COVID-19 pandemic. On August 13, 2020, FDA issued an EUA to Baxter for REGIOCIT, subject to the terms of the authorization. On August 23, 2020, FDA issued an EUA to ASPR/HHS for COVID-19 convalescent plasma, subject to the terms of the authorization. On November 9, 2020, FDA issued an EUA to Eli Lilly and Company for bamlanivimab, subject to the terms of the authorization (technical correction on November 10, 2020). On November 19, 2020, FDA issued an EUA to Eli Lilly and Company for OLUMIANT (baricitinib), for use in combination with VEKLURY (remdesivir), subject to the terms of the authorization. On November 21, 2020, FDA issued an EUA to Regeneron Pharmaceuticals, Inc. for casirivimab and imdevimab, administered together, subject to the terms of the authorization.
- Authorizations of Emergency Use of Certain Biological Products During the COVID-19 Pandemic; Availability (https://www.federalregister.gov/documents/2021/05/27/2021-11234/authorizations-of-emergency-use-of-certain-biological-products-during-the-covid-19-pandemic) (May 27, 2021)
  - On February 9, 2021, FDA issued an EUA to Eli Lilly and Company for bamlanivimab and etesevimab, administered together, subject to the terms of the authorization
- Authorization and Revocation of Emergency Use of Drugs During the COVID-19 Pandemic; Availability (https://www.federalregister.gov/documents/2021/06/23/2021-13183/authorization-and-revocation-of-emergency-use-of-drugs-during-the-covid-19-pandemic-availability) (June 23, 2021)
  - FDA announced the issuance of an EUA for a drug for use during the COVID-19 pandemic. FDA issued the Authorization under the Federal Food, Drug, and Cosmetic Act (FD&C Act), as requested by B. Braun Melsungen AG. The authorization contains, among other things, conditions on the emergency use of the authorized drug. FDA also annouced the revocation of the authorization issued to Eli Lilly and Company for bamlanivimab alone. FDA revoked this authorization on April 16, 2021. Reprinted in this document is the issuance of the Authorization and the revocation, which include an explanation of the reasons for issuance or revocation.
- Authorizations of Emergency Use of Certain Biological Products During the COVID-19 Pandemic; Availability (https://www.federalregister.gov/documents/2021/08/05/2021-16705/authorizations-of-emergency-use-of-certain-biological-products-during-the-covid-19-pandemic) (August 5, 2021)
  - FDA announced the issuance of two authorizations for biological products for use during the COVID-19 pandemic. On May 26, 2021, FDA issued an EUA to GlaxoSmithKline LLC for sotrovimab, subject to the terms of the authorization. On June 24, 2021, FDA issued an EUA to Genentech, Inc. for ACTEMRA (tocilizumab), subject to the terms of the authorization.
- Authorizations of Emergency Use of Certain Drugs and Biological Products During the COVID-19 Pandemic; Availability (https://www.federalregister.gov/documents/2022/02/04/2022-02359/authorizations-of-emergency-use-of-certain-drugs-and-biological-products-during-the-covid-19) (February 4, 2022)
  - FDA announced the issuance of three EUAs for use during the COVID-19 pandemic. FDA issued one authorization for a biological product as requested by AstraZeneca Pharmaceuticals LP (AZ) (December 8, 2021), one authorization for a drug product as requested by Pfizer, Inc. (Pfizer) (December 22, 2021), and one authorization for a drug product as requested by Merck Sharp & Dohme Corp. (Merck) (December 23, 2021).
- Emergency Use Authorization: Biological Product during the COVID-19 Pandemic (https://www.federalregister.gov/public-inspection/2022-06009/emergency-use-authorization-biological-product-during-the-covid-19-pandemic) (March 22, 2022)
  - FDA announced the issuance of one EUA for a biological product for use during the COVID-19 pandemic. On February 11, 2022, FDA issued an EUA to Eli Lilly and Company (Lilly) for the biological product bebtelovimab, subject to the terms of the authorization
- Revocation notices for COVID-19 drug and biological product EUAs are available at: Emergency Use Authorization--Archived Information (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information)

Office of the Assistant Secretary for Preparedness and Response (ASPR) Important Updates: **COVID-19 Therapeutics** (https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/updates.aspx)

View the FDA's COVID-19 Drugs (https://www.fda.gov/drugs/emergency-preparedness-drugs/coronavirus-covid-19-drugs) page to see all products approved to treat COVID-19 without any remaining EUA authorized uses.

Search: Show 25 entries

Date of First EUA Issuance	Most Recent Letter of Authorization (PDF)	Authorized Use [1]	Fact Sheets and Manufacturer Instructions/ Package Insert (PDF)
+ 02/11/2022	Bebtelovimab (/media/156151/download) (181KB) Letter Granting EUA Amendment (/media/157315/download) (March 30, 2022) (216KB) ASPR and FDA Statement on Shelf-Life Extension of Bebtelovimab (https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/important-update-20May2022.aspx) (May 20, 2022)	Bebtelovimab is authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate. **Bebtelovimab is currently authorized in all U.S. regions until further notice by the Agency.**	Healthcare Providers (/media/156152/download) (772KB) (updated June 16, 2022) Patients, Parents, and Caregivers (/media/156153/download) (150KB) • Spanish (/media/156155/download) (141KB) Frequently Asked Questions on the Emergency Use Authorization of Bebtelovimab (/media/156154/download) (225KB) CDER Scientific Review Documents Supporting EUA (https://www.fda.gov/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological)
+ 12/23/2021	Lagevrio (molnupiravir) (/media/155053/download) (865KB) (reissued March 23, 2022)	Lagevrio is authorized for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options approved or authorized by FDA are not accessible or clinically appropriate.	Healthcare Providers (/media/155054/download) (585KB) • Spanish (/media/155114/download) (589KB) Patients, Parents, and Caregivers (/media/155055/download) (131KB) • Spanish (/media/155115/download) (350KB) COVID-19 Test to Treat locator (https://aspr.hhs.gov/testtotreat/Pages/default.aspx) (Find a treatment location near you, from ASPR) Dear Healthcare Provider Letter (/media/155101/download) (268KB) Frequently Asked Questions on the Emergency Use Authorization of Lagevrio (/media/155056/download) (1.01MB) Prescriber Checklist for Lagevrio (/media/155118/download) (180KB) CDER Scientific Review Documents Supporting EUA (https://www.fda.gov/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological)

Date of First EUA Issuance	Most Recent Letter of Authorization (PDF)	Authorized Use [1]	Fact Sheets and Manufacturer Instructions/ Package Insert (PDF)
+ 12/22/2021	Paxlovid (nirmatrelvir tablets and ritonavir tablets, co-packaged for oral use) (/media/155049/download) (742KB) (reissued March 17, 2022 and April 14, 2022) Letter Granting EUA Amendment (/media/157018/download) (March 18, 2022) (161KB)	Paxlovid is authorized for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.	Healthcare Providers (/media/155050/download) (641KB) Paxlovid Patient Eligibility Screening Checklist and Drug Interaction Tool (https://www.fda.gov/media/158165/download) (1.11MB) (updated June 28, 2022) Patients, Parents, and Caregivers (/media/155051/download) (904KB) • Spanish (/media/155075/download) (166KB) COVID-19 Test to Treat locator (https://aspr.hhs.gov/testtotreat/Pages/default.aspx) (Find a treatment location near you, from ASPR) Dear Healthcare Provider Letter (/media/155071/download) (181KB) Important Dispensing Information for Patients with Moderate Renal Impairment (/media/155072/download) (476KB) Frequently Asked Questions on the Emergency Use Authorization for Paxlovid (/media/155052/download) (203KB) CDER Conversation on Paxlovid for Health Care Providers (/drugs/news-events-human-drugs/fda-updates-paxlovid-health-care-providers) CDER Scientific Review Documents Supporting EUA (https://www.fda.gov/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological)

+ 12/08/2021	Evusheld (tixagevimab co-packaged with cilgavimab) (/media/154704/download)(293KB) (reissued December 20, 2021, February 24, 2022, and May 17, 2022)
	FDA authorizes revisions to Evusheld dosing (https://www.fda.gov/drugs/drug-safety-and-availability/fda-authorizes-revisions-evusheld-dosing) (updated June 29, 2022)
	ASPR and FDA Statement on Shelf-Life Extension of Evusheld (https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/important-update-28June2022.aspx) (June 28, 2022)
	Letter Granting EUA Amendment (/media/159563/download) (June 29, 2022) (168KB)
		For emergency use as pre-exposure prophylaxis for prevention of COVID-19 in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):
		• Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 and
		  ◦ Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination or
		  ◦ For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).
			Healthcare Providers (/media/154701/download) (1.6MB) (updated June 29, 2022)
			• Spanish (/media/155073/download) (870KB) (updated June 29, 2022)
			Patients, Parents, and Caregivers (/media/154702/download) (425KB) (updated June 29, 2022)
			• Spanish (/media/155196/download) (512KB) (updated June 29, 2022)
			Dear Healthcare Provider Letter (/media/159561/download) (439KB) (June 29, 2022)
			New Repeat Dosage Recommendations
			• Spanish (/media/159598/download) (207KB) (June 29, 2022)
			Dear Healthcare Provider Letter (/media/158514/download) (226KB) (May 17, 2022)
			Addition of EVUSHELD EUA Warning and Precaution for Risk of Cross-Hypersensitivity with COVID-19 Vaccines
			Dear Healthcare Provider Letter (/media/156617/download) (144KB) (March 22, 2022)
			Updated EVUSHELD EUA Dosage Recommendations for Patients Who Received an Initial Dose of 150 mg tixagevimab and 150 mg cilgavimab
			• Spanish (/media/156618/download) (227KB) (April 1, 2022)
			Frequently Asked Questions on the Emergency Use Authorization for Evusheld (/media/154703/download) (919KB) (updated June 29, 2022)
			CDER Scientific Review Documents Supporting EUA (https://www.fda.gov/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological)

+ 06/24/2021	Actemra (Tocilizumab (/media/150319/download)) (107KB)	For the treatment of COVID-19 in hospitalized adults and pediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).	Healthcare Providers (/media/150321/download) (231KB) Patients, Parents, and Caregivers (/media/150320/download) (47KB) Frequently Asked Questions on the Emergency Use Authorization of Actemra (Tocilizumab) (/media/150345/download) (128KB) CDER Scientific Review Documents Supporting EUA (/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological)
+ 05/26/2021	Sotrovimab (/media/149532/download) (375KB) (reissued October 8, 2021, December 16, 2021 and February 23, 2022) Letter Granting EUA Amendment (/media/155097/download) (December 22, 2021) (161KB) ASPR and FDA Statement on Shelf-Life Extension of Sotrovimab (https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/important-update-12May2022.aspx) (May 12, 2022) Important updates about sotrovimab (https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Sotrovimab/Pages/default.aspx) (ASPR)	For the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death. **Due to the high frequency of the Omicron BA.2 sub-variant, sotrovimab is not currently authorized in any U.S. region. Therefore, sotrovimab may not be administered for treatment of COVID-19 under the Emergency Use Authorization until further notice by the Agency.** (/drugs/drug-safety-and-availability/fda-updates-sotrovimab-emergency-use-authorization)	Healthcare Providers (/media/149534/download) (1.38MB) (updated March 25, 2022) • Spanish (/media/154377/download) (295KB, March 25, 2022) Patients, Parents, and Caregivers (/media/149533/download) (385KB) (updated March 25, 2022) • Spanish (/media/154376/download) (174KB, March 25, 2022) Frequently Asked Questions on the Emergency Use Authorization of Sotrovimab (/media/149535/download) (257KB) (updated March 25, 2022) CDER Scientific Review Documents Supporting EUA (/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological)
+ 03/12/2021	Propofol-Lipuro 1% (/media/146680/download) (344KB) Letter Granting EUA Amendment (/media/154895/download) (December 16, 2021) (188KB)	To maintain sedation via continuous infusion in patients greater than age 16 with suspected or confirmed COVID-19 who require mechanical ventilation in an ICU setting. [2]	Healthcare Providers (/media/146681/download) (446KB) Patients, Parents, and Caregivers (/media/146682/download) (190KB)
+ 02/09/2021	Bamlanivimab and Etesevimab (/media/145801/download) (900KB) (Reissued February 25, 2021, August 27, 2021, September 16, 2021, December 3, 2021, December 22, 2021 and January 24, 2022) ASPR and FDA Statement on Shelf-Life Extension of Bamlanivimab and Etesevimab (https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/important-update-04May2022.aspx) (May 4, 2022) Important updates about bamlanivimab/etesevimab (https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Bamlanivimab-etesevimab/Pages/default.aspx) (ASPR)	**Due to the high frequency of the Omicron variant, bamlanivimab and etesevimab are not currently authorized in any U.S. region. Therefore, these drugs may not be administered for treatment or post-exposure prevention of COVID-19 under the Emergency Use Authorization until further notice by the Agency.** Bamlanivimab and etesevimab administered together for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.	Healthcare Providers (/media/145802/download) (1.75MB) (updated January 24, 2022) Patients, Parents, and Caregivers (/media/145803/download) (157KB) (updated December 3, 2021) • Spanish (/media/148713/download) (158KB) (updated September 16, 2021) Frequently Asked Questions on the Emergency Use Authorization for Bamlanivimab and Etesevimab (/media/145808/download) (312KB) (updated January 31, 2022) CDER Scientific Review Documents Supporting EUA (/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological)

Date of First EUA Issuance	Most Recent Letter of Authorization (PDF)	Authorized Use [1]	Fact Sheets and Manufacturer Instructions/ Package Insert (PDF)
+ 11/21/2020	REGEN-COV (Casirivimab and Imdevimab) (/media/145610/download) (1.03MB) (Reissued February 3, 2021, February 25, 2021, June 3, 2021, July 30, 2021, September 9, 2021, November 17, 2021 and January 24, 2022) ASPR and FDA Statement on Shelf-Life Extension of REGEN-COV (https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/important-update-27June2022.aspx) (June 27, 2022)	**Due to the high frequency of the Omicron variant, REGEN-COV is not currently authorized in any U.S. region. Therefore, REGEN-COV may not be administered for treatment or post-exposure prevention of COVID-19 under the Emergency Use Authorization until further notice by the Agency.** Casirivimab and imdevimab to be administered together for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.	Healthcare Providers (/media/145611/download) (1.74MB) (updated January 24, 2022) • Spanish (/media/151403/download) (1.03MB) Patients, Parents, and Caregivers (/media/145612/download) (147KB) (updated July 30, 2021) • Spanish (/media/151404/download) (247KB) Dear Healthcare Provider Letter (/media/143901/download) (435KB) (updated September 16, 2021) Statement on Post-Exposure Prophylaxis (/drugs/drug-safety-and-availability/fda-authorizes-regen-cov-monoclonal-antibody-therapy-post-exposure-prophylaxis-prevention-covid-19) (July 30, 2021) Frequently Asked Questions on the Emergency Use Authorization of REGEN-COV (Casirivimab and Imdevimab) (/media/143894/download) (311KB) (updated January 31, 2022) CDER Scientific Review Documents Supporting EUA (/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological) Quick Reference Guide for Co-Packaged REGEN-COV (/media/152051/download) (38KB) (September 16, 2021)
+ 11/19/2020	Baricitinib (Olumiant) (/media/143822/download) (252KB) (Reissued May 10, 2022)	For emergency use by healthcare providers for the treatment COVID-19 in hospitalized pediatric patients 2 to less than 18 years of age requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). **On May 10, 2022, Olumiant was approved for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO.**	Healthcare Providers (/media/143823/download) (Updated May 10, 2022) (272KB) Patients, Parents, and Caregivers (/media/143824/download) (Updated May 10, 2022) (128KB) Frequently Asked Questions on the Emergency Use Authorization for Olumiant (baricitinib) for Treatment COVID-19 (/media/143825/download) (270KB) (Updated May 10, 2022) CDER Scientific Review Documents Supporting EUA (/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological)
+ 08/23/2020	COVID-19 convalescent plasma (/media/141477/download) (365KB) (Reissued February 23, 2021, March 9, 2021 and December 28, 2021) Letter Granting EUA Amendment (/media/149803/download) (June 2, 2021) (107KB) Letter Granting EUA Amendment (/media/156185/download) (February 9, 2022) (26KB)	COVID-19 convalescent plasma with high titers of anti-SARS-CoV-2 antibodies is authorized for the treatment of COVID-19 in patients with immunosuppressive disease or receiving immunosuppressive treatment, in inpatient or outpatient settings.	Healthcare Providers (/media/141478/download) (Updated December 28, 2021) (192KB) Patients and Parents/ Caregivers (/media/141479/download) (Updated December 28, 2021) (151KB) Decision Memorandum (/media/141480/download) (166KB) Decision Memorandum (/media/155159/download) (December 27, 2021) (242KB)
+ 08/13/2020	REGIOCIT replacement solution that contains citrate for regional citrate anticoagulation (RCA) of the extracorporeal circuit (/media/141168/download) (92KB)	To be used as a replacement solution only in adult patients treated with continuous renal replacement therapy (CRRT), and for whom regional citrate anticoagulation is appropriate, in a critical care setting	Healthcare Providers (/media/141170/download) (108KB) Patients and Caregivers (/media/141172/download) (52KB) REGIOCIT package insert for EUA (/media/141186/download) (140KB)
+ 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)

Showing 1 to 13 of 13 entries

Previous 1 Next

[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 Propofol-Lipuro 1% 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.

Information About COVID-19 EUAs for Medical Devices

Information about COVID-19 EUAs for medical devices can be found below and at: Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices (/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices).

On February 4, 2020 (https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency), the Secretary determined pursuant to section 564 of the FD&C Act 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 a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019-nCoV).

On the basis of this determination, the HHS Secretary issued three declarations related to medical devices:

- Determination of Public Health Emergency (https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency) (effective February 4, 2020), and declaration 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
- Emergency Use Declaration (https://www.federalregister.gov/documents/2020/03/10/2020-04823/emergency-use-declaration) (effective March 2, 2020), that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak
- Emergency Use Authorization Declaration (https://www.federalregister.gov/documents/2020/03/27/2020-06541/emergency-use-authorization-declaration) (effective March 24, 2020), 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

For identification of the applicable declaration for each EUA, please see each EUA letter of authorization and/or the corresponding Federal Register notice.

In Vitro Diagnostics

Please see the page In Vitro Diagnostics EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas) for information about in vitro diagnostics EUAs, including templates.

For current SARS-CoV-2 in vitro diagnostic EUAs, see:

- Molecular Diagnostic Tests for SARS-CoV-2 (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2)
- Antigen Diagnostic Tests for SARS-CoV-2 (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2)
- Serology and Other Adaptive Immune Response Tests for SARS-CoV-2 (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2)
- IVDs for Management of COVID-19 Patients (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-ivds-management-covid-19-patients)

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/in-vitro-diagnostics-euas) are available to help facilitate the preparation, submission, and authorization of an EUA.

For additional information, see FAQs on Diagnostic Testing for SARS-CoV-2 (/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2), EUA Authorized Serology Test Performance (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance), and CLIA and University Laboratory Testing FAQ (https://www.cms.gov/files/document/clia-university-lab-testing.pdf) (CMS).

Molecular SARS-CoV-2 Diagnostic Tests for COVID-19 that have been granted a De Novo, 510(k) clearance or PMA

BioFire Respiratory Panel 2.1 (RP2.1) - On March 17, 2021, FDA granted the first marketing authorization using the De Novo review pathway for the BioFire Respiratory Panel 2.1 (RP2.1) (https://www.accessdata.fda.gov/cdrh_docs/pdf20/DEN200031.pdf) (PDF, 630 KB). The BioFire RP2.1 is for the simultaneous qualitative detection and identification of multiple respiratory viral and bacterial nucleic acids in nasopharyngeal swabs (NPS) obtained from individuals suspected of respiratory tract infections, including COVID-19. *Also see the FDA news release: FDA Permits Marketing of First SARS-CoV-2 Diagnostic Test Using Traditional Premarket Review Process (/news-events/press-announcements/fda-permits-marketing-first-sars-cov-2-diagnostic-test-using-traditional-premarket-review-process). With granting of the De Novo for the BioFire RP2.1, the FDA revoked the EUA (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information) for this device, which was initially authorized for emergency use in May 2020.*

The BioFire Respiratory Panel 2.1 (RP2.1) was reviewed under the De Novo premarket review pathway (/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request), a regulatory pathway for low-to-moderate-risk devices of a new type. Along with this De Novo authorization, the FDA is establishing criteria, called special controls, that define the requirements related to labeling and performance testing. When met, the special controls, in combination 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.

BioFire COVID-19 Test 2 - On November 1, 2021, FDA cleared the first 510(k) for a COVID-19 test, the BioFire COVID-19 Test 2 (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K211079) from BioFire Defense, LLC. The test, which has been offered under an EUA since March 2020, is the second SARS-CoV-2 diagnostic test granted marketing authorization that permits the test to be marketed beyond the public health emergency. The BioFire COVID-19 Test 2 is a molecular diagnostic test that detects SARS-CoV-2 in nasopharyngeal swab samples (where the sample is taken from deep inside the nose, reaching the back of the throat), in people with symptoms who are suspected of COVID-19 by their health care provider.

Personal Protective Equipment (PPE)

Please see the page Personal Protective Equipment EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas) for current EUAs.

For additional information, see Recent Final Medical Device Guidance Documents (/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/recent-final-medical-device-guidance-documents), and Non-NIOSH Approved Respirator FAQ (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/faqs-euas-non-niosh-approved-respirators-during-covid-19-pandemic).

See Revoked EUAs for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators and Decontamination and Bioburden Reduction Systems below for information about June 30, 2021 EUA revocations.

Other Medical Device EUAs

Please see the following pages for EUA templates and additional information about other types of medical device EUAs for COVID-19:

- Blood Purification Devices EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/blood-purification-devices-euas)
- Continuous Renal Replacement Therapy and Hemodialysis Devices EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/continuous-renal-replacement-therapy-and-hemodialysis-devices-euas)
- Infusion Pump EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/infusion-pump-euas)
- Remote or Wearable Patient Monitoring Devices EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/remote-or-wearable-patient-monitoring-devices-euas)
- Respiratory Assist Devices EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/respiratory-assist-devices-euas)
- Ventilators and Ventilator Accessories EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas)
- Other Medical Device EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/other-medical-device-euas)

Revoked EUAs for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (FFRs) and Decontamination and Bioburden Reduction Systems

On June 30, 2021, the FDA announced (/news-events/press-announcements/fda-brief-fda-revokes-emergency-use-authorizations-certain-respirators-and-decontamination-systems)the revocation of the following EUAs:

- Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators (https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/revoked-euas-non-niosh-approved-disposable-filtering-facepiece-respirators#imported)(effective July 6, 2021)
- Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China (https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/revoked-euas-non-niosh-approved-disposable-filtering-facepiece-respirators#china) (effective July 6, 2021)
- Decontamination and Bioburden Reduction System EUAs for Personal Protective Equipment (https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations#decontamination) (effective June 30, 2021)

As of the effective date of the revocations, these devices will no longer be authorized for use by health care personnel in health care settings.

For additional information, please see Update: FDA No Longer Authorizes Use of Non-NIOSH-Approved or Decontaminated Disposable Respirators - Letter to Health Care Personnel and Facilities (/medical-devices/letters-health-care-providers/update-fda-no-longer-authorizes-use-non-niosh-approved-or-decontaminated-disposable-respirators). Historical information regarding these EUAs can be found on Historical Information about Device Emergency Use Authorizations (/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations) and Emergency Use Authorization--Archived Information (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information).

Medical Device Federal Register notices

- Authorization of Emergency Use of Certain Medical Devices During COVID-19; Availability (https://www.federalregister.gov/documents/2020/06/05/2020-12117/authorization-of-emergency-use-of-certain-medical-devices-during-covid-19-availability) (through April 10, 2020)
- Authorization of Emergency Use of Certain Medical Devices During COVID-19; Availability (https://www.federalregister.gov/documents/2020/07/14/2020-15137/authorization-of-emergency-use-of-certain-medical-devices-during-covid-19-availability) (April 11, 2020- May 15, 2020)
- Authorization of Emergency Use of Certain Medical Devices During COVID-19; Availability (https://www.federalregister.gov/documents/2020/11/20/2020-25603/authorization-of-emergency-use-of-certain-medical-devices-during-covid-19-availability) (May 15, 2020- September 14, 2020)
- Authorization of Emergency Use of Certain Medical Devices During COVID-19; Availability (https://www.federalregister.gov/documents/2021/04/23/2021-08467/authorization-of-emergency-use-of-certain-medical-devices-during-covid-19-availability) (September 15, 2020 - February 15, 2021)
- Authorization of Emergency Use of Certain Medical Devices During COVID-19; Availability (https://www.federalregister.gov/documents/2021/07/23/2021-15680/authorization-of-emergency-use-of-certain-medical-devices-during-covid-19-availability)(February 16, 2021- May 31, 2021)
- Authorization of Emergency Use of Certain Medical Devices During COVID-19; Availability (https://www.federalregister.gov/documents/2021/10/28/2021-23501/authorization-of-emergency-use-of-certain-medical-devices-during-covid-19-availability) (June 1, 2021 - September 10, 2021)
- Emergency Use Authorization: Certain Medical Devices during COVID-19 (https://www.federalregister.gov/public-inspection/2022-06008/emergency-use-authorization-certain-medical-devices-during-covid-19) (September 11, 2021 - January 24, 2022)
- Revocation notices for device EUAs are made available at: Historical Information about Device Emergency Use Authorizations (https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations)

back to About EUAs

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).

back to top of page (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#top)

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).

back to list of current EUAs

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-selecting-and-preparing-correct-submission/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	EUA Determination and Declaration (Effective Date)	PREP Act Declaration (if applicable)
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)	Declaration Regarding Emergency Use of *In Vitro* Diagnostics for Detection of Ebola Virus (https://www.federalregister.gov/articles/2014/08/12/2014-19026/declaration-regarding-emergency-use-of-in-vitro-diagnostics-for-detection-of-ebola-virus) (August 4, 2014)	

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)	Declaration Regarding Emergency Use of *In Vitro* Diagnostics for Detection of Ebola Virus (https://www.federalregister.gov/articles/2014/08/12/2014-19026/declaration-regarding-emergency-use-of-in-vitro-diagnostics-for-detection-of-ebola-virus) (August 4, 2014)	
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)	Declaration Regarding Emergency Use of *In Vitro* Diagnostics for Detection of Ebola Virus (https://www.federalregister.gov/articles/2014/08/12/2014-19026/declaration-regarding-emergency-use-of-in-vitro-diagnostics-for-detection-of-ebola-virus) (August 4, 2014)	
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)	Declaration Regarding Emergency Use of *In Vitro* Diagnostics for Detection of Ebola Virus (https://www.federalregister.gov/articles/2014/08/12/2014-19026/declaration-regarding-emergency-use-of-in-vitro-diagnostics-for-detection-of-ebola-virus) (August 4, 2014)	
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)	Declaration Regarding Emergency Use of *In Vitro* Diagnostics for Detection of Ebola Virus (https://www.federalregister.gov/articles/2014/08/12/2014-19026/declaration-regarding-emergency-use-of-in-vitro-diagnostics-for-detection-of-ebola-virus) (August 4, 2014)	
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, 797 KB)	Declaration Regarding Emergency Use of *In Vitro* Diagnostics for Detection of Ebola Virus (https://www.federalregister.gov/articles/2014/08/12/2014-19026/declaration-regarding-emergency-use-of-in-vitro-diagnostics-for-detection-of-ebola-virus) (August 4, 2014)	
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)	Declaration Regarding Emergency Use of *In Vitro* Diagnostics for Detection of Ebola Virus (https://www.federalregister.gov/articles/2014/08/12/2014-19026/declaration-regarding-emergency-use-of-in-vitro-diagnostics-for-detection-of-ebola-virus) (August 4, 2014)	
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)	Declaration Regarding Emergency Use of *In Vitro* Diagnostics for Detection of Ebola Virus (https://www.federalregister.gov/articles/2014/08/12/2014-19026/declaration-regarding-emergency-use-of-in-vitro-diagnostics-for-detection-of-ebola-virus) (August 4, 2014)	
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)	Declaration Regarding Emergency Use of *In Vitro* Diagnostics for Detection of Ebola Virus (https://www.federalregister.gov/articles/2014/08/12/2014-19026/declaration-regarding-emergency-use-of-in-vitro-diagnostics-for-detection-of-ebola-virus) (August 4, 2014)	
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, 122 KB) • Patients (/media/117737/download) (PDF, 119 KB) • Instructions for Use (/media/117738/download) (PDF, 2 MB)	Declaration Regarding Emergency Use of *In Vitro* Diagnostics for Detection of Ebola Virus (https://www.federalregister.gov/articles/2014/08/12/2014-19026/declaration-regarding-emergency-use-of-in-vitro-diagnostics-for-detection-of-ebola-virus) (August 4, 2014)	

back to list of current EUAs

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 and Declaration (Effective Date)	PREP Act Declaration (if applicable)
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 Declaration Regarding Emergency Use of New *In Vitro* Diagnostics for Detection of Enterovirus D68 (https://www.federalregister.gov/articles/2015/02/27/2015-04121/determination-and-declaration-regarding-emergency-use-of-new-in-vitro-diagnostics-for-detection-of) (February 6, 2015)	

back to list of current EUAs

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 Determination and Declaration (Effective Date)	PREP Act Declaration (if applicable)
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 DoD (June 7, 2018) Declaration Regarding Emergency Use of Treatment for Hemorrhage or Coagulopathy During an Emergency Involving Agents of Military Combat (https://www.federalregister.gov/documents/2018/07/31/2018-16331/emergency-use-of-treatment-for-uncontrolled-hemorrhage-due-to-agents-of-military-combat-correction) (July 9, 2018)	

back to list of current EUAs

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 Declaration (Effective Date)	PREP Act Declaration (if applicable
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 Declaration Regarding Emergency Use of *in Vitro* Diagnostics for Detection of the Avian Influenza A (H7N9) Virus (https://www.federalregister.gov/articles/2013/04/30/2013-10055/determination-and-declaration-regarding-emergency-use-of-in-vitro-diagnostics-for-detection-of-the) (April 19, 2013) Additional information from HHS (http://www.phe.gov/emergency/news/healthactions/phe/Pages/H7N9-influenza-virus.aspx)	Pandemic Influenza Medical Count (https://www.federalregister.gov/ar 31087/pandemic-influenza-medical amendment)(The amendment of th declaration as amended June 11, 2 2008, declaration and February 29, effective as of January 1, 2016.)
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 Declaration Regarding Emergency Use of *in Vitro* Diagnostics for Detection of the Avian Influenza A (H7N9) Virus (https://www.federalregister.gov/articles/2013/04/30/2013-10055/determination-and-declaration-regarding-emergency-use-of-in-vitro-diagnostics-for-detection-of-the) (April 19, 2013) Additional information from HHS (http://www.phe.gov/emergency/news/healthactions/phe/Pages/H7N9-influenza-virus.aspx)	Pandemic Influenza Medical Count (https://www.federalregister.gov/ar 31087/pandemic-influenza-medical amendment)(The amendment of th declaration as amended June 11, 2 2008, declaration and February 29, effective as of January 1, 2016.)
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 Declaration Regarding Emergency Use of *in Vitro* Diagnostics for Detection of the Avian Influenza A (H7N9) Virus (https://www.federalregister.gov/articles/2013/04/30/2013-10055/determination-and-declaration-regarding-emergency-use-of-in-vitro-diagnostics-for-detection-of-the) (April 19, 2013) Additional information from HHS (http://www.phe.gov/emergency/news/healthactions/phe/Pages/H7N9-influenza-virus.aspx)	Pandemic Influenza Medical Count (https://www.federalregister.gov/ar 31087/pandemic-influenza-medical amendment)(The amendment of th declaration as amended June 11, 2 2008, declaration and February 29, effective as of January 1, 2016.)

back to list of current EUAs

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 Determination and Declaration (Effective Date)	PREP Act Declaration (if applicable)

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)	Determination and Declaration Regarding Emergency Use of *In Vitro* Diagnostics for Detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) (https://www.federalregister.gov/articles/2013/06/05/2013-13333/determination-and-declaration-regarding-emergency-use-of-in-vitro-diagnostics-for-detection-of) (May 29, 2013) Additional information from HHS (http://www.phe.gov/emergency/news/healthactions/phe/Pages/mers-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)	Determination and Declaration Regarding Emergency Use of *In Vitro* Diagnostics for Detection of Middle East Respiratory Syndrome Coronavirus (MERS-CoV) (https://www.federalregister.gov/articles/2013/06/05/2013-13333/determination-and-declaration-regarding-emergency-use-of-in-vitro-diagnostics-for-detection-of) (May 29, 2013) Additional information from HHS (http://www.phe.gov/emergency/news/healthactions/phe/Pages/mers-cov.aspx)	

back to list of current EUAs

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 and Declaration (Effective Date)	PREP Act Declaration (if applicable)
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 Declaration Regarding Nerve Agent or Certain Insecticide (Organophosphorus and/or Carbamate) Poisoning (https://www.federalregister.gov/documents/2017/04/17/2017-07685/determination-and-declaration-regarding-emergency-use-of-injectable-treatments-for-nerve-agent-or) (April 11, 2017)	Nerve Agents and Certain Insecticide and/or Carbamate) Countermeasures (https://www.federalregister.gov/doc 09455/nerve-agents-and-certain-inse organophosphorus-andor-carbamate 11, 2017)

back to list of current EUAs

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 Sheets and Manufacturer Instructions/Package Insert	EUA Determination and Declara
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)	• Healthcare (/media/96355/download) (PDF, 83 KB) • Patients (/media/120190/download) (PDF, 220 KB) • Instructions for Use (/media/96373/download) (PDF, 5.5 MB)	Emergency Use of *In Vitro* Diag Zika Virus and/or Diagnosis of (https://www.federalregister.go 04624/emergency-use-of-in-vitr detection-of-zika-virus-andor-di (February 26, 2016)
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) February 26, 2021 (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) Letter granting EUA amendment(s) (https://www.fda.gov/media/146320/download) (PDF, 143 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)	• Healthcare (/media/120193/download)(PDF, 224 KB) • Patients (/media/120194/download) (PDF, 200 KB) • Instructions for Use (/media/123606/download) (PDF, 1.45MB)	Emergency Use of *In Vitro* Diag Zika Virus and/or Diagnosis of (https://www.federalregister.go 04624/emergency-use-of-in-vitr detection-of-zika-virus-andor-di (February 26, 2016)
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)	• Healthcare (/media/120128/download) (PDF, 53 KB) • Patients (/media/120129/download) (PDF, 27 KB) • Instructions for Use (/media/120130/download) (/media/97712/download)(PDF, 439 KB)	Emergency Use of *In Vitro* Diag Zika Virus and/or Diagnosis of (https://www.federalregister.go 04624/emergency-use-of-in-vitr detection-of-zika-virus-andor-di (February 26, 2016)
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)	• Healthcare (/media/120124/download) (/media/90487/download)(PDF, 232 KB) • Patients (/media/120125/download) (PDF, 213 KB) • Instructions for Use (/media/120126/download) (PDF, 809 KB)	Emergency Use of *In Vitro* Diag Zika Virus and/or Diagnosis of (https://www.federalregister.go 04624/emergency-use-of-in-vitr detection-of-zika-virus-andor-di (February 26, 2016)
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)	• Healthcare (/media/120118/download) (PDF, 208 KB) • Patients (/media/120119/download) (PDF, 190 KB) • Instructions for Use (/media/120120/download) (PDF, 276 KB)	Emergency Use of *In Vitro* Diag Zika Virus and/or Diagnosis of (https://www.federalregister.go 04624/emergency-use-of-in-vitr detection-of-zika-virus-andor-di (February 26, 2016)
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)	• Healthcare (/media/120035/download) (PDF, 229 KB) • Patients (/media/120036/download) (PDF, 188 KB) • Instructions for Use (/media/120037/download) (PDF, 623 KB)	Emergency Use of *In Vitro* Diag Zika Virus and/or Diagnosis of (https://www.federalregister.go 04624/emergency-use-of-in-vitr detection-of-zika-virus-andor-di (February 26, 2016)
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)	• Healthcare (/media/120031/download)(PDF, 170 KB) • Patients (/media/120032/download) (PDF, 133 KB) • Instructions for Use (/media/99449/download) (PDF, 511 KB)	Emergency Use of *In Vitro* Diag Zika Virus and/or Diagnosis of (https://www.federalregister.go 04624/emergency-use-of-in-vitr detection-of-zika-virus-andor-di (February 26, 2016)
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)	• Healthcare (/media/120018/download) (PDF, 270 KB) • Patients (/media/99514/download) (PDF, 236 KB) • Instructions for Use (/media/100103/download) (PDF, 1.9 MB)	Emergency Use of *In Vitro* Diag Zika Virus and/or Diagnosis of (https://www.federalregister.go 04624/emergency-use-of-in-vitr detection-of-zika-virus-andor-di (February 26, 2016)
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)	• Healthcare (/media/120015/download) (PDF, 52 KB) • Patients (/media/120016/download) (PDF, 200 KB) • Instructions for Use (/media/100192/download) (PDF, 505 KB)	Emergency Use of *In Vitro* Diag Zika Virus and/or Diagnosis of (https://www.federalregister.go 04624/emergency-use-of-in-vitr detection-of-zika-virus-andor-di (February 26, 2016)

Abbott RealTime 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)	• Healthcare (/media/120011/download) (PDF, 208 KB) • Patients (/media/120012/download) (PDF, 217 KB) • Instructions for Use (/media/120013/download) (PDF, 1.2 MB)	Emergency Use of *In Vitro* Diag Zika Virus and/or Diagnosis of (https://www.federalregister.go 04624/emergency-use-of-in-vitr detection-of-zika-virus-andor-di (February 26, 2016)
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)	• Healthcare (/media/119920/download) (PDF, 213 KB) • Patients (/media/100182/download) (PDF, 179 KB) • Instructions for Use (/media/119921/download) (PDF, 718 KB)	Emergency Use of *In Vitro* Diag Zika Virus and/or Diagnosis of (https://www.federalregister.go 04624/emergency-use-of-in-vitr detection-of-zika-virus-andor-di (February 26, 2016)
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)	• Healthcare (/media/119916/download) (PDF, 267 KB) • Patients (/media/119917/download) (PDF, 240 KB) • Instructions for Use (/media/119918/download) (PDF, 338 KB)	Emergency Use of *In Vitro* Diag Zika Virus and/or Diagnosis of (https://www.federalregister.go 04624/emergency-use-of-in-vitr detection-of-zika-virus-andor-di (February 26, 2016)
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)	• Healthcare (/media/119907/download) (PDF, 252 KB) • Patients (/media/119908/download) (PDF, 180 KB) • Instructions for Use (/media/119909/download) (PDF, 756 KB)	Emergency Use of *In Vitro* Diag Zika Virus and/or Diagnosis of (https://www.federalregister.go 04624/emergency-use-of-in-vitr detection-of-zika-virus-andor-di (February 26, 2016)
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)	• Healthcare (/media/107081/download) (PDF, 229 KB) • Patients (/media/107092/download) (PDF, 176 KB) • Instructions for Use (/media/107100/download) (PDF, 657 KB)	Emergency Use of *In Vitro* Diag Zika Virus and/or Diagnosis of (https://www.federalregister.go 04624/emergency-use-of-in-vitr detection-of-zika-virus-andor-di (February 26, 2016)

back to list of current EUAs

Related Links

- Coronavirus Disease 2019 (COVID-19) (/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19)
- Summary of Process for EUA Issuance (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/summary-process-eua-issuance)
- Current Emergency Use Authorizations for Medical Devices (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices)
- FAQs: What happens to EUAs when a public health emergency ends? (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/faqs-what-happens-euas-when-public-health-emergency-ends/)
- 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-in-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)
- 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)
- HHS Public Health Emergency EUA Authorization Declarations (http://www.phe.gov/emergency/news/healthactions/Lists/EUA/AllItems.aspx)
- Ebola Preparedness and Response Updates from FDA (/emergency-preparedness-and-response/mcm-issues/ebola-preparedness-and-response-updates-fda)
- Zika Virus Response Updates from FDA (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda)
- Historical Information about Device Emergency Use Authorizations (/medical-devices/emergency-situations-medical-devices/historical-information-about-device-emergency-use-authorizations)