

緊急使用許可



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緊急使用許可 (EUA) について

緊急使用許可 (EUA) 当局は、FDAが、公衆の間に必要な医療対策 (</emergency-preparedness-and-response/about-mcmi/what-are-medical-countermeasures>) (MCM) の利用可能性と使用を促進することにより、感染症を含む化学的、生物学的、放射性、および核 (CBRN) の脅威に対する国の公衆衛生保護の強化を支援することを許可します健康上の緊急事態。

What is an EUA?





連邦食品医薬品化粧品法 (FD&C法 ([/federal-food-drug-and-cosmetic-act-fdc-act](#))) のセクション564に基づき ([/federal-food-drug-and-cosmetic-act-fdc-act](#))、HHSの長官が緊急使用許可が適切であると宣言した場合、FDAは未承認の医療製品または承認された医療製品の未承認の使用を許可することができます。適切で承認された利用可能な代替手段がないなど、特定の基準が満たされた場合に、CBRN脅威エージェントによって引き起こされる深刻なまたは生命を脅かす病気または状態を診断、治療、または予防するための緊急事態。このような使用をサポートするHHS宣言は、HHS、国土安全保障、または国防長官による脅威または潜在的な脅威の4種類の決定のいずれかに基づいている必要があります。

注意：2020年1月31日に発行された (<https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx>) ような公衆衛生上の緊急事態が存在するという公衆衛生サービス法のセクション319に基づく決定は、FDAがEUAを発行することを可能にしません。2020年2月4日、HHS事務局長は、国家安全保障または海外に住む米国市民の健康と安全に重大な影響を与える可能性があり、COVID-19を引き起こすウイルスが関与する公衆衛生緊急事態があると判断しました。EUAの使用をサポートし、この決定に基づく後続のHHS宣言は、以下の青いボックスで説明されています。

終了および取り消されたEUAに関する情報 ([/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information](#))は、[アーカイブされた情報に記載されています \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information\)](#)。

公的準備および緊急時対応法 (PREP法)

PREP法に関する情報は[ここにあります \(https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx\)](https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx)。

PREP法は、公衆衛生サービス法 (PHS法) を修正して、セクション319F-3 (42 USC 247d-6d) を追加しました。HHS長官は、PHS法のセクション319F-3に従って、COVID-19に対する医療対策に関連する活動に対する責任免除を提供するためにいくつかの宣言を発行しました。

PREP法-COVID-19関連情報

- COVID-19に対する医療対策に関する公的準備および緊急時対応法に基づく宣言の通知 (<https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures>) (2020年2月4日)
- COVID-19 PREP法の宣言と修正 (HHS) (<https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx#covid>)
- PREP法および同法に基づく長官の宣言に関する勧告的意見02-02 (<https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>) (PDF、278 KB、2020年5月19日)

ガイダンス

2017年1月、FDAはガイダンスを最終決定しました：[医療製品および関連当局の緊急使用許可 \(/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities\)](#)。詳細については、2017年1月13日の[連邦官報の通知 \(/https://www.federalregister.gov/documents/2017/01/13/2017-00721/emergency-use-authorization-of-medical-products-and-related-authorities-guidance-for-industry-and\)](#)を参照してください。

[印刷可能なPDF \(288 KB\) \(/media/97321/download\)](#)

さらに、2014年1月、FDAは、公衆衛生関係者がEUA当局に対するPAHPRAの改正およびCBRN緊急時のMCMの緊急使用に関連する新しい当局の設立に関して提起した質問に回答するための[質疑応答文書 \(/media/87718/download\)](#) (PDF、762K) を発行しました。。

コロナウイルス病2019 (COVID-19) EUA情報



- **FDAからのコロナウイルス病（COVID-19）の更新** ([/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19](https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19)).
- **認可やファクトシートを含む、すべてのCOVID-19EUAの詳細情報**
 - [ワクチン](#)
 - [薬物および生物学的治療製品](#)
 - [COVID-19医療機器向けEUA](https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices) ([/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices](https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices))、以下を含む：
 - [血液浄化装置EUA](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/blood-purification-devices-euas) ([/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/blood-purification-devices-euas](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/blood-purification-devices-euas))
 - [持続的腎代替療法および血液透析装置EUA](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/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](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/continuous-renal-replacement-therapy-and-hemodialysis-devices-euas))
 - [In Vitro Diagnostics EUA](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas) ([/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas))
 - [個人用保護具EUAの除染システム](#) ([/about-fda/page-not-found](#))
 - [輸液ポンプEUA](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/infusion-pump-euas) ([/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/infusion-pump-euas](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/infusion-pump-euas))
 - [個人用保護具EUA](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas) ([/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas))
 - [リモートまたはウェアラブル患者監視デバイスEUA](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/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](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/remote-or-wearable-patient-monitoring-devices-euas))
 - [呼吸補助装置EUA](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/respiratory-assist-devices-euas) ([/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/respiratory-assist-devices-euas](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/respiratory-assist-devices-euas))
 - [人工呼吸器および人工呼吸器付属品EUA](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas) ([/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/ventilators-and-ventilator-accessories-euas))
 - [その他の医療機器EUA](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/other-medical-device-euas) ([/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/other-medical-device-euas](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/other-medical-device-euas))
 - [医療機器向けCOVID-19EUAに関する情報](#)

ワクチン

HHS長官は、2020年3月27日に発効したFD & C法のセクション564に従って、COVID-19パンデミック中の薬物および生物学的製品の緊急使用の許可を正当化する状況が存在すると宣言しました。その後FDAによって発行されたEUAはこの青いボックスの下の表。

- [公衆衛生上の緊急事態の決定およびFD & C法](https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency) (<https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency>) (2020年2月4日) のセクション564 (b) に基づく正当な承認を正当化する状況が存在するという宣言 (<https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency>)
- [緊急使用許可宣言](https://www.federalregister.gov/documents/2020/04/01/2020-06905/emergency-use-authorization-declaration) (<https://www.federalregister.gov/documents/2020/04/01/2020-06905/emergency-use-authorization-declaration>) (2020年3月27日)

COVID-19ワクチンの詳細については、以下を参照してください。

- [COVID-19ワクチン](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines) ([/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines](https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines))
- [ワクチンの緊急使用許可の説明](https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained) ([/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained](https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained))
- [インフォグラフィック：研究から緊急使用許可までのCOVID-19ワクチンの道](https://www.fda.gov/media/143890/download) (<https://www.fda.gov/media/143890/download>) (PDF、723 KB)
- [利害関係者のためのワクチンEUAの質問と回答](https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/vaccine-eua-questions-and-answers-stakeholders) ([/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/vaccine-eua-questions-and-answers-stakeholders](https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/vaccine-eua-questions-and-answers-stakeholders))

連邦官報の通知：

- [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) (<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.



検索:

見せる エントリ

最初のEUA 発行日	最新の承認書 (PDF)	許可された使用	ファクトシートと製造元の指示/添付文書 (PDF)
+ 2021年2月 27日	<p>ヤンセンCOVID-19ワクチン (https://www.fda.gov/media/146303/download) (409KB) (2021年6月10日再発行)</p> <p>EUA改正を (/media/147194/download)認める書簡 (2021年3月29日) (/media/147194/download) (152KB)</p> <p>EUA改正を (/media/147865/download)認める書簡 (2021年4月23日) (/media/147865/download) (229KB)</p> <p>(/media/150064/download)同意書 (/media/150064/download) (2021年6月10日) (26KB)</p> <p>同意書 (/media/150136/download) (2021年6月15日) (57KB)</p> <p>(/media/150163/download)同意書 (/media/150163/download) (2021年6月16日) (70KB)</p> <p>(/media/150567/download)同意書 (/media/150567/download) (2021年7月2日) (317.7KB)</p> <p>EUA改正を (/media/150723/download)認める書簡 (2021年7月12日) (/media/150723/download) (210KB)</p> <p>(/media/150743/download)同意書 (/media/150743/download) (2021年7月13日) (213KB)</p> <p>同意書 (/media/151141/download) (2021年7月28日) (63KB)</p> <p>EUA改正を (/media/151868/download)認める書簡 (2021年8月30日) (/media/151868/download) (80KB)</p> <p>(/media/152046/download)同意書 (/media/152046/download) (2021年9月8日) (353KB)</p> <p>(/media/152171/download)同意書 (/media/152171/download) (2021年9月14日) (253KB)</p> <p>(/media/152547/download)同意書 (/media/152547/download) (2021年9月29日) (28KB)</p>	<p>18歳以上の個人のための コロナウイルス病2019 (COVID-19) の予防のため に</p>	<p>医療提供者 (https://www.fda.gov/media/146304/download) (543KB)</p> <p>受信者と介護者 (https://www.fda.gov/media/146305/download) (98KB)</p> <ul style="list-style-type: none"> 複数の追加言語で受信者と介護者のファクトシートを表示する (https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine#translated) <p>ヤンセンCOVID-19ワクチンに関するよくある質問 (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine-frequently-asked-questions)</p> <p>決定覚書 (/media/146338/download) (974KB、2021年2月の最初のEUA発行)</p> <p>決定覚書 (/media/150081/download) (362KB、2021年6月EUA再発行)</p> <p>決定覚書補遺 (/media/150139/download) (59KB、2021年6月EUA再発行)</p> <p>ヤンセンCOVID-19ワクチンに関する詳細情報 (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine)</p> <p>COVID-19ワクチンの有効期限の日付の延長 (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/expiration-dating-extension#coviddvaccines)</p> <p>決定覚書補遺 (/media/150571/download) (61KB、2021年7月1日特定のヤンセンCOVID-19ワクチンバッチの評価)</p> <p>決定覚書補遺 (/media/150745/download) (58KB、2021年7月13日特定のヤンセンCOVID-19ワクチンバッチの評価)</p> <p>決定覚書補遺 (/media/152100/download) (60KB、2021年9月8日特定のヤンセンCOVID-19ワクチンバッチの評価)</p> <p>決定覚書補遺 (/media/152170/download) (55KB、2021年9月14日特定のヤンセンCOVID-19ワクチンバッチの評価)</p> <p>決定覚書補遺 (/media/152567/download) (57KB、2021年9月29日特定のヤンセンCOVID-19ワクチンバッチの評価)</p>
+ 2020年12月 18日	<p>Moderna COVID-19ワクチン (/media/144636/download) (469KB) (2021年2月25日、7月7日、8月12日再発行)</p> <p>EUA改正を (/media/147284/download)認める書簡 (2021年4月1日) (/media/147284/download) (193KB)</p> <p>EUA改正を (/media/150387/download)認める書簡 (2021年6月25日) (/media/150387/download) (90KB)</p> <p>EUA改正を (/media/151855/download)認める書簡 (2021年8月30日) (/media/151855/download) (58KB)</p>	<p>18歳以上の個人のための コロナウイルス病2019 (COVID-19) の予防のため に</p>	<p>医療提供者 (/media/144637/download) (311KB)</p> <ul style="list-style-type: none"> 複数の追加言語でワクチンを管理している医療提供者向けのファクトシートを表示する (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine#translated) <p>受信者と介護者 (/media/144638/download) (109KB)</p> <ul style="list-style-type: none"> 複数の追加言語で受信者と介護者のファクトシートを表示する (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine#translated) <p>決定覚書 (/media/144673/download) (769KB)</p> <p>ModernaCOVID-19ワクチンに関するよくある質問 (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine-frequently-asked-questions)</p> <p>ModernaCOVID-19ワクチンに関する詳細情報 (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine)</p> <p>決定覚書 (/media/151611/download) (65KB、2021年8月¹日EUA再発行)</p>

最初のEUA 発行日	最新の承認書 (PDF)	許可された使用	ファクトシートと製造元の指示/添付文書 (PDF)
+ 2020年12月11日	<p>ファイザー-BioNTechCOVID-19ワクチン (/media/150386/download) (408KB) (2021年2月25日、5月10日、6月25日、8月12日、8月23日、9月22日再発行)</p> <p>EUA改正を (/media/144955/download)認める書簡 (2021年1月6日) (/media/144955/download) (164KB)</p> <p>EUA改正を (/media/145493/download)認める書簡 (2021年1月22日) (/media/145493/download) (190KB)</p> <p>EUA改正を (/media/147390/download)認める書簡 (2021年4月6日) (/media/147390/download) (166KB)</p> <p>EUA改正を (/media/148877/download)認める書簡 (2021年5月19日) (/media/148877/download) (184KB)</p> <p>(/media/151731/download)同意書 (/media/151731/download) (2021年8月22日) (68KB)</p>	<p>12歳以上の人々の2019コロナウイルス病 (COVID-19) の予防のために</p> <p>2021年8月23日、FDAは、COVID-19の予防のために、現在Comirnatyとして知られているPfizer-BioNTechCOVID-19ワクチンを承認しました。</p>	<p>医療提供者 (/media/144413/download) (1.2MB)</p> <p>受信者と介護者 (/media/144414/download) (220KB)</p> <ul style="list-style-type: none"> 複数の追加言語で受信者と介護者のファクトシートを表示する (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biotech-covid-19-vaccine#translated). <p>決定覚書 (/media/144416/download) (709KB、2020年12月の最初のEUA発行)</p> <p>決定覚書 (/media/148542/download) (868KB、2021年5月EUA再発行)</p> <p>ファイザーに関するよくある質問-BioNTechCOVID-19ワクチン (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biotech-covid-19-vaccine-frequently-asked-questions).</p> <p>ファイザーに関する詳細情報-BioNTechCOVID-19ワクチン (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biotech-covid-19-vaccine).</p> <p>決定覚書 (/media/151613/download) (93KB、2021年8月12日EUA再発行)</p> <p>決定覚書 (/media/152432/download) (362KB、2021年9月24日)</p>

3つのエントリのうち1つから3つを表示

前 1 次

薬物および生物学的治療製品

HHS長官は、2020年3月27日に発効したFD & C法のセクション564に従って、COVID-19パンデミック中の薬物および生物学的製品の緊急使用の許可を正当化する状況が存在すると宣言しました。その後FDAによって発行されたEUAはこの青いボックスの下の表。

- [公衆衛生上の緊急事態の決定およびFD & C法](https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency) (<https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency>) (2020年2月4日) のセクション564 (b) に基づく正当な承認を正当化する状況が存在するという宣言 (<https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency>).
- [緊急使用許可宣言](https://www.federalregister.gov/documents/2020/04/01/2020-06905/emergency-use-authorization-declaration) (<https://www.federalregister.gov/documents/2020/04/01/2020-06905/emergency-use-authorization-declaration>) (2020年3月27日)

関連情報: [FDAがCOVID-19と治療薬との闘い](https://www.fda.gov/media/136832/download) (<https://www.fda.gov/media/136832/download>) (PDF、610 KB)

COVID-19 EUFAERSパブリックダッシュボード

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.

連邦官報の通知:

- [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) (<https://www.federalregister.gov/documents/2020/09/11/2020-20041/authorizations-and-revocation-of-emergency-use-of-drugs-during-the-covid-19-pandemic-availability>).
 - 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)
(<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>).

 - 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.
- [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)
(<https://www.federalregister.gov/documents/2021/06/23/2021-13183/authorization-and-revocation-of-emergency-use-of-drugs-during-the-covid-19-pandemic-availability>).

 - 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 announced 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)
(<https://www.federalregister.gov/documents/2021/08/05/2021-16705/authorizations-of-emergency-use-of-certain-biological-products-during-the-covid-19-pandemic>).

 - 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.

検索 :

見せる エントリー

最初のEUA発行日	最新の承認書 (PDF)	許可された使用 ¹	ファクトシートと製造元の指示/添付文書 (PDF)
+ 2021年6月24日	アクテムラ (トシリズマブ) (/media/150319/download) (107KB)	全身性コルチコステロイドを投与されており、酸素補給、非侵襲的または侵襲的人工呼吸器、または体外式膜型人工肺 (ECMO) を必要とする入院中の成人および小児患者 (2歳以上) のCOVID-19の治療に。	医療提供者 (/media/150321/download) (231KB) 患者、保護者、介護者 (/media/150320/download) (47KB) アクテムラ (トシリズマブ) の緊急使用許可に関するよくある質問 (/media/150345/download) (128KB)
+ 2021年5月26日	ソトロビマブ (/media/149532/download) (388KB) (2021年10月8日再発行)	成人および小児患者 (12歳以上で体重40 kg以上) の軽度から中等度のCOVID-19の治療で、SARS-CoV-2ウイルス検査の結果が陽性であり、入院または死亡を含む重症COVID-19への進行。	医療提供者 (/media/149534/download) (552KB) (2021年10月8日更新) 患者、保護者、介護者 (/media/149533/download) (140KB) ソトロビマブの緊急使用許可に関するよくある質問 (/media/149535/download) (288KB) EUAをサポートするCDER科学レビュー文書 (/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological)
+ 2021年3月12日	プロポフォール-リプロ1% (/media/146680/download) (344KB)	ICU設定で機械的人工呼吸を必要とするCOVID-19が疑われる、または確認された16歳以上の患者に持続注入による鎮静を維持すること。 ²	医療提供者 (/media/146681/download) (420KB) 患者、保護者、介護者 (/media/146682/download) (172KB)

最初のEUA発行日	最新の承認書 (PDF)	許可された使用 ¹	ファクトシートと製造元の指示/添付文書 (PDF)
+ 2021年2月9日	<p>バムラニビマブとエテセビマブ (/media/145801/download) (488KB) (2021年2月25日、2021年8月27日、2021年9月16日再発行)</p> <p>バムラニビマブおよびエテセビマブの認可された州、準州、および米国の管轄区域 (/media/151719/download) (116KB) (2021年10月8日)</p>	<p>バムラニビマブとエテセビマブは、成人および小児患者（12歳以上で体重40 kg以上）の軽度から中等度のCOVID-19の治療のために一緒に投与され、SARS-CoV-2 ウイルス検査の直接的な結果が陽性でした。入院や死亡など、重症COVID-19に進行するリスクが高い。</p>	<p>医療提供者 (/media/145802/download) (737KB) (2021年9月16日更新)</p> <p>患者、保護者、介護者 (/media/145803/download) (157KB) (2021年9月16日更新)</p> <ul style="list-style-type: none"> スペイン語 (/media/148713/download) (158KB) (2021年9月16日更新) <p>親愛なる医療提供者の手紙 (/media/145804/download) (370KB)</p> <p>曝露後予防に関する声明 (/drugs/drug-safety-and-availability/fda-authorizes-bamlanivimab-and-etesevimab-monoclonal-antibody-therapy-post-exposure-prophylaxis) (2021年9月16日)</p> <p>バムラニビマブおよびエテセビマブの緊急使用許可に関するよくある質問 (/media/145808/download) (342KB) (2021年9月16日更新)</p> <p>バムラニビマブ/エテセビマブ (https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab-etesevimab/Pages/default.aspx)に関するASPRおよびFDAの通知</p> <p>(https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab-etesevimab/Pages/May-26%2c-2021-Update.aspx)</p> <p>(https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab-etesevimab/Pages/default.aspx)</p> <p>EUAをサポートするCDER科学レビュー文書 (/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological)</p>
+ 2020年11月21日	<p>REGEN-COV (カシリビマブおよびイムデビマブ) (/media/145610/download) (506KB) (2021年2月3日、2021年2月25日、2021年6月3日、2021年7月30日および2021年9月9日再発行)</p>	<p>カシリビマブとイムデビマブは、成人および小児患者（12歳以上で体重40 kg以上）の軽度から中等度のCOVID-19の治療のために一緒に投与され、直接SARS-CoV-2 ウイルス検査の結果が陽性であり、入院や死亡など、重症COVID-19に進行するリスクが高い。</p>	<p>医療提供者 (/media/145611/download) (477KB) (2021年9月16日更新)</p> <ul style="list-style-type: none"> スペイン語 (/media/151403/download) (623KB) <p>患者、保護者、介護者 (/media/145612/download) (147KB) (2021年7月30日更新)</p> <ul style="list-style-type: none"> スペイン語 (/media/151404/download) (247KB) <p>親愛なる医療提供者の手紙 (/media/143901/download) (435KB) (2021年9月16日更新)</p> <p>曝露後予防に関する声明 (/drugs/drug-safety-and-availability/fda-authorizes-regen-cov-monoclonal-antibody-therapy-post-exposure-prophylaxis-prevention-covid-19) (2021年7月30日)</p> <p>REGEN-COV (カシリビマブおよびイムデビマブ) の緊急使用許可に関するよくある質問 (/media/143894/download) (311KB) (2021年7月30日更新)</p> <p>EUAをサポートするCDER科学レビュー文書 (/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological)</p> <p>共同パッケージ化されたREGEN-COVのクイックリファレンスガイド (/media/152051/download) (38KB) (2021年9月16日)</p>
+ 2020年11月19日	<p>バリシチニブ (オルミアント) (/media/143822/download) (2021年7月28日改訂)</p>	<p>医療提供者が、酸素補給、非侵襲的または侵襲的人工呼吸器、または体外式膜型人工肺 (ECMO) を必要とする2歳以上の入院中の成人および小児患者におけるCOVID-19治療のための緊急使用。</p>	<p>医療提供者 (/media/143823/download) (2021年7月28日更新) (155KB)</p> <p>患者、保護者、介護者 (/media/143824/download) (2021年7月28日更新) (55KB)</p> <p>治療のためのオルミアント (バリシチニブ) の緊急使用許可に関するよくある質問COVID-19 (/media/143825/download) (270KB) (2021年7月28日更新)</p> <p>EUAをサポートするCDER科学レビュー文書 (/drugs/coronavirus-covid-19-drugs/cder-scientific-review-documents-supporting-emergency-use-authorizations-drug-and-biological)</p>

最初のEUA発行日	最新の承認書 (PDF)	許可された使用 ¹	ファクトシートと製造元の指示/添付文書 (PDF)
+ 2020年8月23日	COVID-19回復期血漿 (/media/141477/download) (285KB) (2021年2月23日および2021年3月9日再発行) EUA改正を (/media/149803/download) 認める書簡 (2021年6月2日) (107KB)	コロナウイルス病2019 (COVID-19) の入院患者の治療用	医療提供者 (/media/141478/download) (176KB) 患者と親/介護者 (/media/141479/download) (124KB) 決定算書 (/media/141480/download) (166KB)
+ 2020年8月13日	体外回路 (/media/141168/download) (92KB) の 局所クエン酸塩抗凝固 (RCA) 用のクエン酸塩を含むREGIOCIT代替ソリューション (/media/141168/download)	持続的腎代替療法 (CRRT) で治療され、局所クエン酸塩抗凝固療法が適切である成人患者にのみ、救命救急治療で代替液として使用されます。	ヘルスケアプロバイダー (/media/141170/download) (108キロバイト) 患者と介護者 (/media/141172/download) (52キロバイト) EUAためREGIOCIT添付文書 (/media/141186/download) (140キロバイト)
+ 2020年5月8日	Fresenius Kabi Propoven 2% (/media/137888/download) (209KB)	ICU設定で機械的人工呼吸を必要とするCOVID-19が疑われるまたは確認された16歳以上の患者に持続注入による鎮静を維持するため ²	医療提供者 (/media/137889/download) (288KB) 患者および親/介護者 (/media/137890/download) (39KB) 証明済み2%ウォールチャート (/media/137891/download) (2.4MB)
+ 2020年5月1日	特定の入院COVID-19患者のためのレムデシビル (/media/137564/download) (423KB) (2020年8月28日、2020年10月1日、および2020年10月22日再発行)	3.5kgから40kg未満の入院小児患者または3.5kg以上の12歳未満の入院小児患者における疑わしいまたは実験室で確認されたCOVID-19の治療のための認可された医療提供者による緊急使用のため。 2020年10月22日、FDAは Veklury (レムデシビル) を承認しました (/news-events/press-announcements/fda-approves-first-treatment-covid-19) 入院を必要とするCOVID-19の治療のための成人および小児患者 (12歳以上で体重40kg以上) で使用するため。 Vekluryは、入院患者の病院でのケアに匹敵する急性のケアを提供できる病院または医療環境でのみ投与する必要があります。この承認には、2020年5月1日に最初に発行された緊急使用許可 (EUA) に基づいてVekluryの使用が許可された全人口は含まれません。 Vekluryは、3歳の入院小児患者におけるCOVID-19の疑いまたは検査で確認された治療のために、認可されたヘルスケアプロバイダーによる緊急使用のためにVekluryを引き続き認可します。 追加情報については、以下も参照してください： COVID-19の治療のための Veklury (レムデシビル) の FDA承認-安全性と有効性の科学 (/drugs/news-events-human-drugs/fdas-approval-veklury-remdesivir-treatment-covid-19-science-safety-and-effectiveness)	医療提供者 (/media/137566/download) (375KB) 患者と親/介護者 (/media/137565/download) (94KB) <ul style="list-style-type: none"> スペイン語 (/media/139460/download) (563KB) 特定の入院患者に対するVeklury (レムデシビル) のEUAに関するよくある質問 (194KB (/media/137574/download)) (2021年2月4日更新) <ul style="list-style-type: none"> スペイン語 (/media/138804/download) (195KB)

11エントリのうち1から10を表示

¹ COVID-19を引き起こすウイルスにより、重度の呼吸器疾患などの救命救急を必要とする患者が増加しています。その結果、人工呼吸器を装着した患者の鎮静用のプロポフォールなど、治療に使用される適切なFDA承認薬が不足しています。

² この公衆衛生上の緊急事態の状況では、COVID-19が疑われる、または確認された患者にのみ使用するために、医療提供者にフレゼニウスプロポベン2%エマルジョンまたはプロポフォール-リプロ1%の制限を求めることは現実的ではありません。したがって、この認可はそのような患者に使用を制限するものではありません。

³ multiBic / multiPlusソリューションには、multiBic透析液と補液およびmultiPlus透析液が含まれます。multiBic補液は、CDERによって薬剤として規制されています。multiFiltrate PROシステム、multiBic透析液、およびmultiPlus透析液ソリューションは、CDRHによってデバイスとして規制されています。

医療機器向けCOVID-19EUAに関する情報

医療機器のCOVID-19EUAに関する情報は、以下および次の場所にあります。**コロナウイルス病2019 (COVID-19) 医療機器の緊急使用許可 (</medical-devices/emergency-use-authorizations-medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices>)**。

2020 (<https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency>)年2月4日 (<https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency>)、長官はFD&C法のセクション564に従って、国家安全保障または海外に住む米国市民の健康と安全に影響を与える重大な可能性があり、小説を含む公衆衛生緊急事態があると決定しました (新規) コロナウイルス (nCoV) は、2019年に中国のフーベイ県武漢市で最初に検出されました (2019-nCoV)。

この決定に基づいて、HHS長官は医療機器に関連する3つの宣言を発行しました。

- **公衆衛生緊急事態の決定** (<https://www.federalregister.gov/documents/2020/02/07/2020-02496/determination-of-public-health-emergency>) (2020年2月4日発効)、およびCOVID-19を引き起こすウイルスの検出および/または診断のためのinvitro診断の緊急使用の承認を正当化する状況が存在するという宣言
- (<https://www.federalregister.gov/documents/2020/03/10/2020-04823/emergency-use-declaration>)COVID-19の発生時に個人用呼吸器保護装置の緊急使用の許可を正当化する状況が存在するという**緊急使用宣言** (<https://www.federalregister.gov/documents/2020/03/10/2020-04823/emergency-use-declaration>) (2020年3月2日発効)
- (<https://www.federalregister.gov/documents/2020/03/27/2020-06541/emergency-use-authorization-declaration>)COVID-19発生時の不足により、医療機器として使用される代替製品を含む医療機器の緊急使用の承認を正当化する状況が存在するという**緊急使用許可宣言** (<https://www.federalregister.gov/documents/2020/03/27/2020-06541/emergency-use-authorization-declaration>) (2020年3月24日発効)

各EUAに適用される宣言の識別については、各EUA承認書および/または対応する官報通知を参照してください。

関連情報：FDAがCOVID-19と医療機器との闘い (<https://www.fda.gov/media/136702/download>) (PDF、708 KB)

体外診断

Please see the page **[In Vitro Diagnostics EUAs \(/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas\)](/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 \(/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-molecular-diagnostic-tests-sars-cov-2\)](/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 \(/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2\)](/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 \(/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-serology-and-other-adaptive-immune-response-tests-sars-cov-2\)](/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 \(/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-ivds-management-covid-19-patients\)](/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).

De Novo、510 (k) クリアランスまたはPMAが付与されたCOVID-19の分子SARS-CoV-2診断テスト

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 \(/medical-devices/premarket-submissions/de-novo-classification-request\)](#), 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.

個人用保護具 (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.

その他の医療機器EUA

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 \(/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/other-medical-device-euas\)](#)



NIOSHが承認していない使い捨てフィルターフェイスピースレスピレーター（FFR）および除染およびバイオバーデン削減システムのEUAを取り消す

On June 30, 2021, the FDA [announced \(/news-events/press-announcements/fda-brief-fda-revokes-emergency-use-authorizations-certain-respirators-and-decontamination-systems\)](/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 \(https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/revoked-euas-non-niosh-approved-disposable-filtering-facepiece-respirators#imported\)](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 \(https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/revoked-euas-non-niosh-approved-disposable-filtering-facepiece-respirators#china\)](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 \(https://www.fda.gov/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations#decontamination\)](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 \(/medical-devices/letters-health-care-providers/update-fda-no-longer-authorizes-use-non-niosh-approved-or-decontaminated-disposable-respirators\)](/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 \(/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations\)](/medical-devices/emergency-use-authorizations-medical-devices/historical-information-about-device-emergency-use-authorizations) and [Emergency Use Authorization--Archived Information \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information\)](/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information).

医療機器官報の通知

- [Authorization of Emergency Use of Certain Medical Devices During COVID-19; Availability \(https://www.federalregister.gov/documents/2020/06/05/2020-12117/authorization-of-emergency-use-of-certain-medical-devices-during-covid-19-availability\)](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 \(https://www.federalregister.gov/documents/2020/07/14/2020-15137/authorization-of-emergency-use-of-certain-medical-devices-during-covid-19-availability\)](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 \(https://www.federalregister.gov/documents/2020/11/20/2020-25603/authorization-of-emergency-use-of-certain-medical-devices-during-covid-19-availability\)](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 \(https://www.federalregister.gov/documents/2021/04/23/2021-08467/authorization-of-emergency-use-of-certain-medical-devices-during-covid-19-availability\)](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 \(https://www.federalregister.gov/documents/2021/07/23/2021-15680/authorization-of-emergency-use-of-certain-medical-devices-during-covid-19-availability\)](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)
- [Revocation notices for EUAs are made available on the EUA archive page \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information\)](/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information).

[EUAについてに戻る](#)

その他の現在のEUA

以下の表は、現在のEUAに関する情報を示しています。

- [炭疽菌EUA](#)
- [エボラウイルスEUA情報](#)
- [エンテロウイルスD68（EV-D68）EUA情報](#)
- [フリーズドライ血漿情報](#)
- [H7N9インフルエンザEUA情報](#)

- [中東呼吸器症候群コロナウイルス \(MERS-CoV\) EUA情報](#)
- [神経ガスEUA情報](#)
- [ジカウイルスEUA情報](#)

有効ではなくなったEUA(</emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information>)に関する情報は、[EUAアーカイブページで](#) (</emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information>)入手できます (</emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information>)。

[ページのトップに戻る](#) (</emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#top>)

炭疽菌EUA

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](#)

エボラウイルスEUA情報

[Ebola preparedness and response updates from FDA](#) (</emergency-preparedness-and-response/mcm-issues/ebola-preparedness-and-response-updates-fda>) (all agency activities)

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

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

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

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

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

EZ1 Real-time RT-PCR Assay (DoD)	August 5, 2014 (initial issuance) October 10, 2014 (reissuance)	Authorization (/media/89984/download) (PDF, 61 KB)	FR notice (https://www.federalregister.gov/articles/2014/09/17/2014-22086/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-ebola-zaire-virus).	<ul style="list-style-type: none"> Healthcare (/media/89986/download), (PDF, 58 KB) Patients (/media/89988/download), (PDF, 59 KB) Instruction Booklet (/media/89989/download), (PDF, 1.1 MB)
CDC Ebola Virus NP Real-time RT-PCR Assay (CDC)	October 10, 2014 (initial issuance) March 2, 2015 (reissuance) October 8, 2019 (amended)	Authorization (/media/91083/download) (PDF, 282 KB) Letter granting EUA amendment(s) (PDF, 134 KB). (/media/131606/download).	FR notice (https://www.federalregister.gov/articles/2014/12/24/2014-30108/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-zaire-virus).	<ul style="list-style-type: none"> Healthcare (/media/91087/download), (PDF, 207 KB) Patients (/media/91092/download), (PDF, 149 KB) Instructions for Use (/media/91097/download), (PDF, 496 KB)
CDC Ebola Virus VP40 Real-time RT-PCR Assay (CDC)	October 10, 2014 (initial issuance) March 2, 2015 (reissuance) October 8, 2019 (amended)	Authorization (/media/91105/download) (PDF, 285 KB) Letter granting EUA amendment(s) (PDF, 135 KB). (/media/131605/download).	FR notice (https://www.federalregister.gov/articles/2014/12/24/2014-30108/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-zaire-virus).	<ul style="list-style-type: none"> Healthcare (/media/91111/download), (PDF, 207 KB) Patients (/media/91118/download), (PDF, 149 KB) Instructions for Use (/media/91142/download), (PDF, 494 KB)
FilmArray NGDS BTE 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).	<ul style="list-style-type: none"> Healthcare (/media/91149/download), (PDF, 40 KB) Patients (/media/91153/download), (PDF, 40 KB) Instructions for Use (/media/91077/download), (PDF, 740 KB)
FilmArray Biothreat-E test (Biofire Defense, LLC)	October 25, 2014 November 12, 2019 (amended)	Authorization (/media/89580/download) (PDF, 73 KB) Letter granting EUA amendment(s) (PDF, 152 KB). (/media/132517/download).	FR notice (https://www.federalregister.gov/articles/2015/02/09/2015-02467/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus).	<ul style="list-style-type: none"> Healthcare (/media/89585/download), (PDF, 227 KB) Patients (/media/89604/download), (PDF, 191 KB) Instructions for Use (/media/89614/download), (PDF, 1.6 MB)
RealStar Ebolavirus RT-PCR Kit 1.0 (altona Diagnostics, GmbH)	November 10, 2014 (initial issuance) November 26, 2014 (reissuance)	Authorization (/media/123410/download) (PDF, 263 KB)	FR notice (https://www.federalregister.gov/articles/2015/02/09/2015-02467/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus).	<ul style="list-style-type: none"> Healthcare (/media/120428/download), (PDF, 81 KB) Patients (/media/120429/download), (PDF, 92 KB) Instructions for Use (/media/120430/download), (PDF, 79 KB)
LightMix Ebola Zaire rRT-PCR Test (Roche Molecular Systems, Inc.)	December 23, 2014	Authorization (/media/120431/download) (PDF, 2.2 MB)	FR notice (https://www.federalregister.gov/articles/2015/03/17/2015-06039/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-ebola-zaire-virus).	<ul style="list-style-type: none"> Healthcare (/media/120432/download), (PDF, 59 KB) Patients (/media/120433/download), (PDF, 60 KB) Instructions for Use (/about-fda/page-not-found), (PDF, 328 KB)

Xpert Ebola Assay (Cepheid)	March 23, 2015	Authorization (/media/91315/download) (PDF, 240 KB)	FR notice (https://www.federalregister.gov/articles/2015/06/05/2015-13699/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-ebola-virus).	<ul style="list-style-type: none"> Healthcare (/media/91934/download) (PDF, 310 KB) Patients (/media/91939/download) (PDF, 211 KB) Instructions for Use (/media/91944/download) (PDF, 625 KB)
Idylla Ebola Virus Triage Test (Biocartis NV)	May 26, 2016	Authorization (/media/98460/download) (PDF, 321 KB)	FR notice (https://www.federalregister.gov/articles/2016/07/08/2016-16176/authorizations-of-emergency-use-in-vitro-diagnostic-device-for-detection-of-ebola-zaire-virus).	<ul style="list-style-type: none"> Healthcare (/media/98451/download) (PDF, 203 KB) Patients (/media/98442/download) (PDF, 163 KB) Instructions for Use (/media/98434/download) (PDF, 2.1 MB)
DPP Ebola Antigen System (Chembio Diagnostic Systems, Inc.)	November 9, 2018 April 2, 2019 (amended)	Authorization (/media/117735/download) (PDF, 103 KB) Letter Granting EUA Amendment(s) (/media/122553/download) (PDF, 87 KB)	FR notice (https://www.federalregister.gov/documents/2019/02/13/2019-02134/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-ebola-virus).	<ul style="list-style-type: none"> Healthcare (/media/117736/download) (PDF, 12 KB) Patients (/media/117737/download) (PDF, 119 KB) Instructions for Use (/media/117738/download) (PDF, 2 MB)

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エンテロウイルスD68 (EV-D68) EUA情報

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
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).	<ul style="list-style-type: none"> Healthcare (/media/92008/download) (PDF, 214 KB) Patients (/media/120426/download) (PDF, 150 KB) Instructions for Use (/media/120427/download) (PDF, 531 KB) 	Determination and D New In Vitro Diagnostics (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)

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フリーズドライ血漿情報

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
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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)	<ul style="list-style-type: none"> • Fact Sheet for U.S. Military Medical Personnel (/media/119949/download) (PDF, 132 KB) • Fact Sheet for Recipients (/media/119948/download) (PDF, 101 KB) 	Determination by Declaration Rega Hemorrhage or C Agents of Militar (https://www.fed16331/emergenc-hemorrhage-due-9,2018)
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H7N9インフルエンザEUA情報

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

Medical Product	Date of EUA Issuance	Letter of Authorization	Federal Register Notice for EUA	Fact Sheet and Manufacturer Instructions/Package Insert	EUA Determination and D
CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel- Influenza A/H7 (Eurasian Lineage) Assay	April 22, 2013 (initial issuance) March 27, 2018 (reissuance)	Authorization (/media/85910/download) (PDF, 301 KB), re-issued March 27, 2018	FR notice (https://www.federalregister.gov/articles/2013/06/25/2013-15096/authorization-of-emergency-use-of-an-in-vitro-diagnostic-for-detection-of-the-novel-avian-influenza)	<ul style="list-style-type: none"> • 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 Declar Diagnostics for Detection (https://www.federalregis10055/determination-and-vitro-diagnostics-for-dete) Additional information fro (http://www.phe.gov/emeinfluenza-virus.aspx)
Quidel Lyra Influenza A Subtype H7N9 Assay	February 14, 2014	Authorization (/media/87767/download) (PDF, 57 KB)	FR notice (https://www.federalregister.gov/articles/2014/04/17/2014-08706/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-novel-influenza-a)	<ul style="list-style-type: none"> • Healthcare (/media/87775/download) (PDF, 42 KB) • Patients (/media/87780/download) (PDF, 40 KB) 	Determination and Declar Diagnostics for Detection (https://www.federalregis10055/determination-and-vitro-diagnostics-for-dete) Additional information fro (http://www.phe.gov/emeinfluenza-virus.aspx)
A/H7N9 Influenza Rapid Test	April 25, 2014	Authorization (/medical-devices/emergency-situations-medical-devices/ah7n9-influenza-rapid-test-letter-authorization)	FR notice (https://www.federalregister.gov/articles/2014/06/23/2014-14547/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-novel-influenza-a)	<ul style="list-style-type: none"> • 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 Declar Diagnostics for Detection (https://www.federalregis10055/determination-and-vitro-diagnostics-for-dete) Additional information fro (http://www.phe.gov/emeinfluenza-virus.aspx)

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中東呼吸器症候群コロナウイルス (MERS-CoV) EUA情報

For more information about the diagnostics below, also see [Emergency Use Authorizations \(/about-fda/page-not-found\)](/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
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)	<ul style="list-style-type: none"> 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 of Emergency Use of Diagnostic for Coronavirus (https://www.fda.gov/oc/2013/06/05/cdc-novel-coronavirus-2012-real-time-rt-pcr-assay) Additional information (http://www.pdcov.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)	<ul style="list-style-type: none"> 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 of Emergency Use of Diagnostic for Coronavirus (https://www.fda.gov/oc/2015/07/17/realstar-mers-cov-rt-pcr-kit) Additional information (http://www.pdcov.aspx)

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神経ガスEUA情報

On July 9, 2018, FDA approved (https://www.accessdata.fda.gov/drugsatfda_docs/applletter/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 \(https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/212319s000lbl.pdf\)](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
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Atropine Auto-Injector (Rafa Laboratories Ltd.)	<p>April 11, 2017 (initial issuance)</p> <p>May 23, 2017 (amended)</p> <p>January 24, 2018 (amended)</p> <p>March 6, 2018 (amended)</p> <p>May 15, 2018 (amended)</p>	<p>Letter of Authorization (/media/104550/download) (PDF, 514 KB)</p> <p>Letter granting EUA amendment(s) (/media/105590/download) (PDF, 28 KB)</p> <p>2nd letter granting EUA amendment(s) (/media/110881/download) (PDF, 33 KB)</p> <p>3rd letter granting EUA amendment(s) (/media/111656/download) (PDF, 85 KB)</p> <p>4th letter granting EUA amendment(s) (/media/113102/download) (PDF, 42 KB)</p>	<p>FR notice (https://www.federalregister.gov/documents/2017/06/30/2017-13664/emergency-use-authorizations-injectable-treatment-for-nerve-agent-or-certain-insecticide).</p>	<ul style="list-style-type: none"> • Healthcare (/media/104559/download) (PDF, 531 KB) • Patients and Caregivers (/media/104564/download) (PDF, 675 KB) 	<p>Determination and Certain Insecticide Poisoning (https://www.federalregister.gov/documents/2017/06/30/2017-13664/emergency-use-authorizations-injectable-treatment-for-nerve-agent-or-certain-insecticide)</p>
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ジカウイルスEUA情報

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

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

For more information about the diagnostics below, also see [Emergency Use Authorizations \(/about-fda/page-not-found\)](/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](mailto:CDRH-ZIKA-Templates@fda.hhs.gov?Subject=EUA%20template%20request)).

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/pmnm.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/pmnm.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/pmnm.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
<p>CDC Zika Immunoglobulin M (IgM) Antibody Capture Enzyme-Linked Immunosorbent Assay</p> <p>CDC statement on this EUA (http://www.cdc.gov/media/releases/2016/s0226-laboratory-test-for-zika-virus.html)</p>	<p>February 26, 2016 (initial issuance)</p> <p>June 29, 2016 (amended)</p> <p>November 15, 2016 (amended)</p> <p>December 6, 2016 (amended)</p> <p>May 3, 2017 (amended)</p> <p>July 31, 2017 (amended)</p> <p>April 16, 2018 (amended)</p> <p>September 26, 2018 (amended)</p>	<p>Letter granting EUA amendment(s) (/media/101616/download) (PDF, 155 KB)</p> <p>Letter granting EUA amendment(s) (/media/101586/download) (PDF, 123 KB)</p> <p>Letter granting EUA amendment(s) (/media/120186/download) (PDF, 110 KB)</p> <p>Letter granting EUA amendment(s) (/media/120187/download) (PDF, 113 KB)</p> <p>Letter granting EUA amendment(s) (/media/120188/download) (PDF, 131 KB)</p> <p>Letter granting EUA amendment(s) (/media/120189/download) (PDF, 131 KB)</p>	<p>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)</p>
<p>CDC Triplex Real-time RT-PCR Assay (Triplex rRT-PCR)</p> <p>CDC statement on this EUA (http://www.cdc.gov/media/releases/2016/s0318-zika-lab-test.html)</p>	<p>March 17, 2016 (initial issuance)</p> <p>September 21, 2016 (amended)</p> <p>January 12, 2017 (amended)</p> <p>February 28, 2017 (amended)</p> <p>April 6, 2017 (amended)</p> <p>February 26, 2021 (amended)</p>	<p>Authorization (/media/96683/download) (PDF, 82 KB)</p> <p>Letter granting EUA amendment(s) (/media/100200/download) (PDF, 223 KB)</p> <p>Letter granting EUA amendment(s) (/media/102439/download) (PDF, 223 KB)</p> <p>Letter granting EUA amendment(s) (/media/103400/download) (PDF, 223 KB)</p> <p>Letter granting EUA amendment(s) (/media/120192/download) (PDF, 126 KB)</p> <p>Letter granting EUA amendment(s) (https://www.fda.gov/media/146320/download) (PDF, 143 KB)</p>	<p>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)</p>
<p>Zika Virus RNA Qualitative Real-Time RT-PCR (Quest Diagnostics Infectious Disease, Inc.)</p>	<p>April 28, 2016 (initial issuance)</p> <p>October 7, 2016 (reissuance)</p> <p>April 11, 2017 (amended)</p>	<p>Authorization (/media/122435/download) (PDF, 339 KB)</p> <p>Letter granting EUA amendment(s) (/media/120127/download) (PDF, 126 KB)</p>	<p>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)</p>
<p>RealStar Zika Virus RT-PCR Kit U.S. (altona Diagnostics GmbH)</p>	<p>May 13, 2016 (initial issuance)</p> <p>October 31, 2016 (amended)</p> <p>March 6, 2017 (amended)</p>	<p>Authorization (/media/120121/download) (PDF, 342 KB)</p> <p>Letter Granting EUA Amendment(s) (/media/120122/download) (PDF, 130 KB)</p> <p>Letter Granting EUA Amendment(s) (/media/120123/download) (PDF, 130 KB)</p>	<p>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)</p>

Aptima Zika Virus assay (Hologic, Inc.)	June 17, 2016 (initial issuance) September 7, 2016 (amended) April 12, 2017 (amended) March 8, 2018 (amended)	Authorization (/media/120114/download) (PDF, 305 KB) Letter granting EUA amendment(s) (/media/122434/download) (PDF, 126 KB) Letter granting EUA amendment(s) (/media/120116/download) (PDF, 124 KB) Letter granting EUA amendment(s) (/media/120117/download) (PDF, 130 KB)	FR notice (https://www.federalregister.gov/articles/2016/07/08/2016-16177/authorizations-of-emergency-use-in-vitro-diagnostic-device-for-detection-of-zika-virus)
Zika Virus Real-time RT-PCR Test (Viracor Eurofins)	July 19, 2016 (initial issuance) February 28, 2017 (amended)	Authorization (/media/120033/download) (PDF, 334 KB) Letter granting EUA amendment(s) (/media/120034/download) (PDF, 124 KB)	FR notice (https://www.federalregister.gov/articles/2016/09/07/2016-21353/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-zika-virus#h-6)
VERSANT Zika RNA 1.0 Assay (kPCR) Kit (Siemens Healthcare Diagnostics Inc.)	July 29, 2016 (initial issuance) December 19, 2016 (amended)	Authorization (/media/99444/download) (PDF, 78 KB) Letter granting EUA amendment(s) (/media/120030/download) (PDF, 124 KB)	FR notice (https://www.federalregister.gov/documents/2016/10/28/2016-26066/emergency-use-authorizations-in-vitro-diagnostic-devices-for-detection-and-or-diagnosis-of-zika-virus)
Sentosa SA ZIKV RT-PCR Test (Vela Diagnostics USA, Inc.)	September 23, 2016	Authorization (/media/120017/download) (PDF, 355 KB)	FR notice (https://www.federalregister.gov/documents/2016/11/03/2016-26532/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)
Zika Virus Detection by RT-PCR Test (ARUP Laboratories)	September 28, 2016	Authorization (/media/120014/download) (PDF, 98 KB)	FR notice (https://www.federalregister.gov/documents/2016/11/03/2016-26532/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)
Abbott 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)
Zika ELITe MGB Kit U.S. (ELITechGroup Inc. Molecular Diagnostics)	December 9, 2016	Authorization (/media/119919/download) (PDF, 312 KB)	FR notice (https://www.federalregister.gov/documents/2017/01/09/2017-00084/authorization-of-emergency-use-of-an-in-vitro-diagnostic-device-for-detection-of-zika-virus)

Gene-RADAR Zika Virus Test (Nanobiosym Diagnostics, Inc.)	March 20, 2017	Authorization (/media/119915/download) (PDF, 313 KB)	FR notice (https://www.federalregister.gov/documents/2017/06/30/2017-13720/emergency-use-authorizations-in-vitro-diagnostic-devices-for-detection-of-zika-virus)
TaqPath Zika Virus Kit (Thermo Fisher Scientific)	August 2, 2017	Authorization (/media/119906/download) (PDF, 292 KB)	FR notice (https://www.federalregister.gov/documents/2017/10/26/2017-23224/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)
CII-ArboViroPlex rRT-PCR Assay (Columbia University)	August 11, 2017	Authorization (/media/107073/download) (PDF, 377 KB)	FR notice (https://www.federalregister.gov/documents/2017/10/26/2017-23224/authorizations-of-emergency-use-of-in-vitro-diagnostic-devices-for-detection-of-zika-virus)

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関連リンク

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- [EUA発行のプロセスの概要 \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/summary-process-eua-issuance\)](#)
- [医療機器の現在の緊急使用許可 \(/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices\)](#)
- [In vitro診断 \(IVD\) 用のPre-EUAをFDAに提出する方法 \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/how-submit-pre-eua-in-vitro-diagnostics-fda\)](#) (テストメーカー向け)
- [EUAの下でIVDテストを実施する研究所のための情報 \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/information-laboratories-implementing-ivd-tests-under-eua\)](#)
- [2019年コロナウイルス感染時の医療機器の緊急使用許可を公開するプロセス](#)
(<https://www.federalregister.gov/documents/2020/06/02/2020-11898/process-for-publishing-emergency-use-authorizations-for-medical-devices-during-coronavirus-disease>) (2020年6月2日)
- [緊急使用許可-アーカイブされた情報 \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information\)](#)
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- [21世紀の治療法：MCM関連の治療規定 \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/21st-century-cures-act-mcm-related-cures-provisions\)](#)
- [2013年のパンデミックおよびオールハザード準備再承認法 \(PAHPRA\) \(/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/pandemic-and-all-hazards-preparedness-reauthorization-act-2013-pahpra\)](#)
- [公的準備および緊急時対応 \(PREP\) 法](#) (<https://www.phe.gov/preparedness/legal/prepact/pages/default.aspx>)
- [HHS公衆衛生緊急EUA認可宣言](#) (<http://www.phe.gov/emergency/news/healthactions/Lists/EUA/AllItems.aspx>)
- [FDAからのエボラ準備と対応の最新情報 \(/emergency-preparedness-and-response/mcm-issues/ebola-preparedness-and-response-updates-fda\)](#)
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- [デバイスの緊急使用許可に関する履歴情報 \(/medical-devices/emergency-situations-medical-devices/historical-information-about-device-emergency-use-authorizations\)](#)