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Abbott Laboratories Official Title of the Study: Abbott Laboratories Alinity s Blood Screening Assays – Clinical Evaluation Protocol

NCT Number: NCT03285295

Type of Document: Informed Consent Form: Information Sheet for Central IRB

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Clinical Research Subject Information Sheet

TITLE:	Abbott Laboratories Alinity s Blood Screening Assays – Clinical Evaluation
PROTOCOL NO.:	9DY-02-14U01-03 WIRB® Protocol #20170871
SPONSOR:	Abbott Laboratories
INVESTIGATOR:	Name Address City, State Zip Country
STUDY-RELATED PHONE NUMBER(S):	Name (24 Hour Phone Number)

The Blood Center is doing a clinical research study to evaluate new versions under development of the blood tests currently used to detect Hepatitis B, Hepatitis C, HIV and HTLV viruses and Chagas disease in donor blood. If you agree to participate in this study, the blood samples used for routine blood donation may be tested with research tests. Your results using the new tests will be compared with the results for the current tests. As with the infectious disease tests already done, we will contact you if the results suggest that you have any infection. State law also requires that we contact local health authorities if your blood tests are positive for HIV or hepatitis.

The new tests (Alinity s blood screening assays) are investigational, meaning they have not been approved by the US Food and Drug Administration (FDA) for detection of these pathogens.

This study is for research purposes only. The only alternative is to not participate in this study.

Funding for this study is provided by Abbott Laboratories. Approximately 23,000 – 90,000 blood donors from multiple blood collection centers across the United States may be participating in this clinical study.

You will not receive any payment for permitting your donated blood sample to be used in the research testing.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Your participation in this study will not involve any additional procedures or time beyond the normal blood donation process. If the results are different than on the current test we will ask you to participate in a follow-up study involving additional blood samples. You may choose to decline participation in this follow-up study, but if you do participate, you will be asked to sign a separate consent form.

The risk of having your blood tested with the new study test is not any greater than having your blood tested with the current test.

Although you will not receive a direct benefit from this study, the results may allow for better test systems to protect the blood supply.

Your participation in this study is voluntary. If you do not want to participate, you may decide not to donate today and wait until the research study is completed. However, you may be able to donate at another site and our staff can provide you with information on alternative blood donation sites. If you decide not to participate now or after your blood is drawn, there is no penalty to you or any loss of benefits. However, information collected prior to your withdrawal may still be used or disclosed after your withdrawal.

If you have questions, concerns, or complaints about this study, or you feel you have been injured by your participation, or would like to request that your test results not be used for this study, call the Principal Investigator at [Insert Number].

Your donor records are confidential. The ethics committee and regulatory authorities, such as the FDA, and individuals from Abbott will have access to only your study results. The FDA and Abbott will NOT have access to your identity.

If you have questions about your rights as a study subject, or if you have questions, concerns, or complaints about the research, contact:

Western Institutional Review Board® (WIRB®)
1019 39th Avenue SE Suite 120
Puyallup, Washington 98374-2115
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com

An IRB is a group of people who conduct review of research independent of those sponsoring and doing the work.

WIRB will not be able to answer some study-specific questions. However, you may contact WIRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

You will receive a copy of this study information sheet to keep for future reference.