

COVER PAGE

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: Alinity s Follow-Up Study – Donor Consent for Local IRB

Date of Document: November 17, 2017

Doc No: ARC-DOC-031588	Subdiv: 14 - Donor Management	Doc Level: BSL Attachment	ARC Version: 0.1
Level 4 Subtype:	Training Subtype:	Mang Fac: BHQ	

Attachment:
Alinity s Follow-Up Study - Donor Consent

What this attachment is about

This attachment is used to document a donor's consent to participate in the Alinity s Follow-Up Study (ASFS) when the donor has test results from the Alinity s assays that do not agree with the final test results based on additional testing.

Who should use this attachment

This attachment applies to staff who obtain informed consent from ASFS-eligible donors.

Instructions

The Alinity s consent attachment is used to document the donor's agreement to participate in the ASFS and must be completed prior to collecting follow-up blood samples.

Before sharing this attachment with the donor, delete the instructions pages.

The follow-up study investigator

1. **At the time of donor counseling, ensures the following actions have been taken:**
 - The study has been explained and the donor has had the opportunity to ask questions about the study and risks of participation.
 - Explained that the donor may withdraw at any time
2. **Initiates two copies of the consent—one for the donor's signature and a copy for the donor to keep**
3. **Indicates on Pages 1 and 5 of the consent which disease agents apply to the donor. The disease agents that the donor will need to be tested for will be provided on the follow-up study-notice of donor eligibility [[14.4.frm910](#)].**
4. **Reads the options for participation (on Page 5 of the consent) to the donor and marks the boxes to indicate the donor's choices**
5. **Sends both copies of the consent to the donor, who will bring them to the collection site according to the work instruction on managing sample-only collections and testing [[14.3.706](#)]**

The completed informed consent is maintained as a record in the Alinity s donor case file, according to the work instruction on administering and managing follow-up and research studies [[14.3.705](#)].

For more information, refer to [14.3.705](#).



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The staff administering consent actions

Important: You must obtain written informed consent from the donor prior to **drawing the follow-up blood samples** or any other activities associated with the follow-up study. Only one Alinity s study-specific consent per donor is required.

Failure to obtain proper informed consent is an Institutional Review Board (IRB) violation that must be reported to the Scientific Support Office (SSO). Report a failure to obtain proper informed consent to the SSO as soon as possible. Refer to the work instruction on managing donors in follow-up and research studies for more information [[14.3.705](#)].

1. Identify the donor.

Refer to the reference on forms of identification [[15.4.ref401](#)] for the acceptable documents for identifying potential blood donors.

2. Is the donor underage (less than 18 years old)?

- ☐ If yes, the donor's parent or legal guardian, donor, and staff issuing the consent must sign the assent section (last page of the consent). This is true even in states where minors are allowed to donate blood.
- ☐ If no, go to the next step.

3. Ask the donor to read the informed consent.

4. Answer the donor's questions as appropriate.

Contact the study principal investigator/designee, regional medical director, the IRB, or a donor counselor at the phone numbers provided at the end of this consent, if needed.

5. Ask the donor to sign his or her name on the consent.

After reading the information in the consent and having all questions answered to his or her satisfaction, the donor must select one or more of the following study activities. This portion of the form may be completed by a research counselor with information provided by the donor during the donor's counseling session.

- Collection of follow-up samples
- Agrees to have follow-up samples stored for future use
- Does not agree to have follow-up samples stored for future use

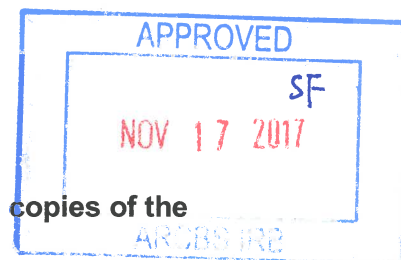
6. Affix a donation identification number (DIN) label to both copies of the consent.

7. Give a copy of the consent to the donor, for his or her records, after the donor reads and agrees to the consent.

It is not necessary to provide the donor with a signed copy.

8. Return the signed consent to the region.


The region ensures the consent is sent to the Donor and Client Support Center (DCSC) to be maintained in the donor's case file [[14.4.ref144](#)].



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 American Red Cross Donor and Client Support Center	Alinity s Follow-Up Study - Donor Consent	Charlotte 9013-J Perimeter Woods Dr. Charlotte, NC 28216 Toll Free: 866-236-3276 Fax: 888-719-3535 DCSCMailbox@redcross.org	Philadelphia 700 Spring Garden St. Philadelphia, PA 19123 Toll Free: 866-236-3276 Fax: 888-719-3535 DCSCMailbox@redcross.org
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Read this form and ask any questions you may have before agreeing to additional testing as part of this investigational (research) follow-up study. Your participation in this follow-up study is voluntary. If you decide to be a part of this follow-up study, you will be asked to sign and date this consent form. You will be given a blank copy of this form to keep.

What is the purpose of the follow-up study?

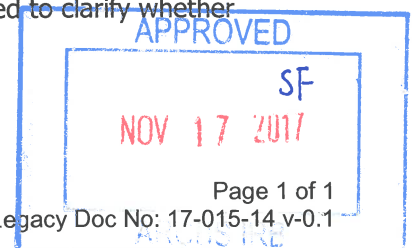
You are invited to participate in an investigational study to evaluate the performance of the Alinity s investigational blood screening assays (tests) developed by Abbott Laboratories using the Alinity s Blood Screening System. The Alinity s Blood Screening System is a blood-screening analyzer that is designed to detect the presence of antibodies (your body's response) or antigens to different disease agents that can be transmitted by blood transfusion. These disease markers include antibodies to hepatitis B virus (HBV), hepatitis C virus (HCV), human T-cell lymphotropic virus (HTLV), *Trypanosoma cruzi* (*T. cruzi*), human immunodeficiency virus (HIV), and the detection of antigens (viral proteins): hepatitis B surface antigen (HBsAg) to HBV and lastly, the p24 core antigen of HIV.


As part of your recent blood donation, you were tested for HIV, HTLV, HBV, HCV, and *T. cruzi* using screening assays licensed by the Food and Drug Administration (FDA) and Abbott's investigational Alinity s blood screening assays. All blood establishments test blood samples for these infectious disease agents to identify possible risks of infections in order to ensure the safety of the blood supply and the public's health. In order to demonstrate the performance characteristics and intended use of each Alinity s investigational blood screening assay, it must be compared to a similar FDA licensed assay.

You were selected as a possible participant in this study because your recent blood donation test results for

- ☐ HBV using the Alinity s investigational assay did not agree with the other tests that we perform for HBV.
- ☐ HCV using the Alinity s investigational assay did not agree with the other tests that we perform for HCV.
- ☐ HIV-1/2 using the Alinity s investigational assay did not agree with the other tests that we perform for HIV
- ☐ HTLV-I/II using the Alinity s investigational assay did not agree with the other tests that we perform for HTLV
- ☐ *T. cruzi* result using the Alinity s investigational assay did not agree with the other tests that we perform for *T. cruzi*

This means that at least one or more than one of your test results from the Alinity s assays did not agree with the final test results based on additional testing. The purpose of this follow-up study is to obtain additional blood samples that may help better understand the Alinity s blood screening assays test results of your reactive blood donation. Using your follow-up sample, you will be tested for the disease agent(s) selected above using the investigational Alinity s blood screening assay(s) and corresponding FDA licensed assay(s). If your follow-up sample is reactive other assays will be used to clarify whether infection with the disease agent(s) selected above is present or absent.



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What will happen if I take part in the follow-up study?

If you decide to participate, we will take a blood sample (no more than 6 tubes, approximately 60 mL or 2 ounces) from your arm today. If you choose to take part in this study, the time to sign the consent form and provide a blood sample should not take more than 1 hour. Participation in this study should involve only one visit. We may ask you to come in again for additional samples if we are unable to perform or complete testing on your blood sample. Additional follow-up samples, if needed, will be collected from you in the same way and will take the same amount of time.

Your follow-up blood sample will only be tested for the specific disease markers based on the disease agent(s) selected on page 1. Depending on the disease agent, your blood sample may be tested by the following tests:

- Nucleic acid test assays that directly detect genetic material (DNA) of HBV and (RNA) of HCV and HIV
- A test that detects the viral protein that makes up most of the viral core of HIV
- A test that detects the surface protein of the HBV
- Tests that detect antibodies against HBV, HIV, HCV, HTLV, and *T. cruzi* in your blood. These tests indicate whether your immune system has responded to an infection from these disease agents.

There is no cost to you for any of these tests. We will share with you the results of the tests that we perform on each blood sample, and we will explain their significance.

What are the possible risks of participation?

- There are small risks to giving a blood sample. You may have minor discomfort or bruising of your arm.
- The risk of learning about a reactive test is that the information may alarm you.

Will I be paid for being in this study?

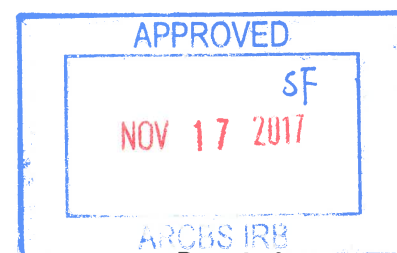
There will be no compensation for this study.


Are there benefits to being in this study?

The benefits of participating in the study are that you will receive more information about the significance of your test result, and you will help us learn more about the performance characteristics of the investigational Alinity s blood screening assays. You will receive additional counseling and a copy of your test results each time you provide a follow-up blood sample. You may be considered for reentry if your follow-up sample tests non-reactive and they meet other FDA required criteria following a reactive but unconfirmed test result. The additional test we perform may be useful for your doctor to review in the evaluation of your health.

What alternative choices do I have?

- **Your alternative is to not participate in this study.** If you choose not to take part in this investigational study, no additional testing will be performed.
- Your decision whether or not to participate will not change or influence your future relations with the American Red Cross.



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Will my results be confidential?

The American Red Cross will make every effort to keep confidential any information we obtain in connection with this study or any future tests that can be identified to you. The only data we will collect from you are results of any blood testing done by the American Red Cross or Abbott Laboratories.

- Confidential information will not be disclosed without your written permission unless required by law. The test kit manufacturer, Abbott Laboratories, will not have any information that can link test results to you.
- Your study records and blood samples will be given a code number. You will not be listed by your name in the study records.
- The FDA may have access to the data from this study as part of a review of the records. In any written reports or publications, you will not be identified or identifiable.
- By signing this document you are allowing personnel at the American Red Cross to permit Abbott to have access to your test results for the purpose of collecting data, verifying the data is correct, and checking that the study is conducted properly.

Will my blood samples be stored?

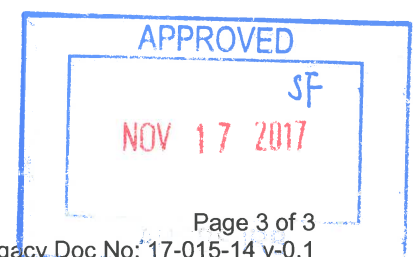
Yes. A portion of your blood sample may be stored frozen indefinitely at the American Red Cross for testing in the future for research related to blood safety or for commercial profit. Abbott Laboratories will not retain any of your samples; testing of the Alinity s investigational assays is being conducted at American Red Cross National Testing Laboratory.


- Each new test will be evaluated by a committee that will consider your rights as a research participant.
- There will be no human genetic tests performed on your sample.
- Your sample could be used for future research studies performed by the American Red Cross or distributed to another investigator for future research studies without additional informed consent from you.
- If your sample is being used without additional informed consent, you will not be informed of the details of any specific research studies that might be conducted using your coded blood sample, including the purposes of the research, and you might have chosen not to consent to some of those specific research studies.
- No personal identifiers will be available as part of your stored sample to researchers performing the additional testing.
- Your sample can potentially be used for commercial profit. If your sample is used for commercial profit, you will not be compensated.
- You will be notified of any abnormal test results that may impact your health.

Can I stop being in this study?

Yes. If you decide to participate, you are free to discontinue participation at any time.

- If you decide to withdraw from the study, we will no longer contact you for information or additional blood samples, but your previous test results and any stored blood samples will be kept as part of the study unless you instruct us in writing to destroy them.
- If you do not wish for your sample to be retained for future study, written requests should be mailed to the study Principal Investigator, Dr. Susan Stramer, American Red Cross, 9315 Gaither Road, Gaithersburg, MD 20877.



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What if I am injured during the study?

In the event that you suffer physical injury as a direct result of your participation in this research activity, the American Red Cross will assume responsibility for making immediate medical care available to you. This care will be provided without charge as long as you notify us (please see our contact information below) or Dr. Susan Stramer within 15 days of the date of the injury or appearance of symptoms, and consent to the care offered.

There is no provision for monetary compensation to you at the expense of the American Red Cross for incidences such as lost wages, disability, injury, or discomfort resulting from such physical injury. To contact us regarding further information concerning treatment and payment of medical expenses in the event of an injury, please see our contact information below or contact Dr. Susan Stramer.

Whom do I contact if I have any additional questions or concerns about the study?

If you have any questions, please ask us, and we will be happy to answer them. Please contact us at the number provided below. You will be given a copy of this form to keep.

Contact Information

If you have any questions, please do not hesitate to contact us. You can call a Red Cross donor counselor at

Phone Number: _____

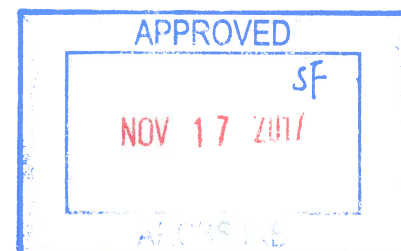
Donation Location: _____

Local contacts

Physician Name: _____

Phone Number: _____

Address or Email: _____



Study Researcher


If you have questions about your participation in this investigational study, you may contact the study principal investigator:

Name: Dr. Susan Stramer, Principal Investigator

Phone: (866) 771-5534

Address: American Red Cross, 9315 Gaither Road, Gaithersburg, MD 20877

If you have questions about your rights as a participant in research, call the American Red Cross Institutional Review Board administrator at (877) 738-0856.

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Alinity s Follow-Up Study Consent

I have read the explanation of this study and have been given the opportunity to ask questions about the study and the potential risks of participation. I may withdraw at any time after signing this form should I choose to discontinue participation in this study.

Consent and Assent Instructions:

Consent: Subjects 18 years and older must sign on the subject line below.
For subjects under 18, consent is provided by the parent or guardian.

Assent: Written assent is required for subjects age 16 or 17 years using the Assent section on the following page.

Please select **one or more** of the following study criteria:

☐ I agree to participate in this follow-up study to have additional tests performed on my blood samples.

If you agreed to have blood samples drawn, please check the box that applies to you:

☐ I agree to allow my blood sample to be stored for future use by the American Red Cross. Therefore, I am allowing my samples and related coded information to be used for research related to blood safety.

☐ I do not agree to allow my blood samples to be stored by the American Red Cross.

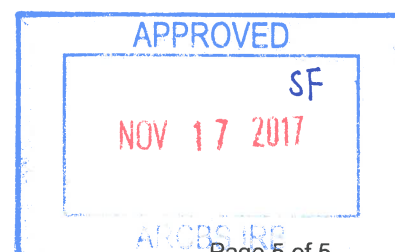
Donor Name:

Print name

Signature

Date (mm/dd/yyyy)

DIN→





Received 11/15/17