

## **Fact Sheet for Pregnant Women: Understanding Results from the Zika MAC-ELISA**

**June 29, 2016**

### **Dear Madam:**

You are being given this Fact Sheet because your blood or cerebrospinal fluid (CSF) has been tested for evidence of Zika virus infection. This testing was done because your health care provider believes you may have been exposed to the virus. The Zika MAC-ELISA is a test to help determine if you have recently been infected with Zika virus.

This Fact Sheet contains information to help you understand the risks and benefits of using the Zika MAC-ELISA. If possible, you may want to discuss with your health care provider the risks and benefits described in this Fact Sheet and any additional questions you may have.

### **What is Zika virus Infection?**

Zika virus infection is caused by the Zika virus, which is most often spread to people through mosquito bites. A woman infected with Zika virus during pregnancy can pass the virus to her developing baby. Zika virus can also be passed by an infected man to his partner during sex. Since 2015, a large number of people infected with Zika virus have been reported in many South and Central American and Caribbean countries.

Most people who are infected with Zika virus do not have any symptoms. Those that 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.

Infection with Zika virus during pregnancy can cause microcephaly (where the baby's head is smaller than expected, a sign of incomplete brain development) and other severe brain defects. However, detection of Zika virus infection in the mother does not mean there is definite harm to the developing baby. Some women who had Zika virus infection during pregnancy have delivered apparently healthy babies. Women who are infected with Zika virus while pregnant should be monitored more closely by their health care providers throughout their pregnancy.

There have also been reports of a possible link between Zika virus infection and an illness that can cause temporary paralysis (Guillain-Barré syndrome).

### **What is the Zika MAC-ELISA?**

The Zika MAC-ELISA is a laboratory test designed to detect proteins the human body makes to fight a Zika virus infection. These proteins, called antibodies, appear in the blood starting soon after the start of illness and last for up to 12 weeks. In some people, they are present for longer than 12 weeks. If the Zika MAC-ELISA detects these antibodies, the test is positive. If the Zika MAC-ELISA does not detect these antibodies, the test is negative.

The Zika MAC-ELISA has not been cleared or approved by the U.S. Food and Drug Administration (FDA). However, FDA has authorized the emergency use of this test under an Emergency Use Authorization (EUA).

**Why was my sample tested using the Zika MAC-ELISA?**

Your blood or CSF sample(s) were tested because you have symptoms that resemble Zika virus infection, because you live in or have traveled recently to a place where Zika virus infection is known to occur, and/or because you have another possible exposure to Zika virus (e.g., sexual transmission). The sample(s) collected from you was tested using the Zika MAC-ELISA to help find out whether you may have been recently infected with Zika virus. The test results, along with other information, could help your health care provider make decisions about how to take care of you and better monitor your pregnancy.

**What are the known risks and benefits of the CDC Zika MAC-ELISA?**

Besides possible discomfort or other complications that can happen when your specimen is collected, there is still a risk that the test result will be incorrect (see next paragraphs for more information). The benefit of having this test is that the results of this test, along with other information, can help your health care provider make decisions about how to take care of you and your developing baby.

**If this test is positive for Zika virus, does it mean that I have Zika virus infection?**

If you have a positive result with the Zika MAC-ELISA, it is likely that you recently were infected with the Zika virus. There is a chance that this test can give a positive result that is wrong; this is called a “false positive” result. There are some other very closely related viruses (such as dengue virus) that can cause the human body to produce antibodies that may cause the test to be positive.

If your result from this test is positive or equivocal (unclear), your health care provider or health department will determine if your results should be evaluated with additional testing and/or with testing from other samples that may have been collected from you. It is important that you work with your health care provider or health department to help you understand the next steps you should take. They will also work closely with you to monitor the health and development of your baby.

**If this test is positive for Zika virus, does it mean that my child will have a birth defect?**

No, not necessarily. Studies have reported that some, but not all, babies born to women with positive Zika test results during pregnancy were born with microcephaly and other problems. At this time, we do not know how often a baby will have microcephaly or other problems if a woman is infected with Zika while she is pregnant. Your doctor or other health care provider will watch your pregnancy more closely if you have a positive Zika virus test. This test can also give positive results when the patient has had an infection with a virus other than Zika virus (see above). The results of this test are not conclusive - a positive test result for Zika virus infection during pregnancy signals to your doctor or other healthcare provider to watch your pregnancy more closely, meaning he or she might do more ultrasounds or other tests to check the growth and development of your fetus and check for any signs of Zika virus infection.

**If this test is negative, does it mean that I do not have Zika virus infection?**

Even if you have a negative test, you may have been infected with Zika virus. If your sample was collected just after you became ill, it is possible that your body had not yet had enough time to make antibodies for the test to measure. If the sample was collected more than 12 weeks after your illness, it is possible that your body has already fought off the virus and the amount of antibodies is so low that they cannot be measured. Your health care provider will help you to interpret your test results and work with you to continue to monitor your health and the health of your baby.

**What is an Emergency Use Authorization (EUA)?**

An EUA is a tool that FDA can use to allow the use of certain medical products for emergencies based on scientific data. The U.S. Secretary of Health and Human Services (HHS) has declared that circumstances exist to allow the emergency use of authorized diagnostic tests for Zika virus infection, such as the Zika MAC-ELISA, under an EUA.

At this time, there are no FDA approved/cleared alternative tests available that detect Zika virus infection. FDA has authorized the emergency use of the Zika MAC-ELISA to test for antibodies to Zika virus in blood and CSF. Use of this test is authorized only for the duration of the potential emergency, unless it is terminated or revoked by FDA sooner.

**How can I learn more?**

Information about Zika virus is available at the CDC website:

<http://www.cdc.gov/zika/index.html>

Any significant new findings that negatively impact the performance of the test and that are observed during the course of the emergency use of the Zika MAC-ELISA will be made available at: <http://www.cdc.gov/zika/index.html>.

Please also contact your health care provider if you have any questions.