

Fact Sheet for Pregnant Women: Understanding Results from the ZIKV *Detect*TM IgM Capture ELISA

August 17, 2016

Dear Madam:

You are being given this Fact Sheet because your blood 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 test being used on your specimen is called the ZIKV *Detect*TM IgM Capture ELISA, which is a laboratory test designed 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 ZIKV *Detect*TM IgM Capture 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 individual to their partner during sex. Since 2015, a large number of people infected with Zika virus have been reported in many South and Central American countries 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, joint pain, rash, 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 in babies. 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 ZIKV *Detect*TM IgM Capture ELISA?

The ZIKV *Detect*TM IgM Capture 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 Zika illness and last for up to 12 weeks. If the ZIKV *Detect*[™] IgM Capture ELISA detects these antibodies, the test is positive. If the ZIKV *Detect*[™] IgM Capture ELISA does not detect these antibodies, the test is negative.

The U.S. Food and Drug Administration (FDA) has not cleared or approved this test. No FDA-cleared or approved tests exist that can tell whether you have or have had Zika virus infection. However, FDA has authorized the use of this test under an Emergency Use Authorization (EUA).

Why was my sample tested using the ZIKV *Detect*[™] IgM Capture ELISA?

Your blood sample was tested because you have symptoms of Zika virus infection, 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 (e.g., sexual transmission). The sample collected from you was tested using the ZIKV *Detect*[™] IgM Capture 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 monitor your pregnancy.

What are the known risks and benefits of InBios' ZIKV *Detect*[™] IgM Capture ELISA?

Besides possible discomfort and other complications that can happen when your specimen is collected, there is 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 Zika test result, 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 (e.g., dengue virus and West Nile virus, which, like Zika virus, are called “flaviviruses”) 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, your health care provider or health department will determine if your results should be evaluated with additional testing. It is important that you work with your health care provider or health department to help you understand the next steps you should take for yourself. 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 baby will have a birth defect?

No, not necessarily. While evidence shows that Zika virus infection during pregnancy is 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 doctor or other health care 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 baby and check for

any signs of Zika virus infection.

If this test is positive for “other flavivirus” (e.g., dengue virus or West Nile virus) does it mean that I have dengue virus infection or West Nile virus infection?

If you have a positive test result for “other flavivirus,” it is likely you have a dengue virus infection or a West Nile virus infection. If your result from this test is positive for other flavivirus, additional testing may be required and your health care provider or health department will work with you to help you understand the steps you should take to care for yourself.

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

Even if you have a negative test result, 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 ZIKV *Detect*[™] IgM Capture 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 ZIKV *Detect*[™] IgM Capture ELISA to test for antibodies to Zika virus in blood. Use of this test is authorized only for the duration of the threat of the 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 ZIKV *Detect*[™] IgM Capture ELISA will be made available at the InBios website: <http://www.inbios.com>.

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