Kim Sapsford-Medintz, PhD
MCM EUA Team Lead, Division of Microbiology Devices
OIR, CDRH, FDA

FDA EMERGENCY USE AUTHORIZATION: THE ZIKA VIRUS EXPERIENCE

BARDA Industry Day
October 29-30, 2018 Washington DC
Acknowledgements

DMD EUA Team - OIR/CDRH

FDA CBER

FDA Office of the Commissioner

Office of Counterterrorism and Emerging Threats

FDA Office of Chief Counsel

CDC
CMS
NIH
BARDA/ASPR
WHO
Overview

• The Emergency Use Authorization
• IVD and EUAs
• DMD EUA Program
• IVD EUAs Past and Present
• Zika EUAs
• EUA After the Storm
• Resources

www.fda.gov
EUA Authority (FD&C Act § 564)

• With an EUA, FDA can authorize:
  – Use of unapproved MCMs (despite lacking the amount of data that would be necessary for approval)
  – Unapproved use of approved MCMs (e.g., for a new indication)

to **diagnose**, treat, or prevent serious or life-threatening diseases or conditions caused by CBRN threat agents **when certain criteria and pre-requisites are met**
EUA Circumstances

DOD SECRETARY
Determination of Military Emergency or Significant Potential for Military Emergency

DHS SECRETARY
Determination of Domestic Emergency or Significant Potential for Domestic Emergency

HHS SECRETARY
Determination of Public Health Emergency or Significant Potential for Public Health Emergency

DHS SECRETARY
Identification of Material Threat

HHS SECRETARY
Declaration that Circumstances Exist Justifying the EUA

FDA COMMISSIONER
Issuance of EUA (if criteria for issuance met)

Termination of Declaration & EUA

Consultation with ASPR, CDC, NIH

http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm411445.htm
EUA Authority (FD&C Act § 564)...

continued

• Criteria:
  – Serious or life-threatening illness/condition caused a CBRN agent
  – Based on totality of scientific evidence, reasonable belief:
    • product may be effective
    • Known/potential benefits outweigh known/potential risks
  – No adequate, approved, available alternative to the product
• **Letter of Authorization** - Conditions of authorization = safeguards, such as:
  
  – Information on emergency use, including “not FDA-approved”
    
    • Fact sheets for patients and healthcare providers
  
  – Record keeping and monitoring of adverse events
  
  – Collection of information
  
  – Conditions also clarify roles (e.g., manufacturer, distributors, laboratories)
Final Guidance

Emergency Use Authorization of Medical Products and Related Authorities

Guidance for Industry and Other Stakeholders

U.S. Department of Health and Human Services
Food and Drug Administration
Office of the Commissioner
Office of the Chief Scientist
Office of Counterterrorism and Emerging Threats
## EUA Vs. Premarket: In Vitro Diagnostics

<table>
<thead>
<tr>
<th>Requirements</th>
<th>Emergency Use Authorization (EUA)</th>
<th>Premarket Notification or Application</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Special Circumstances</strong></td>
<td>Requires declaration by the HHS Secretary that circumstances exist justifying the EUA. There is no adequate, approved, and available alternative to the product</td>
<td>No</td>
</tr>
<tr>
<td><strong>Analytical Evaluation</strong></td>
<td>Limited</td>
<td>Extensive</td>
</tr>
<tr>
<td><strong>Clinical Evaluation</strong></td>
<td>Limited</td>
<td>Extensive</td>
</tr>
<tr>
<td><strong>Duration</strong></td>
<td>Temporary - remains in effect for the duration of the declaration unless revoked sooner</td>
<td>Not Limited</td>
</tr>
<tr>
<td><strong>CGMP</strong></td>
<td>Expected but limits or waivers may be granted in an EUA on a case-by-case basis</td>
<td>Required</td>
</tr>
</tbody>
</table>

www.fda.gov
# HHS Secretary Declaration of Emergency or Threat

<table>
<thead>
<tr>
<th>Virus/Agent</th>
<th>Family</th>
<th>Date of Declaration</th>
<th>Use of In Vitro Diagnostics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zika Virus</td>
<td>Flaviviridae</td>
<td>February 26, 2016</td>
<td>Emergency Use of <em>In Vitro</em> Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection</td>
</tr>
<tr>
<td>Enterovirus D68</td>
<td>Picornaviridae</td>
<td>February 6, 2015</td>
<td>Emergency Use of New <em>In Vitro</em> Diagnostics for Detection of Enterovirus D68</td>
</tr>
<tr>
<td>Ebola</td>
<td>Filoviridae</td>
<td>August 4, 2014</td>
<td>Emergency Use of <em>In Vitro</em> Diagnostics for Detection of Ebola Virus</td>
</tr>
<tr>
<td>MERS-CoV</td>
<td>Coronaviridae</td>
<td>May 29, 2013</td>
<td>Emergency Use of <em>In Vitro</em> Diagnostics for Detection of Middle East Respiratory Syndrome Coronavirus</td>
</tr>
<tr>
<td>Influenza H7N9</td>
<td>Orthomyxoviridae</td>
<td>April 19, 2013</td>
<td>Emergency Use of <em>In Vitro</em> Diagnostics for Detection of the Avian Influenza A (H7N9) Virus</td>
</tr>
</tbody>
</table>

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http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm
# DMD EUA Program

<table>
<thead>
<tr>
<th>Proactive Outreach To Test Developers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Develop Relationships with Partners</td>
</tr>
<tr>
<td>Internal and Externally, Nationally and Internationally</td>
</tr>
<tr>
<td>BARDA, CDC, NIAID, DOD, WHO</td>
</tr>
<tr>
<td>Pre-EUA Submissions</td>
</tr>
<tr>
<td>Early engagement with firms – it is never too early to contact FDA</td>
</tr>
<tr>
<td>Draft EUA Review Template</td>
</tr>
<tr>
<td>Dynamic Review Team</td>
</tr>
<tr>
<td>DMD EUA PROGRAM</td>
</tr>
<tr>
<td>-----------------</td>
</tr>
<tr>
<td>Proactive Outreach with Test Developers</td>
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</tbody>
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| **Develop Relationships with Partners**  
Internal and Externally, Nationally and Internationally  
BARDA, CDC, NIAID, DOD, WHO |
| Pre-EUA Submissions  
Early engagement with firms – it is never too early to contact FDA |
| Draft EUA Review Template |
| Dynamic Review Team |
Partner Relationships Can......

• Address:
  – Issues of sample availability
  – Issues of cross reactivity panels
  – In the case of Ebola - Overcome limited availability of BSL-3/4 testing facilities
Partner Relationships Can......

• Address:
  – Issues of sample availability
  – Issues of cross reactivity panels
  – In the case of Ebola - Overcome limited availability of BSL-3/4 testing facilities
Partner Relationships Can......

• Facilitate:
  – Identification of firms with diagnostic products
  – Outreach
  – Understanding of diagnostic needs
  – Harmonization of assay requirements – WHO EUAL Listing and FDA EUA
  – Supply field data (WHO EUAL evaluation for diagnostics)
  – Mutual assistance with performance review/validation
# DMD EUA Program

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EUA Interactive Review

Firm and FDA Interact

Draft EUA Review Template

Pre-EUA Submission

EUA Declaration

Firm and FDA Interact

Pre-EUA Submission

Draft EUA Review Template

EUA Submission

Emergency Use Authorization

Firm and FDA Interact
DMD EUA Program

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</table>
Draft EUA Review Template

• Draft EUA Review Templates developed to streamline data submission as well as data review and review documentation

• Outlines FDA’s current recommendations for the analytical and clinical validation studies needed in support of an EUA submission for an infectious disease IVD
<table>
<thead>
<tr>
<th>NAAT</th>
<th>Emergency Use Authorization (EUA)</th>
<th>De novo 510(k)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Limit of Detection (LoD)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Inclusivity</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>Some <em>in silico</em></td>
<td>Some <em>in silico</em></td>
</tr>
<tr>
<td>Exclusivity</td>
<td>Limited</td>
<td>Extensive</td>
</tr>
<tr>
<td></td>
<td>Some <em>in silico</em></td>
<td>Some <em>in silico</em></td>
</tr>
<tr>
<td>Interference</td>
<td>Situation specific</td>
<td>Yes</td>
</tr>
<tr>
<td>Precision</td>
<td>No</td>
<td>Yes - Multisite</td>
</tr>
<tr>
<td>Fresh Vs. Frozen</td>
<td>Fresh specimens preferred</td>
<td>Fresh specimens preferred</td>
</tr>
<tr>
<td>Specimen Stability</td>
<td>Preferred</td>
<td>Yes is needed</td>
</tr>
<tr>
<td>Clinical Evaluation</td>
<td>Limited – natural clinical specimens</td>
<td>Extensive – natural clinical specimens</td>
</tr>
</tbody>
</table>
Draft EUA Review Template

- **Criteria:**
  - Serious or life-threatening illness/condition caused a CBRN agent
  - Based on totality of scientific evidence, reasonable belief:
    - product may be effective
    - Known/potential benefits outweigh known/potential risks
  - No adequate, approved, available alternative to the product
Draft EUA Review Template

• **Dynamic Template**: Draft document, adapted depending on specific circumstances of the outbreak, Analyte & Technology (e.g., molecular, serology), starting point

• **Assist EUA Submitter and FDA Reviewers**:  
  – Submitter fills out the template  
  – Template serves as basis for interactive review  
  – Template will later serve as sponsor’s EUA Submission AND  
  – Review memorandum for FDA
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EUA Public Documents

http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm#zika

http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMLegalRegulatoryandPolicyFramework/ucm182568.htm

TaqPath Zika Virus Kit (Thermo Fisher Scientific)

On August 2, 2017, the FDA issued an Emergency Use Authorization (EUA) for emergency use of Thermo Fisher Scientific’s (“Thermo Fisher”) TaqPath Zika Virus Kit (ZIKV) for the qualitative detection of RNA from Zika virus in human serum and urine (collected alongside a patient-matched serum 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 serum 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
- Manufacturer Instructions/Package Insert

LIAISON® XL Zika Capture IgM Assay (DiaSorin Incorporated)

Gene-RADAR® Zika Virus Test (Nanobiosym Diagnostics, Inc.)

Zika ELIfle MGB® Kit U.S. (ELItechGroup Inc. Molecular Diagnostics)

Abbott RealTime Zika (Abbott Molecular Inc.)

Zika Virus Detection by RT-PCR Test (ARUP Laboratories)
Post EUA

FDA’s role once an entity is issued an EUA:

• Follow up quickly with manufacturers if potential issues with performance are observed e.g., false positive or false negative results.

• Monitor supply and device usage as applicable.

• Effectively authorize modifications to EUA through Amendments (e.g., new specimen types, instruments).

• Follow up on reports of misuse of test and/or fraudulent claims
# EUA Diagnostics

## EUA Declaration

<table>
<thead>
<tr>
<th></th>
<th>H1N1</th>
<th>H7N9</th>
<th>MERS-CoV</th>
<th>Ebola</th>
<th>Enterovirus D68</th>
<th>Zika</th>
</tr>
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</table>

## Original EUA Diagnostics:

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<th>Enterovirus D68</th>
<th>Zika</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molecular</td>
<td>17</td>
<td>2</td>
<td>2</td>
<td>9</td>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td>Antigen</td>
<td>1</td>
<td>1</td>
<td>0</td>
<td>3*</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Serology</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>18</td>
<td>3</td>
<td>2</td>
<td>12</td>
<td>1</td>
<td>20</td>
</tr>
</tbody>
</table>

*Includes one product that was authorized for two different intended uses

^Includes one product that was authorized but later withdrawn by the company

## EUA Re-authorizations and Amendment Granting's:

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<tr>
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<th>H7N9</th>
<th>MERS-CoV</th>
<th>Ebola</th>
<th>Enterovirus D68</th>
<th>Zika</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total</strong></td>
<td>10</td>
<td>1</td>
<td>2</td>
<td>24</td>
<td>0</td>
<td>30</td>
</tr>
</tbody>
</table>
Common Challenges for EUA IVDs

• Evolving knowledge over the course of the emergency
• Lack of knowledge of the disease biology and natural course of infection, especially at beginning of emergency
• Uncertainty of best specimen type for molecular assays, especially at the beginning of emergency
• Availability of well-characterized specimens for assay development, testing and validation
• What is the best assay format, assay targets (target molecular sequence, antigens, what are important IgM epitopes, etc.)?
Zika EUAs

1st Serological Assay
- Zika MAC-ELISA
  - CDC
  - EUA: 2/26/2016

1st Molecular Assay
- Trioplex rRT-PCR
  - CDC
  - EUA: 3/17/2016

1st Commercial Serological Assay
- ZIKV Detect IgM Capture ELISA
  - InBios
  - EUA: 8/17/2016

- DPP Zika IgM Assay System
  - Chembio Dx
  - EUA: 9/27/2017

>140 EUA Inquiries

20 EUA Requests

20 EUA issued, 1 withdrawn (15 molecular, 5 IgM)
Challenges for Zika Virus IVDs

• Typically low viral load
• ~80% individuals are asymptomatic
• Short diagnostic window for molecular assays (< 14 days) = reliance on serological IgM assays
• Potential cross-reactivity of serological assays with other Flaviviruses – dengue, West Nile, yellow fever – problematic in South America and Puerto Rico
• PRNT follow-up testing
• Serological clinical specimens - BARDA
FDA Reference Materials

- Two Zika Virus Strains – Asian Lineage*
  - S1
  - S2
- Sensitivity Evaluation
- Blinded Panel
- FDA Protocol

*Developed in collaboration with CBER

- Sensitivity Evaluation
  48 member panel (9 donors) containing plasma from patients initially PCR positive.*
- Cross-reactivity Evaluation
  21 West Nile and 20 Dengue single bleed specimens before 2016 outbreak.**

*Developed in collaborations with Blood Systems Research Institute (BSRI); National Heart, Lung, and Blood Institute (NHLBI) was the funding source that enabled the generation of the Zika panels; **Developed in collaboration with CBER
Evolving EUA

• **FDA Email boxes** developed and monitored to facilitate:
  o Initial interactions, request EUA Review Templates
    o [CDRH-ZIKA-Templates@fda.hhs.gov](mailto:CDRH-ZIKA-Templates@fda.hhs.gov)
  o Report issues with EUA IVDs once in use
    o [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)

• **Tri-Agency Task Force for Emergency Diagnostics (TTFED)** – includes CDC, CMS and FDA:
  o Created to promote coordination among the 3 federal agencies to provide support for the implementation of IVD assays authorized under an Emergency Use Authorization (EUA)
After the Storm

EUA is not a substitute or short-cut for approval or clearance

• Development of 510k Requirements
• Outreach to Manufacturers:
  - Recommend pre-Submission (Q-Sub) in order to disseminate the 510k requirements without the need for a Guidance
  - Problem: Lack of Incentives - BARDA
FDA EUA IVD Resources

- FDA Zika Response Updates Website
  - [http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm485199.htm](http://www.fda.gov/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/ucm485199.htm) (also available in Spanish and Portuguese)

- FDA Medical Countermeasures Initiative (MCMi)
  - [www.fda.gov/medicalcountermeasures](http://www.fda.gov/medicalcountermeasures)

- FDA EUA Website (official updates, current & terminated EUAs, guidance)
  - [www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm](http://www.fda.gov/EmergencyPreparedness/Counterterrorism/ucm182568.htm)

- FDA Draft Guidance on EUAs and other MCM Emergency Use Authorities

- FDA MCM Emergency Use Authorities Website (official updates)

- DMD Contact Information
  - Uwe Scherf, M.Sc., Ph.D., Director, Division of Microbiology uwe.scherf@fda.hhs.gov

- Email Contact for Interactive Review and Guidance
  - CDRH-ZIKA-Templates@fda.hhs.gov
For Zika molecular IVDs FDA developed tables summarizing the performance and key characteristics of each test.

**Table 1: Molecular Zika Virus (ZIKV) Emergency Use Authorization (EUA) Assays - Performance Characteristics**

<table>
<thead>
<tr>
<th>EUA Holder Assay Name*</th>
<th>Authorized Human Specimens‡</th>
<th>ZIKV Gene Target(s)</th>
<th>ZIKV Limit of Detection§ (Specimen)</th>
<th>Clinical Performance^ (Specimen) [Rate] (95% CI)</th>
<th>FDA Reference Material Testing (RNA NAAT Detectable Units/mL)</th>
</tr>
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<tbody>
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<td><strong>EUA Holder Assay Name</strong>*</td>
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<td><strong>FDA Reference Material Testing (RNA NAAT Detectable Units/mL)</strong></td>
</tr>
<tr>
<td>Centers for Disease Control and Prevention (CDC)</td>
<td>Serum (S) Whole blood (WB) Cerebrospinal fluid (CSF) Amniotic fluid (AF) Urine (U)</td>
<td>Envelope</td>
<td>(S) 19300 GCE/mL (U) 53800 GCE/mL (WB) 2430 GCE/mL</td>
<td>(S) 100.0% [19/19] (83.2-100%) (WB) 96.1% [146/152] (91.7-98.2%)</td>
<td>(S) 3300 (U) 1000</td>
</tr>
<tr>
<td>Quest Diagnostics Infectious Disease, Inc.</td>
<td>Serum Urine</td>
<td>Envelope and Membrane</td>
<td>(S) 250 copies/mL (U) 500 copies/mL</td>
<td>(S) 94.6% [53/56] (85.4-98.2%) (U) 100% [60/60] (94.0-100%)</td>
<td>(S) 1000 (U) 1000</td>
</tr>
<tr>
<td>altona Diagnostics GmbH</td>
<td>Serum EDTA Plasma Urine</td>
<td>Proprietary</td>
<td>(S) 251.6 GEO/mL (U) 79.6 GEO/mL</td>
<td>(S) 96.8% [60/62] (89.0-99.1%) (U) 95.1% [39/41] (83.9-98.7%)</td>
<td>(S) 3162 (U) 3162</td>
</tr>
</tbody>
</table>

## FDA EUA IVD Resources

### Table 2: Molecular Zika Virus (ZIKV) Emergency Use Authorization (EUA) Assays - Key Characteristics

<table>
<thead>
<tr>
<th>EUA Holder Assay Name* (Date of Authorization)</th>
<th>Authorized Human Specimens (Volume)</th>
<th>RNA Extraction</th>
<th>Reaction Amplification Set-up</th>
<th>Approx. Turn Around Time per run</th>
<th>Approx. Through-put^ per Instrument (Specimens per run)</th>
<th>Summary Characteristics</th>
</tr>
</thead>
</table>
| Centers for Disease Control and Prevention (CDC) Trioplex Real-time RT-PCR Assay March 17, 2016 | Serum Whole blood Cerebrospinal fluid Amniotic fluid Urine (140 – 1000 µL) | X X X | 4 h | Low (24) | First PCR assay to be granted an EUA 
Trioplex - Differentiation of ZIKV, DENV and CHIKV 
2 different instruments for PCR 
4 automated and 1 manual sample prep 
Limited hand-on time for sample prep. and transfer to PCR cycler; manual sample prep requires manual PCR set up as well. 
Sample Input: 1.0 mL (automated); 0.14 mL (manual) 
5 sample types authorized: Serum, whole blood, CSF, amniotic fluid and urine |
| Quest Diagnostics Infectious Disease, Inc. Zika Virus RNA Qualitative Real-Time RT-PCR April 28, 2016 | Serum Urine (500 µL) | X X | 5h | Low (30) | Reference Laboratory 
1 instrument for PCR 
1 automated sample prep method 
Limited hand-on time for sample prep. and transfer to PCR cycler. 
Sample Input: 0.5 mL 
1 sample type authorized: Serum |
| altona Diagnostics GmbH RealStar Zika Virus RT-PCR Kit U.S. | Serum EDTA Plasma Urine |  |  | | 7 different instruments for PCR 
2 automated and 1 manual sample prep 
Limited hand-on time for sample prep. and transfer to PCR cycler; manual sample prep |
FDA
U.S. FOOD & DRUG
ADMINISTRATION