

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the LIAISON XL Zika Capture IgM II. Testing should be conducted on specimens from people who meet Centers for Disease Control and Prevention (CDC) Zika clinical and/or epidemiological criteria for testing. All information and guidance, including for Zika virus laboratory testing, may change as more data is gathered on this virus. Please check the CDC's Zika virus website (see links provided in "How can I learn more" section) regularly for the most current information.

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**All patients whose specimens are tested with this assay should receive the Fact Sheet for Patients: LIAISON XL Zika Capture IgM II**

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#### What is an EUA?

The United States (U.S.) FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the use of in vitro diagnostic devices (IVDs) under EUA for the detection of Zika virus and/or diagnosis of Zika virus infection.

An IVD made available under an EUA has not undergone the full validation of an FDA-approved or cleared IVD. However, based on the totality of scientific evidence, it is reasonable to believe that this IVD may be effective in the detection of Zika virus, in the absence of an FDA-approved or cleared alternative. The EUA for this test is in effect for the duration of the Zika emergency, unless terminated or revoked (after which the test may no longer be used). An FDA approved or cleared IVD should be used instead of an IVD under EUA, when applicable and available.

#### What do I need to know about Zika virus testing?

Current information on Zika virus infection for healthcare providers, including case definitions and information about clinical signs and symptoms and/or epidemiological criteria, is available on CDC's website. Testing should be performed according to the CDC-issued guidance *U.S. Laboratories Testing for Zika Virus Infection*. The algorithms included within the CDC

guidance outline the appropriate Zika testing approach based on the presence of signs and symptoms, epidemiological risk factors, pregnancy status, and the time between onset of symptoms or suspected exposure and specimen collection.

In general, anti-Zika virus IgM is typically detectable in serum starting soon after onset of symptoms and is reliably detectable for approximately 12 weeks following infection.

- Serum is the primary diagnostic specimen for Zika virus RNA and serologic testing, and should be the primary specimen for collection and testing.
- The LIAISON XL Zika Capture IgM II can be used to test serum collected from patients between 8 days up to 10 weeks from likely risk of Zika virus exposure or post-onset of symptoms.
- Testing should be performed according to the CDC-issued guidance on individuals meeting the CDC Zika virus clinical and/or epidemiological criteria for testing.
- The LIAISON XL Zika Capture IgM II testing should be performed by laboratories in the U.S. that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform high or moderate complexity tests, or by similarly qualified non-U.S. laboratories.
- If a specimen is collected prior to 8 days post-onset of symptoms or likely risk of Zika virus exposure the patient should be asked to return and provide a second blood sample at least 7 days after the initial blood specimen.

Specimens should be collected with appropriate infection control precautions and according to the manufacturer's instructions for the specimen collection device, handling, and storage. Serum should be collected in serum separator tubes and centrifuged after collection to reduce the likelihood of hemolysis. Additional guidance

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**In the U.S. and its territories, Zika virus infection and disease (non-congenital and congenital) are nationally notifiable conditions and should be reported to the local or state health department.**

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**Report Adverse events**, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling **1-800-FDA-1088**

for collection of body fluid specimens for Zika diagnostic testing may be found at the CDC website.

history in making a final diagnosis and patient management decisions.

#### How can I learn more?

##### **CDC websites:**

**General:** <https://www.cdc.gov/zika/about/index.html>

**Pregnancy:** <https://www.cdc.gov/zika/pregnancy/index.html>

**Healthcare Providers:** <https://www.cdc.gov/zika/hc-providers/index.html>

**Lab Guidance:** <https://www.cdc.gov/zika/laboratories/lab-guidance.html>

**Specimen Collection:** <https://www.cdc.gov/zika/laboratories/test-specimens-bodyfluids.html>

##### **FDA websites:**

**EUAs:**(includes links to patient fact sheet and manufacturer's instructions)

<https://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.html>

##### **Manufacturer: DiaSorin Incorporated**

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For Technical Assistance: E-Mail: [ps@diasorin.com](mailto:ps@diasorin.com)

Any significant new findings that negatively impact the performance of the test will be made available at [www.diasorin.com/](http://www.diasorin.com/)

#### What are the Possible Test Results for this Test?

The LIAISON XL Zika Capture IgM II may give one of four possible test results: (1) presumptive Zika IgM positive, (2) presumptive recent Zika positive, (3) presumptive recent Zika negative, or (4) negative.

#### What does it mean if the specimen tests positive for Zika virus IgM Antibodies?

A presumptive positive test (i.e., presumptive Zika IgM positive or presumptive recent Zika positive) result for Zika virus indicates that anti-Zika virus IgM antibodies were detected in the patient's specimen. A presumptive positive test result in an authorized specimen collected from a patient is not definitive for diagnosis of Zika virus infection. Confirmation of a presumptive positive result requires additional testing by CDC or by qualified laboratories designated by CDC and in consultation with CDC, using the CDC-issued algorithm. Laboratory test results should always be considered in the context of clinical observations, epidemiological data, and travel

The LIAISON XL Zika Capture IgM II has been designed to minimize the likelihood of false positive test results. Cross-reactivity of any of the components of this test resulting in false positive results is possible, especially for patients who have received yellow fever or Japanese encephalitis vaccinations or had a recent or prior dengue virus infection. Because of potential cross-reactivity with dengue virus, the plaque reduction neutralization test (PRNT) for confirmation of presumptive positive results is not currently routinely recommended for patients with a history of flavivirus infections or those who reside in areas where Zika and/or dengue virus are known to circulate. This can make it difficult to identify which flavivirus is causing the patient's current illness. In the event of a false positive result, risks to patients could include the following: delayed diagnosis and treatment of alternative sources of infections; in the case of pregnant women, an unnecessary increase in the monitoring of a woman's pregnancy.

While there is an established association between Zika virus infection during pregnancy and microcephaly, detection of Zika virus RNA in specimens collected from a pregnant woman does not provide definitive information about the health of her fetus or indicate imminent harm to her fetus. If a pregnant woman is diagnosed with Zika virus infection based on detection of Zika virus RNA, issues such as timing of infection during the course of pregnancy, symptoms, and other factors may help determine the risk to her fetus. Patient management should follow current CDC guidelines.

#### What does it mean if the specimen tests negative for Zika virus IgM Antibodies?

A negative test (i.e., presumptive recent Zika negative or negative) result for anti-Zika virus IgM antibodies does not rule out Zika virus infection and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of Zika virus infection, especially if the patient specimen was collected prior to 8 days post-onset of symptoms (before anti-Zika virus antibody levels are expected to become detectable by the assay) or more than 10 weeks after the infection (as anti-Zika virus IgM antibody levels are expected to drop).

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When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with Zika virus infection. Such patients should have additional testing performed (see CDC testing guidance). Absence of laboratory evidence of Zika virus infection cannot definitively rule out Zika virus infection in persons with epidemiological risk factors. Results should be considered in the context of clinical signs and symptom onset, or in the absence of symptoms, time since exposure.

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