

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

February 26, 2016

Dear Madam:

You are being given this Fact Sheet because your blood or cerebrospinal fluid (CSF) was tested for evidence of Zika virus infection. This testing is being done because you have symptoms of Zika virus infection and/or you live in or have traveled to areas with ongoing Zika virus transmission. The test being used for your specimen(s) is called the Zika MAC-ELISA, which is a laboratory test designed to help detect Zika virus infection in humans.

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 providers the risks and benefits described in this Fact Sheet.

What is Zika virus Infection?

Zika virus infection is caused by the Zika virus and most often spread to people through mosquito bites. Spread from mother to fetus and through sex has also been documented. Since 2015, a large number of Zika virus infection cases have been reported in several South and Central American countries. Cases have also been reported in the United States among persons who have traveled recently to these 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.

There have been reports from Brazil of a possible link between Zika virus infection and an illness that can cause temporary paralysis (Guillain-Barré syndrome). There have also been reports of birth defects and other poor pregnancy outcomes in pregnant women with Zika virus infection. The connection between Zika virus infection and birth defects is not well understood. Zika virus infection in a mother does not definitely mean a poor pregnancy outcome will occur. However, pregnant women who have had a Zika virus infection should be monitored more closely by their health care providers throughout their pregnancy.

What is the Zika MAC-ELISA?

The Zika MAC-ELISA is a laboratory test to detect proteins the human body makes to fight a Zika virus infection. These proteins, called antibodies, appear in the blood starting 4-5 days after the start of illness and last for up to 12 weeks. In some people, they are present for longer than 12 weeks.

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) are being tested because you have symptoms that resemble Zika virus infection and/or because you live in or have traveled recently to places where Zika virus infection is known to occur. The sample(s) collected from you will be tested using the Zika MAC-ELISA to help determine whether you may have been recently infected with Zika virus. The test results, along with other information, could help your doctor 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 during sample collection, 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 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), you should ask your health care provider or health department if additional testing has or will be carried out to rule out a false positive result. 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 child.

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

No, not necessarily. First, the link between Zika virus infection and poor pregnancy outcomes, such as birth defects, is not well understood. Having Zika virus infection does not necessarily mean harm to the child. Second, this test can give positive results when the patient has a history of infection with some other viruses (see above). While the results of this test are not conclusive, a positive or equivocal test result may lead your doctors to conduct additional testing or to follow your pregnancy more closely.

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

If you have a negative test, it does not necessarily mean that you have not 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.

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 and any significant new findings 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.