

## Fact Sheet for Patients: Understanding Results from the **LightMix® Zika rRT-PCR Test**

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### 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 health care provider believes you may have been exposed to the virus. The test used on your sample(s) is called the **LightMix® Zika rRT-PCR Test**, 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 **LightMix® Zika rRT-PCR Test**. You may want to discuss with your health care 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 baby.

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 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. Women who are infected with Zika virus while pregnant should be monitored more closely by their health care 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 **LightMix® Zika rRT-PCR Test**?

The **LightMix® Zika rRT-PCR Test** is a laboratory test designed to detect Zika virus.

### Why was my sample tested using the **LightMix® Zika rRT-PCR Test**?

Your sample(s) were tested because you have signs and symptoms of Zika virus infection, and 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 **LightMix® Zika rRT-PCR Test** to help find out whether you may be infected with Zika virus.

### What are the known and potential risks and benefits of the **LightMix® Zika rRT-PCR Test**?

Besides possible discomfort and other complications that can happen when your sample is collected, there is a risk that the test result is incorrect (see below for more information). The benefit of having this test is that the results of this test can help inform your healthcare providers when making recommendations about your care and, if you are pregnant, the care of

your developing baby. 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 health care 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 baby.

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 baby. 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 a Zika virus infection?**

A negative test result means that Zika 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 result for the **LightMix® Zika rRT-PCR Test** is negative, you should ask your health care provider or health department if additional testing may be needed. It is important that you work with your health care 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 baby.

**Is this test FDA-approved or cleared?**

The US Food and Drug Administration (FDA) has not cleared or approved the **LightMix® Zika rRT-PCR Test** 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 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 **LightMix® Zika rRT-PCR Test**, under an EUA.

FDA has authorized the emergency use of the **LightMix® Zika rRT-PCR Test** to test for the presence of Zika virus in your blood 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>.

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 **LightMix® Zika rRT-PCR Test** will be made available at [lifescience.roche.com](http://lifescience.roche.com).

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