

the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection;

*Title of Information Collection:* National Provider Identifier (NPI) Application and Update Form and Supporting Regulations in 45 CFR 142.408, 45 CFR 162.406, 45 CFR 162.408; *Use:* The National Provider Identifier Application and Update Form is used by health care providers to apply for NPIs and furnish updates to the information they supplied on their initial applications. The form is also used to deactivate their NPIs if necessary. The original application form was approved in February 2005 and has been in use since May 23, 2005. The form is available on paper or can be completed via a web-based process. Health care providers can mail a paper application, complete the application via the web-based process via the National Plan and Provider Enumeration System (NPPES), or have a trusted organization submit the application on their behalf via the Electronic File Interchange (EFI) process. The Enumerator uses the NPPES to process the application and generate the NPI. NPPES is the Medicare contractor tasked with issuing NPIs, and maintaining and storing NPI data. *Form Number:* CMS-10114 (OMB control number: 0938-0931); *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Not-for-profit institutions, and Federal government; *Number of Respondents:* 1,473,185; *Total Annual Responses:* 1,473,185; *Total Annual Hours:* 250,442. (For policy questions regarding this collection contact Kimberly McPhillips at 410-786-5374).

2. *Type of Information Collection Request:* Reinstatement without change of a previously approved collection; *Title of Information Collection:* Hospice Request for Certification and Supporting Regulations; *Use:* The Hospice Request for Certification Form is the identification and screening form used to initiate the certification process and to determine if the provider has sufficient personnel to participate in the Medicare program. *Form Number:* CMS-417 (OMB Control number: 0938-0313); *Frequency:* Annually; *Affected Public:* Private Sector—Business or other for-profits; *Number of Respondents:* 851; *Total Annual Responses:* 851; *Total Annual Hours:* 213. (For policy questions regarding this collection contact Thomas Pryor at 410-786-1332.)

Dated: October 23, 2017.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

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

#### Authorizations of Emergency Use of In Vitro Diagnostic Devices 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 two Emergency Use Authorizations (EUs) (the Authorizations) for in vitro diagnostic devices for detection of the Zika virus in response to the Zika virus outbreak in the Americas. FDA issued these Authorizations under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as requested by Thermo Fisher Scientific and The Center for Infection and Immunity, Columbia University. The Authorizations contain, among other things, conditions on the emergency use of the authorized in vitro diagnostic devices. The Authorizations follow 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 Authorizations, which include an explanation of the reasons for issuance, are reprinted in this document.

**DATES:** The Authorization for Thermo Fisher Scientific is applicable as of August 2, 2017; the Authorization for The Center for Infection and Immunity, Columbia University is effective as of August 11, 2017.

**ADDRESSES:** Submit written requests for single copies of the EUs 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 Authorizations may be sent. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the Authorizations.

#### 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 360(e) 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 Requests for In Vitro Diagnostic Devices for Detection of the Zika Virus

On February 26, 2016, the Secretary of HHS determined that there is a significant potential for a public health emergency that has a significant

<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.

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 5, 2017, Thermo Fisher Scientific requested, and on August 2, 2017, FDA issued, an EUA for the TaqPath Zika Virus Kit (ZIKV), subject to the terms of the Authorization. On July 31, 2017, The Center for Infection and Immunity, Columbia University requested, and on August 11, 2017, FDA issued, an EUA for the CII-ArboViroPlex rRT-PCR assay, subject to the terms of the Authorization.

## III. Electronic Access

An electronic version of this document and the full text of the Authorizations are available on the internet at <https://www.regulations.gov>.

## IV. The Authorizations

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

August 2, 2017

Faith Du  
Regulatory Analyst  
Thermo Fisher Scientific  
6055 Sunol Blvd.  
Pleasanton, CA 94566

Dear Ms. Du:

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 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).<sup>1</sup> 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,<sup>2</sup> 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.

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 U.S. citizens living abroad and that involves Zika virus.<sup>3</sup> Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis

<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...similarly qualified non-U.S. laboratories" as "authorized laboratories."

<sup>2</sup> Available at <http://www.cdc.gov/zika/laboratories/lab-guidance.html> (last updated on July 24, 2017).

<sup>3</sup> As amended by the Pandemic and All-Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section

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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>4</sup>

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 TaqPath Zika Virus Kit (ZIKV) (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 epidemiological 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 TaqPath Zika Virus Kit (ZIKV) 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 TaqPath Zika Virus Kit (ZIKV), when used with the specified instrument(s) 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 TaqPath Zika Virus Kit (ZIKV) 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 TaqPath Zika Virus Kit (ZIKV) for detecting Zika virus and diagnosing Zika virus infection.<sup>5</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 TaqPath Zika Virus Kit (ZIKV) by authorized laboratories for the detection of RNA from Zika virus and diagnosis of Zika virus infection in individuals

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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>4</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).

<sup>5</sup> No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

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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 epidemiological criteria for which Zika virus testing may be indicated).

#### **The Authorized TaqPath Zika Virus Kit (ZIKV)**

The TaqPath Zika Virus Kit (ZIKV) is a lyophilized real-time reverse transcription polymerase chain reaction (rRT-PCR) assay for the qualitative detection of RNA from Zika virus in human serum, urine (collected alongside a patient-matched serum specimen), and other authorized specimen types.

To perform the TaqPath Zika Virus Kit (ZIKV), the RNA is first extracted and purified from the patient specimen. The RNA is then reverse transcribed into cDNA which is amplified using the primer set and detected using the specific probe. The rRT-PCR is performed on the Applied Biosystems QuantStudio Dx Real-time PCR instrument, or other authorized instruments.

The TaqPath Zika Virus Kit (ZIKV) includes the following materials or other authorized materials: Twelve (12) lyophilized strip tubes with each strip comprised of eight (8) assay tubes containing lyophilized one-step RT-PCR reagents: primers, probes, reverse transcription and amplification reagents, reverse transcriptase and Human Peptidylprolyl Isomerase A (PPIA) endogenous control. The kit also contains twelve (12) flat cap strips for sealing the assay tubes following sample addition, and a desiccant pouch to adsorb moisture. The TaqPath Zika Virus Kit (ZIKV) also requires the use of additional materials and ancillary reagents that are not included with the test but are commonly used in clinical laboratories and are described in the authorized TaqPath Zika Virus Kit (ZIKV) Instructions for Use.

The TaqPath Zika Virus Kit (ZIKV) requires the following control materials, or other authorized control materials; all controls listed below must generate expected results in order for a test to be considered valid, as outlined in the TaqPath Zika Virus Kit (ZIKV) Instructions for Use:

- **Zika Virus Positive Control:** Live or inactivated Zika virus – run with each batch of patient specimens. Monitors for failures of nucleic acid extraction and isolation, rRT-PCR reagents and reaction conditions.
- **Negative Control:** DNase and RNase-free water – run with each batch of patient specimens. Monitors for reagent and system contamination.
- **Endogenous Internal Control:** All clinical samples are tested for the Human Peptidylprolyl Isomerase A (PPIA) gene (using the PPIA primer and probe set included in the TaqPath Zika Virus Kit (ZIKV)) to control for specimen quality and as an indicator that nucleic acid resulted from the extraction process.

The above described TaqPath Zika Virus Kit (ZIKV), when labeled consistently with the labeling authorized by FDA entitled “TaqPath Zika Virus Kit (ZIKV) Instructions for Use” (available at <http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm>), which may be revised by Thermo Fisher in consultation with, and with concurrence of, 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

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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 TaqPath Zika Virus Kit (ZIKV) is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients, including pregnant women:

- Fact Sheet for Healthcare Providers: Interpreting TaqPath Zika Virus Kit (ZIKV) Test Results
- Fact Sheet for Patients: Understanding Results from the TaqPath Zika Virus Kit (ZIKV)

As described in Section IV below, Thermo Fisher and its authorized distributors are also authorized to make available additional information relating to the emergency use of the authorized TaqPath Zika Virus Kit (ZIKV) 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 TaqPath Zika Virus Kit (ZIKV) 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 evidence available to FDA, that it is reasonable to believe that the authorized TaqPath Zika Virus Kit (ZIKV) 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 TaqPath Zika Virus Kit (ZIKV), 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 TaqPath Zika Virus Kit (ZIKV) 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 TaqPath Zika Virus Kit (ZIKV) 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 a geographic region with active Zika virus transmissions at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

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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 TaqPath Zika Virus Kit (ZIKV) 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 TaqPath Zika Virus Kit (ZIKV).
- 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:

#### Thermo Fisher and Its Authorized Distributor(s)

- A. Thermo Fisher and its authorized distributor(s) will distribute the authorized TaqPath Zika Virus Kit (ZIKV) with the authorized labeling only to authorized laboratories. Changes to the authorized labeling may be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OIR/CDRH.
- B. Thermo Fisher and its authorized distributor(s) will provide to authorized laboratories the authorized TaqPath Zika Virus Kit (ZIKV) Fact Sheet for Healthcare Providers and the authorized TaqPath Zika Virus Kit (ZIKV) Fact Sheet for Patients.
- C. Thermo Fisher and its authorized distributor(s) will make available on their websites the authorized TaqPath Zika Virus Kit (ZIKV) Fact Sheet for Healthcare Providers and the authorized TaqPath Zika Virus Kit (ZIKV) Fact Sheet for Patients.
- D. Thermo Fisher 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. Thermo Fisher and its authorized distributor(s) will ensure that the authorized

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laboratories using the authorized TaqPath Zika Virus Kit (ZIKV) have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.<sup>6</sup>

- F. Through a process of inventory control, Thermo Fisher and its authorized distributor(s) will maintain records of device usage.
- G. Thermo Fisher and its authorized distributor(s) will collect information on the performance of the test. Thermo Fisher 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 Thermo Fisher becomes aware.
- H. Thermo Fisher and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized TaqPath Zika Virus Kit (ZIKV) that is consistent with, and does not exceed, the terms of this letter of authorization.

#### **Thermo Fisher**

- I. Thermo Fisher will notify FDA of any authorized distributor(s) of the TaqPath Zika Virus Kit (ZIKV), including the name, address, and phone number of any authorized distributor(s).
- J. Thermo Fisher 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 made to this EUA and its authorized accompanying materials (e.g., Fact Sheets, Instructions for Use).
- K. Thermo Fisher may request changes to the authorized TaqPath Zika Virus Kit (ZIKV) Fact Sheet for Healthcare Providers and the authorized TaqPath Zika Virus Kit (ZIKV) Fact Sheet for Patients. Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OIR/CDRH.
- L. Thermo Fisher may request the addition of other instruments for use with the authorized TaqPath Zika Virus Kit (ZIKV). Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OIR/CDRH.
- M. Thermo Fisher may request the addition of other extraction methods for use with the authorized TaqPath Zika Virus Kit (ZIKV). Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OIR/CDRH.

<sup>6</sup> For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Thermo Fisher, other authorized distributor(s), and authorized laboratories consult with the applicable country, state or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition (see <http://www.cdc.gov/zika/>).



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- N. Thermo Fisher may request the addition of other specimen types for use with the authorized TaqPath Zika Virus Kit (ZIKV). Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OIR/CDRH.
- O. Thermo Fisher may request the addition and/or substitution of other control materials for use with the authorized TaqPath Zika Virus Kit (ZIKV). Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OIR/CDRH.
- P. Thermo Fisher may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized TaqPath Zika Virus Kit (ZIKV). Such requests will be made by Thermo Fisher in consultation with, and require concurrence of, DMD/OIR/CDRH.
- Q. Thermo Fisher will assess traceability<sup>7</sup> of the TaqPath Zika Virus Kit (ZIKV) with FDA-recommended reference material(s). After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, Thermo Fisher will update its labeling to reflect the additional testing.
- R. Thermo Fisher will track adverse events and report to FDA under 21 CFR Part 803.

#### Authorized Laboratories

- S. Authorized laboratories will include with reports of the results of the TaqPath Zika Virus Kit (ZIKV) the authorized Fact Sheet for Healthcare Providers 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.
- T. Authorized laboratories will perform the TaqPath Zika Virus Kit (ZIKV) using the KingFisher Flex Purification System (KingFisher) and MagMAX Pathogen RNA/DNA Kit or with other authorized extraction methods.
- U. Authorized laboratories will perform the TaqPath Zika Virus Kit (ZIKV) on the Applied Biosystems QuantStudio Dx Real-time PCR instrument, or other authorized instruments.
- V. Authorized laboratories will perform the TaqPath Zika Virus Kit (ZIKV) on human serum, or urine (collected with a patient-matched serum specimen), or other authorized specimen types.
- W. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.<sup>8</sup>

<sup>7</sup> Traceability refers to tracing analytical sensitivity/reactivity back to a FDA-recommended reference material.

<sup>8</sup> For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Thermo Fisher, other authorized distributor(s), and authorized laboratories consult with the applicable country, state or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition. <http://www.cdc.gov/zika/>.

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- X. Authorized laboratories will collect information on the performance of the test and report to DMD/OIR/CDRH (via email [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)) and Thermo Fisher any suspected occurrence of false positive or false negative results of which they become aware.
- Y. All laboratory personnel using the test should be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

**Thermo Fisher, Its Authorized Distributor(s) and Authorized Laboratories**

- Z. Thermo Fisher, 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**

- AA. All advertising and promotional descriptive printed matter relating to the use of the authorized TaqPath Zika Virus Kit (ZIKV) 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.
- BB. All advertising and promotional descriptive printed matter relating to the use of the authorized TaqPath Zika Virus Kit (ZIKV) 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.

No advertising or promotional descriptive printed matter relating to the use of the authorized TaqPath Zika Virus Kit (ZIKV) may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

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The emergency use of the authorized TaqPath Zika Virus Kit (ZIKV) 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,

A handwritten signature in dark ink, appearing to read 'Scott Gottlieb', is written over a horizontal line.

Scott Gottlieb, M.D.  
Commissioner of Food and Drugs

Enclosures



August 11, 2017

W. Ian Lipkin, MD  
Director  
The Center for Infection and Immunity  
Columbia University  
722 West 168th St., 17<sup>th</sup> Floor  
New York, NY 10032

Dear Dr. Lipkin:

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 The Center for Infection and Immunity, Columbia University's ("Columbia University") CII-ArboViroPlex rRT-PCR assay for the qualitative detection and differentiation of RNA from Zika virus, dengue virus, chikungunya virus, and West Nile virus in serum; and for the qualitative detection of Zika virus RNA in urine (collected alongside a patient-matched serum specimen). The assay is intended for use with specimens collected 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).<sup>1</sup> Assay results are for the identification of Zika, dengue, chikungunya, and West Nile viral RNA. Viral 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,<sup>2</sup> 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.

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 U.S. citizens living abroad and that involves Zika virus.<sup>3</sup> Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis

<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... similarly qualified non-U.S. laboratories" as "authorized laboratories."

<sup>2</sup> Available at <http://www.cdc.gov/zika/laboratories/lab-guidance.html> (last updated on July 24, 2017).

<sup>3</sup> As amended by the Pandemic and All Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section

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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>4</sup>

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 CII-ArboViroPlex rRT-PCR 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 epidemiological 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 CII-ArboViroPlex rRT-PCR 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 CII-ArboViroPlex rRT-PCR assay, when used with the specified instrument(s) 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 CII-ArboViroPlex rRT-PCR 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 CII-ArboViroPlex rRT-PCR assay for detecting Zika virus and diagnosing Zika virus infection.<sup>5</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 CII-ArboViroPlex rRT-PCR assay by authorized laboratories for the qualitative detection and differentiation of RNA from Zika virus, dengue virus,

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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>4</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).

<sup>5</sup> No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

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chikungunya virus, and West Nile virus in serum, and for the qualitative detection of Zika virus RNA in urine (collected alongside a patient-matched serum specimen) 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 epidemiological criteria for which Zika virus testing may be indicated).

#### **The Authorized CII-ArboViroPlex rRT-PCR assay**

The CII-ArboViroPlex rRT-PCR assay is a multiplex one-step real-time reverse transcription polymerase chain reaction (rRT-PCR) assay for the qualitative detection and differentiation of RNA from Zika virus, dengue virus, chikungunya virus, and West Nile virus in serum, and other authorized specimen types. The CII-ArboViroPlex rRT-PCR assay can also be used for the qualitative detection of Zika virus RNA in urine when collected alongside a patient-matched serum specimen and other authorized whole blood derived specimen types.

To perform the CII-ArboViroPlex rRT-PCR assay, the RNA is first extracted and purified from the patient specimen. The RNA is then reverse transcribed into cDNA which is amplified using the primer set and detected using the specific probe. The rRT-PCR is performed on the CFX96 Real-Time PCR Detection System (Bio-Rad), or other authorized instruments.

The CII-ArboViroPlex rRT-PCR assay includes the following materials or other authorized materials:

- ZIKV-MIX, DENV-MIX, CHIKV-MIX, WNV-MIX and RP-MIX vials containing primers and probes for the assay targets and internal control
- ZPC, DPC, CP, WPC, HSC, eHSC, NTC vials containing the positive and negative controls used in the assay
- Diluent vial used to reconstitute dried vials

The CII-ArboViroPlex rRT-PCR assay also requires the use of additional materials and ancillary reagents that are not included with the test but are commonly used in clinical laboratories and are described in the authorized CII-ArboViroPlex rRT-PCR assay Instructions for Use.

The CII-ArboViroPlex rRT-PCR assay requires the following control materials, or other authorized control materials; all controls listed below must generate expected results in order for a test to be considered valid, as outlined in the CII-ArboViroPlex rRT-PCR assay Instructions for Use:

- Human Specimen Control: A human cell culture preparation used as an extraction control and positive control for the RNase P primer and probe set that is extracted and tested concurrently with the test specimens.
- Extracted Human Specimen Control (eHSC): Extracted total nucleic acid from a human cell culture preparation known to contain RNase P (eHSC), but negative for viral targets, is used as a control for performance of RNase P primer/probe set and PCR reagent function.
- Positive Controls for viruses: Run with each batch of patient specimens. Monitors for failures of rRT-PCR reagents and reaction conditions.
  - ZIKV Positive Control (ZPC), synthetic *in vitro* transcribed RNA

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- DENV Positive Control (DPC), synthetic *in vitro* transcribed RNA
- CHIKV Positive Control (CPC), synthetic *in vitro* transcribed RNA
- WNV Positive Control (WPC), synthetic *in vitro* transcribed RNA
- No Template Control (NTC): Sterile, nuclease-free water—two NTC run with each PCR plate. Monitors for reagent and system contamination.
- RNase P control in clinical samples: All clinical samples and HSC are tested for human RNase P, using the RP primer and probe set, to control for specimen quality and as an indicator that nucleic acid resulted from the extraction process.

The above described CII-ArboViroPlex rRT-PCR assay, when labeled consistently with the labeling authorized by FDA entitled “CII-ArboViroPlex rRT-PCR assay Instructions for Use” (available at <http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm>), which may be revised by Columbia University in consultation with, and with concurrence of, 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 CII-ArboViroPlex rRT-PCR assay is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients, including pregnant women:

- Fact Sheet for Healthcare Providers: Interpreting CII-ArboViroPlex rRT-PCR Assay Test Results
- Fact Sheet for Patients: Understanding Results from the CII-ArboViroPlex rRT-PCR Assay

As described in Section IV below, Columbia University and its authorized distributors are also authorized to make available additional information relating to the emergency use of the authorized CII-ArboViroPlex rRT-PCR 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 CII-ArboViroPlex rRT-PCR 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 evidence available to FDA, that it is reasonable to believe that the authorized CII-ArboViroPlex rRT-PCR 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 CII-

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ArboViroPlex rRT-PCR 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 CII-ArboViroPlex rRT-PCR 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 CII-ArboViroPlex rRT-PCR 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 a geographic region with active Zika virus transmissions at the time of travel, or other epidemiological 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 CII-ArboViroPlex rRT-PCR 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 CII-ArboViroPlex rRT-PCR 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:



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**Columbia University and Its Authorized Distributor(s)**

- A. Columbia University and its authorized distributor(s) will distribute the authorized CII-ArboViroPlex rRT-PCR assay with the authorized labeling only to authorized laboratories. Changes to the authorized labeling may be made by Columbia University in consultation with, and require concurrence of, DMD/OIR/CDRH.
- B. Columbia University and its authorized distributor(s) will provide to authorized laboratories the authorized CII-ArboViroPlex rRT-PCR assay Fact Sheet for Healthcare Providers and the authorized CII-ArboViroPlex rRT-PCR assay Fact Sheet for Patients.
- C. Columbia University and its authorized distributor(s) will make available on their websites the authorized CII-ArboViroPlex rRT-PCR assay Fact Sheet for Healthcare Providers and the authorized CII-ArboViroPlex rRT-PCR assay Fact Sheet for Patients.
- D. Columbia University 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. Columbia University and its authorized distributor(s) will ensure that the authorized laboratories using the authorized CII-ArboViroPlex rRT-PCR assay have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.<sup>6</sup>
- F. Through a process of inventory control, Columbia University and its authorized distributor(s) will maintain records of device usage.
- G. Columbia University and its authorized distributor(s) will collect information on the performance of the test. Columbia University 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 Columbia University becomes aware.
- H. Columbia University and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized CII-ArboViroPlex rRT-PCR assay that is consistent with, and does not exceed, the terms of this letter of authorization.

**Columbia University**

- I. Columbia University will notify FDA of any authorized distributor(s) of the CII-

<sup>6</sup> For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Columbia University, other authorized distributor(s), and authorized laboratories consult with the applicable country, state, or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition (see <http://www.cdc.gov/zika/>).

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ArboViroPlex rRT-PCR assay, including the name, address, and phone number of any authorized distributor(s).

- J. Columbia University 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 made to this EUA and its authorized accompanying materials (e.g., Fact Sheets, Instructions for Use).
- K. Columbia University may request changes to the authorized CII-ArboViroPlex rRT-PCR assay Fact Sheet for Healthcare Providers and the authorized CII-ArboViroPlex rRT-PCR assay Fact Sheet for Patients. Such requests will be made by Columbia University in consultation with, and require concurrence of, DMD/OIR/CDRH.
- L. Columbia University may request the addition of other instruments for use with the authorized CII-ArboViroPlex rRT-PCR assay. Such requests will be made by Columbia University in consultation with, and require concurrence of, DMD/OIR/CDRH.
- M. Columbia University may request the addition of other extraction methods for use with the authorized CII-ArboViroPlex rRT-PCR assay. Such requests will be made by Columbia University in consultation with, and require concurrence of, DMD/OIR/CDRH.
- N. Columbia University may request the addition of other specimen types for use with the authorized CII-ArboViroPlex rRT-PCR assay. Such requests will be made by Columbia University in consultation with, and require concurrence of, DMD/OIR/CDRH.
- O. Columbia University may request the addition and/or substitution of other control materials for use with the authorized CII-ArboViroPlex rRT-PCR assay. Such requests will be made by Columbia University in consultation with, and require concurrence of, DMD/OIR/CDRH.
- P. Columbia University may request the addition and/or substitution of other ancillary reagents and materials for use with the authorized CII-ArboViroPlex rRT-PCR assay. Such requests will be made by Columbia University in consultation with, and require concurrence of, DMD/OIR/CDRH.
- Q. Columbia University will assess traceability<sup>7</sup> of the CII-ArboViroPlex rRT-PCR assay with FDA-recommended reference material(s). After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, Columbia University will update its labeling to reflect the additional testing.
- R. Columbia University will track adverse events and report to FDA under 21 CFR Part 803.

#### **Authorized Laboratories**

<sup>7</sup> *Traceability* refers to tracing analytical sensitivity/reactivity back to a FDA-recommended reference material.

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- S. Authorized laboratories will include with reports of the results of the CII-ArboViroPlex rRT-PCR assay the authorized Fact Sheet for Healthcare Providers 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.
- T. Authorized laboratories will perform the CII-ArboViroPlex rRT-PCR assay using the NucliSENS easyMAG automated extraction platform (bioMérieux) or with other authorized extraction methods.
- U. Authorized laboratories will perform the CII-ArboViroPlex rRT-PCR assay on the CFX96 Real-Time PCR Detection System (Bio-Rad), or other authorized instruments.
- V. Authorized laboratories will perform the CII-ArboViroPlex rRT-PCR assay for Zika virus, dengue virus, chikungunya virus, and West Nile virus on human serum or other authorized specimen types.
- W. Authorized laboratories will perform the CII-ArboViroPlex rRT-PCR assay for Zika virus on human urine when collected alongside a patient-matched serum specimen and other authorized whole blood derived specimen types.
- X. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.<sup>8</sup>
- Y. Authorized laboratories will collect information on the performance of the test and report to DMD/OIR/CDRH (via email: [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)) and Columbia University any suspected occurrence of false positive or false negative results of which they become aware.
- Z. All laboratory personnel using the test should be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

**Columbia University, Its Authorized Distributor(s), and Authorized Laboratories**

- AA. Columbia University, 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**

- BB. All advertising and promotional descriptive printed matter relating to the use of the

<sup>8</sup> For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Columbia University, other authorized distributor(s), and authorized laboratories consult with the applicable country, state, or territory health department(s). According to CDC, Zika virus disease is a nationally notifiable condition (<http://www.cdc.gov/zika/>).

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authorized CII-ArboViroPlex rRT-PCR 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.

CC. All advertising and promotional descriptive printed matter relating to the use of the authorized CII-ArboViroPlex rRT-PCR 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 and differentiation of RNA from Zika virus, dengue virus, chikungunya virus, and West Nile virus, 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.

No advertising or promotional descriptive printed matter relating to the use of the authorized CII-ArboViroPlex rRT-PCR 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 CII-ArboViroPlex rRT-PCR 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,



Scott Gottlieb, M.D.  
Commissioner of Food and Drugs

Enclosures

Dated: October 20, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017–23224 Filed 10–25–17; 8:45 am]

BILLING CODE 4164–01–C

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2017–N–5818]

#### Pharmacy Compounding Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

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

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Pharmacy Compounding Advisory Committee (PCAC). The general function of the committee is to provide advice on scientific, technical, and medical issues concerning drug compounding under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), and, as required, any other product for which FDA has regulatory responsibility, and to make appropriate recommendations to the Agency. The meeting will be open to the public.

**DATES:** The meeting will be held on November 20, 2017, from 8:30 a.m. to 5 p.m. and November 21, 2017, from 8:30 a.m. to 11:30 a.m.

**ADDRESSES:** FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions, including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2017–N–5818. The docket will close on November 17, 2017. Submit either electronic or written comments on this public meeting by November 17, 2017. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before November 17, 2017. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of

November 17, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before November 3, 2017, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

You may submit comments as follows:

#### *Electronic Submissions*

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- **Mail/Hand delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

**Instructions:** All submissions received must include the Docket No. FDA–2017–N–5818 for “Pharmacy Compounding Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.” Received comments will be placed in

the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions**—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

**Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

#### **FOR FURTHER INFORMATION CONTACT:**

Cindy Chee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: [PCAC@fda.hhs.gov](mailto:PCAC@fda.hhs.gov), or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting