



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-1486]

Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection of Zika Virus;  
Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the issuance of two Emergency Use Authorizations (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 Nanobiosym Diagnostics, Inc. and DiaSorin 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 Nanobiosym Diagnostics, Inc. is effective as of March 20, 2017; the Authorization for DiaSorin Inc. is effective as of April 5, 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 assure that medical countermeasures may be used in emergencies to diagnose, treat, or prevent serious or life-threatening diseases or conditions caused by biological, chemical, nuclear, or radiological agents when there are no adequate, approved, and available alternatives.

Section 564(b)(1) of the FD&C Act provides that, before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of the following grounds: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents; (2) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to U.S. military forces of attack with a biological, chemical, radiological, or nuclear agent or agents; (3) a determination by the Secretary of HHS that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of U.S. citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or (4) the identification of a material threat by the Secretary of Homeland Security under section 319F-2 of the Public Health Service (PHS) Act (42 U.S.C. 247d-6b) sufficient to affect national security or the health and security of U.S. citizens living abroad.

Once the Secretary of HHS has declared that circumstances exist justifying an authorization under section 564 of the FD&C Act, FDA may authorize the emergency use of a drug, device, or biological product if the Agency concludes that the statutory criteria are satisfied. Under section 564(h)(1) of the FD&C Act, FDA is required to publish in the Federal Register a notice of each authorization, and each termination or revocation of an authorization, and an explanation of the reasons for the action. Section 564 of the FD&C Act permits FDA to authorize the introduction into interstate commerce of a drug, device, or biological product intended for use when the Secretary of HHS has declared that circumstances exist justifying the

authorization of emergency use. Products appropriate for emergency use may include products and uses that are not approved, cleared, or licensed under sections 505, 510(k), or 515 of the FD&C Act (21 U.S.C. 355, 360(k), and 360e) or section 351 of the PHS Act (42 U.S.C. 262). FDA may issue an EUA only if, after consultation with the HHS Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances), FDA<sup>1</sup> concludes: (1) That an agent referred to in a declaration of emergency or threat can cause a serious or life-threatening disease or condition; (2) that, based on the totality of scientific evidence available to FDA, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that: (A) The product may be effective in diagnosing, treating, or preventing (i) such disease or condition; or (ii) a serious or life-threatening disease or condition caused by a product authorized under section 564, approved or cleared under the FD&C Act, or licensed under section 351 of the PHS Act, for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and (B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under section 564(b)(1)(D) of the FD&C Act, if applicable; (3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition; and (4) that such other criteria as may be prescribed by regulation are satisfied.

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

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

## II. EUA Requests for In Vitro Diagnostic Devices for Detection of the Zika Virus

On February 26, 2016, the Secretary of HHS determined that there is a significant potential for a public health emergency that has a significant 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 February 24, 2017, Nanobiosym Diagnostics, Inc. requested, and on March 20, 2017, FDA issued, an EUA for the Gene-RADAR<sup>®</sup> Zika Virus Test, subject to the terms of the Authorization. On March 30, 2017, DiaSorin Inc. requested, and on April 5, 2017, FDA issued an EUA for the LIAISON<sup>®</sup> XL Zika Capture IgM Assay, subject to the terms of the Authorization.

## III. Electronic Access

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

## IV. The Authorizations

Having concluded that the criteria for issuance of the Authorizations under section 564(c) of the FD&C Act are met, FDA has authorized the emergency use of two in vitro diagnostic

devices for detection of Zika virus subject to the terms of the Authorizations. The Authorizations in their entirety (not including the authorized versions of the fact sheets and other written materials) follow and provide an explanation of the reasons for issuance, as required by section 564(h)(1) of the FD&C Act:



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring, MD 20993

March 20, 2017

Anita Goel, MD, Ph.D.  
Chairman and CEO  
Nanobiosym Diagnostics, Inc.  
245 First Street, 18<sup>th</sup> Floor  
Cambridge, MA 02142

Dear Dr. Goel:

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 Nanobiosym Diagnostics, Inc.'s ("Nanobiosym") Gene-RADAR<sup>®</sup> Zika Virus Test for the qualitative detection of RNA from Zika virus in human serum from individuals meeting Centers for Disease Control and Prevention (CDC) Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated), by laboratories in the United States (U.S.) that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests, or by similarly qualified non-U.S. laboratories, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3).<sup>1</sup> Test results are for the identification of Zika virus RNA. Zika virus RNA is generally detectable in serum during the acute phase of infection and, according to the updated CDC Guidance for U.S. Laboratories Testing for Zika Virus Infection,<sup>2</sup> up to 14 days in serum, following onset of symptoms, if present. Positive results are indicative of current infection.

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

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

<sup>2</sup> Available at <http://www.cdc.gov/zika/laboratories/lab-guidance.html> (last updated on November 16, 2016).

<sup>3</sup> As amended by the Pandemic and All Hazards Preparedness Reauthorization Act, Pub. L. No. 113-5, under section 564(b)(1)(C) of the Act, the Secretary may make a determination of a public health emergency, or of a significant potential for a public health emergency.

Page 2 – Dr. Anita Goel, Nanobiosym Diagnostics, Inc.

of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or diagnosis of Zika virus infection, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).<sup>4</sup>

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the Gene-RADAR<sup>®</sup> Zika Virus 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 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 Gene-RADAR<sup>®</sup> Zika Virus Test for the detection of Zika virus and diagnosis of Zika virus infection in the specified population meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. The Zika virus can cause Zika virus infection, a serious or life-threatening disease or condition to humans infected with the virus;
2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the Gene-RADAR<sup>®</sup> Zika Virus Test, when used with the specified instrument(s) and in accordance with the Scope of Authorization, may be effective in detecting Zika virus and diagnosing Zika virus infection, and that the known and potential benefits of the Gene-RADAR<sup>®</sup> Zika Virus Test for detecting Zika virus and diagnosing Zika virus infection outweigh the known and potential risks of such product; and
3. There is no adequate, approved, and available alternative to the emergency use of the Gene-RADAR<sup>®</sup> Zika Virus Test for detecting Zika virus and diagnosing Zika virus infection.<sup>5</sup>

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

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized Gene-RADAR<sup>®</sup> Zika Virus Test by authorized laboratories for the detection of RNA from Zika virus and diagnosis of Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or

<sup>4</sup> HHS. *Determination and Declaration Regarding Emergency Use of in Vitro Diagnostic Tests for Detection of Zika Virus and/or Diagnosis of Zika Virus Infection*. 81 Fed. Reg. 10878 (March 2, 2016).

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

Page 3 – Dr. Anita Goel, Nanobiosym Diagnostics, Inc.

travel to a geographic region with active Zika transmission at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

#### **The Authorized Gene-RADAR<sup>®</sup> Zika Virus Test**

The Gene-RADAR<sup>®</sup> Zika Virus Test is a real-time reverse transcription polymerase chain reaction (rRT-PCR) assay for the qualitative detection of RNA from Zika virus in human serum and other authorized specimen types.

To perform the Gene-RADAR<sup>®</sup> Zika Virus Test, the RNA is first extracted and purified from the patient specimen. The RNA is then reverse transcribed into cDNA which is amplified using the primer set and detected using the specific probe. The rRT-PCR is performed on the Gene-RADAR<sup>®</sup> Platform, or other authorized instruments.

The Gene-RADAR<sup>®</sup> Zika Virus Test includes the following materials or other authorized materials: Gene-RADAR<sup>®</sup> Zika Virus Kit Buffer 1 (containing primers, probes and reaction buffer), Gene-RADAR<sup>®</sup> Zika Virus Internal Process Control, Gene-RADAR<sup>®</sup> Zika Virus Positive/Negative Control, Gene-RADAR<sup>®</sup> Nanochips for use with samples and controls. The Gene-RADAR<sup>®</sup> Zika Virus Test also requires the use of additional materials and ancillary reagents that are not included with the test but are commonly used in clinical laboratories and are described in the authorized Gene-RADAR<sup>®</sup> Zika Virus Test Instructions for Use.

The Gene-RADAR<sup>®</sup> Zika Virus Test requires the following control materials, or other authorized control materials; all controls listed below must generate expected results in order for a test to be considered valid, as outlined in the Gene-RADAR<sup>®</sup> Zika Virus Test Instructions for Use:

- Gene-RADAR<sup>®</sup> Zika Virus Positive Control: Synthetic Zika RNA target sequence that can be amplified and detected – run with each batch of patient specimens. Monitors for failures of rRT-PCR reagents and reaction conditions.
- Negative Control: DNase and RNase-free water – run with each batch of patient specimens. Monitors for reagent and system contamination.
- Gene-RADAR<sup>®</sup> Zika Virus Internal Process Control: inactivated and stabilized MS2 Bacteriophage, requires extraction – added to each sample and control during the extraction step. The MS2 RNA is co-extracted and co-amplified with the target nucleic acid, and monitors for integrity of the kit reagents, equipment function and the presence of amplification inhibitors in the samples.

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

The above described Gene-RADAR<sup>®</sup> Zika Virus Test is authorized to be accompanied by the

Page 4 – Dr. Anita Goel, Nanobiosym Diagnostics, Inc.

following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients, including pregnant women:

- Fact Sheet for Healthcare Providers: Interpreting Gene-RADAR<sup>®</sup> Zika Virus Test Results
- Fact Sheet for Patients: Understanding Results from the Gene-RADAR<sup>®</sup> Zika Virus Test

As described in Section IV below, Nanobiosym and its authorized distributors are also authorized to make available additional information relating to the emergency use of the authorized Gene-RADAR<sup>®</sup> Zika Virus 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 Gene-RADAR<sup>®</sup> Zika Virus Test in the specified population, when used for detection of Zika virus and to diagnose Zika virus infection and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of such a product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized Gene-RADAR<sup>®</sup> Zika Virus Test may be effective in the detection of Zika virus and diagnosis of Zika virus infection, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

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

The emergency use of the authorized Gene-RADAR<sup>®</sup> Zika Virus 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 Gene-RADAR<sup>®</sup> Zika Virus Test described above is authorized to detect Zika virus and diagnose Zika virus infection in individuals meeting CDC Zika virus clinical criteria (e.g., clinical signs and symptoms associated with Zika virus infection) and/or CDC Zika virus epidemiological criteria (e.g., history of residence in or travel to a geographic region with active Zika virus transmissions at the time of travel, or other epidemiological criteria for which Zika virus testing may be indicated).

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

Page 5 – Dr. Anita Goel, Nanobiosym Diagnostics, Inc.

### **III. Waiver of Certain Requirements**

I am waiving the following requirements for the Gene-RADAR<sup>®</sup> Zika Virus Test 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 Gene-RADAR<sup>®</sup> Zika Virus 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:

#### **Nanobiosym and Its Authorized Distributor(s)**

- A. Nanobiosym and its authorized distributor(s) will distribute the authorized Gene-RADAR<sup>®</sup> Zika Virus Test with the authorized labeling only to authorized laboratories. Changes to the authorized labeling may be made by Nanobiosym in consultation with, and require concurrence of, DMD/OIR/CDRH.
- B. Nanobiosym and its authorized distributor(s) will provide to authorized laboratories the authorized Gene-RADAR<sup>®</sup> Zika Virus Test Fact Sheet for Healthcare Providers and the authorized Gene-RADAR<sup>®</sup> Zika Virus Test Fact Sheet for Patients.
- C. Nanobiosym and its authorized distributor(s) will make available on their websites the authorized Gene-RADAR<sup>®</sup> Zika Virus Test Fact Sheet for Healthcare Providers and the authorized Gene-RADAR<sup>®</sup> Zika Virus Test Fact Sheet for Patients.
- D. Nanobiosym 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. Nanobiosym and its authorized distributor(s) will ensure that the authorized laboratories using the authorized Gene-RADAR<sup>®</sup> Zika Virus Test have a process in place for reporting test results to healthcare providers and relevant public health

Page 6 – Dr. Anita Goel, Nanobiosym Diagnostics, Inc.

authorities, as appropriate.<sup>6</sup>

- F. Through a process of inventory control, Nanobiosym and its authorized distributor(s) will maintain records of device usage.
- G. Nanobiosym and its authorized distributor(s) will collect information on the performance of the test. Nanobiosym 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 Nanobiosym becomes aware.
- H. Nanobiosym and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized Gene-RADAR<sup>®</sup> Zika Virus Test that is consistent with, and does not exceed, the terms of this letter of authorization.

**Nanobiosym Diagnostics, Inc.**

- I. Nanobiosym will notify FDA of any authorized distributor(s) of the Gene-RADAR<sup>®</sup> Zika Virus Test, including the name, address, and phone number of any authorized distributor(s).
- J. Nanobiosym 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. Nanobiosym may request changes to the authorized Gene-RADAR<sup>®</sup> Zika Virus Test Fact Sheet for Healthcare Providers and the authorized Gene-RADAR<sup>®</sup> Zika Virus Test Fact Sheet for Patients. Such requests will be made by Nanobiosym in consultation with, and require concurrence of, DMD/OIR/CDRH.
- L. Nanobiosym may request the addition of other instruments for use with the authorized Gene-RADAR<sup>®</sup> Zika Virus Test. Such requests will be made by Nanobiosym in consultation with, and require concurrence of, DMD/OIR/CDRH.
- M. Nanobiosym may request the addition of other extraction methods for use with the authorized Gene-RADAR<sup>®</sup> Zika Virus Test. Such requests will be made by Nanobiosym in consultation with, and require concurrence of, DMD/OIR/CDRH.
- N. Nanobiosym may request the addition of other specimen types for use with the authorized Gene-RADAR<sup>®</sup> Zika Virus Test. Such requests will be made by Nanobiosym in consultation with, and require concurrence of, DMD/OIR/CDRH.

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

Page 7 – Dr. Anita Goel, Nanobiosym Diagnostics, Inc.

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

#### **Authorized Laboratories**

- S. Authorized laboratories will include with reports of the results of the Gene-RADAR<sup>®</sup> Zika Virus Test the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
- T. Authorized laboratories will perform the Gene-RADAR<sup>®</sup> Zika Virus Test using the QIAamp<sup>®</sup> Viral RNA Mini Kit or with other authorized extraction methods.
- U. Authorized laboratories will perform the Gene-RADAR<sup>®</sup> Zika Virus Test on the Gene-RADAR<sup>®</sup> Platform, or other authorized instruments.
- V. Authorized laboratories will perform the Gene-RADAR<sup>®</sup> Zika Virus Test on human serum or other authorized specimen types.
- W. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.<sup>8</sup>
- X. Authorized laboratories will collect information on the performance of the test and report to DMD/OIR/CDRH (via email [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)) and Nanobiosym any suspected occurrence of false positive or false negative results of which they become aware.

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

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

Page 8 – Dr. Anita Goel, Nanobiosym Diagnostics, Inc.

- Y. All laboratory personnel using the test should be appropriately trained in RT-PCR techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use the test in accordance with the authorized labeling.

**Nanobiosym, Its Authorized Distributor(s) and Authorized Laboratories**

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

**Conditions Related to Advertising and Promotion**

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

No advertising or promotional descriptive printed matter relating to the use of the authorized Gene-RADAR<sup>®</sup> Zika Virus 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 Gene-RADAR<sup>®</sup> Zika Virus Test as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

Page 9 – Dr. Anita Goel, Nanobiosym Diagnostics, Inc.

**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,



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Stephen Ostroff, M.D.  
Acting Commissioner of Food and Drugs

Enclosures



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring, MD 20993

April 5, 2017

Mari Meyer  
Vice President, Regulatory and Clinical Affairs, North America  
DiaSorin Incorporated  
1951 Northwestern Avenue  
Stillwater, MN 55082

Dear Ms. Meyer:

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 DiaSorin Incorporated's ("DiaSorin") LIAISON<sup>®</sup> XL Zika Capture IgM Assay for the presumptive qualitative detection of Zika virus IgM antibodies in human sera 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,<sup>1</sup> pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3). Specimens used with the LIAISON<sup>®</sup> XL Zika Capture IgM Assay should be collected between 8 days and 10 weeks after onset of symptoms or risk of exposure. Where there are presumptive Zika IgM positive and presumptive recent Zika positive results from the LIAISON<sup>®</sup> XL Zika Capture IgM Assay, 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.

On February 26, 2016, pursuant to section 564(b)(1)(C) of the Act (21 U.S.C. § 360bbb-3(b)(1)(C)), the Secretary of Health and Human Services (HHS) determined that there is a significant potential for a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves Zika virus.<sup>2</sup> Pursuant to section 564(b)(1) of the Act (21 U.S.C. § 360bbb-3(b)(1)), and on the basis of such determination, the Secretary of HHS then declared that circumstances exist justifying the authorization of the emergency use of *in vitro* diagnostic tests for detection of Zika virus and/or

<sup>1</sup> 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."

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

Page 2 – Ms. Meyer, DiaSorin Inc.

diagnosis of Zika virus infection, subject to the terms of any authorization issued under 21 U.S.C. § 360bbb-3(a).<sup>3</sup>

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act (21 U.S.C. § 360bbb-3(c)) are met, I am authorizing the emergency use of the LIAISON<sup>®</sup> XL Zika Capture IgM Assay (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 LIAISON<sup>®</sup> XL Zika Capture IgM Assay 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 LIAISON<sup>®</sup> XL Zika Capture IgM Assay may be effective in diagnosing recent Zika virus infection, and that the known and potential benefits of the LIAISON<sup>®</sup> XL Zika Capture IgM Assay for diagnosing Zika virus infection outweigh the known and potential risks of such product, when, for presumptive Zika IgM positive and presumptive recent 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 LIAISON<sup>®</sup> XL Zika Capture IgM Assay for diagnosing Zika virus infection.<sup>4</sup>

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

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the authorized LIAISON<sup>®</sup> XL Zika Capture IgM Assay 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

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

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

epidemiological criteria for which Zika virus testing may be indicated) when, for presumptive Zika IgM positive and presumptive recent Zika positive results, additional testing (as described in the Instructions for Use document) is performed<sup>5</sup> 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 LIAISON<sup>®</sup> XL Zika Capture IgM Assay**

The LIAISON<sup>®</sup> XL Zika Capture IgM Assay is an automated immunoassay utilizing chemiluminescent detection technology for the *in vitro* presumptive qualitative detection of Zika virus IgM antibodies in human sera 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 test procedure is based on capturing human IgM and IgG antibodies from the patient specimen using magnetic particles functionalized with either anti-human-IgM antibody or anti-human-IgG antibody followed by the addition of Zika virus specific NS1 antigen and detector conjugate. The IgG result is used as an aid in the identification of a recent Zika viral infection when the IgM result falls in the dual cut-off zone as outlined in the LIAISON<sup>®</sup> XL Zika Capture IgM Assay Instructions for Use.

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 presumptive Zika IgM positive or presumptive recent Zika positive results, 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 automated assay uses two separate reagent packs (ZIKV-M and ZIKV-C Reagent Integrals) which contain magnetic beads coated with either a monoclonal anti-human-IgM antibody or a monoclonal anti-human-IgG antibody. Calibrators, patient sera or controls are then incubated with both reagent packs during the LIAISON<sup>®</sup> XL Zika Capture IgM Assay procedure and either human IgM antibodies or human IgG antibodies are captured by the appropriate magnetic particles. Following a wash cycle, the magnetic particles are then incubated with a recombinant Zika virus NS1 antigen-isoluminol conjugate, washed and reagents added to induce chemiluminescence that can be measured by the LIAISON<sup>®</sup> XL Analyzer or other instruments that may be authorized. The LIAISON<sup>®</sup> XL Zika Capture IgM Assay requires both the ZIKV-M and ZIKV-C Reagent Integrals to be calibrated under specific conditions described in the authorized LIAISON<sup>®</sup> XL Zika Capture IgM Assay Instructions for Use.

The LIAISON<sup>®</sup> XL Zika Capture IgM Assay includes the following materials, or other authorized materials:

- **ZIKV-M Reagent Integral:**

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<sup>5</sup> As discussed in the Instructions for Use document, the additional testing for presumptive Zika IgM positive or presumptive recent Zika positive results is to be performed using the latest CDC testing algorithms for the diagnosis of Zika virus infection.

Page 4 – Ms. Meyer, DiaSorin Inc.

- Magnetic Particles – coated with a mouse monoclonal antibody to human IgM
- Calibrator 1 - Human serum/defibrinated plasma containing Zika virus IgM
- Calibrator 2 - Human serum/defibrinated plasma containing Zika virus IgM
- Specimen Diluent
- Assay Buffer
- **ZIKV-C Reagent Integral:**
  - Magnetic Particles – coated with a mouse monoclonal antibody to human IgG
  - Specimen Diluent
  - Assay Buffer
- **Additional components not on the Reagent Integrals:**
  - ZIKV-M Conjugate Lyophilized – recombinant Zika virus NS1 antigen conjugated to an isoluminol derivative
  - ZIKV-C Conjugate Lyophilized – recombinant Zika virus NS1 antigen conjugated to an isoluminol derivative
  - ZIKV-C Calibrator 1- Human serum/defibrinated plasma containing Zika virus IgG
  - ZIKV-C Calibrator 2- Human serum/defibrinated plasma containing Zika virus IgG

The LIAISON<sup>®</sup> XL Zika Capture IgM Assay requires the following control materials or other authorized control materials, which are not provided with the test:

- **LIAISON<sup>®</sup> XL Zika Capture IgM Control Set:** The positive control aids in verifying the validity of the kit.

Controls listed above must be performed once per day of use, or according to the guidelines or requirements of local regulations or accredited organizations. Controls must generate expected results in order for patient results to be considered valid.

The LIAISON<sup>®</sup> XL Zika Capture IgM Assay also requires the use of additional materials and ancillary reagents commonly used in clinical laboratories and that are described in the authorized LIAISON<sup>®</sup> XL Zika Capture IgM Assay Instructions for Use.

The above described LIAISON<sup>®</sup> XL Zika Capture IgM Assay, when labeled consistently with the labeling authorized by FDA entitled “LIAISON<sup>®</sup> XL Zika Capture IgM Assay Instructions for Use” (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 DiaSorin 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 – Ms. Meyer, DiaSorin Inc.

The above described LIAISON<sup>®</sup> XL Zika Capture IgM Assay is authorized to be accompanied by the following information pertaining to the emergency use, which is authorized to be made available to healthcare providers and patients:

- Fact Sheet for Healthcare Providers: Interpreting LIAISON<sup>®</sup> XL Zika Capture IgM Assay Results
- Fact Sheet for Patients: Understanding Results from the LIAISON<sup>®</sup> XL Zika Capture IgM Assay

Other Fact Sheets developed by DiaSorin 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 LIAISON<sup>®</sup> XL Zika Capture IgM Assay and to be made available to healthcare providers and patients.

As described in Section IV below, DiaSorin is also authorized to make available additional information relating to the emergency use of the authorized LIAISON<sup>®</sup> XL Zika Capture IgM Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the authorized LIAISON<sup>®</sup> XL Zika Capture IgM Assay 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 LIAISON<sup>®</sup> XL Zika Capture IgM Assay 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 LIAISON<sup>®</sup> XL Zika Capture IgM Assay, 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 LIAISON<sup>®</sup> XL Zika Capture IgM Assay under this EUA must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the LIAISON<sup>®</sup> XL Zika Capture IgM Assay 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 – Ms. Meyer, DiaSorin 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 LIAISON<sup>®</sup> XL Zika Capture IgM Assay during the duration of this EUA:

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

### **IV. Conditions of Authorization**

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

#### **DiaSorin and Its Authorized Distributor(s)**

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

Page 7 – Ms. Meyer, DiaSorin Inc.

public health authority(ies) of this EUA, including the terms and conditions herein.

- E. DiaSorin and its authorized distributor(s) will ensure that authorized laboratories using the authorized LIAISON<sup>®</sup> XL Zika Capture IgM Assay have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.<sup>6</sup>
- F. Through a process of inventory control, DiaSorin and its authorized distributor(s) will maintain records of device usage.
- G. DiaSorin and its authorized distributor(s) will collect information on the performance of the assay. DiaSorin 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 DiaSorin becomes aware.
- H. DiaSorin and its authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized LIAISON<sup>®</sup> XL Zika Capture IgM Assay that is consistent with, and does not exceed, the terms of this letter of authorization.

**DiaSorin**

- I. DiaSorin will notify FDA of any authorized distributor(s) of the LIAISON<sup>®</sup> XL Zika Capture IgM Assay, including the name, address, and phone number of any authorized distributor(s).
- J. DiaSorin 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. DiaSorin may request changes to the authorized LIAISON<sup>®</sup> XL Zika Capture IgM Assay Fact Sheet for Healthcare Providers and the authorized LIAISON<sup>®</sup> XL Zika Capture IgM Assay Fact Sheet for Patients. DiaSorin may also develop new LIAISON<sup>®</sup> XL Zika Capture IgM Assay 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 DiaSorin in consultation with, and require concurrence of, OCET/OCS/OC and DMD/OIR/CDRH.
- L. DiaSorin may request the addition of other instruments for use with the authorized LIAISON<sup>®</sup> XL Zika Capture IgM Assay. Such requests will be made by DiaSorin in consultation with, and require concurrence of, DMD/OIR/CDRH.
- M. DiaSorin may request the addition of other ancillary reagents for use with the authorized LIAISON<sup>®</sup> XL Zika Capture IgM Assay. Such requests will be made by DiaSorin in

<sup>6</sup> For questions related to reporting Zika test results to relevant public health authorities, it is recommended that DiaSorin 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 – Ms. Meyer, DiaSorin Inc.

- consultation with, and require concurrence of, DMD/OIR/CDRH.
- N. DiaSorin may request the addition of other specimen types for use with the authorized LIAISON® XL Zika Capture IgM Assay. Such requests will be made by DiaSorin in consultation with, and require concurrence of, DMD/OIR/CDRH.
- O. DiaSorin may request the addition of other control materials for use with the authorized LIAISON® XL Zika Capture IgM Assay. Such requests will be made by DiaSorin in consultation with, and require concurrence of, DMD/OIR/CDRH.
- P. DiaSorin may request substitution for or changes to the authorized materials used in the detection process of the human anti-Zika IgM and human anti-Zika IgG in the specimen. Such requests will be made by DiaSorin in consultation with, and require concurrence of, DMD/OIR/CDRH.
- Q. DiaSorin will track adverse events and report to FDA under 21 CFR Part 803.
- R. DiaSorin will evaluate the performance of the LIAISON® XL Zika Capture IgM Assay 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, DiaSorin will update its labeling, in consultation with, and with concurrence of, DMD/OIR/CDRH, to reflect the additional testing.
- S. DiaSorin will assess traceability<sup>7</sup> of the LIAISON® XL Zika Capture IgM Assay with any FDA-recommended reference material(s). After submission to FDA and DMD/OIR/CDRH's review of and concurrence with the data, DiaSorin will update its labeling to reflect the additional testing.
- T. DiaSorin will track the performance of the LIAISON® XL Zika Capture IgM Assay and report to DMD/OIR/CDRH on a semi-annual basis.

#### **Authorized Laboratories**

- U. Authorized laboratories will include with reports of the results of the LIAISON® XL Zika Capture IgM Assay the authorized Fact Sheet for Healthcare Providers and the authorized Fact Sheet for Patients, and any additional LIAISON® XL Zika Capture IgM Assay 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 LIAISON® XL Zika Capture IgM Assay on serum or with other authorized specimen types.
- W. Authorized laboratories will perform the LIAISON® XL Zika Capture IgM Assay on the LIAISON® XL Analyzer or on other authorized instruments.

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

Page 9 – Ms. Meyer, DiaSorin Inc.

- X. Within the United States and its territories, authorized laboratories will report all presumptive Zika IgM positive and presumptive recent Zika positive results to DiaSorin.
- Y. Authorized laboratories will have a process in place to assure that, for presumptive Zika IgM positive and presumptive recent 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.
- Z. Authorized laboratories will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.<sup>8</sup>
- AA. Authorized laboratories will collect information on the performance of the assay and report to DMD/OIR/CDRH (via email [CDRH-EUA-Reporting@fda.hhs.gov](mailto:CDRH-EUA-Reporting@fda.hhs.gov)) and DiaSorin any suspected occurrence of false negative and false positive results and significant deviations from the established performance characteristics of which they become aware.
- BB. 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 algorithm used for the interpretation of results of the LIAISON<sup>®</sup> XL Zika Capture IgM Assay.

**DiaSorin, Its Authorized Distributor(s), and Authorized Laboratories**

- CC. DiaSorin, 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**

- DD. All advertising and promotional descriptive printed matter relating to the use of the authorized LIAISON<sup>®</sup> XL Zika Capture IgM Assay 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.
- EE. All advertising and promotional descriptive printed matter relating to the use of the authorized LIAISON<sup>®</sup> XL Zika Capture IgM Assay shall clearly and conspicuously state that:
  - This test has not been FDA cleared or approved;
  - This test has been authorized by FDA under an EUA for use by authorized laboratories;

<sup>8</sup> For questions related to reporting Zika test results to relevant public health authorities, it is recommended that DiaSorin 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 10 – Ms. Meyer, DiaSorin Inc.

- 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 LIAISON<sup>®</sup> XL Zika Capture IgM Assay may represent or suggest that this test is safe or effective for the diagnosis of Zika virus infection.

The emergency use of the authorized LIAISON<sup>®</sup> XL Zika Capture IgM Assay as described in this letter of authorization must comply with the conditions and all other terms of this authorization.

#### **V. Duration of Authorization**

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

Sincerely,



Stephen M. Ostroff, M.D.  
Acting Commissioner of Food and Drugs

Enclosures

Dated: June 26, 2017.

Anna K. Abram,

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

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