Approved: 22Jul 2016

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:	**Robert Rainer MD**

Research Site Address(es):

The Blood Connection Inc
1099 Bracken Rd
Piedmont SC 29673

Daytime Telephone Number(s): 864-751-3028

24- hour Contact Number(s): 864-308-6764

The Blood Connection is participating in a research study on a new test system used to detect Zika Virus. To participate, you must meet the following criteria:

- To donate without parental consent, you must be age 18 or older and consent to participating in this research study.
- To donate if you are ages 16-17, you may participate with the permission of a parent (or legal guardian), and your consent to participating in this research study.

If you donate today, your test results may be used to evaluate the new test system. About 6-10 tablespoons of your donation may be used for this research study. 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. 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.

Your blood sample will not be labeled with your name or other information that would identify you directly. Instead, it will have a unique code that allows for it to be linked to some of your donor history information kept at the Blood Connection where you gave your blood plasma donation. This link means that your specimen can be identified but only indirectly. This helps protect your personal information. Your donation will not be used for genetic testing.

You will be notified if your results are positive for Zika virus, and you will be invited to participate in a voluntary follow-up study involving additional blood samples. In the event you are asked to participate in a follow-up study, you will be asked to sign a consent form.

If your results are positive for Zika, the Blood Connection will discuss with you the potential risk for sexual transmission of Zika Virus and, if you are pregnant, the potential harm to the fetus. You should also discuss these results with your primary care physician. 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.

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 now or after your donation is taken, there is no penalty to you. If you decline testing we will be unable to use your whole blood or red blood cells. However, we will inform you whether you may donate plasma or platelets. If you have questions about this study or would like to request that your test results not be used for this study, please inform the study team by contacting the Principal Investigator at 864-751-3028 (daytime) or 864-308-6764 (outside of normal working hours).

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 of 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.

SUBJECT'S STATEMENT OF CONSENT

I consent to take part in this research study. This study and the information in this consent form have been explained to me. I have read all pages of this form, or they have been read to me. I have had an opportunity to ask questions and they have been answered to my satisfaction. I have been told that I have not given up any legal rights. I voluntarily agree to take part in this research study.

Printed Name of Study Participant

Signature of Study Participant **Date of Signature**

The information about the study was described to the study participant in a language he/she understood.

Printed Name of Person Obtaining Consent

Signature of Person Obtaining Consent **Date of Signature**

Statement of the Witness *(*applicable if study participant cannot read)*

The information in the consent form was accurately explained to, and appeared to be understood by the study participant. Informed consent was freely given.

Printed Name of Impartial Witness

Signature of Impartial Witness **Date of Signature**

PARENTAL CONSENT FOR A CHILD TO PARTICIPATE IN RESEARCH

*(*applicable if study participant is age 16-17))*

As parent or legal guardian, I give permission for _____ (child's name) to become a participant in the research study described in this form.

Child's Date of Birth: _____

Parent/Guardian Name (Printed):

Parent/Guardian Signature **Date of Signature**

SUBJECT'S ASSENT (16-17 years)

- I have read this form or had it read to me.
- I don't have to be in this study if I don't want to.
- I can stop at any time and no one will be upset with me.
- I have asked any questions I have so far about the study.
- My questions have been answered.

I agree to take part in this study.

Child's Name (please print)

Signature of Child, as able **Date of Signature**

STATEMENT OF PERSON CONDUCTING ASSENT DISCUSSION

- I have explained the study in language understood by the participant.
- I have answered all the questions of the participant relating to this research.
- The participant agrees to be in the research.
- I believe the participant's decision to enroll is voluntary.
- The study Investigator and study staff agree to respect the participant's physical or emotional dissent at any time during this research when that dissent pertains to anything being done solely for the purpose of this research.

Printed Name of Person Obtaining Assent

Signature of Person Obtaining Assent **Date of Signature**