

You are being given this Fact Sheet because your sample(s) were tested for Zika virus. Testing was done because your healthcare provider believes you may have been exposed to Zika virus.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of Zika virus infection. After reading this Fact Sheet, if you have questions or would like to discuss the information provided further, please talk to your healthcare provider.

---

**Zika virus is primarily spread to people through mosquito bites, but it also can be transmitted from an infected individual to their partner during sex and from an infected pregnant woman to her developing baby.**

---

#### **What is Zika virus infection?**

Zika virus infection is caused by the Zika virus. Many people who are infected with Zika virus do not have any symptoms. Those who do usually have mild illness with symptoms that may include fever, rash, joint pain, or redness of the eyes. These symptoms often resolve on their own within a week.

#### **What risks are there of Zika virus infection during pregnancy?**

Infection with Zika virus during pregnancy can cause birth defects, such as microcephaly (a condition where the baby's head is smaller than expected and is associated with incomplete brain development). However, detection of Zika virus infection in the mother does not mean there is definite harm to the developing baby. Women who are infected with Zika virus while pregnant should be monitored more closely by their healthcare providers throughout their pregnancy.

#### **What is the LIAISON XL Zika Capture IgM II test?**

The test is designed to detect proteins, called antibodies, the human body makes to fight a Zika virus infection.

#### **Why was my sample tested?**

Your sample(s) were tested because your healthcare provider believes you may have been exposed to Zika virus based on your signs and symptoms, and/or because:

- You live in or have recently traveled to a place where Zika virus infection is known to occur, and/or
- Because you have another possible exposure to Zika virus (for example, sexual transmission).

The sample(s) collected from you were tested to help find out whether you may be infected with Zika virus.

#### **What are the known and potential risks and benefits of the test?**

Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Risk that the test result is incorrect (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care and, if you are pregnant, that of your developing baby.
- The results of this test may help limit the spread of Zika virus in your community.

#### **What does it mean if I have a positive Zika virus test result?**

If you have a positive test result, it is very likely that you have or have had a Zika virus infection. There is a very small chance that this test can give a positive result that is wrong (a false positive result). If your result from this test is positive, your healthcare provider will work with you to take care of yourself and, if you are pregnant, monitor the health and development of your baby.

---

**How can I learn more?** The most up-to-date information on the Zika virus is available at the CDC websites:

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

If you have a pregnant partner and you are positive for Zika virus infection you should use barrier methods, such as condoms, consistently and correctly, or abstain from sex with your partner, for the duration of the pregnancy to lessen the risk that you may transmit Zika virus infection to your pregnant partner. If you have a positive test result for Zika virus and you are considering becoming pregnant or have a partner who might become pregnant, then you should discuss the risks with your healthcare provider.

**If I am pregnant and have a positive Zika test result, does it mean that my baby will have a birth defect?**

Not necessarily. Although evidence shows that Zika virus infection during pregnancy can be a cause of birth defects and other poor pregnancy outcomes, not all Zika virus infections result in these pregnancy problems. At this time, we do not know how often babies will have microcephaly or other problems if a woman is infected with Zika virus while she is pregnant.

---

**A positive test result for Zika virus infection during pregnancy signals to your healthcare provider to watch your pregnancy more closely, meaning they might do more ultrasounds or other tests to check the growth and development of your baby and check for any signs of Zika virus infection.**

---

**What does it mean if I have a negative test result?**

A negative test result means that antibodies to Zika virus were not found in your sample. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with a Zika virus infection. You may also get a negative result if your sample was collected just after you became ill and before your body has had enough time to make antibodies for the test to measure. In this situation, your

healthcare provider may ask you to return 7 days later to provide a second blood sample for testing. You may also get a negative result if your sample was collected more than 10 weeks after your illness, as your body may have already fought off the virus and the amount of antibodies is so low that they cannot be measured by this test.

Your healthcare provider will help you to interpret your test results and work with you to continue to monitor your health and, if you are pregnant, the health of your developing baby.

**Is this test FDA-approved or cleared?**

No. This test is not yet approved or cleared by the United States (U.S.) FDA. An FDA approved or cleared test should be used, when applicable and available. Instead, FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). This EUA is supported by the Secretary of Health and Human Services' (HHS's) declaration that circumstances exist to justify the use of diagnostic tests under EUA for the detection of Zika virus and/or diagnosis of Zika virus infection. This EUA will remain in effect (meaning this test can be used) for the duration of the Zika emergency, unless it is terminated or revoked by HHS or FDA (after which the test may no longer be used).

---

**How can I learn more?** The most up-to-date information on the Zika virus is available at the CDC websites:

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