APPENDIX C

EXAMPLES OF NOTIFICATION LETTERS FOR POSITIVE INFECTIONOUS AND GENETIC DISEASE TESTS
NOTIFICATION LETTER FOR CONFIRMED ANTI-HTLV-I POSITIVE TEST RESULT

Date

Dear Donor:

Thank you for your recent placental blood donation. Let me assure you, THIS IS NOT A LETTER ABOUT AIDS.

We test all blood for Human T Cell Lymphotropic Virus Type I/II antibodies (anti-HTLV-I). This recently discovered virus may be associated with some diseases in a small number of people exposed to it. This virus is not associated with HIV-1/2, the AIDS viruses. When we tested your blood, your first test was positive and a second, different test for HTLV-I was also positive.

Having HTLV-I antibodies in your blood does not mean that you will definitely develop any associated illness. However, these positive test results may be important information for your future health. For these reasons, we have enclosed an HTLV-I fact sheet, and we recommend you share these test results with your doctor.

Blood with positive test results cannot be given to another person. Therefore, we were unable to use the placental unit you donated. In addition, we are informing you that you must never be a blood donor.

If you want more information about this letter or would like to schedule an appointment to discuss your test results, call insert phone number here and ask for insert name here.

Thank you for your support.

Sincerely,

Insert name here

Notes: Enclose anti-HTLV-I Supplemental Positive Fact Sheet.
FACT SHEET FOR POSITIVE TEST RESULT FOR THE HUMAN T LYMPHOTROPIC VIRUS, TYPE I ANTIBODY (Anti-HTLV-I)

What does a positive Anti-HTLV-I test result mean?

FIRST, HTLV-I IS NOT THE AIDS VIRUS (HIV-1). HTLV-I DOES NOT CAUSE AIDS.

A positive anti-HTLV-I test result means that the person is infected by HTLV-I; this virus was recently found in the United States. Most people infected with HTLV-I come from (or have parents who come from) Japan, the Caribbean basin, South America, or Africa.

This test result means that a sample of the donor’s blood tested positive, more than once, on a screening test for anti-HTLV-I. A different, more specific test for anti-HTLV-I confirmed the results of the screening test.

How does HTLV-I infection affect a person’s health?

HTLV-I infection does not appear to affect the health of most infected persons. Less than 1% of infected persons will develop cancer of the blood (leukemia) or a neurologic disease sometime during their lives.

How does a person become infected by HTLV-I?

- From sexual intercourse with an infected partner.
- From sharing needles for illegal drugs or steroids.
- From an infected woman who breastfeeds.
- Rarely, from an infected blood transfusion.

What should a person with a positive anti-HTLV-I test result do?

- A person with a positive anti-HTLV-I test result should have a medical check-up. The purpose of a check-up is to find out if there are any signs of blood or neurologic disease. A doctor may recommend anti-HTLV-I tests for sexual partners and, depending on the results, may advise that condoms be used to prevent further spread of HTLV-I infection by sexual intercourse.
- Do not donate blood, semen, body organs, or other tissue.
- Do not share needles or syringes.
- Do not breastfeed.

Should a person with a positive anti-HTLV-I test result donate blood?

No. Another person (patient) could be infected by blood donated by people with positive anti-HTLV-I test results.

Please carefully read the letter that accompanies this Fact Sheet.
NOTIFICATION LETTER 1 FOR HIV - 1/2 TEST RESULT

Date

Dear Donor:

Thank you for your recent placental blood donation.

In the information that we gave you when you donated, we explained that your blood would be tested for certain viruses. When we tested your blood, one of these tests was abnormal. It is important that we discuss the results of this test with you.

Please call insert name, phone number, between the hours of here to schedule an appointment to discuss your test results. To protect your privacy, it is our policy not to discuss specific test results over the phone.

Sincerely,

Insert name here

Notes:  Do not enclose any Fact Sheet. Do not enclose test result form. Certified mail/return receipt requested.
NOTIFICATION LETTER 2 FOR HIV TEST RESULT

Date

Dear Donor:

Thank you for your recent blood donation or blood sample. We are writing to let you know the results of some of the tests we did on your blood and how these test results will affect your future as a blood donor.

We test all blood for evidence of human immunodeficiency viruses (HIV). Some of your HIV test results are abnormal. The enclosed test result report form identifies the names of the tests done and the test results.

These abnormal test results indicate HIV infection and are important information about your health. For these reasons, we have enclosed a copy of an informational pamphlet which explains the meaning of your test results and includes recommendations you should follow to protect your health and the health of others. **We strongly recommend that you share these test results with your doctor.**

Blood with positive test results cannot be given to another person. Therefore, we were unable to use the placental blood that you donated. In addition, we are informing you that you must never be a blood donor.

If you want more information about this letter or would like to schedule an appointment to discuss your test results, please call **insert phone number here** and ask for **insert name here**.

Sincerely,

*Insert name here*

Notes: Enclose HIV Ag Fact Sheet. Enclose test result form. Certified mail/return receipt requested.
FACT SHEET FOR HUMAN IMMUNODEFICIENCY VIRUS

What does a positive human immunodeficiency virus screening test result mean?

The blood test screens for the presence or absence of viral particles, such as antigens, or protein material, such as antibodies, to see if your body may have been exposed to certain infectious agents, such as viruses. The cord blood bank uses screening tests on placental blood donations for the same reason. However, other things (vaccinations, for example) may cause screening tests to be abnormal when there is no viral infection.

A positive screening test for HIV antigen may indicate that you have been infected by a human immunodeficiency virus (HIV), the virus that causes AIDS. Positive screening test results, however, require the use of a more specific test, a confirmatory test, to make sure you really have been infected with HIV.

What does a confirmatory test result mean?

Confirmatory tests are different than screening tests and confirmatory test methods are approved by the FDA. They are used to determine if the screening test is truly abnormal (positive). It is important that you see your personal physician or contact insert name of CBB Medical Director here for follow-up testing and information if your confirmatory test is positive.

Insert appropriate test here
Since your confirmatory test for HIV antigen (neutralization) is positive, you may have been exposed recently to human immunodeficiency virus. You can be exposed to HIV by sharing needles, being exposed to the blood of infected persons, or by sexual contact with an infected person. If you are infected with HIV, you can spread the virus to others by sharing needles, through blood transfusions or through other exposure to your blood, and by having sexual contact. You may not have any symptoms associated with this infection, but you can still have the virus and could infect others.

Since your confirmatory anti-HIV test result (Western blot) is indeterminate, we cannot be certain, based on the tests that we performed on your donation, that you have not been exposed to a human immunodeficiency virus. A very small number of persons having an indeterminate anti-HIV test result may have been infected with HIV. Most indeterminate results, however, do not indicate that you have been exposed to HIV. These results are caused by other factors in a person’s blood and are not related to exposure to the HIV virus or AIDS. If you have an indeterminate confirmatory test, you are probably not infected with HIV virus. However, your personal physician is best able to review your results to determine if it is likely that they represent a true positive. Your physician may also want to perform additional tests. You are not eligible to continue to donate blood, even if your doctor determines that you have not been exposed to HIV.

Since your confirmatory anti-HIV test result (Western blot) is positive, you have been infected with human immunodeficiency virus. You can be infected with HIV by sharing needles, being exposed to the blood of infected persons, or by sexual contact with an infected person. Persons infected with HIV can spread the virus to others by sharing needles, by blood transfusions or exposure to your blood, and by
sexual contact. You may not have any symptoms associated with this infection, but you still have the
virus and could infect others. There are several types of human immunodeficiency viruses and the
cord blood bank tested your blood for anti-HIV-1 and anti-HIV-2. Both of these viruses can cause
problems with your immune system (AIDS). You are no longer eligible to donate blood. It is
important that you see your personal physician for follow-up testing and information if your
confirmatory test is positive.

There are several types of human immunodeficiency viruses. Your blood was tested for HIV antigen as
well as antibodies to HIV-1 and HIV-2 (anti-HIV-1/2). Both of these viruses can cause problems with
your immune system (AIDS). You may test confirmed positive for HIV antigen, but negative for
antibodies. If this happens, this probably indicates a very recent exposure to HIV (within the past few
weeks).

You are no longer eligible to donate blood. Note: The law in certain states requires that we notify
public or state health departments of confirmed positive test results for HIV. These agencies may
contact donors who have had confirmed positive HIV test results.

Your personal physician can evaluate your test results in terms of your overall health and help you
decide how best to take care of yourself. If you don’t have a personal physician with whom you feel
comfortable, call the local medical society or HIV/AIDS service organization for a referral. You’ll
need to build a comfortable, ongoing relationship, so it is important to find a doctor or clinic with staff
knowledgeable about AIDS. Recent medical research indicates that early treatment for people infected
with HIV helps them live longer and delays the onset of symptoms and HIV-related illnesses. People
are learning to live with HIV as a chronic illness.

What do’s and don’ts should you follow regarding your HIV antigen test?

- Do eat a balanced diet, get enough sleep, exercise, and take care of yourself.
- Do try to avoid infections by not eating raw eggs or raw or undercooked meat. Maintain good
  kitchen hygiene. Don’t clean up bird droppings or dog or cat feces. Avoid being in a closed
  room with others who have respiratory infections.
- Do try to avoid stress. Listen to your body. It will tell you when you’re under stress (through
  tension in your neck or shoulders, an upset stomach, or some other way). You must discover
  how you best deal with stress.
- Do not share things that can be contaminated with blood or body fluids, such as needles,
  toothbrushes, razor blades, or tweezers.
- Do not donate blood, plasma, semen, body organs, or other tissues. Do not breastfeed.
- Do not use drugs, alcohol, or nicotine. Drugs may hamper your immune system. If you use
  them, get help. Talk to your HIV/AIDS counselor, or call the National Institute of Drug Abuse
  Hotline, toll free at 1-800-662-HELP.

How can you protect others?

- Abstinence, that is, not having sexual intercourse of any kind, is the best way to prevent the
  spread of HIV from one person to another through sex. If you are sexually involved with
  someone, it is important to talk with your partner. You and your partner need to take
precautions to prevent new or further infections. If you and your partner choose to be sexually active, find out how to use condoms and spermicides. Have oral, vaginal, or anal sex only when using a condom and spermicide.

Condoms are effective but not foolproof. They can break, tear, or slip off. By properly using latex condoms every time you have sex, the risk of infection is reduced. Never use the same condom more than once.

Condoms are important whether you are heterosexual or homosexual, and even if your partner is also infected. Continue to protect yourself and your partner during sex from sexually transmitted diseases, including repeated infections with HIV.

- Inform your current sexual partner(s) and anyone else you may have had sex with since you became infected. This isn’t easy to do, but it is very important. Your counselor may help you to make it easier with less blame and guilt. Urge current and ex-partners to seek HIV/AIDS counseling and testing. This can help stop the spread of the virus to others.

- Tell your doctor, dentist, and other health care workers about your test results. These people may need to know this to plan the best care for you. Discuss with them whether or not to put the test results in your medical or dental records. If you are concerned that your doctor or dentist might refuse to treat you, or if you don’t have one, contact the county medical or dental society or an HIV/AIDS service organization in your area. They are listed in telephone directories.

What about emotional support?

Learning that you are infected with HIV can be frightening. Most people have found their family and friends supportive and caring. Choose carefully, however, with whom you share your medical information—the more people you tell, the less control you have over this information. Many people do not know as much about HIV infection and AIDS as you do. They may need to be reminded that HIV is not spread by casual, nonsexual contact such as a handshake or hug.

There are many others who are facing the same problem you are. Many of these people have found help by joining support groups. If you’d like to learn more about support groups in your area, or if you prefer individual, professional help, ask your HIV/AIDS counselor for referrals, or call a local HIV/AIDS service organization.

What if I do get sick?

It is important for you to know when to call your doctor. You should be aware of the following warning signs. If any of these persist for more than a few days, contact your doctor.

- Tender or enlarged lymph glands in your neck, jaw, armpit, or groin. They’ll be large enough to feel easily.
- Unexplained shortness of breath, which can be serious and should be evaluated medically if it persists longer than a few minutes.
- Constant fatigue, which is not the feeling you have when you don’t want to go to work, but a real exhaustion that won’t go away.
- Unexplained diarrhea.
- Persistent or recurring fever, either a persistent high-grade fever of over 100°F or one that keeps going up and down for at least two weeks. Chills or night sweats, i.e., waking up with your bed and bedclothes wet.
- Unexplained weight loss of ten pounds or more.
- Unusual bruising or bleeding.
- Persistent white spots or unusual blemishes in the mouth.
- Severe motor, behavioral, or cognitive changes. An example of a motor problem might be suddenly finding yourself unable to hold something in your hand. An example of a behavioral problem might be suddenly becoming uncontrollably talkative, if you are normally a rather quiet person. An example of a cognitive change might be losing the ability to add correctly or having trouble remembering.

For more information, contact:

- The National AIDS Information Hotline (toll free): 1-800-342-AIDS.
  For Spanish-speaking persons, Linea Nacional de SIDA: 1-800-344-SIDA.
  For deaf or hearing-impaired persons, TTY/TDD Hotline: 1-800-AIDS-TTY.
- Your doctor or health care worker.
- Your local or state public health department.
- The HIV/AIDS service organization of your choice.
# HUMAN IMMUNODEFICIENCY VIRUSES (HIV) RELATED TEST RESULTS

Name of Donor: ____________________________________________________________

Hospital ID: ______________________________________________________________

Date of This Report: ________________________________________________________

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibodies to HIV-1/HIV-2 combination screening test (ELISA)</td>
<td>Repeat Reactive</td>
</tr>
<tr>
<td>Antibodies to HIV-1 screening test (ELISA) (This test is not done routinely.)</td>
<td>Repeat Reactive</td>
</tr>
<tr>
<td>Antibodies to HIV-2 screening test (ELISA) (This test is not done routinely.)</td>
<td>Repeat Reactive</td>
</tr>
<tr>
<td>Anti-HIV-1 confirmatory test - Western blot</td>
<td>Positive</td>
</tr>
<tr>
<td>Anti-HIV-2 supplemental test - Western blot (unlicensed)</td>
<td>Repeat Reactive</td>
</tr>
<tr>
<td>HIV-1 p24 antigen screening test (ELISA)</td>
<td>Repeat Reactive</td>
</tr>
<tr>
<td>HIV-1 p24 antigen confirmatory test</td>
<td>Positive</td>
</tr>
</tbody>
</table>

Notes: Send with all HIV-related notification letters.
NOTIFICATION LETTER FOR HbsAg CONFIRMED POSITIVE TEST RESULT

Date

Dear Donor:

Thank you for your recent placental blood donation. We are writing to let you know the results of some of the tests we did on your blood and how these results will affect your future as a blood donor. Let me assure you, THIS IS NOT A LETTER ABOUT AIDS.

We test all blood for infection with the hepatitis B virus. Hepatitis is an inflammation of the liver and is usually caused by a virus. When we tested your blood, the first test was positive and a second test confirmed this result. These positive test results may be very important for your health and for the health of others. For these reasons, we have enclosed a hepatitis B fact sheet and a summary of your hepatitis-related test results which we recommend you review with your doctor.

Blood with positive test results cannot be given to another person. Therefore, we were unable to use the placental blood you donated. In addition, we are informing you that you must never be a blood donor.

If you want more information about this letter or your test results, please call insert phone number here and ask for insert name here.

Sincerely,

Insert name here

Notes:   Enclose HbsAg Fact Sheet. Enclose test result form. Mail First Class.
FACT SHEET FOR POSITIVE TEST RESULT FOR
HEPATITIS B SURFACE ANTIGEN (HbsAg)

What does a positive hepatitis B surface antigen (HbsAg) test result mean?

A positive test for HbsAg means that a person has a hepatitis B virus infection in his or her blood. An infected person can spread the infection to others by sharing needles for illegal drugs or steroids, by sexual intercourse, or by a blood transfusion. A mother can spread the infection to her newborn baby.

All people with a positive test result for HbsAg have some form of hepatitis B, but most will not have any symptoms of the disease. Some people, even when their infection seems mild, may go on to have serious liver disease over time.

How does hepatitis B infection affect a person’s health?

Many people are “carriers” of the infection for many years without feeling ill. Others may have a recent infection that will lead to acute viral hepatitis with fever, jaundice (yellowing of the skin and whites of the eyes), and dark urine. Very rarely, a person with a positive HbsAg test result will develop cirrhosis (liver failure) or cancer of the liver.

What are the other tests for viral hepatitis performed and what do they mean?

Three hepatitis-related tests, besides HbsAg, are performed for each donor. When one test result is abnormal, we report all hepatitis-related test results to the donor. The donor may wish to review these test results with a doctor. These are the other tests:

Hepatitis B Core Antibody (Anti-HBc). This test detects the body’s response to a hepatitis B virus infection. A positive test result usually means the person has recovered from a past infection. For some people, this test result may be a sign of current hepatitis B infection.

Antibody to Hepatitis C Virus (Anti-HCV). This test detects the body’s response to a hepatitis C virus infection. A positive test result usually means the person has a hepatitis C infection.

Alanine Aminotransferase (ALT). The ALT test measures an enzyme in liver cells that leaks into the blood when the liver is infected or irritated. The liver can be infected by a virus or irritated by exercise, alcohol, toxins, or certain medications. Rarely, being overweight can irritate the liver. A person with an abnormal ALT test result may have a viral infection or inflammation of the liver.

What should a person with a positive HbsAg test result do?

- Donors should see their doctor for a medical check-up and take their hepatitis-related test results with them. That is the only way to find out what the test result means for them.
- Tell your doctor or dentist about this test result before receiving treatment.
- Some doctors may recommend hepatitis testing for sexual partners and other people in the household. The doctor may advise them to have a hepatitis B vaccination, if they do not have
positive hepatitis test results. This may be important for a woman who is considering pregnancy, because hepatitis B can be a serious illness for a pregnant woman and her baby.

- Stop donating blood, semen, body organs, and other tissue.
- Do not share things that can be contaminated with blood or body fluids, like toothbrushes, razor blades, or needles.

**Should a person with a positive HbsAg test result donate blood?**

No. Another person (patient) could be infected by blood donated by people with positive HbsAg test results.

**Please carefully read the letter that accompanies this fact sheet.**
NOTIFICATION LETTER FOR ANTI-HBc EIA REPEAT REACTIVE TEST RESULT

Dear Donor:

Thank you for your recent placental blood donation. We are writing to let you know the results of one of the tests we did on your blood and how these results will affect your future as a blood donor. Let me assure you, THIS IS NOT A LETTER ABOUT AIDS.

We tested your blood for hepatitis B core antibodies (anti-HBc). When we tested your blood, the test was positive for hepatitis B core antibodies.

Hepatitis is an inflammation of the liver and is usually caused by a virus. Hepatitis B core antibodies merely indicate that a person might have been infected in the past and is now fully recovered. Often people with these antibodies never even felt sick or knew that they had the virus.

Please read on carefully; the rest of this letter should answer all of your questions.

Some important things to know about this test result are as follows:

- This test result does not mean that you have an illness or an infectious disease. If you are feeling well, there is no need for a medical check-up or additional laboratory testing.
- Sometimes this test is positive even if there was no infection.
- There is no evidence that people with this test result are considered capable of spreading hepatitis by casual or sexual contact.
- Although there is no evidence that you could spread an infection by casual or sexual contact, there is a slight chance that a unit of your blood could transmit hepatitis to a person (patient) receiving it.

Just in case you do want to discuss these results with your doctor, we have attached a summary of your hepatitis-related test results, along with a fact sheet on hepatitis B core antibodies.

If you want more information about your test results, please call insert phone number here and ask for insert name here.

Sincerely,

Insert name here

Notes: Enclose Anti-HBc Fact Sheet. Enclose test result form. Mail First Class.
FACT SHEET FOR POSITIVE TEST RESULT FOR
HEPATITIS B CORE ANTIBODY (ANTI-HBc)

What does a positive hepatitis B core antibody (anti-HBc) test result mean?

A positive anti-HBc test result usually means the person has recovered from a past hepatitis B infection. Hepatitis is an inflammation of the liver and is usually caused by a virus. It is possible that people with this test result might never have felt sick or known of their infection. These test results do not necessarily mean that you could infect other people through casual or sexual contact. In some cases, this test result may be positive even if there is no disease.

- This result does not mean that you have an illness or an infectious disease. If you are feeling well, there is no need for a medical check-up or additional laboratory testing.
- There is no evidence that people who have this test result are capable of spreading hepatitis by casual or sexual contact.
- Although there is no evidence that you could spread an infection by casual or sexual contact, there is a slight chance that a unit of your blood could transmit hepatitis to a person (patient) receiving it.

What does a positive anti-HBc test result mean about a person’s health?

Usually, a positive anti-HBc test result means the person has recovered from a past infection and cannot be infected by the hepatitis B virus again. These people may never have felt sick or known of their infection. More than 5% of people in the United States have this test result and it does not affect their health. If the results of other hepatitis-related tests are normal, the person is unlikely to have viral hepatitis or another liver-related illness.

What are the other tests for viral hepatitis performed and what do they mean?

Other hepatitis-related tests, besides anti-HBc, are performed for each placental blood donor. When one test result is abnormal, we report all hepatitis-related test results to the donor. The donor may wish to review these test results with a doctor. These are the other hepatitis-related tests performed on all donated umbilical blood:

Hepatitis B Surface Antigen (HbsAg). This test detects the presence of the hepatitis B virus in a person’s blood. A positive test result means the person is infected by the hepatitis B virus.

Antibody to Hepatitis C Virus (anti-HCV). This test detects the body’s response to hepatitis C virus infection. A positive test result usually means the person has a hepatitis C infection.

What should a person with a positive anti-HBc test result do?

- If the anti-HBc test result is the only abnormal hepatitis-related test result after a routine donation, and the person is feeling well, there is no need to make a special appointment to see a doctor.
A person should tell a health care provider about the positive anti-HBc test result during the next routine visit.

**Should a person with a positive anti-HBc test result donate blood or pheresis products?**

People with one positive anti-HBc test result remain eligible to donate blood and pheresis products. However, if their anti-HBc test is positive on a future donation, only the plasma part of their blood will be used and they will no longer be eligible to donate blood or pheresis products.
NOTIFICATION LETTER FOR ANTI-HCV EIA REPEAT REACTIVE
SUPPLEMENTAL TEST POSITIVE

Date

Dear Donor:

Thank you for your recent placental blood donation. We are writing to let you know the results of one of the tests we did on your blood and how these results will affect your future as a blood donor. Let me assure you, THIS IS NOT A LETTER ABOUT AIDS.

We tested your blood for antibodies to the hepatitis C virus (anti-HCV). Hepatitis is an inflammation of the liver and is usually caused by a virus. When we tested your blood, your first test was positive for antibodies to the hepatitis C virus. A supplemental test for anti-HCV was also positive.

Because positive test results usually mean either a past or present infection with the hepatitis C virus, these positive test results may be important for your health. For these reasons, we have enclosed a hepatitis C fact sheet and a summary of your hepatitis-related test results, which we recommend you review with your doctor.

Blood with positive test results cannot be given to another person. Therefore, we were unable to use the placental blood you donated. In addition, we are informing you that you must never be a blood donor.

If you want more information about this letter or your test results, please call insert phone number here and ask for insert name here.

Sincerely,

Insert name here

Notes: Enclose Positive Supplemental Anti-HCV Fact Sheet. Enclose test result form. Mail First Class.
FACT SHEET FOR POSITIVE SUPPLEMENTAL TEST RESULT FOR HEPATITIS C VIRUS ANTIBODY (ANTI-HCV)

What does a positive supplemental test result for antibodies to hepatitis C virus (anti-HCV) mean?

This test result means that a person’s blood sample tested positive, more than once, on a screening test for hepatitis C virus infection. To provide more information, an additional supplemental test for anti-HCV was performed. The results from this test were also positive.

A positive test result for anti-HCV usually means the hepatitis C virus is still present in the body. However, in some cases, it means the person used to be infected with the hepatitis C virus, but has recovered. The person might never have known of his or her hepatitis C infection.

How can hepatitis C infection affect a person’s health?

Most people with these positive anti-HCV test results have no obvious illness. Some are in the early stages of liver disease. The hepatitis C virus can cause hepatitis (yellow jaundice), cirrhosis (liver failure), or potentially, liver cancer. The only way to tell which people have liver disease is by a medical check-up. People taking prescription medicine should notify their doctors about positive anti-HCV test results.

What are the other tests for viral hepatitis and what do they mean?

Three hepatitis-related tests, besides anti-HCV, are performed for each donor. When one test result is abnormal, we report all hepatitis-related test results to the donor. Donors may wish to review these test results with their doctor. These are the other tests:

Hepatitis B Surface Antigen (HBsAg). This test detects the presence of the hepatitis B virus in a person’s blood. A positive test result means the person is infected by the hepatitis B virus.

Hepatitis B Cord Antibody (Anti-HBc). This test detects the body’s response to a hepatitis B virus infection. A positive test result usually means the person has recovered from a past infection. For some people, this test result may be a sign of current hepatitis B infection.

Alanine Aminotransferase (ALT). The ALT test measures an enzyme in liver cells that leaks into the blood when the liver is infected or irritated. The liver can be infected by a virus or irritated by exercise, alcohol, toxins, or certain medications. Rarely, being overweight can irritate the liver. People with an abnormal ALT test result may have a viral infection or irritation of the liver.

What should a person with a positive supplemental test result for anti-HCV do?

- A person with a positive supplemental anti-HCV test result should see a doctor for a medical check-up. Usually the check-up will indicate normal health. If a medical check-up detects liver disease, the doctor may recommend changes in personal behavior or medication.
Tell your doctor or dentist about this result before receiving treatment.
Do not donate blood, semen, body organs, or other tissue.
The U.S. Public Health Service recommends that people with positive anti-HCV test results check with their doctors for specific guidance about sexual behavior. Hepatitis C infection may be spread by sexual intercourse, although it is very uncommon and probably requires multiple exposures.

**Should a person with a positive supplemental test result for anti-HCV donate blood?**

No. Another person (patient) could be infected by blood donated by people with positive anti-HCV test results.

**Please carefully read the letter that accompanies this fact sheet.**
HEPATITIS-RELATED TEST RESULTS

Name of Donor: _________________________________________________________

Hospital ID: _________________________________________________________

Date of This Report: _________________________________________________________

Please read the enclosed fact sheet for further explanation of your test results.*

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Repeat Reactive (Positive)</td>
</tr>
<tr>
<td>Hepatitis B Surface Antigen (HbsAg)</td>
<td></td>
</tr>
<tr>
<td>ELISA (Screening Test)</td>
<td></td>
</tr>
<tr>
<td>HBsAg Confirmatory Neutralization</td>
<td></td>
</tr>
<tr>
<td>Antibody to Hepatitis B Core (Anti-HBc)</td>
<td></td>
</tr>
<tr>
<td>ELISA (Screening Test) Total Antibody Test **</td>
<td></td>
</tr>
<tr>
<td>Antibody to Hepatitis C Virus (Anti-HCV)</td>
<td></td>
</tr>
<tr>
<td>ELISA (Screening Test)</td>
<td></td>
</tr>
<tr>
<td>Antibody to Hepatitis C Virus (Anti-HCV)</td>
<td>Positive</td>
</tr>
<tr>
<td>Supplemental Test, Performed When Anti-HCV</td>
<td></td>
</tr>
<tr>
<td>EIA is Repeat Reactive (RIBA) Unlicensed</td>
<td></td>
</tr>
</tbody>
</table>

***Donor ALT Level __________ I U/L. (Alanine Aminotransferase or SGPT) Cutoff: 120 I U/L.

Cutoff: If your ALT level is equal to or above this value (considered a high elevation), your blood cannot be given to another person.

Comments: _______________________________________________________________________________________

* Insert this statement when fact sheets are included with notification letter.
** Anti-HBc total antibody test: IgM and IgG.
*** If the ALT level is below the cutoff, insert the actual ALT level or the statement “Within Normal Limits.” If the ALT level is equal to or greater than the cutoff, the actual ALT level must be inserted.

Notes: Send with all hepatitis-related notification letters.
NOTIFICATION LETTER FOR POSITIVE SYPHILIS SCREENING TEST

Date

Dear Donor:

Thank you for your recent placental donation. We are writing to let you know the results of one of the tests we did on your blood.

We test all blood for infection with syphilis. Syphilis is a sexually transmitted disease that can be treated with medication. When we tested your blood, your first test was positive and a second, different test for syphilis confirmed this result.

These positive test results may be important for your health and for the health of others. For more information, we have enclosed a copy of your test results and a syphilis fact sheet. We strongly advise that you inform your doctor about this test result and follow his or her recommendations for medical treatment.

If you have any questions after reading this letter and the enclosed fact sheet, please call insert phone number here and ask for insert name here.

Note: The law in insert State Name here requires that we notify the public or state health department of confirmed positive test results. We have notified the health department of your syphilis test results, and it is possible that they will contact you about these test results.

Sincerely,

Insert name here

Notes: Enclose Confirmed Positive Syphilis Fact Sheet. Enclose Syphilis Test Result Form. Mail First Class.
FACT SHEET FOR CONFIRMED POSITIVE TEST RESULT FOR SYPHILIS

What does a positive syphilis test result mean?

Syphilis is a sexually transmitted infectious disease that has several stages and can have severe medical consequences if left untreated. A positive test result almost always means that a person has a syphilis infection now or has had infection in the past.

How does a syphilis infection affect a person’s health?

Syphilis is a serious health problem. Treatment with antibiotics is effective and very important.

If syphilis infection is left untreated, complications that could occur include:

- Joint disease.
- Cardiac disease.
- Neurologic problems.
- Women who become pregnant and who have not been treated may have children with severe congenital abnormalities.

How does a person become infected by syphilis?

- Having sexual intercourse with an infected partner.
- An infected mother can spread syphilis to a fetus or to a newborn during delivery.
- Very rarely, from an infected blood transfusion.

What should people with positive syphilis test results do?

If test results are due to a current or untreated infection:

- Contact a doctor.
- Tell sexual partners immediately so that they can be tested and receive medical treatment if necessary.
- Follow the doctor’s advice about safe sex practices.

If test results are due to a previously treated infection:

- If a person is feeling well, there is no need to see a doctor or take any special action.
- A person should contact his/her doctor if he/she is not feeling well or if he/she has been treated for syphilis in the past but has reason to believe that these test results show a new infection.

Should people with a positive syphilis test result donate blood?

A person who has a positive syphilis test result and has been treated may donate blood twelve months after the diagnosis or positive test result for syphilis, whichever came first.

Please carefully read the letter that accompanies this fact sheet.
# SYPHILIS TEST RESULTS

**Name of Donor:** _________________________________________________________

**Hospital ID:** _________________________________________________________

**Date of This Report:** __________________________________________________

<table>
<thead>
<tr>
<th>Test Name</th>
<th>Reactive (Positive)</th>
<th>Non-Reactive (Negative)</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Check syphilis screening test used:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ RPR</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ PK-TP</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>□ Other: ________________</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Check syphilis confirmatory test used: | | | |
| □ FTA-ABS | | | |
| □ RPR* (when performed as part of the PK-TP confirmatory testing) | | | |
| □ Quantitative RP1** | | | |
| □ Other: ________________ | | | |

* Reactive RPR test results may indicate current infection.

** This result is provided for you to share with your physician. This information can be used as a baseline for monitoring treatment if your syphilis confirmatory test (FTA-ABS) is positive. If your syphilis confirmatory test (FTA-ABS) is negative or inconclusive, this information is not relevant.

Insert the following note when confirmatory testing is performed by Public Health Department:

**Note:** Confirmatory testing was performed by the state/public health department.

**Notes:** Enclose this form with syphilis-related notification letters.
Date

Dear Donor:

Thank you for allowing us to collect your newborn’s umbilical cord blood on [insert date here]. As discussed with you at that time, a sample of your baby’s blood would potentially be screened for certain genetic diseases that might be passed to a patient needing these cells for transplantation. Because your baby’s blood was recently identified as a close match for a patient, it was tested to see if your child had a disease called “Adrenoleukodystrophy.” YOUR CHILD DOES NOT HAVE THIS DISEASE. It will not influence your child directly. You, the child’s mother, may also be a carrier. Therefore, we recommend that you seek genetic counseling since you could have a boy with this disease.

If you have a male child, he should be evaluated by his pediatrician to see if he has signs and symptoms of this disease and have his blood tested. Moreover, it is possible that the test performed on the frozen umbilical cord blood was inaccurate. Enclosed is a Fact Sheet on Adrenoleukodystrophy; please take this sheet and this letter to your pediatrician. This is only necessary if you have a male child.

If you plan to have additional children, you have a 50:50 chance of having a boy and all boys will have the disease. It will be important for your daughter (from whom the cord blood was collected) to know about this risk as well.

A genetic counselor will be made available to you. Please call us to schedule an appointment at [insert phone number and name here].

Sincerely,

[Insert name here]

Notes: Enclose Positive Test for Adrenoleukodystrophy Fact Sheet. Mail First Class.
DRAFT FACT SHEET FOR POSITIVE GENETIC SCREENING TEST FOR ADRENOLEUKODYSTROPHY

What does it mean to be a “carrier” of Adrenoleukodystrophy?

One in ??? individuals in the United States are “carriers” for Adrenoleukodystrophy. This is the progressive neurological disorder that results in blindness, deafness, and early death. This disease has been treated with “Lorenzo’s Oil” and by bone marrow transplantation. This disease almost always occurs in males and very rarely in females. The most important aspect of being a “carrier” is having the knowledge that you are a carrier and that you have all male children tested for this disease. If you are considering the possibility of having additional children, it is important that you talk with a genetic counselor. You have a 50:50 chance of having a boy and boys will develop the disease.

Will being a “carrier” effect my personal health or the health of my baby?

Being a “carrier” has no effect on your personal health or the health of your female children.

Why should I seek the advice of a genetic counselor?

You need to know the risks of having a child affected with the disease as well as the tests available for prenatal diagnosis (e.g., amniocentesis).

How do I determine if I am really a carrier?

These tests were developed using fresh blood samples from potential patients and not frozen umbilical cord blood. Therefore, it is possible that the test result is not accurate. It is possible that you are not a carrier. We recommend that you and your child be rechecked to determine if you are carriers. A blood sample can be obtained by your doctor and sent to a genetics laboratory for retesting. You will be notified of the results within one week.

What do I do if I have a male child?

All male children born to you must be tested for this disease. Early diagnosis and medical treatment could be advantageous to their well being.

What are the signs and symptoms of Adrenoleukodystrophy?

Adrenoleukodystrophy presents with ... to be completed by Bill Krivit.
Date

Dear Donor:

Thank you for allowing us to collect your newborn’s umbilical cord blood on insert date here. As discussed with you at that time, a sample of your baby’s blood would potentially be screened for certain genetic diseases that might be passed to a patient needing these cells for transplantation. Because your baby’s blood was recently identified as a close match for a patient, it was tested to see if your child had a disease called “Gaucher’s Disease.” YOUR CHILD DOES NOT HAVE THIS DISEASE. It will not influence your child directly. You, the child’s mother, may also be a carrier. Therefore, we recommend that you seek genetic counseling since you could have a boy with this disease.

It is possible that the test performed on the frozen umbilical cord blood was inaccurate.

A genetic counselor will be made available to you. Please call us to schedule an appointment at insert phone number and name here.

Sincerely,

Insert name here

Notes: Mail First Class.