

by industry and regulators alike to enable a harmonized and smooth implementation of Q3D on a global basis.

The U.S. regional workshop is intended to clarify key aspects of ICH Q3D: Guideline on Elemental Impurities by elaborating on those key topics. It will include: (1) A discussion of how to apply Q3D concepts to routes of administration, not addressed in Q3D, (2) justification for elemental impurity levels higher than an established permissible daily exposure (PDE) (3) application of Q3D concepts to determine safe levels of elements not included in Q3D, (4) discussion of the rationale for limits on large volume parenterals, (5) elaboration of the concepts outlined in the Q3D Sections on Risk Assessment and Control of Elemental Impurities and (6) options for converting between PDEs and concentrations.

In addition, case studies may be presented to illustrate the concepts described previously, and frequently asked questions will be discussed. The presentation of the material will follow the modules that are available on the ICH Web site, [www.ich.org](http://www.ich.org), and will include time for questions and discussion. Breakout sessions will be provided to discuss key topics and provide feedback to participants. Material will be presented by members of the ICH Q3D Implementation Working Group. The agenda for the workshop will be made available on the internet at <http://www.fda.gov/Drugs/NewsEvents/ucm498553.htm>.

**Registration:** If you wish to attend this meeting, visit the following Web site to register: <https://www.eventbrite.com/e/regional-public-workshop-on-ich-q3d-implementation-of-guideline-for-elemental-impurities-tickets-25492458630>. Please register by August 15, 2016. If you are unable to attend the meeting in person, you can register to view a live Webcast on the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Your registration must also contain your complete contact information, including name, title, affiliation, address, email address, and phone number. Registrations may be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, the number of participants from each organization may be limited based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special

accommodations because of a disability, please contact Amanda Roache (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Dated: July 1, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2016-N-1486]

#### Authorization of Emergency Use of an In Vitro Diagnostic Device for Detection of Zika Virus; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the issuance of an Emergency Use Authorization (EUA) (the Authorization) for an in vitro diagnostic device for detection of the Zika virus in response to the Zika virus outbreak in the Americas. FDA issued this Authorization under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by Hologic, Inc. The Authorization contains, among other things, conditions on the emergency use of the authorized in vitro diagnostic device. The Authorization follows the February 26, 2016, determination by the Secretary of Health and Human Services (HHS) 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 U.S. citizens living abroad and that involves Zika virus. On the basis of such determination, the Secretary of HHS declared on February 26, 2016, that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under the FD&C Act. The Authorization, which includes an explanation of the reasons for issuance, is reprinted in this document.

**DATES:** The Authorization is effective as of June 17, 2016.

**ADDRESSES:** Submit written requests for single copies of the EUA to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-

0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the Authorization may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorization.

#### FOR FURTHER INFORMATION CONTACT:

Carmen Maher, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4347, Silver Spring, MD 20993-0002, 301-796-8510 (this is not a toll free number).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. With this EUA authority, FDA can help assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad,

and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. 247d-6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the **Federal Register** a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances),

FDA<sup>1</sup> concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as may be prescribed by regulation are satisfied.

No other criteria for issuance have been prescribed by regulation under section 564(c)(4) of the FD&C Act. Because the statute is self-executing, regulations or guidance are not required for FDA to implement the EUA authority.

## II. EUA Request for an In Vitro Diagnostic Device for Detection of the Zika Virus

On February 26, 2016, the Secretary of HHS determined that there is a

<sup>1</sup>The Secretary of HHS has delegated the authority to issue an EUA under section 564 of the FD&C Act to the Commissioner of Food and Drugs.

significant potential for a public health emergency that has a significant potential to affect national security or the health and security of U.S. citizens living abroad and that involves Zika virus. On February 26, 2016, under section 564(b)(1) of the FD&C Act, and on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under section 564 of the FD&C Act. Notice of the determination and declaration of the Secretary was published in the **Federal Register** on March 2, 2016 (81 FR 10878). On June 15, 2016, Hologic, Inc. requested, and on June 17, 2016, FDA issued, an EUA for the Aptima® Zika Virus assay, subject to the terms of the Authorization.

## III. Electronic Access

An electronic version of this document and the full text of the Authorization are available on the Internet at <http://www.regulations.gov>.

## IV. The Authorization

Having concluded that the criteria for issuance of the Authorization under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of an in vitro diagnostic device for detection of Zika virus subject to the terms of the Authorization. The Authorization in its entirety (not including the authorized versions of the fact sheets and other written materials) follows and provides an explanation of the reasons for its issuance, as required by section 564(h)(1) of the FD&C Act:

**BILLING CODE 4164-01-P**



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring, MD 20993

June 17, 2016

Ken Hood, MBA  
Senior Director, Regulatory Affairs  
Hologic, Inc.  
10210 Genetic Center Drive  
San Diego, CA 92121

Dear Mr. Hood:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of Hologic, Inc.'s Aptima<sup>®</sup> 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), 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).<sup>1</sup> Assay results are for the identification of Zika viral RNA. Zika viral RNA is generally detectable in serum during the acute phase of infection (approximately 7 days following onset of symptoms, if present). Positive results are indicative of current infection.

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) 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.<sup>2</sup> 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* diagnostic tests 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).<sup>3</sup>

<sup>1</sup> For ease of reference, this letter will refer to "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" as "authorized laboratories."

<sup>2</sup> As amended by the Pandemic and All Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act, the Secretary may make a determination of a public health emergency, or of a significant potential for a public health emergency.

<sup>3</sup> HHS. *Determination and Declaration Regarding Emergency Use of in Vitro Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection*. 81 Fed. Reg. 10878 (March 2, 2016).

Page 2- Mr. Hood, Hologic, Inc.

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the Aptima<sup>®</sup> Zika Virus assay (as described in the Scope of Authorization section of this letter (Section II)) in 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 described in the Scope of Authorization section of this letter (Section II)) for the detection of Zika virus infection by authorized laboratories, subject to the terms of this authorization.

### **I. Criteria for Issuance of Authorization**

I have concluded that the emergency use of the Aptima<sup>®</sup> Zika Virus assay for the detection of Zika virus and diagnosis of Zika virus infection in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The Zika virus can cause Zika virus infection, a serious or life-threatening disease or condition to humans infected with the virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Aptima<sup>®</sup> Zika Virus assay, when used with the specified instrument and in accordance with the Scope of Authorization, may be effective in detecting Zika virus and diagnosing Zika virus infection, and that the known and potential benefits of the Aptima<sup>®</sup> Zika Virus assay for detecting Zika virus and diagnosing Zika virus infection outweigh the known and potential risks of such product; and
3. There is no adequate, approved, and available alternative to the emergency use of the Aptima<sup>®</sup> Zika Virus assay for detecting Zika virus and diagnosing Zika virus infection.<sup>4</sup>

### **II. Scope of Authorization**

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Aptima<sup>®</sup> Zika Virus assay by authorized laboratories for the detection of RNA from Zika virus and diagnosis of Zika virus infection in 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).

#### **The Authorized Aptima<sup>®</sup> Zika Virus Assay**

Hologic, Inc.'s Aptima<sup>®</sup> Zika Virus assay is a transcription-based nucleic acid amplification test for the *in vitro* qualitative detection of Zika virus RNA in serum and plasma 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.,

<sup>4</sup> No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

Page 3- Mr. Hood, Hologic, Inc.

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). The Aptima<sup>®</sup> Zika Virus assay can also be used with other authorized specimen types. The Aptima<sup>®</sup> Zika Virus assay involves three main steps, which take place in a single tube: sample preparation, Zika virus RNA target amplification by transcription-mediated amplification, and detection of the amplification products (amplicon) by the Hybridization Protection Assay. The Aptima<sup>®</sup> Zika Virus assay is performed using the Panther System or other authorized instruments. The Panther System automates the processing, interpretation, and management of nucleic acid testing. The assay incorporates an internal control, or other authorized control materials, to monitor nucleic acid capture, amplification, and detection, as well as operator or instrument error.

The Aptima<sup>®</sup> Zika Virus assay kit includes the following materials or other authorized materials: Internal Control Reagent, Target Capture Reagent, Amplification Reagent, Enzyme Reagent, Probe Reagent, Selection Reagent, and Aptima<sup>®</sup> Zika Virus assay positive and negative calibrators. The following ancillary kits or other authorized ancillary reagents are required for Aptima<sup>®</sup> Zika Virus assay, but not included with the test: Aptima<sup>®</sup> Auto Detect Reagents kit and Aptima<sup>®</sup> Assay Fluids kit.

The above described Aptima<sup>®</sup> Zika Virus assay, when labeled consistently with the labeling authorized by FDA entitled "Aptima<sup>®</sup> Zika Virus assay Instructions for Use" (available at <http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm>), which may be revised by Hologic, Inc. in consultation with the Division of Microbiology Devices (DMD)/Office of In Vitro Diagnostics and Radiological Health (OIR)/Center for Devices and Radiological Health (CDRH), is authorized to be distributed to and used by authorized laboratories under this EUA, despite the fact that it does not meet certain requirements otherwise required by federal law.

The above described Aptima<sup>®</sup> Zika Virus assay is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to health care providers, pregnant women, and other patients:

- Fact Sheet for Health Care Providers: Interpreting Aptima<sup>®</sup> Zika Virus Assay Test Results
- Fact Sheet for Pregnant Women: Understanding Results from the Aptima<sup>®</sup> Zika Virus Assay Test
- Fact Sheet for Patients: Understanding Results from the Aptima<sup>®</sup> Zika Virus Assay

As described in Section IV below, Hologic, Inc. is also authorized to make available additional information relating to the emergency use of the authorized Aptima<sup>®</sup> Zika Virus assay that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized Aptima<sup>®</sup> Zika Virus assay in the specified population, when used for detection of Zika virus and to diagnose Zika virus infection and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific

Page 4- Mr. Hood, Hologic, Inc.

evidence available to FDA, that it is reasonable to believe that the authorized Aptima<sup>®</sup> Zika Virus assay may be effective in the detection of Zika virus and diagnosis of Zika virus infection, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in section I above, and concludes that the authorized Aptima<sup>®</sup> Zika Virus assay, when used for detection of Zika virus and to diagnose Zika virus infection in the specified population (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the authorized Aptima<sup>®</sup> Zika Virus assay under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the Aptima<sup>®</sup> Zika Virus assay described above is authorized to detect Zika virus and diagnose Zika virus infection in 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 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).

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

### III. Waiver of Certain Requirements

I am waiving the following requirements for the Aptima<sup>®</sup> Zika Virus assay during the duration of this EUA:

- Current good manufacturing practice requirements, including the quality system requirements under 21 CFR Part 820 with respect to the design, manufacture, packaging, labeling, storage, and distribution of the Aptima<sup>®</sup> Zika Virus assay.
- Labeling requirements for cleared, approved, or investigational devices, including labeling requirements under 21 CFR 809.10 and 21 CFR 809.30, except for the intended use statement (21 CFR 809.10(a)(2), (b)(2)), adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)), any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4), and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12).

### IV. Conditions of Authorization

Pursuant to section 564 of the Act, I am establishing the following conditions on this authorization:

Page 5- Mr. Hood, Hologic, Inc.

**Hologic, Inc. and Its Authorized Distributor(s)**

- A. Hologic, Inc. and its authorized distributor(s) will distribute the authorized Aptima<sup>®</sup> Zika Virus assay with the authorized labeling, as may be revised by Hologic, Inc. in consultation with DMD/OIR/CDRH, only to authorized laboratories.
- B. Hologic, Inc. and its authorized distributor(s) will provide to authorized laboratories the authorized Aptima<sup>®</sup> Zika Virus Assay Fact Sheet for Health Care Providers, the authorized Aptima<sup>®</sup> Zika Virus Assay Fact Sheet for Pregnant Women, and the authorized Aptima<sup>®</sup> Zika Virus Assay Fact Sheet for Patients.
- C. Hologic, Inc. and its authorized distributor(s) will make available on their website(s) the authorized Aptima<sup>®</sup> Zika Virus Assay Fact Sheet for Health Care Providers, the authorized Aptima<sup>®</sup> Zika Virus Assay Fact Sheet for Pregnant Women, and the authorized Aptima<sup>®</sup> Zika Virus Assay Fact Sheet for Patients.
- D. Hologic, Inc. and its authorized distributor(s) will inform authorized laboratories and relevant public health authority(ies) of this EUA, including the terms and conditions herein.
- E. Hologic, Inc. and its authorized distributor(s) will ensure that authorized laboratories using the authorized Aptima<sup>®</sup> Zika Virus assay have a process in place for reporting test results to health care providers and relevant public health authorities, as appropriate.<sup>5</sup>
- F. Through a process of inventory control, Hologic, Inc. and its authorized distributor(s) will maintain records of device usage.
- G. Hologic, Inc. and its authorized distributor(s) will collect information on the performance of the test. Hologic, Inc. will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the test of which Hologic, Inc. becomes aware.
- H. Hologic, Inc. and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized Aptima<sup>®</sup> Zika Virus assay that is consistent with, and does not exceed, the terms of this letter of authorization.

**Hologic, Inc.**

- I. Hologic, Inc. will notify FDA of any authorized distributor(s) of the Aptima<sup>®</sup> Zika Virus assay, including the name, address, and phone number of any authorized distributor(s).
- J. Hologic, Inc. will provide its authorized distributor(s) with a copy of this EUA, and communicate to its authorized distributor(s) any subsequent amendments that might be

<sup>5</sup> For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Hologic, Inc. and authorized laboratories consult with the applicable country, state, or territory health department(s). According to CDC, Zika is a nationally notifiable condition. <http://www.cdc.gov/zika/>.

Page 6- Mr. Hood, Hologic, Inc.

made to this EUA and its authorized accompanying materials (e.g., fact sheets, instructions for use).

- K. Hologic, Inc. may request changes to the authorized Aptima<sup>®</sup> Zika Virus Assay Fact Sheet for Health Care Providers, the authorized Aptima<sup>®</sup> Zika Virus Assay Fact Sheet for Pregnant Women, and the authorized Aptima<sup>®</sup> Zika Virus Assay Fact Sheet for Patients. Such requests will be made by Hologic, Inc. in consultation with, and require concurrence of, DMD/OIR/CDRH.
- K. Hologic, Inc. may request the addition of other instruments for use with the authorized Aptima<sup>®</sup> Zika Virus assay. Such requests will be made by Hologic, Inc. in consultation with, and require concurrence of, DMD/OIR/CDRH.
- L. Hologic, Inc. may request the addition of other ancillary reagents for use with the authorized Aptima<sup>®</sup> Zika Virus assay. Such requests will be made by Hologic, Inc. in consultation with, and require concurrence of, DMD/OIR/CDRH.
- M. Hologic, Inc. may request the addition of other specimen types for use with the authorized Aptima<sup>®</sup> Zika Virus assay. Such requests will be made by Hologic, Inc. in consultation with, and require concurrence of, DMD/OIR/CDRH.
- N. Hologic, Inc. may request the addition of other control materials for use with the authorized Aptima<sup>®</sup> Zika Virus assay. Such requests will be made by Hologic, Inc. in consultation with, and require concurrence of, DMD/OIR/CDRH.
- O. Hologic, Inc. will assess traceability<sup>6</sup> of the Aptima<sup>®</sup> Zika Virus assay with an FDA-recommended reference material. After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, Hologic, Inc. will update its labeling to reflect the additional testing.
- P. Hologic, Inc. will track adverse events and report to FDA under 21 CFR Part 803.

#### Authorized Laboratories

- Q. Authorized laboratories will include with reports of the results of the Aptima<sup>®</sup> Zika Virus assay the authorized Fact Sheet for Health Care Providers, the authorized Fact Sheet for Pregnant Women, and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- R. Authorized laboratories will perform the Aptima<sup>®</sup> Zika Virus assay on the Panther System or other authorized instruments.
- S. Authorized laboratories will perform the Aptima<sup>®</sup> Zika Virus assay using the Aptima<sup>®</sup> Auto Detect Reagents kit and Aptima<sup>®</sup> Assay Fluids kit or other authorized ancillary reagents.

<sup>6</sup> Traceability refers to tracing analytical sensitivity/reactivity back to a FDA recommended reference material.

Page 7- Mr. Hood, Hologic, Inc.

- T. Authorized laboratories will perform the Aptima<sup>®</sup> Zika Virus assay on serum, plasma, or other authorized specimen types.
- U. Authorized laboratories will have a process in place for reporting test results to health care providers and relevant public health authorities, as appropriate.<sup>7</sup>
- V. Authorized laboratories will collect information on the performance of the test and report to Hologic, Inc., any suspected occurrence of false positive or false negative results of which they become aware.
- W. All laboratory personnel using the test should be appropriately trained in nucleic acid amplification techniques and use appropriate laboratory and personal protective equipment when handling this kit.

**Hologic, Inc., Its Authorized Distributor(s) and Authorized Laboratories**

- X. Hologic, Inc., its authorized distributor(s), and authorized laboratories will ensure that any records associated with this EUA are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

**Conditions Related to Advertising and Promotion**

- Y. All advertising and promotional descriptive printed matter relating to the use of the authorized Aptima<sup>®</sup> Zika Virus assay shall be consistent with the Fact Sheets and authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.
- Z. All advertising and promotional descriptive printed matter relating to the use of the authorized Aptima<sup>®</sup> Zika Virus assay shall clearly and conspicuously state that:
  - This test has not been FDA cleared or approved;
  - This test has been authorized by FDA under an EUA for use by authorized laboratories;
  - This test has been authorized only for the detection of RNA from Zika virus and diagnosis of Zika virus infection, not for any other viruses or pathogens; and
  - This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

<sup>7</sup> For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Hologic, Inc. and authorized laboratories consult with the applicable, country, state or territory health department(s) and/or CDC. According to CDC, Zika is a nationally notifiable condition. <http://www.cdc.gov/zika/>.

Page 8- Mr. Hood, Hologic, Inc.

No advertising or promotional descriptive printed matter relating to the use of the authorized Aptima® Zika Virus assay may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized Aptima® Zika Virus assay as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

**V. Duration of Authorization**

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,



Robert M. Califf, M.D.  
Commissioner of Food and Drugs

Enclosures

Dated: July 1, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016-16177 Filed 7-7-16; 8:45 am]

BILLING CODE 4164-01-C

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Office of the National Coordinator for Health Information Technology; Announcement of Requirements and Registration for “Blockchain and Its Emerging Role in Healthcare and Health-related Research”

**AGENCY:** Office of the National Coordinator for Health Information Technology, HHS.

*Award Approving Official:* Karen DeSalvo, National Coordinator for Health Information Technology.

**ACTION:** Notice.

**SUMMARY:** The “Blockchain and Its Emerging Role in Healthcare and Health-related Research.” Ideation Challenge solicits white papers on the topic of Blockchain Technology and the potential use for Healthcare. Winners will be invited to present their submission at an upcoming industry-wide workshop co-hosted with the National Institute of Standards and Technology (NIST). The statutory authority for this Challenge is Section 105 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111-358).

**DATES:**

- Submission period begins: June 20.
- Submission period ends: July 29.
- Evaluation begins: August 1.
- Evaluation ends: August 16.
- Winners notified: August 17.
- Winners Announced: August 20.
- Winner Presentation: September 26th–27th.

**FOR FURTHER INFORMATION CONTACT:**

Debbie Bucci, *debbie.bucci@hhs.gov* (preferred), (202) 690-0213.

**SUPPLEMENTARY INFORMATION:**

**Subject of Challenge**

A blockchain is a data structure that can be timed-stamped and signed using a private key to prevent tampering. There are generally three types of blockchain: Public, private and consortium. Potential uses include:

- Digitally sign information,
- Computable enforcement of policies and contracts (smart contracts),
- Management of Internet of Things devices,
- Distributed encrypted storage, and
- Distributed trust.

Proponents of blockchain suggest that it could be used to address concerns

regarding the privacy, security and the scalability of health records. Critics ascertain that it would take enormous processing power and specialized equipment that far exceeds the benefits. Although most would acknowledge blockchain’s potential it is still evolving and maturing, especially with respect to its applicability to the health care.

This Ideation Challenge solicits White Papers on the topic of Blockchain Technology and the Potential for Its Use in Health IT and/or Healthcare Related Research Data.

This nationwide call may be addressed by an individual investigator or a investigator team. Interested parties should submit a White Paper no longer than 10 pages describing the proposed subject. Investigators or co-investigators may participate in no more than three submissions. A limited number of these submissions will be selected. The selection of a White Paper will result in an invitation to present at an upcoming industry-wide workshop on September 26th–27th at NIST Headquarters in Gaithersburg, MD.

**Objective**

The goal of this Ideation Challenge is to solicit White Papers that investigate the relationship between blockchain technology and its use in Health IT and/or Health Related research. The paper should discuss the cryptography and underlying fundamentals of blockchain technology, examine how the use of blockchain can advance industry interoperability needs expressed in the Nationwide Interoperability Roadmap, patient centered outcomes research (PCOR), precision medicine, and other health care delivery needs, as well as provide recommendations for blockchain’s implementation.

In lieu of a monetary award, challenge winners will be provided the opportunity to present their White Papers at an industry-wide “Blockchain & Healthcare Workshop” co-hosted by ONC and NIST.

**Submission Requirements**

Include a White Paper, not longer than ten (10) pages in length, that:

- Educates its audience on the technology; and
- Can be used to determine whether there is a place in Health IT and/or Healthcare related Research for the technology.
- The paper should:
  - Describe the value of blockchain to the health-care system;
  - Identify potential gaps;
  - Discuss the effectiveness of the solution and the solutions ability to function in the “real world.” This

discussion may include information regarding meeting privacy and security standards, implementation and potential performance issues, and cost implications. Risk analysis and mitigation would be appropriate to include here as well.

- Discuss the solution’s link to the stated objectives in the Nationwide Interoperability Roadmap, PCOR, precision medicine and other national health care delivery priorities.

**How To Enter**

Challenge participants will have five (5) weeks from the date of the posting of this Notice. Those submissions must comply with the requirements provided above. Up to eight submissions may be selected as winners. The names of the winners will be posted on the *Challenge.gov* Web site, as well as the names of any participants receiving an honorary mention. Honorary mentions may be given to highly ranked submissions.

**Eligibility Rules for Participating in the Challenge**

To be eligible to win a prize under this Challenge, an individual or entity:

1. Shall have registered to participate in the Challenge under the rules promulgated by the Office of the National Coordinator for Health Information Technology.
2. Shall have complied with all the stated requirements of the Blockchain and Its Emerging Role in Healthcare and Health-related Research Challenge.
3. In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States.
4. May not be a Federal entity or Federal employee acting within the scope of their employment.
5. Shall not be an HHS employee working on their applications or Submissions during assigned duty hours.
6. Shall not be an employee of the Office of the National Coordinator for Health Information Technology.
7. Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.
8. Federal contractors may not use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge Submission.

An individual or entity shall not be deemed ineligible because the