Fact Sheet for Patients:
Understanding Results from the DPP® Zika IgM Assay System

September 27, 2017

Dear Patient:

You are being given this Fact Sheet because your blood was tested for evidence of Zika virus infection. This testing was done because your healthcare provider believes you may have been exposed to Zika virus. The test used on your sample(s) is called the DPP® Zika IgM Assay System, 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 DPP® Zika IgM Assay System. You may want to discuss with your healthcare provider the benefits and risks 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 and is primarily spread to people through mosquito bites. Zika virus can also be passed by infected individuals to their partner during sex. A woman infected with Zika virus during pregnancy can pass the virus to her developing fetus. Many 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 typically resolve on their own within a week.

Infection with Zika virus during pregnancy can cause microcephaly (a condition where the baby's head is smaller than expected, which is a sign of incomplete brain development) and other severe brain defects in babies. However, detection of Zika virus infection in a pregnant woman does not mean there is definite harm to the developing fetus. Women who are infected with Zika virus while pregnant should be monitored more closely by their healthcare providers throughout their pregnancy. Current information on Zika virus infection is available at http://www.cdc.gov/zika/symptoms/index.html. Additional information for pregnant women and those who are considering becoming pregnant is available at http://www.cdc.gov/zika/pregnancy/index.html.

What is the DPP® Zika IgM Assay System?

The DPP® Zika IgM Assay System 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 soon after the start of illness and become detectable by the DPP® Zika IgM Assay System by 8 days after the first symptoms of Zika infection or exposure to Zika virus. The antibodies last for up to 12 weeks, but in some people, they are present for longer than 12 weeks. However, the DPP® Zika IgM Assay System is used for testing blood collected no earlier than 8 days after symptoms were first noted or likely risk of Zika virus exposure. If the DPP® Zika IgM Assay System detects these antibodies, the test is positive (i.e., reactive). If the DPP® Zika IgM Assay System does not detect these antibodies, the test is negative (i.e., non-reactive).

Why was my sample tested using the DPP® Zika IgM Assay System?
Your sample was tested because you have signs and 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(s) collected from you were tested using the DPP® Zika IgM Assay System to help find out whether you may have been recently infected with Zika virus.

What are the known and potential risks and benefits of the DPP® Zika IgM Assay System?
Besides possible discomfort or other complications that can happen when your sample(s) are collected, there is a risk that the test result is incorrect (see below for more information). If your blood was collected earlier than 8 days or later than 12 weeks from when you think you had symptoms or had a risk of exposure to Zika virus, please inform your healthcare provider, as this may increase the risk of a test result that is incorrect. Please be aware that, if your blood sample was collected earlier than 8 days, your healthcare provider may ask you to return 7 days later to provide a second blood sample for testing.

The benefit of having this test is that the results of this test, along with other information, can help inform your healthcare providers when making recommendations about your care and, if you are pregnant, the care of your developing fetus. The results of this test may help limit the spread of Zika virus in your community. For more information, see
http://www.cdc.gov/zika/prevention/protect-yourself-and-others.html

If this test is positive for Zika virus, does it mean that I have Zika virus infection?
If you have a positive result, it is likely that you have had a recent Zika virus infection. It is possible that you may have had a recent Zika virus infection and not have had any symptoms. 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, your healthcare 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 healthcare provider or health department to help you understand the next steps you should take and, if you are pregnant, to monitor the health and development of your fetus.

If you have a pregnant partner and you are positive for Zika virus infection, you should use condoms and/or other barriers (e.g., dental dams) consistently and correctly during sex, or abstain from sex with your partner, for the duration of the pregnancy, to lessen the risk that you may pass Zika virus infection to your 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.

Information about steps to take if you are diagnosed with Zika virus infection is available at
http://www.cdc.gov/zika/symptoms/treatment.html.

If I am pregnant and my test is positive for Zika virus, does it mean that my child will have a birth defect?
No, not necessarily. Although 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 problems. At this time, we do not know how likely it is that a baby will have microcephaly or other problems if his/her mother is infected with Zika virus while she is pregnant.

A positive test result for Zika virus infection during pregnancy signals to your healthcare providers to watch your pregnancy more closely, meaning they might do more ultrasounds or other tests to check the growth and development of your fetus. More information for pregnant women who have tested positive for Zika virus infection is available at: http://www.cdc.gov/zika/pregnancy/protect-yourself.html.

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 and before 8 days from when you think you had symptoms or had a risk of exposure to Zika virus, it is possible that your body had not yet 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. 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 by this assay. 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 fetus.

Is this test FDA-approved or cleared?
The U.S. Food and Drug Administration (FDA) has not cleared or approved the DPP® Zika IgM Assay System test or any other test to detect Zika virus infection. However, FDA has authorized the use of this test under 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 diagnostic tests for Zika virus infection, such as the DPP® Zika IgM Assay System, under an EUA.

FDA has authorized the emergency use of the DPP® Zika IgM Assay System to test for antibodies to Zika virus in your specimens only for the duration 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.

Information about any significant new findings that are observed during the course of the emergency use of the DPP® Zika IgM Assay System will be made available at the Chembio website: http://www.chembio.com/.

Please also contact your healthcare provider if you have any questions.