

Zika Virus Research Information

Sponsor / Study Title: Hologic, Inc. / Pre-pivotal Procleix® Zika Virus Assay Testing of Donations From Donors of Whole Blood and Blood Components

Protocol Number: B10383-ZIKVPS-CSP-01

Principal Investigator: Phillip Williamson, PhD

Telephone: 602-343-7197

Additional Contacts: For Immediate Assistance:
Sub-Principal Investigator: Robert C. Blaylock, M.D.: 801-584-5272
Donor Counseling Services:
Rami Al-Tigar, BS Technical Supervisor: 801-584-5273
Wendy Tronier, BS Technical Supervisor: 801-583-2787, Ext. 2467
Lucinda Manning, BS Manager: 801-584-5274
Kathy Reeder, BS Lead: 801-583-2787, Ext. 4202
Betty Kong, BS Lead: 801-583-2787, Ext. 3121

Please read this form carefully. Take time to ask the donor center staff as many questions about the use of your blood for research studies as you would like. The donor center staff can explain words or information that you do not understand. Reading this form and talking to the donor center staff may help you decide whether to donate or not.

You are being asked to participate in a research study to evaluate a new test for detection of a mosquito-borne agent known as Zika virus. Zika is a virus that rarely causes paralytic nervous system damage, but in pregnancy, can cause loss of the baby or serious birth defects. Most people do not get sick after infection. Only one in five people will have fever, rash, joint pain, and conjunctivitis (red eyes) lasting a few days to a week. Zika is usually transmitted by the bite of an infected mosquito. It can also be transmitted by sex with an infected man, from a pregnant mother to her baby and by blood transfusion.

This donor center is doing a research study to understand the effectiveness of a new test to detect the Zika virus in donated blood and prevent patient exposure. Some of this research is conducted with other institutions, such as blood bank organizations, academic centers and biomedical companies. 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.

Samples linked to your identifying information will be tested for ZIKA virus. If your test results suggest that you may be infected, this donation center will attempt to contact you to notify you and explain the significance of the results. The donation center will discuss the potential risk for sexual transmission of Zika Virus, and potential harm to the fetus during pregnancy. You will be notified in person, by phone, or by letter. If your test results suggest that you may be infected, you should 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.

If the results suggest that you may have a Zika virus infection, you will be invited to participate in a voluntary follow-up study involving additional blood samples. Should you choose to participate, an additional informed consent process will be required.

Your participation in this research study is entirely voluntary. You will not be paid for your participation in this study. Your participation will not require any additional procedures or time beyond the normal donation process. The risk of having your donation tested with the study test is not any greater than having your donation tested for other infectious diseases, although a positive result may alarm you. There is a very low chance that your blood sample may give a false positive result. If the test is positive, the blood that you donate will not be used for transfusion. There will be no costs or payments to you for your participation in this study. 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.

Zika Virus Research Information

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 Hologic, Inc. Your age, gender, general geographic location, and test results may be used to evaluate important information about Zika virus, but this information is combined with information about other donors and not identified with you.

You may refuse to participate by notifying the blood collection staff that you will not be donating blood or blood components today. 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 decide not to participate at this time, your decision will not change your future relationship with the blood center and there is no penalty to you. If you decide not to participate after your donation is taken, call the Principal Investigator at the number(s) above.

An Independent Review Board (IRB) is a group of people who review research studies to protect the rights and welfare of research participants. If you have questions or complaints about your rights as a study participant contact the Chesapeake IRB:

- By mail:
Study Subject Adviser
Chesapeake IRB
6940 Columbia Gateway Drive, Suite 110
Columbia, MD 21046
- or call **toll free**: 877-992-4724
- or by **email**: adviser@chesapeakeirb.com

Please reference the following number when contacting the Study Subject Adviser: Pro00017603.

If you have scientific questions or questions about your participation in these studies, you may contact our Donor Counseling Service at **801-584-5272**, **Operational Hours**: Monday and Friday: 7:30 A.M.- 2:30 P.M.; Tuesday through Thursday: 12:00 -7:00 P.M.; Saturday and Sunday: 8:00 A.m.- 3:00 P.M. By signing your Blood Donation Record, you are giving consent to allow us to use a portion of your blood donation and associated information for research purposes related to Zika virus.

Although you feel well and healthy at the time of your donation, please call us immediately at the phone number beside our donor center's name below if you develop any of the following symptoms within 14 days of your blood donation:

- Fever
- Rash
- Muscle or joint pain
- Eye pain or redness
- Headache

By notifying us as soon as possible after developing any of these symptoms you may prevent the blood you donated today from being transfused and possibly infecting a patient.

NOTE: If you recall being in an area where Zika is actively transmitted in the past 4 weeks, please call us. Although you are feeling well, you could be infected with Zika.

Donor Center Components Laboratory: 801-584-5275