Emergency Use Authorizations

This page lists current and terminated Emergency Use Authorizations that make available diagnostic and therapeutic medical devices to diagnose and respond to public health emergencies.

Zika Virus Emergency Use Authorization

On February 26, 2016, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS), Sylvia Burwell, determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves Zika virus. Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

Sentosa® SA ZIKV RT-PCR Test (Vela Diagnostics USA, Inc.)

On September 23, 2016, the FDA issued an Emergency Use Authorization (EUA) for emergency use of Vela Diagnostics USA, Inc.'s *Sentosa*® SA ZIKV RT-PCR Test for the qualitative detection of RNA from Zika virus in human serum, EDTA plasma, and urine (collected alongside a patient-matched serum or plasma

specimen) from individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated), by laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3). Test results are for the identification of Zika virus RNA. Zika virus RNA is generally detectable in these specimens during the acute phase of infection and, according to the updated CDC Guidance for U.S. Laboratories Testing for Zika Virus Infection, up to 14 days in serum and urine (possibly longer in urine), following onset of symptoms, if present. Positive results are indicative of current infection.

- Letter of Authorization
- Fact Sheet for Healthcare Providers
- Fact Sheet for Patients
- Labeling

LightMix® Zika rRT-PCR Test (Roche Molecular Systems, Inc.)

On August 26, 2016, the FDA issued an Emergency Use Authorization (EUA) for emergency use of Roche Molecular Systems, Inc.'s LightMix® Zika rRT-PCR Test for the qualitative detection of RNA from Zika virus in human serum and EDTA plasma from individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated), by laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3). Test results are for the identification of Zika virus RNA. Zika virus RNA is generally detectable in these specimens during the acute phase of infection and, according to the updated CDC Guidance for U.S. Laboratories Testing for Zika Virus Infection, approximately 7 days following onset of symptoms, if present. Positive results are indicative of current infection.

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ZIKV Detect™ IgM Capture ELISA (InBios International, Inc.)

On August 17, 2016, the FDA issued an Emergency Use Authorization (EUA) for emergency use of InBios International, Inc.'s ("InBios"), ZIKV Detect™ IgM Capture ELISA for the presumptive detection of Zika virus IgM antibodies in human sera collected from individuals meeting the Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated), by laboratories in the United States that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories. Where there are presumptive Zika positive, possible Zika positive, or presumptive other flavivirus positive results from the ZIKV Detect™ IgM Capture ELISA, confirmation of the presence of anti-Zika IgM antibodies or other flavivirus IgM antibodies requires additional testing, as described in the authorized Instructions for Use document, and/or consideration alongside test results for other patient-matched specimens using the latest CDC guideline for the diagnosis of Zika virus infection.

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xMAP® MultiFLEX™ Zika RNA Assay (Luminex Corporation)

On August 4, 2016, the FDA issued an Emergency Use Authorization (EUA) to authorize the emergency use of the Luminex Corporation's xMAP® MultiFLEX™ Zika RNA Assay for the qualitative detection of RNA from Zika virus in human

serum, plasma, and urine (collected alongside a patient-matched serum or plasma specimen) from individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated), by laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories.

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VERSANT® Zika RNA 1.0 Assay (kPCR) Kit (Siemens Healthcare Diagnostics Inc .)

On July 29, 2016, the FDA issued an Emergency Use Authorization (EUA) to authorize the emergency use of the Siemens Healthcare Diagnostics Inc.'s VERSANT® Zika RNA 1.0 Assay (kPCR) Kit for the qualitative detection of RNA from Zika virus in human serum, EDTA plasma, and urine (collected alongside a patient-matched serum or plasma specimen) from individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated), by laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories.

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Viracor-IBT Laboratories, Inc.'s Zika Virus Real-time RT-PCR Test

On July 19, 2016 the FDA issued an Emergency Use Authorization (EUA) to authorize the emergency use of Viracor-IBT Laboratories, Inc.'s ("Viracor-IBT") Zika Virus Real-time RT-PCR test for the qualitative detection of RNA from Zika virus in human serum, plasma or urine (collected alongside a patient-matched serum or plasma specimen) from individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated). Testing is limited to Viracor-IBT's laboratory in Lee's Summit, MO, or other laboratories designated by Viracor-IBT that are also certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

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Aptima® Zika Virus Assay (Hologic, Inc.)

On June 17, 2016 the FDA issued an Emergency Use Authorization (EUA) to authorize the emergency use of Hologic, Inc.'s Aptima® Zika Virus assay for the qualitative detection of RNA from Zika virus in human serum and plasma specimens from individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated), by laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high complexity tests, or by similarly qualified non-U.S. laboratories.

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RealStar® Zika Virus RT-PCR Kit U.S. (altona Diagnostics)

On May 13, 2016 the FDA issued an Emergency Use Authorization (EUA) to authorize the emergency use of altona Diagnostics RealStar® Zika Virus RT-PCR Kit U.S. for the qualitative detection of RNA from Zika virus in serum or urine (collected alongside a patient-matched serum specimen) from individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika virus transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated), by laboratories in the United States that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high complexity tests, or by similarly qualified non-U.S. laboratories.

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Zika Virus RNA Qualitative Real-Time RT-PCR (Focus Diagnostics)

On April 28, 2016 the FDA issued an Emergency Use Authorization (EUA) to authorize the emergency use of Focus Diagnostics, Inc.'s, Zika Virus RNA Qualitative Real-Time RT-PCR test for the qualitative detection of RNA from Zika virus in human serum specimens from individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated), by qualified laboratories designated by Focus Diagnostics, Inc., and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), to perform high complexity tests.

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Zika MAC-ELISA (CDC)

On February 26, 2016, the FDA issued an Emergency Use Authorization (EUA) to authorize the emergency use of Centers for Disease Control and Prevention's (CDC) Zika Immunoglobulin M (IgM) Antibody Capture Enzyme-Linked Immunosorbent Assay (Zika MAC-ELISA) for the presumptive detection of Zika virus-specific IgM in human sera or cerebrospinal fluid (CSF) that is submitted alongside a patient-matched serum specimen from individuals meeting CDC Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., recent history of travel to geographic regions during a period of active Zika virus transmissions at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated as part of a public health response), by qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3). Where there are positive or equivocal results from the Zika MAC-ELISA, confirmation of the presence of anti-Zika IgM antibodies requires additional testing by CDC, or by authorized laboratories in consultation with CDC, using the CDC-issued algorithm.

In response to CDC's request to amend this EUA, on June 29, 2016 FDA reissued the February 26, 2016, EUA in its entirety with the CDC-requested amendments incorporated. The amendments: (1) update the language for the CDC Zika virus clinical and epidemiological criteria; (2) update the language related to additional testing of positive or equivocal test results using the CDC algorithm; (3) allow use of Zika COS-1 Recombinant Antigen (CDC catalog #AV0005) as Zika Viral Antigen in addition to Lyophilized Zika Vero E6 Tissue Culture Antigen (CDC catalog #AV002 or AV003); and (4) as described in Section IV. Conditions of Authorization of this letter, enable certain changes or additions to be made by CDC in consultation with, and with concurrence by, FDA's Division of Microbiology Devices (DMD)/Office of In Vitro Diagnostics and Radiological Health (OIR)/Center for Devices and Radiological Health (CDRH). The Instructions for Use and Fact Sheets also have been updated to incorporate

these amendments, where applicable.

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Trioplex Real-time RT-PCR Assay (CDC)

On March 17, 2016, the FDA issued an Emergency Use Authorization (EUA) to authorize the emergency use of Centers for Disease Control and Prevention's (CDC) Trioplex Real-time RT-PCR Assay (Trioplex rRT-PCR) for the qualitative detection and differentiation of RNA from Zika virus, dengue virus, and chikungunya virus in human sera or cerebrospinal fluid (collected alongside a patient-matched serum specimen), and for the qualitative detection of Zika virus RNA in urine and amniotic fluid (each collected alongside a patient-matched serum specimen). The assay is intended for use with specimens collected from individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated as part of a public health investigation). Testing is performed by qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).

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2015 Enterovirus D68 (EV-D68) Emergency Use Authorization

On February 6, 2015, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS), Sylvia Burwell, determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves EV-D68. Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of in vitro diagnostics for the detection of EV-D68, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

EV-D68 2014 rRT-PCR Assay (CDC) - May 12, 2015

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2014 Ebola Virus Emergency Use Authorizations

On September 22, 2006, then-Secretary of the Department of Homeland Security (DHS), Michael Chertoff, determined, pursuant to section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. § 247d-6b), that the Ebola virus presents a material threat against the United States population sufficient to affect national security. Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS declared on August 5, 2014, that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of Ebola virus, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).

EZ1 Real-time RT-PCR Assay (DoD) - October 10, 2014

CDC Ebola Virus NP Real-time RT-PCR Assay (CDC) - March 2, 2015

CDC Ebola Virus VP40 Real-time RT-PCR Assay (CDC) - March 2, 2015

FilmArray Biothreat-E Test (BioFire Defense, LLC) - October 25, 2014

FilmArray NGDS BT-E Assay (BioFire Defense, LLC) - March 2, 2015

RealStar® Ebolavirus RT-PCR Kit 1.0 (altona Diagnostics GmbH) - November 26, 2014

LightMix® Ebola Zaire rRT-PCR Test (Roche Molecular Systems, Inc.) - December 23, 2014

ReEBOV™ Antigen Rapid Test (Corgenix Inc.) - March 16, 2015

Xpert® Ebola Assay (Cepheid) - March 23, 2015

OraQuick® Ebola Rapid Antigen Test (OraSure Technologies, Inc.) - July 31, 2015 & March 4, 2016

Idylla™ Ebola Virus Triage Test (Biocartis NV) - May 26, 2016

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2013 Coronavirus Emergency Use Authorization (Potential Emergency)

On May 29, 2013 Secretary Kathleen Sebelius determined that Middle East respiratory syndrome coronavirus (MERS-CoV) poses a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad. On the basis of this determination the Secretary declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of the Middle East respiratory syndrome coronavirus (MERS-CoV).

CDC Novel Coronavirus 2012 Real-time RT-PCR Assay (CDC) - June 10, 2014

RealStar® MERS-CoV RT-PCR Kit U.S. - February 12, 2016

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2013 H7N9 Influenza Emergency Use Authorization (Potential Emergency)

On April 19, 2013 Secretary Kathleen Sebelius determined that avian influenza A(H7N9) poses a significant potential for a public health emergency that has a

significant potential to affect national security or the health and security of United States citizens living abroad. On the basis of this determination the Secretary declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection of the avian influenza A(H7N9) virus.

Note that Secretary's determination and declaration were issued based on revised authorities under the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PAHPRA).

CDC Human Influenza Virus Real-Time RT-PCR Diagnostic Panel-Influenza A/H7 (Eurasian Lineage) Assay (CDC) - April 22, 2013

Lyra™ Influenza A Subtype H7N9 Assay (Quidel Corporation) - February 14, 2014

A/H7N9 Influenza Rapid Test (Arbor Vita Corporation) - April 25, 2014

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Historical Information

- Historical Information about Device Emergency Use Authorizations [ARCHIVED]

Termination of Declaration Letters

- Letter: Termination of Declaration of Emergency Justifying Emergency Use Authorization (EUA) of Certain In Vitro Diagnostic Tests (6/22/10) [ARCHIVED]
- Letter: Termination of Declaration of Emergency Justifying the Authorization of Emergency Use of Certain Personal Respiratory Protection Devices (6/22/10) [ARCHIVED]
- Letter: Disposition of Certain Personal Respiratory Protection Devices Authorized for Emergency Use (6/22/10) [ARCHIVED]
- Federal Register: Termination of Declarations Justifying Emergency Use Authorizations of Certain In Vitro Diagnostic Devices, Antiviral Drugs, and Personal Respiratory Protection Devices (6/25/10)

Additional Information

- Emergency Use Authorization of Medical Products and Related Authorities
- Flu.gov
- CDC Information on Avian Influenza A (H7N9) Virus
- CDC H1N1 Flu Page
- Questions About Personal Protective Equipment (PPE)
- Detection of Novel Influenza A (H1N1) Virus by Laboratory Testing [ARCHIVED]

More in Emergency Situations (Medical Devices)

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