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Medical Countermeasures Initiative Update

October 10, 2019



## FDA allows marketing of first rapid diagnostic test for detecting Ebola virus antigens

On October 10, 2019, FDA allowed marketing of a rapid diagnostic test 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.

“Today’s marketing authorization provides another important tool in the effort to fight Ebola, which continues to be a priority of the U.S. Government, especially as we work with our partners, including the World Health Organization, to help address the current Ebola outbreak in the Democratic Republic of Congo (DRC),” said Acting FDA Commissioner Ned Sharpless, M.D.

Since the West African Ebola epidemic that began in 2014, FDA has authorized a number of diagnostic tests for EVD under the Emergency Use Authorization (EUA) pathway to assist with the public health response. Today’s marketing authorization of the first EVD presumptive rapid diagnostic test for Ebola virus antigens through the [De Novo review pathway](#) reflects the ongoing collaboration between the U.S. Government and test developers to gather additional data on EUA products.

[Read the FDA news release](#)

### Related links:

- [OraQuick Ebola Rapid Antigen Test De Novo letter](#) (PDF, 255 KB)

- [Ebola Preparedness and Response Updates from FDA](#)
  - [Emergency Use Authorization](#)
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## EUA Updates

### EUA amendments

- **October 8, 2019:** In response to CDC's request, FDA concurred with modifications to the Healthcare Provider and Patient Fact Sheets for the [CDC Ebola Virus NP Real-time RT-PCR Assay](#) (PDF, 136 KB) and for the [CDC Ebola Virus VP40 Real-time RT-PCR Assay](#) (PDF, 135 KB) to reflect changes to the CDC testing algorithm and updated epidemiological information concerning Ebola virus disease. *For more information including links to the revised fact sheets, see [Emergency Use Authorizations \(Devices\)](#)*

### EUA revocations

- **October 10, 2019:** FDA [granted the De Novo classification request](#) (PDF, 255 KB) for OraSure Technologies Inc.'s ("OraSure's") OraQuick Ebola Rapid Antigen Test, and established a new classification regulation for "Device to detect antigens of biothreat microbial agents in human clinical specimens" (class II) in 21 CFR 866.4002. FDA has concluded that this is an adequate, approved, and available alternative for the OraSure devices which were initially authorized for emergency use in 2015, for use with whole blood specimens and 2016, for cadaveric oral fluid. FDA determined that the criteria for issuance of both EUAs under section 564(c) of the Federal Food, Drug and Cosmetic Act (the Act) are no longer met and revoked the EUAs for: (1) OraQuick Ebola Rapid Antigen Test for use with whole blood specimens issued on July 31, 2015, and amended on March 18, 2016, and January 30, 2019, and (2) OraQuick Ebola Rapid Antigen Test for use with cadaveric oral fluid issued on March 4, 2016, and amended on November 14, 2016, and February 1, 2019, pursuant to section 564(g)(2) of the Act. *For more information, see [Historical Information about Device Emergency Use Authorizations and Emergency Use Authorization--Archived Information](#)*



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## Events

- **New! October 16, 2019:** [Webinar: Consideration of Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions – Final Guidance](#), 12:00 - 1:30 p.m. ET

- **October 16-17, 2019:** [Regulatory Education for Industry \(REdI\): Pharmaceutical Quality Symposium](#) (College Park, MD and webcast) - FDA will discuss the latest developments in pharmaceutical quality and provide case studies that illustrate the most effective ways to address quality issues and interact with the agency.
- **November 8, 2019:** [Vaccines and Related Biological Products Advisory Committee public meeting](#) (Silver Spring, MD and webcast) - The committee will discuss and make recommendations on the development of chikungunya vaccines.
- **November 12-14, 2019:** [Regulatory Education for Industry \(REdI\): Clinical Investigator Training Course](#) (College Park, MD) This course provides an intermediate-level study of clinical trial principles with in-depth coverage of clinical trial design, issues in safety and efficacy, investigator responsibilities, understanding the investigator brochure, and FDA requirements across Centers. Upon completion, attendees should understand pre-clinical research, clinical trials, and FDA submissions for licensure of medical products.
- **November 18, 2019:** [Development of Best Practices in Physiologically Based Pharmacokinetic Modeling To Support Clinical Pharmacology Regulatory Decision-Making Public Workshop](#) (Silver Spring, MD and webcast) - To discuss best practices and evidentiary criteria in the use of physiologically based pharmacokinetic (PBPK) modeling approaches to support regulatory decision-making; share experiences and cases where applying PBPK modeling and simulation highlight the opportunities and limitations of this approach; obtain input from stakeholders on when, where, how, and with what limitations PBPK modeling and simulation may be applied in regulatory decision-making; and discuss the knowledge gaps and research needed to advance PBPK modeling sciences in drug development to support regulatory decisions. [Register](#) by **November 8, 2019**.
- **New! November 18-19, 2019:** [Enhancing the Clinical Trial Enterprise for Antibacterial Drug Development](#) (Silver Spring, MD and webcast) - Co-sponsored by FDA, the Infectious Diseases Society of America (IDSA), the National Institute of Allergy and Infectious Diseases (NIAID), and Pew, this workshop will bring together a diverse array of subject matter experts in the fields of infectious diseases (ID), academics and industry and other government bodies to better understand the current state of U.S.-based ID trials and how to enhance enrollment and research in such trials. Register by **November 14, 2019**.
- **New! November 18-21, 2019:** [Chemical and Biological Defense Science & Technology \(CBD S&T\) Conference](#) (Cincinnati, OH) - Hosted by the Defense Threat Reduction Agency (DTRA). FDA will be presenting as part of a panel on Alternate and Innovative Mechanisms to Conduct Medical Countermeasure Discovery and Development with the Federal Government. [Register](#) by **November 1, 2019**.
- **New! November 22, 2019:** [Blood Products Advisory Committee meeting](#) (Silver Spring, MD and webcast) - The committee will meet in open session to discuss scientific considerations for cold stored platelet products intended for transfusion, including product characterization, duration of storage and clinical indications for use. The committee will hear presentations on available characterization and functional studies of cold stored platelets, clinical studies, and the potential role of cold stored platelets in clinical care in military and civilian patient populations. The committee will also discuss the clinical studies needed to support the indications for use of cold stored platelet products stored beyond 3 days.

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## Information for industry

- **Reminder:** Draft guidance - [Interacting with the FDA on Complex Innovative Trial Designs for Drugs and Biological Products](#) - Provides guidance to sponsors and applicants on interacting with the FDA on complex innovative trial design (CID) proposals for drugs or biological products. FDA is issuing this guidance to satisfy, in part, a mandate under section 3021 of the 21st Century Cures Act (Cures Act). In accordance with the Cures Act mandate, this guidance discusses the use of novel trial designs in the development and regulatory review of drugs and biological products, how sponsors may obtain feedback on technical issues related to modeling and simulation, and the types of quantitative and qualitative information that should be submitted for review. Comment by **December 23, 2019**. (September 20, 2019)
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## In case you missed it

- **MCM approval:** FDA cleared the [Bacillus anthracis Detection Kit](#), a real-time polymerase chain reaction (PCR) test kit intended for the qualitative *in vitro* diagnostic (IVD) detection of target DNA sequences for *B. anthracis*, the bacteria that causes anthrax. This test is indicated for use in CLIA-certified high-complexity laboratories in response to a confirmed *B. anthracis* event only in accordance with the guidelines provided by public health authorities prior to or during a public health emergency. (October 1, 2019)
- **Reminder:** FDA announced two new innovation challenges on device sterilization. Submissions for both are due **October 15, 2019**.
  - [FDA Innovation Challenge 1: Identify New Sterilization Methods and Technologies](#) - The goal of this challenge is to identify safe and effective sterilization methods or technologies for medical devices that do not rely on ethylene oxide.
  - [FDA Innovation Challenge 2: Reduce Ethylene Oxide Emissions](#) - The goal of this challenge is to develop strategies or technologies to reduce emissions to as close to zero as possible from the ethylene oxide sterilization process.
- You want to make a difference. FDA wants to hire you. Follow [@FDAJobs](#) on Twitter, or visit [www.fda.gov/jobs](http://www.fda.gov/jobs).



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