Fact Sheet: Grifols Procleix Plasmodium Assay Investigational Study Donor Information for Informed Consent

This information sheet for informed consent explains the investigational study being performed to evaluate the performance of the investigational Procleix Plasmodium Assay (test), developed by Grifols Diagnostic Solutions Inc. There will be no human genetic tests performed on your donation.

The study involves testing your blood sample for the presence of RNA (genetic material) to five different species of *Plasmodium* (that is, *P. falciparum*, *P. ovale*, *P. vivax*, *P. malariae*, and *P. knowlesi*), the causative agents of malaria, using the investigational Procleix Plasmodium Assay. *Plasmodium* is a parasite that infects red blood cells and causes malaria in humans. By participating in this investigational study, you help protect the public health by supporting the development of new blood safety tests. The study plans to enroll about 170, 000 people.

Before you agree to participate, it is important that you read and understand the following explanation of the study. Your participation in this investigational study is completely voluntary and of little risk to you. If you choose to participate, a small amount of blood from your donation today may be used in a study being conducted by the American Red Cross and Grifols Diagnostic Solutions Inc. If you choose not to participate in the investigational study, you will have to wait until the conclusion of the study to donate. There will be no alternative sites to donate until the conclusion of this study.

Why is this investigational study being done?

All blood establishments test blood samples to identify possible risks of infections 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) approves for this purpose. The purpose of this study is to test the ability of an investigational nucleic acid test called transcription-mediated amplification (TMA) to detect the parasites that cause malaria in people (*Plasmodium falciparum* [or *P. falciparum*]) as well as other rarer species of *Plasmodium* (*P. malariae*, *P. vivax*, *P. ovale*, and *P. knowlesi*). An investigational assay is a test that is not approved by the FDA and is only allowed to be used in research. Malaria in people is caused by these *Plasmodium* parasites that are carried by mosquitoes. Malaria can be transmitted to people by a bite from a mosquito carrying the parasite or by exposure to *Plasmodium*-infected blood.

What will happen if I take part in this study?

- Your participation in this study will not involve any time beyond the normal blood donation process. Your blood sample may be tested with the investigational Procleix Plasmodium Assay. If the investigational assay screening test is reactive, your sample may be tested by additional tests, as volume permits, to determine if you are infected or had a previous exposure to malaria. You will be notified if you test reactive with the investigational assay (test). Because this assay is investigational, it is not known if the result will be accurate. The result should not be used to make any treatment decisions.
- At some sites, an additional tube of blood may be collected for the purpose of the study (there will be no additional blood draws).
- We will also notify you of the results of additional tests performed to confirm the result.
- No medication or treatment will be given as part of this investigational study. Your sample will not be used for testing unrelated to blood safety without your consent.
- If you test reactive on the investigational Procleix Plasmodium Assay, we may ask you to return and participate in a separate follow-up study so that we may better understand whether you were infected with *Plasmodium* or continue to be infected. The follow-up study would involve providing blood samples; some donors may be asked to provide samples on multiple occasions. These samples

would be used for testing that will help us better understand the performance of the investigation Procleix Plasmodium Assay and malaria in humans.
- If you test reactive for malaria by the investigational screening test, you will be deferred from donating blood for a period of 3 years.
- Any new important information that is discovered during the study that may influence your willingness to continue participation in the study will be provided to you.

What alternative choices do I have?
You can choose not to participate in the study. If you choose not to participate in the study, you can come back to this site or other sites to donate after the investigational study has been completed. Alternatively, you can donate in a neighboring American Red Cross blood region that is not participating in this study.

What are the possible risks of taking part in this study?
The risks of participating in the study are small. There is a small chance that the investigational Procleix Plasmodium Assay will give a false-reactive result. Whether we believe that you are infected with *Plasmodium* or tested falsely reactive, you will be deferred for 3 years from blood donation.

What are the benefits of taking part in this study?
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 if you have an active infection.

What are the costs or payments for participation?
There will be no costs or payments to you for your participation in this study. If you have a reactive test result, you may be asked to participate in the follow-up study. You will learn more about the follow-up study if you test reactive. The investigational test to be evaluated in this study may have commercial value if it is licensed by the FDA. If licensed, you will not be compensated or benefit financially.

Will my results be confidential?
- The American Red Cross and the test kit manufacturer, Grifols, will make every effort to keep any information that we obtain in connection with this study that can be used to identify you confidential. 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. Study records may be shared with additional researchers/investigators for future research. If so, personal identifiers will be removed so study records cannot be identified with you.
- 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 and federal agencies will be notified if you test reactive. The notification includes providing them your identifying information.

Is participation in the investigational study voluntary?
Your participation in the study is voluntary. You may decide not to participate at any time, without penalty or loss of benefits to which you are entitled, and without harm to your rights or future

relationship with the American Red Cross. If you decide not to participate, you cannot donate blood at this location until the conclusion of the study.

Can I withdraw from the investigational study?
Yes. You are free to discontinue participation at any time without harm to your rights or future relationship with the American Red Cross by notifying the study Principal Investigator. If you begin donating 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 Grifols may remove you from the study without your consent if it is discovered that you do not meet the study requirements, or if the study is canceled.

Will my blood samples be stored?
- If you agree, portions of your donation sample may be saved and frozen indefinitely by the American Red Cross or Grifols for testing in the future for research related to blood safety.
- Your sample will not be used for human genetic testing or any other testing unrelated to blood safety without your consent.
- Your stored sample will be labeled with a code number and not your name. Only authorized American Red Cross staff will be able to link a code number on your stored sample to your identifying information. Your identifying information will not be available to external researchers. Samples saved for testing in the future for research related to blood safety could be used for commercial profit that will not be shared with you.
- Your sample, even if personal identifiers are removed, will not be distributed to other researchers outside the American Red Cross or Grifols.
- You will be notified by the American Red Cross, by phone or letter, about any abnormal test results that may impact your health.

Whom do I contact about this study?
If you have any 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. Paula Saá at (866) 771-5534. If you have questions about your rights as an investigational study 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.