

The following is a summary of the estimated annual burden hours for recalling firms (manufacturers, processors, and distributors) to comply

with the reporting requirements of FDA's recall regulations, recognizing that there may be a vast difference in the information collection and reporting

time involved in different recalls of FDA's regulated products. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Firm initiated recall (§ 7.46) and recall communications (§ 7.49)	2,853	1	2,853	25	71,325
Recall status reports (§ 7.53)	2,853	13	37,089	10	370,890
Termination of a recall (§ 7.55(b))	2,853	1	2,853	10	28,530
Total					470,745

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

I. Total Annual Reporting

A. Firm Initiated Recall and Recall Communications

We request firms that voluntarily remove or correct foods and drugs (human or animal), cosmetics, medical devices, biologics, and tobacco to immediately notify the appropriate FDA District Office of such actions. The firm is to provide complete details of the recall reason, risk evaluation, quantity produced, distribution information, firms' recall strategy, and a contact official as well as requires firms to notify their direct accounts of the recall and to provide recipients with a ready means of reporting to the recalling firm. Under these portions of the collection of information, the Agency estimates it will receive 2,853 responses annually based on the average number of recalls over the last 3 fiscal years. The number of responses multiplied by the number of respondents equals 2,853. The average burden hours, 25, multiplied by

total number of annual responses equal 71,325.

B. Recall Status Reports

We request that recalling firms provide periodic status reports so FDA can ascertain the progress of the recall. This request only applies to firms with active recalls, and periodic status reports are estimated to be reported every 2 to 4 weeks. This collection of information will generate approximately 2,853 responses annually, based on the average number of recalls over the last 3 fiscal years, 8,560. The number of respondents multiplied by the number of responses per respondents (13) equals a total number of annual responses of 37,089. The total number of responses, 37,089, multiplied by an average burden hours of 10 per response equals a total of 370,890 total hours.

C. Termination of a Recall

We provide the firms an opportunity to request in writing that FDA end the

recall. The Agency estimates it will receive 2,853 responses annually based on the average number of terminations over the past 3 fiscal years. The total annual responses of 2,853 multiplied by the average burden hours of 10 per response equals a total number of hours of 28,530.

II. Total Annual Third-Party Disclosure Burden

Recall Communications. We request that firms notify their consignees of the recall and to provide recipients with a ready means of reporting to the recalling firm. Under this portion of the collection of information, the Agency estimates firms will provide 4,433,562 notifications annually based on the number of respondents/consignees (2,853) multiplied by the number of disclosures per respondent (1,554). The total number of hours is 248,279 (based on 4,433,562 multiplied by 0.056 hours).

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN ¹

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Recall communications (§ 7.49)	2,853	1,554	4,433,562	0.056	248,279

¹ There are no capital costs or operating and maintenance costs associated with this information collections.

FDA regulates many different types of products including, but not limited to, medical products, food and feed, cosmetics, and tobacco products. FDA notes that not all third-party disclosures provided by firms to their consignees are similar in nature and may entail different methods and mediums of communication. FDA estimates the burden for third-party disclosure per recall event to be an average of 25 hours. This burden estimate factored out to the average number of consignees per recall

(1,554) results in a burden per disclosure estimate of approximate hours (25 hours per recall/1,554 disclosures/recall = 0.056 hours).

Dated: November 9, 2017.
Anna K. Abram,
Deputy Commissioner for Policy, Planning, Legislation, and Analysis.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6152]

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 (EUAs) (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 Siemens Healthcare Diagnostics, Inc. and Chembio Diagnostic Systems, Inc. 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 Siemens Healthcare Diagnostics, Inc. is effective as of September 18, 2017; the Authorization for Chembio Diagnostic Systems, Inc. is effective as of September 27, 2017.

ADDRESSES: Submit written requests for single copies of the EUAs 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 ensure 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), FDA¹ 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

¹ 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.

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 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 September 8, 2017, Siemens Healthcare Diagnostics, Inc. requested, and on September 18, 2017, FDA issued, an EUA for the ADVIA Centaur Zika test, subject to the terms of the Authorization. On September 14, 2017, Chembio Diagnostic Systems, Inc. requested, and on September 27, 2017, FDA issued an EUA for the DPP Zika IgM Assay System, 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) follow and provide an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act:

BILLING CODE 4164-01-P



September 18, 2017

Matthew Gee, M.Sc.
Senior Manager, Regulatory Affairs
Siemens Healthcare Diagnostics Inc.
511 Benedict Avenue
Tarrytown, NY 10591-5097

Dear Mr. Gee:

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 Siemens Healthcare Diagnostics Incorporated's ("Siemens Healthcare Diagnostics") ADVIA Centaur Zika test for the presumptive qualitative detection of Zika virus IgM antibodies in human serum and plasma (potassium EDTA or lithium heparin, each collected alongside a patient-matched serum specimen) specimens collected from individuals meeting the 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 or moderate complexity tests, or by similarly qualified non-U.S. laboratories,¹ pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3). Specimens from symptomatic patients or returning travelers from endemic areas should not be collected prior to 8 days after onset of symptoms or risk of exposure, respectively. Where there are presumptive Zika positive results from the ADVIA Centaur Zika test, confirmation of the presence of anti-Zika IgM antibodies requires additional testing, as described in the Scope of Authorization of this letter (Section II) and in the authorized Instructions for Use document, and/or consideration alongside test results for other patient-matched specimens using the latest CDC testing algorithms for the diagnosis of Zika virus infection.²

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

¹ 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 or moderate complexity tests, or by similarly qualified non-U.S. laboratories" as "authorized laboratories."

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

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involves Zika virus.³ 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).⁴

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 ADVIA Centaur Zika test (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 presumptive qualitative 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 ADVIA Centaur Zika test for the presumptive qualitative detection of Zika virus IgM antibodies 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 ADVIA Centaur Zika test may be effective in diagnosing recent Zika virus infection, and that the known and potential benefits of the ADVIA Centaur Zika test for diagnosing Zika virus infection outweigh the known and potential risks of such product, when, for presumptive Zika positive results, additional testing (as described in the Instructions for Use document) is performed and/or test results for other patient-matched specimens (using the latest CDC testing algorithms for the diagnosis of Zika virus infection) are considered; and
3. There is no adequate, approved, and available alternative to the emergency use of the ADVIA Centaur Zika test for diagnosing Zika virus infection.⁵

³ 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.

⁴ 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).

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

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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 ADVIA Centaur Zika test by authorized laboratories for the presumptive qualitative detection of Zika virus IgM antibodies 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) when, for presumptive Zika positive results, additional testing (as described in the Instructions for Use document) is performed⁶ and/or test results for other patient-matched specimens (using the latest CDC testing algorithms for the diagnosis of Zika virus infection) are considered.

The Authorized ADVIA Centaur Zika Test

The ADVIA Centaur Zika test is an immunoassay for the *in vitro* presumptive qualitative detection of Zika virus IgM antibodies in human serum and potassium EDTA or lithium heparin plasma (each collected alongside a patient-matched serum specimen) specimens and other authorized specimen types from individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

The ADVIA Centaur Zika test is comprised of the ADVIA Centaur Zika Ab and ADVIA Centaur Zika IgM assays. All ADVIA Centaur Zika Ab reactive samples must be tested with the ADVIA Centaur Zika IgM assay.

The ADVIA Centaur Zika Ab assay is an antibody capture immunoassay using a 2-pass format. In the first pass, coated microparticles (solid phase) are added to the cuvette, binding antibodies from the patient sample. The captured antibodies are washed and resuspended. In the second pass, the anti-Zika antibodies captured on the Solid Phase are detected by the addition of NS1 antigen labeled with acridinium ester (Lite Reagent) for chemiluminescent detection.

The ADVIA Centaur Zika IgM assay is an IgM capture immunoassay using a 2-pass format. In the first pass, the microparticles, coated with anti-human IgM monoclonal antibody (Solid Phase), are added to the cuvette, binding IgM from the patient sample. The captured IgM antibodies are washed and resuspended. In the second pass, the anti-Zika IgM captured on the Solid Phase is detected by the addition of NS1 antigen labeled with acridinium ester (Lite Reagent) for chemiluminescent detection.

The ADVIA Centaur Zika test includes use of the ADVIA Centaur XP and/or ADVIA Centaur XPT immunoassay analyzers, and other authorized instruments.

⁶ As discussed in the Instructions for Use document, the additional testing for presumptive Zika IgM positive results is to be performed using the latest CDC testing algorithms for the diagnosis of Zika virus infection.

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The ADVIA Centaur Zika test requires the following control materials and assay calibrators:

- ADVIA Centaur ZikaM low calibrator
- ADVIA Centaur ZikaM high calibrator
- ADVIA Centaur ZikaM Calibrator Assigned Value Card and barcode labels
- ADVIA Centaur ZikaM Master Curve Card
- ADVIA Centaur ZikaM Quality Control
 - 2 x 2 mL negative control
 - 2 x 2 mL positive control
 - Lot-specific assigned value card and barcode labels
- ADVIA Centaur ZikaAb Quality Control
 - 2 x 2 mL negative control
 - 2 x 2 mL positive control
 - Lot-specific assigned value card and barcode labels

Quality control requirements should be followed in conformance with local, state, and federal regulations or accreditation requirements and the user laboratory's standard quality control procedures.

The ADVIA Centaur Zika test also requires the use of additional materials and ancillary reagents commonly used in clinical laboratories and that are described in the authorized ADVIA Centaur Zika test Instructions for Use.

The above described ADVIA Centaur Zika test, when labeled consistently with the labeling authorized by FDA entitled "ADVIA Centaur Zika test" (available at <http://www.fda.gov/MedicalDevices/%20Safety/EmergencySituations/ucm161496.htm>), 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. This labeling may be revised by Siemens Healthcare Diagnostics 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).

The above described ADVIA Centaur Zika test 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:

- Fact Sheet for Healthcare Providers: Interpreting ADVIA Centaur Zika Test Results
- Fact Sheet for Patients: Understanding Results from the ADVIA Centaur Zika Test

Other Fact Sheets developed by Siemens Healthcare Diagnostics in consultation with, and with concurrence of, the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OIR/CDRH may be authorized to accompany the above described ADVIA Centaur Zika test and to be made available to healthcare providers and patients.

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As described in Section IV below, Siemens Healthcare Diagnostics is also authorized to make available additional information relating to the emergency use of the authorized ADVIA Centaur Zika test 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 ADVIA Centaur Zika test in the specified population, when used for presumptive qualitative detection of Zika virus IgM antibodies 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 ADVIA Centaur Zika test may be effective in the diagnosis of recent 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 ADVIA Centaur Zika test, when used 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 ADVIA Centaur Zika test 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 ADVIA Centaur Zika test described above is authorized to 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 transmission 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 ADVIA Centaur Zika test during the duration of this EUA:

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- 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 ADVIA Centaur Zika test.
- 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:

Siemens Healthcare Diagnostics and Its Authorized Distributor(s)

- A. Siemens Healthcare Diagnostics and its authorized distributor(s) will distribute the authorized ADVIA Centaur Zika test with the authorized labeling only to authorized laboratories. Siemens Healthcare Diagnostics may request changes to the authorized labeling. Such requests will be made by Siemens Healthcare Diagnostics in consultation with, and require concurrence of, DMD/OIR/CDRH.
- B. Siemens Healthcare Diagnostics and its authorized distributor(s) will provide to authorized laboratories the authorized ADVIA Centaur Zika test Fact Sheet for Healthcare Providers and the authorized ADVIA Centaur Zika test Fact Sheet for Patients, and any additional ADVIA Centaur Zika test Fact Sheets for Healthcare Providers and Patients that OCET/OCS/OC and DMD/OIR/CDRH may authorize.
- C. Siemens Healthcare Diagnostics and its authorized distributor(s) will make available on their websites the authorized ADVIA Centaur Zika test Fact Sheet for Healthcare Providers and the authorized ADVIA Centaur Zika test Fact Sheet for Patients, and any additional ADVIA Centaur Zika test Fact Sheets for Healthcare Providers and Patients that OCET/OCS/OC and DMD/OIR/CDRH may authorize.
- D. Siemens Healthcare Diagnostics and its authorized distributor(s) will inform authorized laboratories and relevant public health authority(ies) of this EUA, including the terms and conditions herein.

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- E. Siemens Healthcare Diagnostics and its authorized distributor(s) will ensure that authorized laboratories using the authorized ADVIA Centaur Zika test have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.⁷
- F. Through a process of inventory control, Siemens Healthcare Diagnostics and its authorized distributor(s) will maintain records of device usage.
- G. Siemens Healthcare Diagnostics and its authorized distributor(s) will collect information on the performance of the test. Siemens Healthcare Diagnostics 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 Siemens Healthcare Diagnostics becomes aware.
- H. Siemens Healthcare Diagnostics and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized ADVIA Centaur Zika test that is consistent with, and does not exceed, the terms of this letter of authorization.

Siemens Healthcare Diagnostics

- I. Siemens Healthcare Diagnostics will notify FDA of any authorized distributor(s) of the ADVIA Centaur Zika test, including the name, address, and phone number of any authorized distributor(s).
- J. Siemens Healthcare Diagnostics 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. Siemens Healthcare Diagnostics may request changes to the authorized ADVIA Centaur Zika test Fact Sheet for Healthcare Providers and the authorized ADVIA Centaur Zika test Fact Sheet for Patients. Siemens Healthcare Diagnostics may also develop new ADVIA Centaur Zika test Fact Sheets for Healthcare Providers and Patients, if appropriate, and may request changes to such Fact Sheets. All such requests listed in this condition of authorization will be made by Siemens Healthcare Diagnostics in consultation with, and require concurrence of, OCET/OCS/OC and DMD/OIR/CDRH.
- L. Siemens Healthcare Diagnostics may request the addition of other instruments for use with the authorized ADVIA Centaur Zika test. Such requests will be made by Siemens Healthcare Diagnostics in consultation with, and require concurrence of, DMD/OIR/CDRH.

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

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- M. Siemens Healthcare Diagnostics may request the addition of other ancillary reagents for use with the authorized ADVIA Centaur Zika test. Such requests will be made by Siemens Healthcare Diagnostics in consultation with, and require concurrence of, DMD/OIR/CDRH.
- N. Siemens Healthcare Diagnostics may request the addition of other specimen types for use with the authorized ADVIA Centaur Zika test. Such requests will be made by Siemens Healthcare Diagnostics in consultation with, and require concurrence of, DMD/OIR/CDRH.
- O. Siemens Healthcare Diagnostics may request the addition of other control materials for use with the authorized ADVIA Centaur Zika test. Such requests will be made by Siemens Healthcare Diagnostics in consultation with, and require concurrence of, DMD/OIR/CDRH.
- P. Siemens Healthcare Diagnostics may request substitution for or changes to the authorized materials used in the detection process of the human anti-Zika IgM in the specimen. Such requests will be made by Siemens Healthcare Diagnostics in consultation with, and require concurrence of, DMD/OIR/CDRH.
- Q. Siemens Healthcare Diagnostics will track adverse events and report to FDA under 21 CFR Part 803.
- R. Siemens Healthcare Diagnostics will evaluate the performance of the ADVIA Centaur Zika test with any FDA-recommended or established panel(s) of characterized clinical specimens, and will submit that performance data to FDA. After DMD/OIR/CDRH's review of and concurrence with the data, Siemens Healthcare Diagnostics will update its labeling, in consultation with, and with concurrence of, DMD/OIR/CDRH, to reflect the additional testing.
- S. Siemens Healthcare Diagnostics will assess traceability⁸ of the ADVIA Centaur Zika test with any FDA-recommended reference material(s). After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, Siemens Healthcare Diagnostics will update its labeling to reflect the additional testing.
- T. Siemens Healthcare Diagnostics will track the performance of the ADVIA Centaur Zika test and report to DMD/OIR/CDRH on a semi-annual basis.

⁸ Traceability refers to tracing analytical sensitivity/reactivity back to a FDA-recommended reference material.

Page 9 – Mr. Gee, Siemens Healthcare Diagnostics Inc.

Authorized Laboratories

- U. Authorized laboratories will include with reports of the results of the ADVIA Centaur Zika test the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients, and any additional ADVIA Centaur Zika test Fact Sheets for Healthcare Providers and Patients that OCET/OCS/OC and DMD/OIR/CDRH may authorize. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- V. Authorized laboratories will perform the ADVIA Centaur Zika test on only human serum or plasma (potassium EDTA or lithium heparin, each collected alongside a patient-matched serum specimen) specimens or with other authorized specimen types.
- W. If non-serum specimens are used with the ADVIA Centaur Zika test, authorized laboratories responsible for collecting the patient specimen must collect a patient-matched serum specimen, or if this is not possible, an additional serum specimen must be collected soon after the original specimen. This is to facilitate any additional testing that may be required, using the latest CDC testing algorithms for the diagnosis of Zika virus infection, to confirm Zika virus infection.
- X. Authorized laboratories must read the results of the ADVIA Centaur Zika test on the ADVIA Centaur XP, ADVIA Centaur XPT, or on other authorized instruments.
- Y. Within the United States and its territories, authorized laboratories will report all Presumptive Zika Positive results to Siemens Healthcare Diagnostics.
- Z. Authorized laboratories will report only the final interpretation of algorithm test results (Presumptive Zika Positive, Negative for IgM antibodies to Zika virus, or Negative for antibodies to Zika virus), as described in the Instructions for Use document, to healthcare providers.
- AA. Authorized laboratories will have a process in place to assure that, for Presumptive Zika Positive results, additional testing (as described in the Instructions for Use document) is performed and/or test results for other patient-matched specimens, using the latest CDC testing algorithms for the diagnosis of Zika virus infection, are considered.
- BB. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.⁹

⁹ For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Siemens Healthcare Diagnostics and authorized laboratories consult with the applicable country, state, or territory health department(s). According to CDC, Zika is a nationally notifiable condition (see <http://www.cdc.gov/zika/>).

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- CC. Authorized laboratories will collect information on the performance of the ADVIA Centaur Zika test and report to DMD/OIR/CDRH (via email CDRH-EUA-Reporting@fda.hhs.gov) and Siemens Healthcare Diagnostics any suspected occurrence of false negative and false positive results and significant deviations from the established performance characteristics of which they become aware.
- DD. All laboratory personnel using the assay must be appropriately trained in performing and interpreting immunoassay techniques, use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the ADVIA Centaur Zika test.

Siemens Healthcare Diagnostics, Its Authorized Distributor(s), and Authorized Laboratories

- EE. Siemens Healthcare Diagnostics, 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

- FF. All advertising and promotional descriptive printed matter relating to the use of the authorized ADVIA Centaur Zika test shall be consistent with the authorized 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.
- GG. All advertising and promotional descriptive printed matter relating to the use of the authorized ADVIA Centaur Zika test 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 diagnosis of Zika virus infection and 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.

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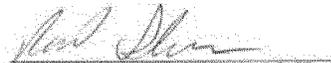
No advertising or promotional descriptive printed matter relating to the use of the authorized ADVIA Centaur Zika test may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized ADVIA Centaur Zika test 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,


Rachel Sherman, M.D., M.P.H.
Principal Deputy Commissioner

Enclosures



September 27, 2017

Thomas D. Ippolito
Vice President, Clinical and Regulatory Affairs
Chembio Diagnostic Systems, Inc.
3661 Horseblock Road
Medford, NY 11763

Dear Mr. Ippolito:

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 Chembio Diagnostic Systems, Inc.'s ("Chembio") DPP Zika IgM Assay System for the presumptive qualitative detection of Zika virus IgM antibodies in human serum (plain or separation gel) and fingerstick whole blood, EDTA venous whole blood, or EDTA plasma (each collected alongside a patient-matched serum specimen) specimens collected from individuals meeting the Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated), by laboratories in the United States that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high or moderate complexity tests, or by similarly qualified non-U.S. laboratories,¹ pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3). Specimens from symptomatic patients or returning travelers from endemic areas should not be collected prior to 8 days after onset of symptoms or risk of exposure, respectively. Where there are reactive results (i.e., presumptive Zika IgM positive), from the DPP Zika IgM Assay System, confirmation of the presence of anti-Zika IgM antibodies requires additional testing, as described in the Scope of Authorization of this letter (Section II) and in the authorized Instructions for Use document, and/or consideration alongside test results for other patient-matched specimens using the latest CDC testing algorithms for the diagnosis of Zika virus infection.²

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

¹ For ease of reference, this letter will refer to "laboratories in the United States that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high or moderate complexity tests, or by similarly qualified non-U.S. laboratories" as "authorized laboratories."

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

Page 2 – Mr. Ippolito, Chembio Diagnostic Systems, Inc.

national security or the health and security of United States citizens living abroad and that involves Zika virus.³ 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).⁴

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 DPP Zika IgM Assay System (as described in the Scope of Authorization section of this letter (Section II)) in individuals meeting CDC Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., 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 presumptive qualitative 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 DPP Zika IgM Assay System for the presumptive qualitative detection of Zika virus IgM antibodies 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 DPP Zika IgM Assay System may be effective in diagnosing recent Zika virus infection, and that the known and potential benefits of the DPP Zika IgM Assay System for diagnosing Zika virus infection outweigh the known and potential risks of such product, when, for reactive results (i.e., presumptive Zika IgM positive), additional testing (as described in the Instructions for Use document) is performed and/or test results for other patient-matched specimens (using the latest CDC testing algorithms for the diagnosis of Zika virus infection) are considered; and
3. There is no adequate, approved, and available alternative to the emergency use of the DPP Zika IgM Assay System for diagnosing Zika virus infection.⁵

³ 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.

⁴ 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).

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

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 DPP Zika IgM Assay System by authorized laboratories for the presumptive qualitative detection of Zika virus IgM antibodies in individuals meeting CDC Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., 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) when, for reactive results (i.e., presumptive Zika IgM positive), additional testing (as described in the Instructions for Use document) is performed⁶ and/or test results for other patient-matched specimens (using the latest CDC testing algorithms for the diagnosis of Zika virus infection) are considered.

The Authorized DPP Zika IgM Assay System

The DPP Zika IgM Assay System is a single-use immunochromatographic lateral flow assay for the *in vitro* presumptive qualitative detection of Zika virus IgM antibodies in human serum (plain or separation gel) and fingerstick whole blood, EDTA venous whole blood, or EDTA plasma (each collected alongside a patient-matched serum specimen) specimens and other authorized specimen types from individuals meeting CDC Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., 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 DPP Zika IgM Assay System employs a dual path platform technology and consists of a sample path that distributes sample onto a reagent strip containing a TEST (T) area and a CONTROL (C) area in the test-control window of the test device. The reagent strip is for the detection of ZIKV IgM antibodies. The test procedure is based on capturing human IgM antibodies from the patient specimen in the TEST (T) area that is functionalized with Zika NS1 antigens followed by the addition of an antibody-binding colored conjugate. The patient specimen is collected and then diluted with sample buffer before being applied to the SAMPLE+BUFFER Well#1 of the DPP Zika Test Device. The specimen migrates along the sample path membrane and is delivered to the TEST (T) area of the reagent strip, where Zika NS1 antigens are immobilized. Zika-specific antibodies, if present in the sample, bind to the immobilized NS1 antigens in the TEST (T) area, while non-specific antibodies bind to the Protein A in the CONTROL (C) area. Running buffer is then added into the BUFFER Well #2, which hydrates the dried antibody-binding colored conjugate causing it to migrate to the TEST area. ZIKV IgM antibodies bound to the TEST (T) area will capture the antibody-binding colored conjugate and detection is performed using the Chembio DPP Micro Reader, or other authorized instruments, that uses assay-specific algorithms to verify the presence of the control line and measure color intensity in the TEST (T) area position; it interprets the results using

⁶ As discussed in the Instructions for Use document, the additional testing for reactive results (i.e., presumptive Zika IgM positive) is to be performed using the latest CDC testing algorithms for the diagnosis of Zika virus infection.

Page 4 – Mr. Ippolito, Chembio Diagnostic Systems, Inc.

assay-specific cut-off values, and reports a reactive, nonreactive, or invalid result along with a numerical intensity value for the IgM test line.

One of the limitations of this test is the possibility of false positive results in patients with a history of infection with other flaviviruses. For reactive results (i.e., presumptive Zika IgM positive), additional testing (as described in the Instructions for Use document) and/or consideration of test results for other patient-matched specimens, using the latest CDC testing algorithms for the diagnosis of Zika virus infection, is therefore required to confirm Zika virus infection.

The DPP Zika IgM Assay System includes use of the DPP Zika Test Device kit and the DPP Micro Reader kit which are comprised of the following materials and instruments, or other authorized materials and instruments:

- The DPP Zika Test Device kit: individually pouched DPP Zika Test Devices each with a desiccant pouch, Microsafe tubes, sample vials, transfer pipets, DPP Zika IgM Sample Buffer- BLUE Cap, DPP Zika IgM Running Buffer – YELLOW Cap, product insert (authorized Instructions for Use) and a quick reference guide.
- The DPP Micro Reader kit: DPP Micro Reader, holder case, USB cable and user manual.

The DPP Zika IgM Assay System requires the following control materials or other authorized control materials, which are not provided with the test:

- DPP Zika IgM Assay Control Pack: DPP Zika Reactive Control, DPP Nonreactive Control and product insert. The assay controls are used to verify and assess the assay performance and verify the user's ability to properly perform the test and to interpret the results.

Quality control requirements should be followed in conformance with local, state, and federal regulations or accreditation requirements and the user laboratory's standard quality control procedures.

The DPP Zika IgM Assay System also requires the use of additional materials and ancillary reagents commonly used in clinical laboratories and that are described in the authorized DPP Zika IgM Assay System Instructions for Use.

The above described DPP Zika IgM Assay System, when labeled consistently with the labeling authorized by FDA entitled "DPP Zika IgM Assay System," "DPP Micro Reader," "DPP Zika IgM Assay Control Pack," and "DPP Zika IgM Assay System Quick Reference Instructions," (available at

<http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm>), 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. This labeling may be revised by Chembio 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).

Page 5 – Mr. Ippolito, Chembio Diagnostic Systems, Inc.

The above described DPP Zika IgM Assay System 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:

- Fact Sheet for Healthcare Providers: Interpreting DPP Zika IgM Assay System Results
- Fact Sheet for Patients: Understanding Results from the DPP Zika IgM Assay System

Other Fact Sheets developed by Chembio in consultation with, and with concurrence of, the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and DMD/OIR/CDRH may be authorized to accompany the above described DPP Zika IgM Assay System and to be made available to healthcare providers and patients.

As described in Section IV below, Chembio is also authorized to make available additional information relating to the emergency use of the authorized DPP Zika IgM Assay System 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 DPP Zika IgM Assay System in the specified population, when used for presumptive qualitative detection of Zika virus IgM antibodies 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 DPP Zika IgM Assay System may be effective in the diagnosis of recent 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 DPP Zika IgM Assay System, when used 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 DPP Zika IgM Assay System 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 DPP Zika IgM Assay System described above is authorized to diagnose Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., 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).

Page 6 – Mr. Ippolito, Chembio Diagnostic Systems, Inc.

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 DPP Zika IgM Assay System 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 DPP Zika IgM Assay System.
- 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:

Chembio and Its Authorized Distributor(s)

- A. Chembio and its authorized distributor(s) will distribute the authorized DPP Zika IgM Assay System with the authorized labeling only to authorized laboratories. Chembio may request changes to the authorized labeling. Such requests will be made by Chembio in consultation with, and require concurrence of, DMD/OIR/CDRH.
- B. Chembio and its authorized distributor(s) will provide to authorized laboratories the authorized DPP Zika IgM Assay System Fact Sheet for Healthcare Providers and the authorized DPP Zika IgM Assay System Fact Sheet for Patients, and any additional DPP Zika IgM Assay System Fact Sheets for Healthcare Providers and Patients that OCET/OCS/OC and DMD/OIR/CDRH may authorize.
- C. Chembio and its authorized distributor(s) will make available on their websites the authorized DPP Zika IgM Assay System Fact Sheet for Healthcare Providers and the authorized DPP Zika IgM Assay System Fact Sheet for Patients, and any additional DPP Zika IgM Assay System Fact Sheets for Healthcare Providers and Patients that OCET/OCS/OC and DMD/OIR/CDRH may authorize.

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- D. Chembio 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. Chembio and its authorized distributor(s) will ensure that authorized laboratories using the authorized DPP Zika IgM Assay System have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.⁷
- F. Through a process of inventory control, Chembio and its authorized distributor(s) will maintain records of device usage.
- G. Chembio and its authorized distributor(s) will collect information on the performance of the assay. Chembio will report to FDA any suspected occurrence of false positive and false negative results and significant deviations from the established performance characteristics of the assay of which Chembio becomes aware.
- H. Chembio and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized DPP Zika IgM Assay System that is consistent with, and does not exceed, the terms of this letter of authorization.
- I. Chembio and its authorized distributor(s) will make available the DPP Zika IgM Control Pack control material or other authorized control materials for purchase at the same time as the DPP Zika IgM Assay System.

Chembio

- J. Chembio will notify FDA of any authorized distributor(s) of the DPP Zika IgM Assay System, including the name, address, and phone number of any authorized distributor(s).
- K. Chembio 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).
- L. Chembio may request changes to the authorized DPP Zika IgM Assay System Fact Sheet for Healthcare Providers and the authorized DPP Zika IgM Assay System Fact Sheet for Patients. Chembio may also develop new DPP Zika IgM Assay System Fact Sheets for Healthcare Providers and Patients, if appropriate, and may request changes to such Fact Sheets. All such requests listed in this condition of authorization will be made by Chembio in consultation with, and require concurrence of, OCET/OCS/OC and DMD/OIR/CDRH.

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

Page 8 – Mr. Ippolito, Chembio Diagnostic Systems, Inc.

- M. Chembio may request the addition of other instruments for use with the authorized DPP Zika IgM Assay System. Such requests will be made by Chembio in consultation with, and require concurrence of, DMD/OIR/CDRH.
- N. Chembio may request the addition of other ancillary reagents for use with the authorized DPP Zika IgM Assay System. Such requests will be made by Chembio in consultation with, and require concurrence of, DMD/OIR/CDRH.
- O. Chembio may request the addition of other specimen types for use with the authorized DPP Zika IgM Assay System. Such requests will be made by Chembio in consultation with, and require concurrence of, DMD/OIR/CDRH.
- P. Chembio may request the addition of other control materials for use with the authorized DPP Zika IgM Assay System. Such requests will be made by Chembio in consultation with, and require concurrence of, DMD/OIR/CDRH.
- Q. Chembio may request substitution for or changes to the authorized materials used in the detection process of the human anti-Zika IgM in the specimen. Such requests will be made by Chembio in consultation with, and require concurrence of, DMD/OIR/CDRH.
- R. Chembio will track adverse events and report to FDA under 21 CFR Part 803.
- S. Chembio will evaluate the performance of the DPP Zika IgM Assay System with any FDA-recommended or established panel(s) of characterized clinical specimens, and will submit that performance data to FDA. After DMD/OIR/CDRH's review of and concurrence with the data, Chembio will update its labeling, in consultation with, and with concurrence of, DMD/OIR/CDRH, to reflect the additional testing.
- T. Chembio will assess traceability⁸ of the DPP Zika IgM Assay System with any FDA-recommended reference material(s). After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, Chembio will update its labeling to reflect the additional testing.
- U. Chembio will track the performance of the DPP Zika IgM Assay System and report to DMD/OIR/CDRH on a semi-annual basis.

Authorized Laboratories

- V. Authorized laboratories will include with reports of the results of the DPP Zika IgM Assay System the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients, and any additional DPP Zika IgM Assay System Fact Sheets for Healthcare Providers and Patients that OCET/OCS/OC and DMD/OIR/CDRH may authorize. Under exigent circumstances, other appropriate methods for disseminating

⁸ Traceability refers to tracing analytical sensitivity/reactivity back to a FDA-recommended reference material.

Page 9 – Mr. Ippolito, Chembio Diagnostic Systems, Inc.

these Fact Sheets may be used, which may include mass media.

- W. Authorized laboratories will perform the DPP Zika IgM Assay System on only human serum (plain or separation gel) and fingerstick whole blood, EDTA venous whole blood, or EDTA plasma (each collected alongside a patient-matched serum specimen) specimens or with other authorized specimen types.
- X. If non-serum specimens are used with the DPP Zika IgM Assay System, authorized laboratories responsible for collecting the patient specimen must collect a patient-matched serum specimen, or if this is not possible, an additional serum specimen must be collected soon after the original specimen. This is to facilitate any additional testing that may be required, using the latest CDC testing algorithms for the diagnosis of Zika virus infection, to confirm Zika virus infection.
- Y. Authorized laboratories must read the results of the DPP Zika IgM Assay System on the DPP Micro Reader or on other authorized instruments. Authorized laboratories must not attempt to interpret the results of the DPP Zika IgM Assay System visually.
- Z. Within the United States and its territories, authorized laboratories will report all reactive results (i.e., presumptive Zika IgM positive) to Chembio.
- AA. Authorized laboratories will have a process in place to ensure that, for reactive results (i.e., presumptive Zika IgM positive), additional testing (as described in the Instructions for Use document) is performed and/or test results for other patient-matched specimens, using the latest CDC testing algorithms for the diagnosis of Zika virus infection, are considered.
- BB. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.⁹
- CC. Authorized laboratories will collect information on the performance of the DPP Zika IgM Assay System and report to DMD/OIR/CDRH (via email CDRH-EUA-Reporting@fda.hhs.gov) and Chembio any suspected occurrence of false negative and false positive results and significant deviations from the established performance characteristics of which they become aware.
- DD. All laboratory personnel using the assay must be appropriately trained in performing and interpreting immunochromatographic techniques, use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the DPP Zika IgM Assay System.

⁹ For questions related to reporting Zika test results to relevant public health authorities, it is recommended that Chembio and authorized laboratories consult with the applicable country, state, or territory health department(s). According to CDC, Zika is a nationally notifiable condition (see <http://www.cdc.gov/zika/>).

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Chembio, Its Authorized Distributor(s), and Authorized Laboratories

EE. Chembio, 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

FF. All advertising and promotional descriptive printed matter relating to the use of the authorized DPP Zika IgM Assay System shall be consistent with the authorized 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.

GG. All advertising and promotional descriptive printed matter relating to the use of the authorized DPP Zika IgM Assay System 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 diagnosis of Zika virus infection and 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 DPP Zika IgM Assay System may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized DPP Zika IgM Assay System 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.

Page 11 – Mr. Ippolito, Chembio Diagnostic Systems, Inc.

Sincerely,



Rachel Sherman, M.D., M.P.H.
Principal Deputy Commissioner

Enclosures

Dated: November 9, 2017.

Anna K. Abram,

*Deputy Commissioner for Policy, Planning,
Legislation, and Analysis.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6159]

Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft document entitled “Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Draft Guidance for Industry.” The draft guidance, when finalized, will provide stakeholders engaged in the development of regenerative medicine therapies with FDA’s current thinking on the expedited development and review of these products. The draft guidance describes the expedited programs available to sponsors of regenerative medicine therapies for serious or life-threatening diseases or conditions (referred to in the draft guidance as serious conditions), including those products designated as regenerative advanced therapies (which FDA refers to as “regenerative medicine advanced therapy” (RMAT) designation); describes how the Center for Biologics Evaluation and Research (CBER) will work with sponsors and encourage flexibility in clinical trial design to facilitate the development of data to demonstrate the safety and effectiveness of regenerative medicine therapies being developed to address

unmet medical needs in patients with serious or life-threatening diseases or conditions; and describes the opportunities for sponsors of regenerative medicine therapies to interact with CBER review staff.

DATES: Submit either electronic or written comments on the draft guidance by February 15, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://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 <http://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–D–6159 for “Expedited Programs for Regenerative Medicine Therapies for Serious Conditions; Draft Guidance for Industry.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <http://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 <http://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