Fact Sheet: Zika Virus Investigational Study Donor Information for Informed Consent

What
Informs donors of an investigational study protocol being performed that tests all donors for Zika virus

Who
Staff who
- Prepare the pre-read materials packets for blood donors
- Provide information materials to donors and determine a donor's eligibility to donate blood and blood components

Instructions
- Discard this instruction page before printing.
- Familiarize yourself with the information sheet in order to answer any donor questions.
- Have extra copies available to provide if the donor wants his or her own copy.
- Provide a copy of this fact sheet to all donors as part of the required pre-donation reading materials.

Revision History

<table>
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<tr>
<th>Revision Number</th>
<th>Summary of Revisions</th>
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<td>0.4</td>
<td>Initial version. Previously released as BSL 16-020-01</td>
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Fact Sheet: Zika Virus Investigational Study Donor Information for Informed Consent

Important Information Regarding Zika Virus

This information sheet explains an investigational study protocol being performed that tests all donors for Zika virus.

This information about Zika virus risk is important for the following reasons:
- Zika virus infection has spread rapidly in the Western Hemisphere outside the United States (U.S.) and Canada as well as in other areas worldwide.
- Zika virus infection is mild in most people, but there is concern that Zika virus infection is causing serious brain injury to infants whose mothers have been infected during pregnancy. It has also been linked to an increase in cases of Guillain-Barré syndrome, a temporary but serious disorder causing paralysis.
- Zika virus can be present in the blood of an infected person who has no symptoms of illness.
- Zika virus has been documented to be transfusion transmitted.
- There are reported cases of sexual transmission of Zika virus by males and females; the length of time that infectious Zika virus is present in semen or vaginal fluid remains unknown.
- Testing for Zika virus is now possible using an investigational nucleic acid test (NAT).

Self-Assessment

DO NOT DONATE TODAY.

If you have been diagnosed with Zika virus infection, please return to make a blood donation more than 120 days after your symptoms resolve.

Zika Virus Investigational Study

Investigational testing is being performed for all donations in the U.S. Your donation will be individually tested for the presence of Zika virus.

Your participation in this investigational study is completely voluntary. You may decide not to participate or discontinue participation at any time without penalty or loss of services that the American Red Cross provides. However, if you decide not to participate in this study, you cannot donate today. The study duration is unknown at this time, but if you want to be notified at the study conclusion, please call (866) 771-5534. If you choose to participate, a small amount of blood from your donation today will be used in the study being conducted by the American Red Cross and Hologic, Inc. (San Diego, California).
**Why is this investigational study being done?**

All blood establishments test blood samples to identify possible risks of infection in order to ensure the safety of the blood supply and the public’s health. Blood establishments do this by using tests that the Food and Drug Administration (FDA) has licensed for this purpose. Currently, there are no licensed tests for the detection of Zika or related viruses, and researchers are trying to develop such tests.

The purpose of this study is to assess the ability of a new investigational test to detect Zika virus. Zika virus is transmitted to people by the bite of mosquitoes that are infected with Zika virus. The mosquito becomes infected with Zika virus when it bites a person who has a Zika virus infection, and after about 1 week, can transmit the virus when biting a healthy person. Zika virus has been shown to be transmitted by transfusion and has been associated with significant clinical diseases and fatalities. Thus, testing is an important step to prevent transmission to and illness in transfused patients.

**What will happen if I take part in this study?**

- Your participation in this study will not involve any additional procedures or time beyond the normal blood donation process. No additional amount of blood will be taken from you today.
- The same samples used for routine blood donation testing will be tested with an investigational screening test for Zika virus and possibly other related viruses. If the investigational screening test is reactive (positive), your sample will be tested by additional investigational tests to determine if you are infected with Zika virus and other related viruses spread by mosquitoes. We will notify you by phone and by letter if you test reactive (positive) with the investigational screening test so that we can assess whether your exposure to Zika virus was a result of travel to a Zika virus risk area. We will also notify you of any abnormal investigational test results that are important to your health.
- No medication or treatment will be given as part of this investigational study. No genetic testing of your sample will be done that is unrelated to determining if you are infected with Zika virus and other related viruses.
- If you test reactive (positive) on the investigational Zika virus screening test, we will ask you to return and participate in a voluntary follow-up study so that we may better understand if you are infected. There will be no costs or payments to you for your participation in this study or the follow-up study if you participate. The follow-up study involves providing blood samples at different times. These samples would be used for testing that will help us better understand human infection with Zika virus and other related viruses.
- If you test reactive for Zika virus by the investigational screening test, whether you are infected or not, you will be deferred as a blood donor for 120 days and until a follow-up sample collected from you shows that you are not infected.
- You are free to discontinue participation at any time by notifying the study principal investigator. If you begin donation and then decide that you do not want to participate, you must notify the blood collection staff before you leave the collection site, and your donation will not be processed further. However, if you decide to withdraw from the study at a later time, the test information collected before your withdrawal may still be used or disclosed after your withdrawal. The principal investigator or Hologic, Inc., may remove you from the study without your consent if it is discovered that you do not meet the study requirements, at the discretion of the principal investigator, or if the study is canceled.
What are the possible risks and benefits of taking part in this study?
The risks of participating in the study are small. There is a small chance that the investigational screening test will give a false-positive result. However, by participating in this investigational study, you help protect the public health by supporting the development of new blood safety tests. In addition, there is the possibility that the investigational screening test will identify you as having an active Zika virus infection.

Will my results be confidential?
- The American Red Cross will make every effort to keep confidential any information that we obtain in connection with this study or any future tests that can be identified with you. Confidential information will not be disclosed without your written permission unless required by law.
- Your study records and blood samples will be given a code number. You will not be listed by your full name in the study records. The blood samples will not have your name or address on them.
- Although the investigational study results may be published, donor names and other identifying information will not be revealed except as required by law. Records are kept as required by state and federal laws. The FDA may need to review and copy donor records in order to verify study data; however, the FDA is committed to protection of the confidentiality of donor identity. As required by U.S. law, the department of health in your state will be notified if you test reactive (positive) by an investigational test for Zika virus.

Will my blood samples be stored?
Some of your sample may be saved, frozen indefinitely by the American Red Cross or its collaborators for testing in the future related to blood safety.
- Each new test will be evaluated by a committee that will consider your rights as a research participant.
- Your sample will not be used for genetic testing or any other testing unrelated to Zika or related viruses or blood safety without your consent.
- No personal identifiers will be available as part of your stored sample to the researchers performing the additional testing.
- You will be notified by phone or by letter about any abnormal test results that may impact your health.

Who do I contact if I have any other questions or concerns about the study?
If you have questions about your participation in this investigational study, or about the investigational study being conducted, or if you do not wish for your sample to be retained for future study, you may contact the study principal investigator, Dr. Susan Stramer, at (866) 771-5534. If you have questions about your rights as a research participant or if you feel you have been injured because of the investigational use of your blood sample, contact the American Red Cross Institutional Review Board administrator at (877) 738-0856.
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