Clinical Research Subject Information Sheet

TITLE: Alinity s Anti-HCV II – Clinical Evaluation Protocol

PROTOCOL NO.: T3M3-02-19H04-01
IRB Protocol #20204503

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 a new version under development of a blood test currently approved by the US Food and Drug Administration (FDA) to detect Hepatitis C antibody in donor blood. If you agree to participate in this study, the blood sample used for routine blood donation may be tested with research tests as well as FDA-approved tests. Your result using the new test will be compared with the result of the current FDA-approved test. As with the Hepatitis C test already done, we will contact you if the result suggests that you have Hepatitis C infection. State law also requires that we contact local health authorities if your blood tests are positive for hepatitis.

The new test (Alinity s Anti-HCV II) is investigational, meaning it has not been approved by the FDA for detection of Hepatitis C antibody.

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 15,000 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 website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website 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 on the new test are different than on the current test, we will ask you to participate in a follow-up study involving collection of an additional blood sample. 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 using the telephone number provided to you on page 1 of this document.

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.

This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

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

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

If you request, you will receive a copy of this study information sheet to keep for future reference.