



September 27, 2023

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Device: Zika Immunoglobulin M (IgM) Antibody Capture Enzyme-Linked Immunosorbent Assay (Zika MAC-ELISA)

EUA Number: EUA160004

Company: Centers for Disease Control and Prevention (CDC)

Indication: This assay is authorized for the qualitative detection of Zika virus IgM antibodies in human sera or cerebrospinal fluid (CSF) that is submitted alongside a patient-matched serum specimen, collected from individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika virus transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated). The assay is intended for use in authorized laboratories, as a part of a multi-test algorithm.

Emergency use of this assay is limited to authorized laboratories.

Authorized Laboratories: Testing is limited to qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, and meet requirements to perform high complexity tests.

Dear Dr. Cohen:

On February 26, 2016, based on your¹, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of the Zika Immunoglobulin M (IgM) Antibody Capture Enzyme-Linked Immunosorbent Assay (Zika MAC-ELISA), pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) for

¹ For ease of reference, this letter will use the term “you” and related terms to refer to Centers for Disease Control and Prevention (CDC).

the indication stated in the letter.² Based on your request, FDA reissued the letter in its entirety with revisions incorporated on June 29, 2016.³ In addition, based on subsequent requests, FDA granted updates on November 15, 2016,⁴ December 6, 2016,⁵ May 3, 2017,⁶ July 31, 2017,⁷ April 16, 2018,⁸ and September 26, 2018.⁹

² The February 26, 2016, letter authorized the Zika Immunoglobulin M (IgM) Antibody Capture Enzyme-Linked Immunosorbent Assay (Zika MAC-ELISA) for the presumptive detection of Zika virus-specific IgM in human sera or cerebrospinal fluid (CSF) that is submitted alongside a patient-matched serum specimen from individuals meeting CDC Zika virus clinical criteria (e.g., a history of clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., recent history of travel to geographic regions during a period of active Zika virus transmissions at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated as part of a public health response), by qualified laboratories designated by CDC and, in the United States, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests. U.S. Food and Drug Administration (FDA). *Authorization of Emergency Use of an In Vitro Diagnostic Device for Diagnosis of Zika Virus Infection; Availability*. 81 Fed. Reg. 17170 (March 28, 2016).

³ On June 29, 2016, the revisions to the February 26, 2016, letter and authorized labeling included: (1) updating the language for the Centers for Disease Control and Prevention (CDC) Zika virus clinical and epidemiological criteria; (2) updating the language related to additional testing of positive or equivocal test results using the CDC-issued algorithm; (3) allowing for CDC to develop additional Fact Sheets for health care providers, pregnant women, and other patients in consultation with, and with concurrence of, FDA's Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and Division of Microbiology Devices (DMD)/Office of In Vitro Diagnostics and Radiological Health (OIR)/Center for Devices and Radiological Health (CDRH); (4) allowing use of Zika COS-1 Recombinant Antigen (CDC catalog #AV0005) as Zika Viral Antigen in addition to Lyophilized Zika Vero E6 Tissue Culture Antigen (CDC catalog #AV002 or AV003); and (5) as described in Section IV. Conditions of Authorization of this letter enable certain changes or additions to be made by CDC in consultation with, and with concurrence of, DMD/OIR/CDRH. The authorized Instructions for Use and Fact Sheets were also updated to incorporate these amendments, where applicable.

⁴ On November 15, 2016, your request was granted to modify the algorithm for results confirmation of the Zika MAC-ELISA as outlined in the draft updated CDC Guidance for U.S. Laboratories Testing for Zika Virus Infection (revised).

⁵ On December 6, 2016, your request was granted to modify the Fact Sheets authorized with the Zika MAC-ELISA to combine the Fact Sheet for Patients and the Fact Sheet for Pregnant Women into one Fact Sheet for Patients and to include updated language to align with the latest CDC Zika Laboratory Guidance, implemented in November 2016.

⁶ On May 3, 2017, your request was granted to modify the Instructions for Use labeling for the CDC Zika Immunoglobulin M (IgM) Antibody Capture Enzyme-Linked Immunosorbent Assay (Zika MAC-ELISA) to (1) add the Dynex Technologies, Inc.'s Agility and DSX systems as acceptable automated instruments for use with the Zika MAC-ELISA, (2) add language recommending an additional negative human serum control be run once daily, (3) include a limitation concerning the use of the Hennessey detecting antibody conjugate 6B6C-1 in conjunction with the Vero E6 antigen when testing infant serum, and (4) update contact information. Minor updates to the authorized Zika MAC-ELISA Fact Sheet for Healthcare Providers requested by FDA were also granted.

⁷ On July 31, 2017, your request was granted to provide an interim update to the Instructions for Use labeling for the CDC Zika Immunoglobulin M (IgM) Antibody Capture Enzyme-Linked Immunosorbent Assay (Zika MAC-ELISA) to provide additional acceptance criteria designed to enhance the precision and accuracy of the assay across all testing laboratories.

⁸ On April 16, 2018, your request was granted to modify the Instructions for Use of the Zika MAC-ELISA to: (1) include a standardized negative control serum and calibration control serum reagent set as one of the materials provided by CDC, (2) include use the Flavivirus group-specific conjugate MAB 6B6C-1/HRP with the Zika MAC-ELISA in CDC laboratories only, (3) integrate the previously granted test result acceptance criteria designed to enhance the precision and accuracy of the assay across all testing laboratories, (4) remove the Hennessey conjugate as a recommended detecting antibody conjugate, and (5) update the specimen handling and safety precautions.

⁹ On September 26, 2018, your request was granted to modify the Instructions for Use of the Zika MAC-ELISA to include a minor update to improve clarity.

On May 22, 2020 you requested that FDA amend your EUA. Based on that request, and having concluded that revising the June 29, 2016, EUA is appropriate to protect the public health or safety under section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), FDA is reissuing the June 29, 2016, letter in its entirety with the revisions incorporated.¹⁰ Pursuant to section 564 of the Act and the Scope of Authorization (Section II) and Conditions of Authorization (Section IV) of this reissued letter, your product¹¹ is now authorized for use consistent with the indication described above.

On February 26, 2016, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves Zika virus.¹² 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).¹³

FDA considered the totality of scientific information available in authorizing the emergency use of your product for the indication above. A summary of the performance information FDA relied upon is contained in the Instructions for Use (identified below). There are FDA-cleared tests for the qualitative detection of Zika virus IgM antibodies, but these are not adequate and available alternatives to your product.¹⁴

¹⁰ The revisions to the June 29, 2016, letter and authorized labeling include: (1) updates to the intended use to reflect updated recommendations to the CDC-issued testing algorithm, including that equivocal or presumptive positive specimens “*may require additional testing*” rather than “*require additional testing*”, and updated scientific knowledge of the duration of Zika IgM antibodies in individuals exposed to the virus, (2) remove use of the Zika Vero E6 Tissue Culture Antigen and Normal Vero E6 Antigen reagents for use with your product, (3) include use of “Human sera positive for Zika IgM antibodies” as an acceptable Zika IgM antibody positive control for use with your product, (4) remove the requirement for QC validation calculation steps, (5) update the number of outer rim wells used to blank the plate, (6) remove the requirement for repeat testing for inconclusive results prior to follow-up PRNT testing, (7) updates to the flavivirus cross-reactivity section to include results of additional testing and update the current limitation with respect for flavivirus cross-reactivity, (8) updates to the clinical performance section based on additional data, and (9) updating the Fact Sheet for Healthcare Providers, Fact Sheet for Patients, and the Letter of Authorization to reflect the updates made and for consistency with language used in more recent authorizations.

¹¹ For ease of reference, this letter will use the term “your product” to refer to the Zika Immunoglobulin M (IgM) Antibody Capture Enzyme-Linked Immunosorbent Assay (Zika MAC-ELISA) for the indication identified above.

¹² 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.

¹³ 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).

¹⁴ To date, the FDA-granted ZIKV Detect 2.0 IgM Capture ELISA (Product Code: QFO; DEN180069) and FDA-cleared (Product Code: QFO) DPP Zika IgM System, DPP Zika IgM System Control Pack, and DPP Micro Reader (K200506), LIAISON XL Zika Capture IgM II and LIAISON XL Zika Capture IgM II Control Set (K192046), and the ADVIA Centaur Zika test, ADVIA Centaur Zika Ab (100 tests), ADVIA Centaur Zika IgM (50 tests), ADVIA Centaur Zika Ab Quality Control, ADVIA Centaur Zika IgM Quality Control (K191578) are available in the United States with FDA clearance for the qualitative detection of Zika virus IgM antibodies in various clinical specimens for the presumptive clinical laboratory diagnosis of Zika virus infection. Available information indicates that these are not adequate and available alternatives to your product.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of your product, described in the Scope of Authorization of this letter (Section II), subject to the terms of this authorization.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of your product 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 Zika MAC-ELISA may be effective in diagnosing Zika virus infection when positive or equivocal results are considered in conjunction with any additional testing that may be recommended using the CDC-issued algorithm and/or are considered alongside test results for other patient- matched specimens using the CDC-issued algorithm, and that the known and potential benefits of the Zika MAC-ELISA for diagnosing Zika virus infection outweigh the known and potential risks of such product when positive or equivocal results are considered in conjunction with any additional testing that may be recommended using the CDC-issued algorithm and/or are considered alongside test results for other patient-matched specimens using the CDC-issued algorithm; and
3. There is no adequate, approved, and available alternative to the emergency use of the Zika MAC-ELISA for diagnosing Zika virus infection.¹⁵

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 indication above.

Authorized Product Details

Your product is an IgM antibody capture enzyme-linked immunosorbent assay intended for the qualitative detection of Zika virus IgM antibodies in human sera or cerebrospinal fluid (CSF) that is submitted alongside a patient-matched serum specimen, collected from individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika virus transmission at the time of travel, or other epidemiologic criteria for which Zika virus testing may be indicated). Your product is intended for use in qualified laboratories designated by the CDC, as a part of a multi-test algorithm.

Assay results are for the presumptive identification of IgM antibodies to Zika virus. Positive and equivocal results are not definitive for diagnosis of Zika virus infection. False positive results are possible in patients with a history of infection with other flaviviruses. Confirmation of the

¹⁵ No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

presence of anti-Zika IgM antibodies in equivocal or presumptive positive specimens may require additional testing using the CDC-issued algorithm. Positive or equivocal results must be considered in conjunction with additional testing using the CDC-issued algorithm and/or considered alongside test results for other patient-matched specimens using the CDC-issued algorithm. Laboratories are required to report positive results to the appropriate public health authorities. Within the United States and its territories, equivocal and presumptive positive results must be reported to CDC by qualified laboratories designated by CDC.

Results of this test cannot be used as the sole basis of patient management decisions and must be combined with clinical observations, patient history, epidemiological information, and other laboratory evidence. Zika IgM antibodies typically develop during the first week of illness; however, limited published data exist on the duration of IgM antibodies and suggest that IgM antibodies are detectable for weeks to months following initial infection.

Negative results do not preclude the possibility of Zika virus infection, past or present. Negative results may be seen in specimens collected before IgM antibodies develop in the first week after illness onset or after the window of detectable IgM closes.

Testing is limited to laboratories certified under CLIA that meet requirements to perform high complexity tests.

To use your product, purified antibody specific for human IgM is immobilized on a test plate to capture IgM antibodies from a human specimen. A serum or CSF specimen from a patient is added to the test plate, and IgM antibodies from the specimen bind to the immobilized antibody. After washing, cultured Zika virus antigen is added and binds to any Zika virus-specific IgM antibodies captured on the plate. A flavivirus specific monoclonal antibody conjugated to horseradish peroxidase is then added. Upon addition of substrate, conjugate that is bound to any immobilized Zika antigen will catalyze a colorimetric reaction that can be measured by a spectrophotometer, or other authorized instruments as may be requested under Condition J. below. The Zika MAC-ELISA includes the materials (or other authorized materials and authorized ancillary reagents as may be requested under Condition J. below) described in the Instructions for Use.

Your product requires control materials (or other authorized control materials as may be requested under Condition J. below) that are described in the Instructions for Use.

The labeling entitled “Zika MAC-ELISA Instructions for Use” (available at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations-medical-devices#zika>), and the following fact sheets (or other authorized facts sheets, as may be requested under Condition J. Below) pertaining to the emergency use, are required to be made available as set forth in the Conditions of Authorization (Section IV), and are collectively referred to as “authorized labeling”:

- Fact Sheet for Healthcare Providers: Interpreting Zika MAC-ELISA Test Results
- Fact Sheet for Patients: Understanding Results from the Zika MAC-ELISA

The above described product, when accompanied by the authorized labeling provided as set forth in the Conditions of Authorization (Section IV), 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 applicable federal law.

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 your product, when used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of your 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 your product may be effective in the diagnosis of Zika virus infection, when used consistent 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 your product (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 your product 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 under Section 564(b)(1)(C) of the Act described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1) of the Act, your product is authorized for the indication above.

III. Waiver of Certain Requirements

I am waiving the following requirements for your product 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 your product, but excluding Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions on this authorization:

Centers for Disease Control and Prevention (CDC) (You) and Authorized Distributor(s)¹⁶

- A. Your product must comply with the following labeling requirements: 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)); 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).
- B. You and authorized distributor(s) must make your product available with the authorized labeling to authorized laboratories.¹⁷
- C. You and authorized distributor(s) must make available on your website(s) the labeling.
- D. You and authorized distributor(s) must inform authorized laboratories and relevant public health authorities of this EUA, including the terms and conditions herein, and any updates made to your product and authorized labeling.
- E. Through a process of inventory control, you and authorized distributor(s) must maintain records of the authorized laboratories to which they distribute your product and number of your product they distribute.
- F. You and authorized distributor(s) must collect information on the performance of your product. You must report any significant deviations from the established performance characteristics of your product of which you become aware to the Division of Microbiology (DMD)/Office of Health Technology 7 (OHT7): Office of In Vitro Diagnostics /Office of Product Evaluation and Quality (OPEQ)/Center for Devices and Radiological Health (CDRH) (via email: CDRH-EUA-Reporting@fda.hhs.gov).
- G. You and authorized distributor(s) are authorized to make available additional information relating to the emergency use of your product that is consistent with, and does not exceed, the terms of this letter of authorization.

Centers for Disease Control and Prevention (CDC)

- H. You must notify FDA of any authorized distributor(s) of your product, including the name, address, and phone number of any authorized distributor(s).

¹⁶ “Authorized Distributor(s)” are identified by you, Centers for Disease Control and Prevention (CDC), in your EUA submission as an entity allowed to distribute your product.

¹⁷ Current stocks of CDC Zika MAC-ELISA products previously distributed to authorized laboratories and labeled as “Research Use Only” may be used by such laboratories for research use and/or diagnostic purposes under this authorization in accordance with the authorized Instructions for Use for the CDC Zika MAC-ELISA. Such stocks used for diagnostic purposes must be used in accordance with the conditions of this authorization.

- I. You must provide authorized distributor(s) with a copy of this EUA and communicate to authorized distributor(s) any subsequent amendments that might be made to this EUA and its authorized accompanying materials (e.g., Fact Sheets).
- J. You may request changes to this EUA for your product, including to the Scope of Authorization (Section II in this letter) or to the authorized labeling, including requests to make available additional authorized labeling specific to an authorized distributor. Such additional labeling may use another name for the product but otherwise must be consistent with the authorized labeling, and not exceed the terms of authorization of this letter. Any request for changes to this EUA should be submitted to DMD/OHT7/OPEQ/CDRH and require appropriate authorization from FDA prior to implementation.
- K. You must comply with the following requirements: 21 CFR 820 Subpart H (Acceptance Activities, 21 CFR 820.80 and 21 CFR 820.86), Subpart I (Nonconforming Product, 21 CFR 820.90), and Subpart O (Statistical Techniques, 21 CFR 820.250).
- L. You must have lot release procedures and the lot release procedures, including the study design and statistical power, must ensure that the tests released for distribution have the clinical and analytical performance claimed in the authorized labeling.
- M. If requested by FDA, you must submit lot release procedures to FDA, including sampling protocols, testing protocols, and acceptance criteria, that you use to release lots of your product for distribution in the U.S. If such lot release procedures are requested by FDA, you must provide it within 48 hours of the request.
- N. You must have a process in place to track adverse events and report to FDA pursuant to 21 CFR Part 803.
- O. You may request change of the CDC-issued algorithm used for confirmatory testing of Zika MAC-ELISA equivocal and presumptive positive results. Such requests must be made by CDC in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.
- P. You must evaluate the analytical limit of detection and assess traceability¹⁸ of your product with any FDA-recommended reference material(s). After submission to and concurrence with the data by FDA, you must update your labeling to reflect the additional testing. Such labeling updates will be made in consultation with, and require concurrence of, DMD/OHT7/OPEQ/CDRH.

Authorized Laboratories

- Q. Authorized laboratories using your product must include with test result reports all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.

¹⁸ Traceability refers to tracing analytical sensitivity/reactivity back to an FDA-recommended reference material.

- R. Authorized laboratories using your product must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized extraction methods, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
- S. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
- T. Within the United States and its territories, authorized laboratories using your product must report all equivocal and presumptive positive results to CDC.
- U. Authorized laboratories using your product must have a process in place to assure that positive or equivocal results are considered in conjunction with any additional testing, and/or are considered alongside test results for other patient-matched specimens, recommended using the CDC-issued algorithm.
- V. Authorized laboratories using your product must have a process in place for reporting test results to health care providers and relevant public health authorities, as appropriate.¹⁹
- W. Authorized laboratories must collect information on the performance of your product and report to DMD/OHT7/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and you (via email: reagents2@cdc.gov) any suspected occurrence of false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
- X. All laboratory personnel using your product should be appropriately trained in performing and interpreting immunoassays techniques, use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling.

Centers for Disease Control and Prevention (CDC), Authorized Distributor(s) and Authorized Laboratories

- Y. You, 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 Printed Materials, Advertising and Promotion

¹⁹ For questions related to reporting Zika test results to relevant public health authorities, it is recommended that CDC and authorized laboratories consult with the applicable country, state, or territory health department(s). According to CDC, Zika is a nationally notifiable condition. <https://wwwn.cdc.gov/nndss/conditions/notifiable/2016/>.

Z. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and meet the requirements set forth in section 502(a), (q)(1), and (r) of the Act, as applicable, and FDA implementing regulations.

AA. No descriptive printed matter, advertising or promotional materials relating to the use of your product may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

BB. All descriptive printed matter, advertising and promotional materials relating to the use of your product shall clearly and conspicuously state that:

- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories;
- This product has been authorized only for the diagnosis of Zika virus infection and not for any other viruses or pathogens; and
- The emergency use of this product 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 declaration is terminated or authorization is revoked sooner.

The emergency use of your product 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,

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration

Enclosure