Zika Virus Response Updates from FDA



Fast Facts (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#facts):
About Zika (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#about) | Locations Affected (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#locations) | Guillain-Barré Syndrome (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#GBS) | Pregnancy (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#pregnant) | Medical Products (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#medicalproducts) | Prevention

Zika Information from FDA (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#FDAinfo):
Updates by Date (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#bydate) | Safety of the Blood Supply | Emergency Use Authorization | Investigational Products (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#products) | Fraudulent Products (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#fraud) | Using Insect Repellants Safely (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#repellents) | Events (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#events) | More About FDA's Role (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#FDArole) | Contact FDA (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#contact) | Related Links (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#links) | Resources for Healthcare Providers (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#links) | Translations (Spanish, Portuguese) (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#translations)

Fast Facts

About Zika

Zika virus is spread to people primarily through the bite of an infected *Aedes* species mosquito. Most people never know that they have been infected with the virus. It is estimated that four out of five people with Zika virus infections have no symptoms at all. When symptoms do occur, the most common symptoms are fever, rash, joint pain, and conjunctivitis (red eyes). Even in those who develop symptoms, the illness is usually mild, with symptoms lasting from several days to a week.



A pregnant woman applies mosquito repellant. Using insect repellants will help to protect her from being bitten by a mosquito that may be carrying a virus such as Zika; this will also protect her unborn baby from the virus. (Image: CDC/Division of Vector-borne Diseases)

Locations Affected

Prior to 2015, Zika virus outbreaks had occurred in areas of Africa, Southeast Asia, and the Pacific Islands. However, in May 2015, the Pan American Health Organization (PAHO) issued an alert (http://www.paho.org/hq/index.php?option=com_docman&task=doc_view&Itemid=270&gid=30078&lang=en) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (PDF, 199 KB) regarding the first confirmed Zika virus infection in Brazil. For information on current outbreaks, see from CDC:

- Zika in the US (https://www.cdc.gov/zika/geo/index.html)
- Zika Travel Information (https://wwwnc.cdc.gov/travel/page/zika-information)

Guillain-Barré Syndrome

Since the outbreak in Brazil began, we have seen reports of Guillain-Barré syndrome (a disorder in which the immune system attacks the nervous system) and birth defects. *More: Zika and Guillain-Barré Syndrome (https://www.cdc.gov/zika/healtheffects/gbs-qa.html), from CDC*

Pregnancy

Zika virus can be transmitted from a pregnant mother to her fetus. Scientists at the Centers for Disease Control and Prevention (CDC) concluded (http://www.cdc.gov/media/releases/2016/s0413-zika-microcephaly.html), after careful review of existing evidence, that Zika virus is a cause of microcephaly (http://www.cdc.gov/ncbddd/birthdefects/microcephaly.html), a condition in which a baby's brain and head is smaller than expected, and other severe fetal brain defects. In the April 13, 2016 report (http://www.nejm.org/doi/full/10.1056/NEJMsr1604338) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) published in the *New England Journal of Medicine*, the CDC authors describe a rigorous weighing of evidence using established scientific criteria.

The finding that Zika virus infection can cause microcephaly and other severe fetal brain defects means that a woman who is infected with Zika during pregnancy has an increased risk of having a baby with these health problems. It does not mean, however, that all women who have Zika virus infection during pregnancy will have babies with problems. As has been seen during the current Zika outbreak, some infected women have delivered babies that appear to be healthy. *More: Zika and pregnancy, from CDC* (http://www.cdc.gov/zika/pregnancy/index.html), *and CDC updates guidance for infants born to mothers with possible Zika virus infection during pregnancy (https://www.cdc.gov/media/releases/2017/p1019-zika-guidance-updated.html) (October 19, 2017)*

Preventing pregnancy: If you decide that now is not the right time to have a baby, talk to your healthcare provider. View information on the safety and effectiveness of FDA-approved medicines and devices for birth control (/consumers/womens-health-topics/birth-control) (en Español Guía de Métodos Anticonceptivos (/media/99609/download) (PDF, 433 KB))

Medical Products

There are no FDA-approved vaccines for Zika virus. Several investigational vaccines (https://www.niaid.nih.gov/diseases-conditions/zika-vaccines) are under development, including early human clinical trials (https://clinicaltrials.gov/ct2/results?term=zika vaccine&Search=Search).

There are no FDA-approved treatments for Zika virus, nor is the FDA aware of treatments in advanced development for Zika at this time. *Also see Zika Virus Treatment Research (https://www.niaid.nih.gov/diseases-conditions/zika-treatment) from NIAID*

Diagnostics: FDA-authorized diagnostic tests for detecting Zika virus antibodies:

- **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 (/news-events/press-announcements/fda-authorizes-marketing-first-diagnostic-test-detecting-zika-virus-antibodies) 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. FDA reviewed the data for the test through the De Novo (/about-fda/cdrh-transparency/evaluation-automatic-class-iii-designation-de-novo-summaries) premarket review pathway. Previously, tests for detecting Zika virus immunoglobulin (IgM) antibodies—including the ZIKV Detect 2.0 IgM Capture ELISA—had been authorized only for emergency use under the FDA's Emergency Use Authorization (EUA) authority. *For more information, see Serological assays below*
- **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=K200506)** – 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.

FDA encourages commercial diagnostic developers and researchers developing laboratory developed tests (/laboratory-developed-tests) for Zika virus to submit an EUA request or consider pursuing a premarket submission. FDA will work interactively with developers to support such requests. See **Zika Virus** (https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices#zika)**Emergency Use Authorization (https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices#zika)** for information about Zika virus diagnostics available under EUA.

FDA stands ready to work with medical product developers to clarify regulatory and data requirements necessary to move products forward in development as quickly as possible.

See also: Zika Symptoms, Diagnosis, & Treatment, from CDC (http://www.cdc.gov/zika/symptoms/index.html)

Prevention

The best way to prevent Zika and other diseases spread by mosquitoes is to avoid being bitten. *More: Prevention, from CDC (http://www.cdc.gov/zika/prevention/index.html)*

Zika Information from FDA

Updates by Date

Latest updates

- **May 20, 2024:** Information for Human Cell, Tissue, and Cellular and Tissue-Based Product (HCT/P) Establishments Regarding FDA's Determination that Zika Virus is no Longer a Relevant Communicable Disease Agent or Disease (/vaccines-blood-biologics/tissue-tissue-products/information-human-cell-tissue-and-cellular-and-tissue-based-product-hctp-establishments-regarding) (RCDAD) - Because Zika virus (ZIKV) is no longer an RCDAD, HCT/P establishments may discontinue screening donors for ZIKV and revise their relevant procedures to reflect this change.
- **March 9, 2023:** FDA held a Grand Rounds lecture: Microphysiological Systems as Novel Disease Models and Drug Development Tools (/science-research/fda-grand-rounds/fda-grand-rounds-microphysiological-systems-novel-disease-models-and-drug-development-tools-03092023). This presentation by researchers from FDA's National Center for Toxicological Research (NCTR) evaluates nonhuman primate testicular organoids for use as an *in vitro* model of Zika virus infection. A recording is available.

Additional updates (2021 and earlier)

- **May 12, 2021:** Information for Blood Establishments Regarding FDA's Determination that Zika Virus is no Longer a Relevant Transfusion-Transmitted Infection (/vaccines-blood-biologics/blood-blood-products/information-blood-establishments-regarding-fdas-determination-zika-virus-no-longer-relevant), and Withdrawal of Guidance titled "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components" - FDA has determined Zika virus (ZIKV) is no longer an RTTI under FDA's regulations because, as discussed further in the guidance, the available evidence demonstrates that ZIKV no longer has sufficient incidence and/or prevalence to affect the potential donor population. Accordingly, FDA withdrew the guidance titled, "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components," dated July 2018.

- **June 3, 2020:** FDA cleared the DPP Zika IgM System (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K192046)for detecting Zika virus IgM antibodies. Previously, the test had been authorized only for emergency use under FDA's EUA authority.
- **November 25, 2019:** Publication - FDA Zika virus reference panel for molecular-based diagnostic devices supports product testing for Emergency Use Authorization and 510(k) submissions (/vaccines-blood-biologics/science-research-biologics/fda-zika-virus-reference-panel-molecular-based-diagnostic-devices-supports-product-testing-emergency) - read the full publication in *The Journal of Molecular Diagnostics* (https://www.sciencedirect.com/science/article/pii/S1525157819303472?via%3Dihub) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- **October 28, 2019:** FDA cleared (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K192046) the LIAISON XL Zika Capture IgM Assay II for the presumptive qualitative detection of Zika virus IgM antibodies in human sera collected from individuals meeting the CDC Zika virus clinical and/or epidemiological criteria. Previously, the test had been authorized only for emergency use under FDA's EUA authority. FDA revoked the EUA for the LIAISON XL Zika Capture IgM Assay II test, initially issued on April 5, 2017.
- **July 17, 2019:** FDA cleared (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K191578)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. FDA revoked the EUA for the ADVIA Centaur Zika test, initially issued on September 18, 2017.
- **July 3, 2019:** In a letter to FDA dated June 18, 2019, Luminex Corporation requested that the EUA for the xMAP MultiFLEX Zika RNA Assay (https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information)issued on August 4, 2016, and amended on January 7, 2017, and May 19, 2017, be withdrawn. Luminex has decided to discontinue manufacture of the product and there is no remaining viable inventory of the xMAP MultiFLEX Zika RNA Assay. As a result, this product will no longer be marketed, and these circumstances make revocation appropriate to protect the public health or safety. Accordingly, on July 3, 2019, FDA revoked the EUA for xMAP MultiFLEX Zika RNA Assay, pursuant to section 564(g)(2) of the Act. As of July 3, 2019, the xMAP MultiFLEX Zika RNA Assay that was authorized by FDA for use by clinical laboratories for the qualitative detection of RNA from Zika virus is no longer authorized by FDA.
- **May 23, 2019:** 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) - 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. FDA reviewed data for the ZIKV Detect 2.0 IgM Capture ELISA test through the De Novo (/about-fda/cdrh-transparency/evaluation-automatic-class-iii-designation-de-novo-summaries) premarket review pathway. *Also see Emergency Use Authorization below*
- **April 18, 2019:** EUA amendment - In response to Siemens Healthcare Diagnostic Inc.'s request, FDA concurred (/about-fda/page-not-found) (PDF, 137 KB) with the request to modify the ADVIA Centaur Zika test to include surfactant in the ADVIA Centaur Zika IgM assay reagent buffers and the related updates of the Instructions for Use (/about-fda/page-not-found) (PDF, 2.8 MB). *For more information, see Emergency Use Authorizations (/about-fda/page-not-found) (Devices)*
- **February 28, 2019: (https://public4.pagefreezer.com/browse/FDA/30-01-2023T10:37/https:/www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/important-information-human-cell-tissue-and-cellular-and-tissue-based-product-hctp-establishments) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)**Important Information for Human Cell, Tissue, and Cellular and Tissue-Based Product (HCT/P) Establishments Regarding Zika Virus Transmission Risk in the World (https://public4.pagefreezer.com/browse/FDA/30-01-2023T10:37/https:/www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/important-information-human-cell-tissue-and-cellular-and-tissue-based-product-hctp-establishments) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) [ARCHIVED] - CDC has changed information on its Blood and Tissue Safety webpage (https://www.cdc.gov/zika/areasatrisk.html)used to communicate epidemiological information about Zika virus (ZIKV) to the blood and tissue collection community. The webpage includes a world map of areas with risk of Zika (https://wwwnc.cdc.gov/travel/page/zika-travel-information) for other countries and territories outside of U.S. states. A new process has been developed to indicate risk for these areas that assigns one of four categories. FDA considers countries and territories outside the U.S. states categorized as "Red" (current outbreak) or "Purple" (any prior or current reports of mosquito-borne Zika transmission) as areas with increased risk of ZIKV transmission.

For updates by date before 2019, please visit our archive (https://wayback.archive-it.org/7993/20190422171620/https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm485199 (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Safety of the Blood Supply

FDA is responsible for regulatory oversight of the U.S. blood supply. FDA works closely with other parts of the Public Health Service (PHS) to establish blood standards, and to identify and respond to potential threats to blood safety or supply.

May 12, 2021: Information for Blood Establishments Regarding FDA's Determination that Zika Virus is no Longer a Relevant Transfusion-Transmitted Infection (/vaccines-blood-biologics/blood-blood-products/information-blood-establishments-regarding-fdas-determination-zika-virus-no-longer-relevant), and Withdrawal of Guidance titled "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components" - FDA has determined Zika virus (ZIKV) is no longer an RTTI under FDA's regulations because, as discussed further in the guidance, the available evidence demonstrates that ZIKV no longer has sufficient incidence and/or prevalence to affect the potential donor population. Accordingly, FDA withdrew the guidance titled, "Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components," dated July 2018.

Zika updates - safety of the blood supply

- On February 28, 2019, FDA published a web page: Important Information for Human Cell, Tissue, and Cellular and Tissue-Based Product (HCT/P) Establishments Regarding Zika Virus Transmission Risk in the World (https://wayback.archive-it.org/7993/20190207184723/https://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm546326.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) (archived) - CDC has changed information on its Blood and Tissue Safety webpage (https://www.cdc.gov/zika/areasatrisk.html)used to communicate epidemiological information about ZIKV to the blood and tissue collection community. The webpage includes a world map of areas with risk of Zika (https://wwwnc.cdc.gov/travel/page/zika-travel-information) for other countries and territories outside of U.S. states. A new process has been developed to indicate risk for these areas that assigns one of four categories. FDA considers countries and territories outside the U.S. states categorized as "Red" (current outbreak) or "Purple" (any prior or current reports of mosquito-borne Zika transmission) as areas with increased risk of ZIKV transmission.
- Revised guidance - On July 6, 2018, FDA announced the availability of a revised final guidance: Revised Recommendations for Reducing the Risk of Zika Virus Transmission by Blood and Blood Components (/about-fda/page-not-found). This revised guidance replaces the August 2016 guidance, which recommended universal nucleic acid testing for Zika virus of individual units of blood donated in the U.S. states and territories. The revised guidance explains that, in order to comply with applicable testing regulations, blood establishments must continue to test all donated Whole Blood and blood components for Zika virus using a nucleic acid test. The revised guidance explains the basis for the FDA's determination that pooled testing of donations using a screening test licensed for such use by the FDA is a sufficient method for complying with these regulations and effectively reducing the risk of Zika Virus transmission, unless there is an increased risk of local mosquito-borne transmission of Zika virus in a specific geographic area that would trigger individual donation testing in that location. Alternatively, blood establishments may use an FDA-approved pathogen-reduction device for plasma and certain platelet products. (Federal Register notice (https://www.federalregister.gov/documents/2018/07/09/2018-14537/guidance-revised-recommendations-for-reducing-risk-of-zika-virus-transmission-by-blood-and-blood)) *Also see: FDA announces revised guidance on the testing of donated blood and blood components for Zika virus (/news-events/fda-brief/fda-announces-revised-guidance-testing-donated-blood-and-blood-components-zika-virus)*
- Revised guidance - On May 2, 2018, FDA issued revised guidance for establishments that make donor eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps): Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus by Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry (/about-fda/page-not-found) (PDF, 86 KB). This guidance updates information in the March 2016 guidance by: This update supports the continuation of recommendations to screen living donors of HCT/Ps for risks of infection with ZIKV based on geographic areas with risk.

  This update supports the continuation of recommendations to screen living donors of HCT/Ps for risks of infection with ZIKV based on geographic areas with risk.

  Previously, on March 1, 2016, as an additional safety measure against the emerging Zika virus outbreak, FDA issued this guidance as a part of ongoing efforts to protect HCT/Ps and blood products from Zika virus transmission. *Read the news release (/news-events/press-announcements/fda-issues-recommendations-reduce-risk-zika-virus-transmission-human-cell-and-tissue-products)*

  1. providing findings from more recent epidemiological studies including impact on public health;
  2. reporting new data that informs the potential for transmission of ZIKV;
  3. discussing the current status of availability of ZIKV tests;
  4. updating sexual contact risk factors;
  5. updating when an area is considered to have an increased risk for ZIKV transmission; and,
  6. providing additional scientific references.
- On July 5, 2018, FDA approved the Procleix Zika Virus Assay, manufactured by Grifols Diagnostics Solutions, Inc. The Procleix Zika Virus Assay is a qualitative nucleic acid test for the detection of Zika virus RNA in individual plasma specimens obtained from volunteer donors of whole blood and blood components for transfusion. It is also intended for use in testing plasma or serum specimens to screen other living donors of organs and human cells, tissues, and cellular and tissue-based products (HCT/Ps), and in testing blood specimens to screen cadaveric donors. The assay is intended for use in testing individual donor samples. It is also intended for use in testing pools of human plasma composed of equal aliquots of not more than 16 individual specimens from volunteer donors of whole blood components.

It is not intended for use as an aid in the diagnosis of Zika virus infection. For more information see the approval letter (/media/114515/download?attachment) (PDF, 41.2 KB) and *Safety of the Blood Supply* (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#blood) *below*

- On October 5, 2017, **FDA approved the first test for screening Zika virus in blood donations (/news-events/press-announcements/fda-approves-first-test-screening-zika-virus-blood-donations).** FDA approved the cobas Zika test, a qualitative nucleic acid test for the detection of Zika virus RNA in individual plasma specimens obtained from volunteer donors of whole blood and blood components, and from living organ donors. It is intended for use by blood collection establishments to detect Zika virus in blood donations, not for the individual diagnosis of Zika virus infection.

  Before October 5, 2017, several blood collection establishments used the cobas Zika test under IND in order to follow the recommendations in the FDA's 2016 guidance document. The data collected from this testing, and from additional studies performed by the manufacturer, demonstrated that the cobas Zika test is an effective test to screen blood donors for Zika virus infection. The test's clinical specificity was evaluated by testing individual samples from blood donations at five external laboratory sites, resulting in clinical specificity of more than 99 percent.

  The cobas Zika test is intended for use on the fully automated cobas 6800 and cobas 8800 systems. The cobas Zika test, cobas 6800, and cobas 8800 systems are manufactured by Roche Molecular Systems, Inc.

  Previously, on March 30, 2016, FDA announced the availability (/news-events/press-announcements/fda-allows-use-investigational-test-screen-blood-donations-zika-virus) of an investigational test to screen blood donations for Zika virus. The screening test may be used under an investigational new drug application (IND) for screening donated blood in areas with active mosquito-borne transmission of Zika virus. Once screening of blood donations for Zika virus using the investigational test begins, blood establishments in Puerto Rico may resume collecting donations of Whole Blood and blood components.
- FDA continues to work with public health authorities in territories with confirmed Zika virus to take rapid and appropriate steps to help ensure safe blood is available. Prior to the revised guidance issued on August 26, 2016, FDA took steps to protect the blood supply in areas with confirmed Zika virus transmission.
- On March 5, 2016, the first batch of blood products arrived in Puerto Rico (http://www.hhs.gov/about/news/2016/03/07/hhs-ships-blood-products-puerto-rico-response-zika-outbreak.html) in response to HHS efforts to arrange and fund shipment of blood from the continental United States to Puerto Rico to ensure an adequate supply of safe blood for island residents. The Commonwealth of Puerto Rico was the first U.S. territory to experience active mosquito-borne Zika transmission.of an investigational test to screen blood donations for Zika virus. The screening test may be used under an investigational new drug application (IND) for screening donated blood in areas with active mosquito-borne transmission of Zika virus. Once screening of blood donations for Zika virus using the investigational test begins, blood establishments in Puerto Rico may resume collecting donations of Whole Blood and blood components.
- On March 13, 2017, the CDC announced that based on a retrospective analysis of Zika virus (ZIKV) infections they identified a potential increased risk to blood and tissue safety, including semen, in Florida's Miami-Dade, Palm Beach, and Broward counties dating back to June 15, 2016. While Miami-Dade County is the only part of Florida currently (July 29, 2016 to present) designated by CDC as an area of active ZIKV transmission for the purposes of blood and tissue safety intervention, people in this part of Florida regularly travel within and between these three counties and may not recognize that they have been in an area of active ZIKV transmission. This information has been added to CDC's webpage (https://www.cdc.gov/zika/areasatrisk.html) used to communicate epidemiological information about ZIKV to the blood and tissue collection community.

  The potential increased risk to blood and tissue safety, and particularly to semen, in this area due to CDC's announcement is considered to be very low. However, as a precaution, the Food and Drug Administration is informing establishments that collect tissues (i.e., human cell, tissues, and cellular and tissue-based products – HCT/Ps) and blood components of the potential increased risk, so they may consider whether and how this new information impacts their practices.

  Also see the FDA's communication to tissue establishments: Important Information for Human Cell, Tissue and Cellular and Tissue-based Product (HCT/P) Establishments Regarding Zika Virus (/vaccines-blood-biologics/safety-availability-biologics/important-information-human-cell-tissue-and-cellular-and-tissue-based-product-hctp-establishments)

Emergency Use Authorization

FDA stands ready to use our authorities to the fullest extent to help facilitate the development and availability of products for Zika virus. Under the FDA's Emergency Use Authorization (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization) (EUA) mechanism, the agency can enable the use of an unapproved medical product, or the unapproved use of an approved medical product, during emergencies, when, among other circumstances, there are no adequate approved, and available alternatives. An EUA is an important mechanism that allows broader access to available medical products under specific circumstances.

Zika EUA information

- While many people with Zika virus infection experience no symptoms, the virus can pose potentially serious risks to the public health. Access to a diagnostic test that can identify patients with Zika virus infections is critical to supporting response efforts and expanding domestic readiness. Potential links between Zika virus infection and neurological complications (i.e., Guillain-Barré Syndrome), as well as microcephaly and other poor pregnancy outcomes associated with Zika virus infection during pregnancy, have also increased the importance of having a diagnostic test available for Zika virus. As there are no commercially available diagnostic tests cleared or approved by the FDA for the detection of Zika virus infection, it was determined that an EUA is crucial to ensure timely access to a diagnostic tool.
- An EUA (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization) is a tool that FDA can use to allow the use of certain medical products for emergencies based on scientific data. The U.S. Secretary of Health and Human Services (HHS) has declared (https://www.federalregister.gov/articles/2016/03/02/2016-04624/emergency-use-of-in-vitro-diagnostic-tests-for-detection-of-zika-virus-andor-diagnosis-of-zika-virus) that circumstances exist to allow the emergency use of authorized diagnostic tests for Zika virus infection.
- Draft EUA review templates for Zika are available to product sponsors/manufacturers 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 currently authorized under EUA

Performance characteristics of Zika virus diagnostic tests

FDA has posted tables detailing performance characteristics of Zika virus diagnostic tests (assays) currently available for use under EUA. The tables include information about analytical sensitivity, along with other performance characteristics determined during EUA evaluation. (May 3, 2018)

- Table 1: Molecular ZIKV EUA Assays - Performance Characteristics (/media/113103/download) (PDF, 200 KB)
- Table 2: Molecular ZIKV EUA Assays - Key Characteristics (/media/113120/download) (PDF, 247 KB)

Tests currently authorized under EUA are listed on the CDRH page, **Emergency Use Authorizations for Medical Devices (/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices)**.

For a list of FDA-authorized diagnostic tests for detecting Zika virus antibodies, see Diagnostics above.

Nucleic acid testing-based assays (molecular tests) - detect genetic material in samples of bodily fluids, such as serum and urine, to diagnose active Zika infection

Serological assays - detect antibodies against Zika virus in the blood, to assess whether individuals who may have recently been exposed to Zika have actually been infected

Also see the August 17, 2017 press release: FDA provides new tools for the development and proper evaluation of tests for detecting Zika virus infection (/news-events/press-announcements/fda-provides-new-tools-development-and-proper-evaluation-tests-detecting-zika-virus-infection) - As an additional measure in the fight against Zika virus, FDA made available a panel of human plasma samples to aid in the regulatory evaluation of serological tests, to help ensure that tests to detect recent Zika infection are accurate and reliable, and to help test manufacturers know if their tests differentiate between infections with Zika virus or other flaviviruses such as Dengue, and West Nile viruses, which all have similar antibodies. *More: Zika Virus Reference Materials (/emergency-preparedness-and-response/mcm-issues/zika-virus-diagnostic-development#panel) and FDA Zika virus reference panel for molecular-based diagnostic devices supports product testing for Emergency Use Authorization and 510(k) submissions (/vaccines-blood-biologics/science-research-biologics/fda-zika-virus-reference-panel-molecular-based-diagnostic-devices-supports-product-testing-emergency)*

> FDA Safety Communication: FDA warns health care providers against relying solely on Zika virus serological IgM assay results (http://wayback.archive-it.org/7993/20170722113716/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm534515.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) [ARCHIVED]; reminds them to wait for confirmatory test results before making patient management decisions.

Investigational Products

Medical Products (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#medical) | Genetically Engineered Mosquitoes (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#mosquitoes)

Medical Products (Vaccines, Therapeutics, Diagnostics)

- **Vaccines and therapeutics: There are no FDA-approved vaccines or treatments for Zika at this time.** Several investigational vaccines (https://www.niaid.nih.gov/diseases-conditions/zika-vaccines) are under development, including early human clinical trials (https://clinicaltrials.gov/ct2/results?term=zika vaccine&Search=Search). FDA is prepared to evaluate the safety and efficacy of any investigational vaccines and therapeutics that might be developed to help mitigate this outbreak.
- **Diagnostics: For a list of FDA-authorized diagnostic tests for detecting Zika virus antibodies, see Diagnostics above.**
    - FDA encourages commercial diagnostic developers and researchers developing laboratory developed tests (/laboratory-developed-tests) for Zika virus to submit an EUA request or consider pursuing a premarket submission. FDA will work interactively with developers to support such requests. See **Zika Virus Diagnostic Development (/emergency-preparedness-and-response/mcm-issues/zika-virus-diagnostic-development)** for information on FDA support for Zika virus diagnostic development and **Emergency Use Authorization** (/emergency-preparedness-and-response/mcm-issues/zika-virus-response-updates-fda#eua) for information about Zika virus diagnostics available under EUA.
    - To help Zika diagnostic manufacturers assess traceability of their tests (a requirement for Emergency Use Authorization), FDA has created the FDA Zika Virus Reference Materials for NAT-based IVD devices (/emergency-preparedness-and-response/mcm-issues/zika-virus-diagnostic-development#panel), available upon request to Zika device developers who have a pre-EUA submission with the agency and have established the analytical and clinical performance of their assay. In July 2017, FDA also made available (/news-events/press-announcements/fda-provides-new-tools-development-and-proper-evaluation-tests-detecting-zika-virus-infection)a panel of human plasma samples to aid in the regulatory evaluation of serological tests to detect recent Zika virus infection. Developers planning a future premarket submission will have priority to receive the panel of human plasma samples, considering the grant of a De Novo classification request for the ZIKV Detect 2.0 IgM Capture ELISA on May 23, 2019. *View an infographic about the FDA Zika Virus Reference Materials (/media/98527/download) (PDF, 120 KB)*

Genetically engineered mosquitoes related to Zika response

Final guidance - October 4, 2017: FDA Issues Final Guidance Clarifying FDA and EPA Jurisdiction over Mosquito-Related Products (https://wayback.archive-it.org/7993/20191212202536/https://www.fda.gov/animal-veterinary/cvm-updates/fda-issues-final-guidance-clarifying-fda-and-epa-jurisdiction-over-mosquito-related-products) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) [ARCHIVED] - The final Guidance for Industry #236 – Clarification of FDA and EPA Jurisdiction over Mosquito-Related Products (/media/133800/download?attachment) (PDF, 85 KB) – clarifies that mosquito-related products intended to function as pesticides by preventing, destroying, repelling, or mitigating mosquitoes for population control purposes, and that are not intended to cure, mitigate, treat, or prevent a disease are not “drugs” under the Federal Food, Drug, & Cosmetic Act, and will be regulated by the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act. The FDA will continue to have jurisdiction over mosquito-related products that are intended to prevent, treat, mitigate, or cure a disease (including by an intent to reduce the level, replication, or transmissibility of a pathogen in mosquitoes). (Federal Register notice (https://www.federalregister.gov/documents/2017/10/05/2017-21494/guidance-clarification-of-the-food-and-drug-administration-and-environmental-protection-agency))

The Zika virus outbreak highlights the importance that novel vector control (http://www.cdc.gov/zika/vector/) measures may play in protecting the public health. Reviewing the use of innovative strategies to help suppress the population of virus-carrying mosquitoes is one of many activities in which FDA is engaged to help mitigate the threat of vector-borne epidemics, such as Zika.

- FDA’s Center for Veterinary Medicine reviewed information in an Investigational New Animal Drug (INAD) file from Oxitec, Ltd., regarding the company’s genetically engineered line of the mosquito *Aedes aegypti* (OX513A), with the intent of suppressing the population of that mosquito at the release site(s). *Ae. aegypti* is known to transmit the debilitating human virus-caused diseases Zika, dengue, yellow fever, and chikungunya. *More: Oxitec Mosquito (/animal-veterinary/animals-intentional-genomic-alterations/oxitec-mosquito)*
- On March 11, 2016, in compliance with FDA regulations, FDA released for public comment a (/animal-veterinary/cvm-updates/fda-releases-final-environmental-assessment-genetically-engineered-mosquito)draft environmental assessment (EA) (/media/133803/download?attachment) (PDF, 33 MB) submitted by Oxitec, Ltd., that assesses the potential environmental impacts of a field trial of the company’s genetically engineered (GE) *Aedes aegypti* mosquitoes (OX513A) in Key Haven, Florida. *Ae. aegypti* is known to transmit potentially debilitating human viral diseases, including Zika, dengue, yellow fever and chikungunya. The FDA also released a preliminary finding of no significant impact (FONSI) (/media/133801/download?attachment) (PDF, 148 KB) that agrees with the draft EA’s conclusion that the field trial of such GE mosquitoes will not result in significant impacts on the environment.
- The goal of the proposed field trial is to determine whether released Oxitec GE mosquitoes will mate with local wild-type *Aedes aegypti* and suppress their population at the release site. The proposed study is not seeking to evaluate whether release of Oxitec’s GE mosquitoes will reduce Zika virus transmission. Oxitec’s mosquitoes are one possible approach that could be incorporated into an integrated program to help mitigate the threat of vector-borne epidemics; however, it is too early to say with any certainty whether such an approach would be successful.

- The public comment period for the draft Environmental Assessment and preliminary Finding of No Significant Impact concerning investigational use of Oxitec OX513A mosquitoes closed on May 13, 2016. Because this is a first of its kind application, FDA understands how important the public comment period process is.
- **August 5, 2016:** FDA Releases Final Environmental Assessment for Genetically Engineered Mosquito (https://wayback.archive-it.org/7993/20170111193633/http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm490246.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) [ARCHIVED] - FDA has completed the environmental review for a proposed field trial to determine whether the release of Oxitec Ltd.'s genetically engineered (GE) mosquitoes (OX513A) will suppress the local *Aedes aegypti* mosquito population in the release area at Key Haven, Florida. After considering thousands of public comments, FDA has published a final environmental assessment (EA) (/media/133804/download?attachment) (PDF, 3 MB) and finding of no significant impact (FONSI) (/media/133802/download?attachment) (PDF, 198 KB) that agrees with the EA's conclusion that the proposed field trial will not have significant impacts on the environment.

  FDA's finalization of the EA and FONSI does not mean that Oxitec's GE mosquitos are approved for commercial use. Oxitec is responsible for ensuring all other local, state, and federal requirements are met before conducting the proposed field trial, and, together with its local partner, the Florida Keys Mosquito Control District, to determine whether and when to begin the proposed field trial in Key Haven, Florida.
- **January 18, 2017:** FDA Requests Comments on Documents Related to Certain Biotechnology and Mosquito-related Products - FDA is requesting public comment on a draft revised guidance (/media/133805/download?attachment) (PDF, 200 KB) on the regulation of animals with intentionally altered genomic DNA, including animals produced through the use of genome editing and genetic engineering, and a draft guidance (/media/133800/download?attachment) (PDF, 74 KB) that clarifies which mosquito-related products FDA regulates and which such products EPA regulates, regardless of whether these mosquito-related products are developed using biotechnology. *Also see Oxitec Mosquito (/animal-veterinary/animals-intentional-genomic-alterations/oxitec-mosquito); Q&A on FDA Regulation of Intentionally Altered Genomic DNA in Animals (/animal-veterinary/animals-intentional-genomic-alterations/qa-fda-regulation-intentionally-altered-genomic-dna-animals); and FDA Voice: FDA's Science-based Approach to Genome Edited Products (http://blogs.fda.gov/fdavoice/index.php/2017/01/fdas-science-based-approach-to-genome-edited-products/)*
- **April 12, 2017:** FDA is extending the comment period (https://www.federalregister.gov/documents/2017/04/13/2017-07470/guidance-regulation-of-intentionally-altered-genomic-dna-in-animals) to continue seeking public input on draft revised guidance for industry #187 - Regulation of Intentionally Altered Genomic DNA in Animals (/media/133805/download?attachment) (PDF, 200 KB). The FDA is taking this action in response to requests for additional time to submit comments. The comment period will now close on June 19, 2017**.** *Also see: FDA Requests Comments on Documents Related to Certain Biotechnology and Mosquito-related Products and Q&A on FDA Regulation of Intentionally Altered Genomic DNA in Animals (/animal-veterinary/animals-intentional-genomic-alterations/qa-fda-regulation-intentionally-altered-genomic-dna-animals)*
- **October 4, 2017:** FDA Issues Final Guidance Clarifying FDA and EPA Jurisdiction over Mosquito-Related Products - The final Guidance for Industry #236 – Clarification of FDA and EPA Jurisdiction over Mosquito-Related Products (/media/133800/download?attachment) (PDF, 85 KB) *(additional details above)*

Fraudulent Products

- Unfortunately, during outbreak situations, fraudulent products claiming to prevent, treat or cure a disease almost always appear. FDA monitors for fraudulent products and false product claims related to the Zika virus and takes appropriate action to protect consumers. Consumers who have seen these fraudulent products or false claims are encouraged to report (/safety/report-problem/reporting-unlawful-sales-medical-products-internet) them to the FDA.

Using Insect Repellents Safely

- All insect repellents, including products combined with sunscreen, should be used according to instructions on the label.
- Use insect repellents that contain active ingredients registered by the Environmental Protection Agency (EPA) (http://www.epa.gov/insect-repellents/find-insect-repellent-right-you) for use on skin and clothing. EPA registration of insect repellent active ingredients indicates the materials have been reviewed and approved for human safety and effectiveness when applied according to instructions on the label.
- Don't use insect repellent on babies. Repellent used on older children should contain no more than 10 percent DEET. Oil of eucalyptus products should not be used in children under 3 years.

Events

- **March 9, 2023:** FDA held a Grand Rounds lecture: Microphysiological Systems as Novel Disease Models and Drug Development Tools (/science-research/fda-grand-rounds/fda-grand-rounds-microphysiological-systems-novel-disease-models-and-drug-development-tools-03092023). This presentation by researchers from FDA's National Center for Toxicological Research (NCTR) evaluates nonhuman primate testicular organoids for use as an *in vitro* model of Zika virus infection. A recording is available.

For a list of events 2019 and earlier, please visit our archive (https://wayback.archive-it.org/7993/20190422171620/https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm485199.h (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

More About FDA's Role

- FDA is committed to working with the global community as it responds to the Zika virus outbreak. The FDA has a critical role in facilitating the development, and availability of investigational products for use against emerging infectious diseases, such as the Zika virus.
- FDA is actively working with our Federal colleagues at the CDC, National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), and is prepared to evaluate the safety and efficacy of any investigational vaccines and therapeutics that might be developed to help mitigate this outbreak. The agency is also encouraging development of diagnostic tests that may be useful for identifying the presence of the virus, and is taking steps to help ensure the safety of our nation's blood supply.
- While FDA cannot comment on the development of specific medical products, it's important to note that every FDA regulatory decision is based on a risk-benefit assessment of scientific data that includes the context of use for the product and the patient population being studied. Approaches that will be able to show whether a product has a favorable risk-benefit profile for its proposed use may require careful planning. This may prove challenging for Zika virus since its symptoms are often mild or nonspecific.
- **Emergency use:** FDA stands ready to use our authorities to the fullest extent to help facilitate the development and availability of products for Zika virus, as we did during the 2014 Ebola epidemic. Under the FDA's Emergency Use Authorization (EUA) (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization)mechanism, the agency can enable the use of an unapproved medical product, or the unapproved use of an approved medical product, during emergencies, when, among other circumstances, there are no adequate approved, and available alternatives. An EUA is an important mechanism that allows broader access to available medical products under specific circumstances.
- **Blood supply:** FDA is responsible for regulatory oversight of the U.S. blood supply. FDA works closely with other parts of the Public Health Service (PHS) to establish blood standards, and to identify and respond to potential threats to blood safety or supply. *More: Keeping Blood Transfusions Safe: FDA's Multi-layered Protections for Donated Blood (/vaccines-blood-biologics/blood-safety-availability/keeping-blood-transfusions-safe-fdas-multi-layered-protections-donated-blood)*

Translations

Español (http://wayback.archive-it.org/7993/20171114170226/https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm497802.htm)
(http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Português (http://wayback.archive-it.org/7993/20171114170234/https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm499738.htm)
(http://www.fda.gov/about-fda/website-policies/website-disclaimer)

Note: Spanish (http://wayback.archive-it.org/7993/20171114170226/https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm497802.ht (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and Portuguese (http://wayback.archive-it.org/7993/20171114170234/https://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm499738.ht (http://www.fda.gov/about-fda/website-policies/website-disclaimer) translations of this page are archived, and were last updated on the date listed at the bottom of the archived page.

Contact FDA

General Info/Consumers
1-888-INFO-FDA / (1-888-463-6332)

Report a Fraudulent Zika Product
Report form and instructions (/safety/report-problem/reporting-unlawful-sales-medical-products-internet)

Press
Office of Media Affairs
fdaoma@fda.hhs.gov (mailto:fdaoma@fda.hhs.gov?subject=Zika media inquiry)
301-796-4540

Clinicians
Emergency Investigational New Drug (EIND) Applications for Antiviral Products (/drugs/investigational-new-drug-ind-application/emergency-investigational-new-drug-eind-applications-antiviral-products)

Diagnostic Product Sponsors/Manufacturers - EUA Templates
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)

Related Links

- Zika Virus Information from CDC (https://www.cdc.gov/zika/index.html)
- Zika Virus Health Information Resources (National Library of Medicine) (https://sis.nlm.nih.gov/dimrc/zikavirus.html)
- How to Avoid Bug Bites (CDC) (http://wwwnc.cdc.gov/travel/page/avoid-bug-bites)
- About Emergency Use Authorization (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization)
- The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective (/drugs/information-consumers-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective)

Resources for Healthcare Providers

- Zika Information for Health Care Providers (CDC) (http://www.cdc.gov/zika/hc-providers/index.html)
- Zika Training for Health Care Providers (CDC) (https://www.cdc.gov/zika/hc-providers/training/training.html)
- When to test for Zika virus (CDC) (http://www.cdc.gov/zika/pdfs/when-to-test-zika.pdf) (PDF, 332 KB)
- Promoting Stress Management for Pregnant Women during the Zika Virus Disease Outbreak: A Resource for Healthcare Providers, and Planning Resources (HHS) (http://www.phe.gov/Preparedness/planning/abc/Pages/zika-stress.aspx)
- Guidance for U.S. Laboratories Testing for Zika Virus Infection (CDC) (http://www.cdc.gov/zika/laboratories/lab-guidance.html)

Was this helpful? Yes No