Fact Sheet for Patients: Understanding Results from the VERSANT® Zika RNA 1.0 Assay (kPCR) Kit

Updated: March 15, 2017

Dear Patient:

You are being given this Fact Sheet because your blood and/or urine has been 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 VERSANT® Zika RNA 1.0 Assay (kPCR) Kit, 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 VERSANT® Zika RNA 1.0 Assay (kPCR) Kit. 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, which 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, joint pain, rash, 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 VERSANT® Zika RNA 1.0 Assay (kPCR) Kit?

The VERSANT® Zika RNA 1.0 Assay (kPCR) Kit is a laboratory test designed to detect Zika virus.

Why was my sample tested using the VERSANT® Zika RNA 1.0 Assay (kPCR) Kit?

Your sample(s) were tested because you have signs and symptoms that resemble 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. The sample(s) collected from you were tested using the VERSANT® Zika RNA 1.0 Assay (kPCR) Kit to help find out whether you were infected with Zika virus.

What are the known risks and benefits of the VERSANT® Zika RNA 1.0 Assay (kPCR) Kit?

Besides possible discomfort or other complications that can happen when your sample(s) are collected, there is a risk that the test result will be incorrect (see below for more information). The benefit of having this test is that the results of this test can help your healthcare provider 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.

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

If you have a positive test result, it is very likely that you have or have had a recent Zika virus infection. It is possible that you may have Zika virus detected and not have any symptoms. There is a very small chance that this test can give a positive result that is wrong; this is called a "false positive" result. If your result from this test is positive, your healthcare provider or health department will work with you to take care of yourself 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 fetus 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?

A negative test result means that virus was not found in your sample. For Zika virus, a negative result for a sample collected while a person has symptoms usually means that Zika virus did not cause your recent illness.

It is possible for this test to give a negative result that is incorrect (a "false negative" result) in some people with a Zika virus infection. You may also get a negative result if your illness/symptoms were very mild and/or started earlier than the date you first noticed them or if the virus could no longer be detected in your sample when it was collected for testing.

If your Zika virus test result for the VERSANT® Zika RNA 1.0 Assay (kPCR) Kit is negative, you should ask your healthcare provider or health department if additional testing may be needed. It is important that you work with your healthcare provider or health department to help you understand the next steps you should take. Your healthcare provider will work with you to continue to monitor your health and, if you are pregnant, the health of your fetus.

What is an Emergency Use Authorization (EUA)?

The US Food and Drug Administration (FDA) has not cleared or approved the VERSANT® Zika RNA 1.0 Assay (kPCR) Kit or any other test to detect Zika virus. No FDA-cleared or approved tests exist that can tell whether you have 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 certain emergencies based on scientific data. The US 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 Siemens VERSANT® Zika RNA 1.0 Assay (kPCR) Kit, under an EUA.

FDA has authorized the emergency use of the VERSANT® Zika RNA 1.0 Assay (kPCR) Kit to test for the presence of Zika virus in your specimens only for the duration of the threat of the emergency, unless the EUA is terminated or revoked by FDA sooner.

How can I learn more?

Information about Zika virus infection is available at the CDC website:
http://www.cdc.gov/zika/index.html.

Information about any significant new findings observed during the course of the emergency use of the VERSANT® Zika RNA 1.0 Assay (kPCR) Kit will be made available at the Siemens Healthcare Molecular Diagnostics website:
http://usa.healthcare.siemens.com/molecular-diagnostics.

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