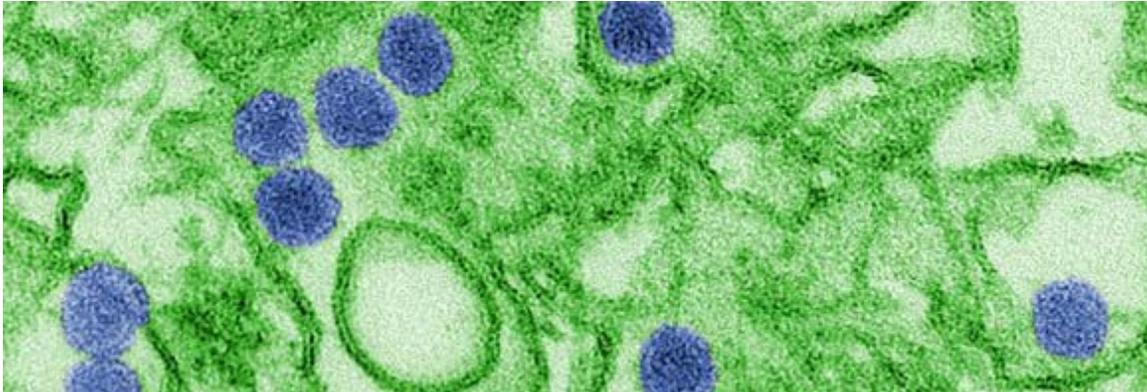

If your email program has trouble displaying this email, [view it as a web page](#).



Medical Countermeasures Initiative Update



May 29, 2019

FDA authorizes marketing of first diagnostic test for detecting Zika virus antibodies

On May 23, 2019, FDA [authorized marketing](#) (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 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 Emergency Use Authorization (EUA) authority.

FDA reviewed data for the ZIKV Detect 2.0 IgM Capture ELISA test through the [De Novo](#) premarket review pathway.

[Read the news release](#)

Related information

- [Zika Virus Response Updates from FDA](#)
 - [Emergency Use Authorization - Zika Virus EUA Information](#)
 - [Zika Virus Diagnostic Development](#)
-

Are you ready for hurricane season?



Hurricane food safety

Before the storm, have on hand:

- ✓ Thermometers (fridge & freezer)
- ✓ Ice / cooler / frozen gel packs
- ✓ Nonperishable food (+ manual can opener)
- ✓ Bottled water
- ✓ Bleach (for disinfecting)

Atlantic hurricane season begins June 1, 2019

FDA reminds consumers to take precautions for storing water and ensuring the safety of food and medical supplies for your family and pets during and after any hurricane-related rain, possible flooding, and power outages. Learn now what you can do to be better prepared.

Related information

- [Hurricane Safety Resources](#)
- [Preparedness Information for Consumers](#)
- [Taking Care of Your Pets During Hurricanes and Floods](#)
- [Food and Water Safety During Power Outages and Floods](#) (including a print & share guide)

Events

- **New! June 4, 2019:** [Tick-Borne Disease Working Group public meeting](#) (Washington, DC and webcast) - Working Group members will focus on plans to develop the next report to the HHS Secretary and Congress on federal tick-borne activities and research.
- **June 6, 2019:** [Antimicrobial Drugs Advisory Committee public meeting](#) (Silver Spring, MD and webcast) - The committee will discuss new drug application (NDA) 212862, pretomanid tablets for oral administration, submitted by The Global Alliance for TB Drug Development, Inc., proposed as part of a combination regimen with bedaquiline and linezolid in adults for the treatment of pulmonary extensively drug resistant and treatment-intolerant or non-responsive multidrug-resistant tuberculosis

(TB).

- **June 26-28, 2019: NIIMBL 2019 National Meeting** (Washington, DC) - The program will feature perspectives from industry and government leaders and showcase the work of the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) community as it develops the cutting-edge technologies and training programs designed to enhance patient access to life-saving medicines. FDA's Dr. Peter Marks, Director of the Center for Biologics Evaluation and Research (CBER), and Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER), are two of the featured speakers on June 27. *(fee)*
 - **New! July 12, 2019: Public meeting: Limited Population Pathway for Antibacterial and Antifungal Drugs** (Silver Spring, MD and webcast). The purpose of the meeting is to provide a public forum for FDA to listen to comments on the draft guidance for industry, [Limited Population Pathway for Antibacterial and Antifungal Drugs](#) that was published in the Federal Register on June 13, 2018. FDA is also reopening the comment period on this draft guidance for comments to be submitted for consideration before we finish work on the final version of the guidance. Register by **July 1, 2019**. Submit comments by **August 12, 2019**.
-

Information for industry

- Draft guidance: [Submitting Documents Utilizing Real-World Data \(RWD\) and Real-World Evidence \(RWE\) to the FDA for Drugs and Biologics](#) - Encourages sponsors and applicants who are using RWD to generate RWE as part of a submission to provide information on their use of RWE to the FDA in a simple, uniform format. The FDA will use this information for internal tracking purposes only. [Comment](#) by **July 8, 2019**. Also see: [FDA In Brief: FDA issues draft guidance to industry on submitting real-world evidence in new drug and biologic applications](#) (May 8, 2019)
 - [2019 Spring Unified Agenda Reflects FDA's Continuity and Consistency](#) - Last week, the federal government published the 2019 "Unified Agenda of Federal Regulatory and Deregulatory Actions" ([Unified Agenda](#)). This semiannual compilation of information about regulations under development by federal agencies across the government provides the public with a concise accounting of our government's recent regulatory actions and future priorities that can have a profound impact on the lives of all Americans. (*FDA Voices by Acting Commissioner Ned Sharpless, MD, May 24, 2019*)
 - Digital Health Update: FDA is [announcing an opportunity](#) to be part of FDA's [Test Plan](#) (PDF, 321 KB) for the [Software Precertification \(Pre-Cert\) Program](#). The opportunity is for companies who plan in the next year to submit a De Novo Request or 510(k) submission for software as a medical device (SaMD). (*May 22, 2019*)
-

In case you missed it

- The White House [released](#) its [Global Health Security Strategy](#) (PDF, 416 KB). The Strategy defines the actions the Administration will take to prevent, detect, and respond to infectious disease threats, whether naturally occurring, accidental, or deliberate. (*May 9, 2019*)
- From NIH - [Human antibody reveals hidden vulnerability in influenza virus](#) - Discovery by NIAID-funded researchers could aid quest for universal flu vaccine. (*May 16, 2019*)

From HHS - The National Biodefense Science Board is [accepting applications](#) for new members. Apply by **June 15, 2019**.

- You want to make a difference. FDA wants to hire you. Follow [@FDAJobs](#) on Twitter, or visit www.fda.gov/jobs.



*Did someone forward you this email? [Subscribe](#)
(select Emergency Preparedness and Response - FDA Medical Countermeasures Initiative (MCMi) News)*

A blue horizontal bar containing five white social media icons: RSS, Twitter, Facebook, YouTube, and Email. Below the icons, the text 'Twitter: @FDA_MCMi' and 'www.fda.gov/medicalcountermeasures' is displayed in white.

Twitter: @FDA_MCMi
www.fda.gov/medicalcountermeasures

U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)
[Privacy Policy](#) | www.fda.gov