Gulf Coast Regional Blood Center
Commit for Life®

copernicus group independent review board

Approved: 19Sep2016

RESEARCH PARTICIPANT INFORMATION SHEET

Protocol Title: A Prospective Study to Evaluate the Specificity of the **cobas®** Zika Test for use with the **cobas®** 6800/8800 System for Screening of Blood Donations for the Presence of Zika Virus RNA

Study #: cX8-ZIKA-412
Sponsor: Roche Molecular Systems, Inc.
Principal Investigator Name: **Susan Rossmann MD PhD**
Research Site Address(es):

Gulf Coast Regional Blood Center
1400 La Concha Ln
Houston TX 77054

Daytime Telephone Number(s): 713-791-6275
24-hour Contact Number(s): 713-790-1200 Ext. 4 Option 4

Additional contact information for your local blood donation center: Please refer either to the donation consent document that you signed at your local donation center or, if your donation consent was electronic, to your local donation center's website.

This donor center is doing a research study on a new test system used to detect Zika Virus. To participate, you must meet the following criteria:

- You must meet the standard donor eligibility criteria.
- If you are a minor (for example age 16-17 years), you may participate if you have obtained permission of a parent (or legal guardian), where required by law, to donate blood and you assent to donate blood.

If you donate, your test results will be used to evaluate the new test system. Any remainder of your donation may be stored up to 3 years after the completion of the study and used for further research related to the Zika virus. Because of changes in blood screening regulations, your participation in this research study is necessary in order to donate today. Your alternative is to not donate today.
If your test results show that you may have a Zika virus infection:

- This donation center will attempt to contact you only if your test results show that you may have a Zika virus infection and their significance will be explained. You will not be contacted if your results do not show that you may have Zika virus infection.
- You will be invited to participate in a voluntary follow-up study involving additional blood samples and you will be asked to sign an additional consent form.
- You should discuss these results with your primary care physician. You should discuss the potential risk of sexual transmission of the Zika virus, and the potential harm to the fetus during pregnancy with either your physician or your donation center.

At any time, you may also visit the Centers for Disease Control and Prevention (CDC) website at ***http://www.cdc.gov/zika/*** for additional information regarding Zika virus.
Although you may not receive a direct benefit from this study, the results may allow for better test systems to become available to protect the blood supply.
You will not be paid for your participation in this study.
The risk of having your donation tested with the study test is not any greater than having your donation tested for other infectious diseases.
Your participation in this study is voluntary. If you decide not to participate after your donation is taken or not to donate today, there is no penalty to you. If you have questions about this study or would like to withdraw from further participation in this research study, call the Principal Investigator at the number(s) above.
The results of all testing on your donation during this study are confidential, except when reportable by law to public health authorities, and to authorized blood center personnel, the U.S. Food and Drug Administration (FDA), and Roche Molecular Systems, Inc.
If you have questions about your rights as a study participant call the Copernicus Group Independent Review Board (IRB) at 1-888-303-2224. An IRB is a group of people who review research independent of those sponsoring and doing the work. Please visit the Copernicus Group IRB website www.cgirb.com for more information about research studies and the role of a research study participant.