Testing Performed:

1. ABO Typing: Performed each time with each donation

2. Rh Typing:
   - Performed along with ABO typing to determine the D antigen status
   - If initially tests, as negative, a weak D test is performed to confirm that the donor is truly D negative and prevent sensitization in the recipient
   - *Weak D: Antigen expression on RBCs is weak/reduced, such that a weakly D positive individual may test as D negative.*

3. Antibody Screen
   - Donor’s plasma is tested for the presence of antibodies against RBC antigens
   - If positive, the donor will not be eligible to donate plasma or platelet products, but can continue to donate whole blood or RBC products

4. Infection Disease Screening.

<table>
<thead>
<tr>
<th>Required Tests Performed on Blood Donors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hepatitis B Surface Antigen (HBsAg)</td>
</tr>
<tr>
<td>2. Hepatitis B Core Antibody (HBcAb)</td>
</tr>
<tr>
<td>3. Hepatitis C Antibody Screen (HCV ELISA)</td>
</tr>
<tr>
<td>4. Hepatitis C Antibody Supplementary (HCV RIBA)</td>
</tr>
<tr>
<td>5. Syphilis Screening Test (MHA-TP)</td>
</tr>
<tr>
<td>6. HTLV-I/II Antibody</td>
</tr>
<tr>
<td>7. HIV-I/II Antibody</td>
</tr>
<tr>
<td>8. Combined HIV and HCV Nucleic Acid Test (HIV/HCV NAT)</td>
</tr>
<tr>
<td>9. West Nile Virus Nucleic Acid Test (WNV NAT)</td>
</tr>
<tr>
<td>10. Trypanosoma cruzi (for Chagas’ disease) Antibody Screening Test (T. cruzi ELISA)</td>
</tr>
<tr>
<td>11. Trypanosoma cruzi Antibody Confirmatory Test (T. cruzi RIPA)</td>
</tr>
</tbody>
</table>

- Tests that are no longer required:
  - ALT: Surrogate marker for hepatitis. Replaced by more specific tests for HCV and HBV
  - p24: An antigen that is expressed in the early phase of HIV infection, prior to seroconversion. This test has been superceded by the NAT for HIV.
- Tests that may be coming:
What Happens When A Donor Unit Tests Positive for an Infectious Disease Marker? *(Some or All May Apply)*

1. What to do with the product:
   - Quarantine components from donation in inventory
   - Recall/withdraw components shipped to other facilities
   - Notify transfusion recipients
   - Perform lookback (for HIV, HCV) on previously donated and transfused products, see section on lookback studies below

2. What to do with the Donor:
   - Defer donor for variable length of time
     - No defer all: Anti-HBc until test positive again on a second donation
     - Permanent: HIV, HCV, HBV(other than anti-HBc) markers, T cruzi, HTLV markers positive. Donor entered into Donor Deferral Registry
     - Syphilis- one year post treatment
     - WNV-120 days
   - Notify and counsel donor:
     - HIV counseling: at UCLA, notification/counseling is performed face-to-face with the donor, with an ID physician specializing in HIV cases is in attendance
     - Other disease markers: Usually notify by letter. *(See Sample Letter A and B, which are letters intended for donors with likely true positive or false positive test results for HCV). Some cases may require phone notification.*
   - Donor re-entry
     - Possible in an increasing number of situations (e.g. Anti-HBc positive x 2, but NAT and other markers negative)
     - Donor usually required to undergo repeat testing.

**Lookback Studies**

1. **What Are Look Back Studies?**

   - Required by the FDA: Blood banks must make efforts to identify and notify recipients of blood components collected from donors who subsequently have tested positive for a transfusion-transmitted infection.
• Lookback are required when there is a possibility that the donor, who is likely infected now, was in a “window” period at the time of previous donations. The previous units might still have been infectious despite negative test results at the time.

• Recipient of previous units must be contacted via letter or other means, and given recommendation on any indicated follow-up. Physicians of the recipient frequently also notified. (See Sample Letter C).

• Often conducted when:
  o The donor recently tested positive for a marker, for which he/she had previously tested negative.
  o A new screening test for a transfusion-transmitted infection was recently introduced, and the donor is positive
  o Donor revealed new historical information (e.g. IV drug use), which was not disclosed on prior donations
Dear «Title» «LastName»:

Thank you for your recent blood donation at the UCLA Blood and Platelet Center.

In order to assure the safety of the blood that we give to our patients, we perform numerous tests on samples of each donor’s blood.

Most of your blood test results are normal. However, you had an abnormal result for antibody to Hepatitis C virus. Your test result was positive (normal is negative). Before we go any further, I want to emphasize to you that HEPATITIS C VIRUS IS NOT THE VIRUS THAT CAUSES AIDS. Hepatitis C virus can cause a spectrum of illnesses that involves the liver; however, in most cases, Hepatitis C virus infection does not produce serious long-term consequences.

As part of our routine donor testing, we first did a screening test that yielded a positive result for antibody to Hepatitis C virus. We performed a second test that is designed to specifically identify the presence of Hepatitis C virus (HCV NAT; NAT = nucleic acid testing) in your blood and this test was also positive. The combination of these test results indicates that you currently carry the Hepatitis C virus.

Your complete test results on your donated unit are as follows:

<table>
<thead>
<tr>
<th>Test Performed</th>
<th>Your Result</th>
<th>Normal</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hepatitis B Surface Antigen (HBsAg)</td>
<td>«HBSAG»</td>
<td>Negative</td>
</tr>
<tr>
<td>2. Hepatitis B Core Antibody (HbcAb)</td>
<td>«HBCORE»</td>
<td>Negative</td>
</tr>
<tr>
<td>3. Hepatitis C Antibody Screen (HCV ELISA)</td>
<td>POSITIVE</td>
<td>Negative</td>
</tr>
<tr>
<td>4. Hepatitis C Nucleic Acid Test (HCV NAT)</td>
<td>POSITIVE</td>
<td>Negative</td>
</tr>
<tr>
<td>5. Syphilis Test (MHA-TP)</td>
<td>«MHA-TP»</td>
<td>Negative</td>
</tr>
<tr>
<td>6. HTLV-I/II Antibody (HTLV Ab)</td>
<td>«HTLV»</td>
<td>Negative</td>
</tr>
<tr>
<td>7. HIV-1/2 Antibody (HIV Ab)</td>
<td>«HIVAb»</td>
<td>Negative</td>
</tr>
<tr>
<td>8. HIV Nucleic Acid Test (HIV NAT)</td>
<td>«HIVNAT»</td>
<td>Negative</td>
</tr>
<tr>
<td>9. West Nile Virus Nucleic Acid Test (WNV NAT)</td>
<td></td>
<td>Negative</td>
</tr>
</tbody>
</table>

What is Hepatitis C Virus?

Hepatitis C virus is a virus that can cause hepatitis, which is an inflammation of the liver. At the time of first infection with Hepatitis C virus, many people will have no symptoms whatsoever, others may have mild flu-like symptoms, and some people may have serious symptoms such as severe abdominal soreness, vomiting, or a yellow coloration to the skin. A small but significant percentage of infected people may remain symptom free for years but may develop severe liver disease over a long time interval.

Am I Contagious?

It is not entirely certain how most people are infected by the Hepatitis C virus. Some people may have been infected through an infectious needle (i.e. people who used IV drugs) or through a blood transfusion (usually prior to 1990). Sexual contact with an infected individual may be a cause of Hepatitis C virus transmission, although the risk of infection through this mode appears remote. Hepatitis C infected individuals should not share razors or toothbrushes, and should practice the usual standards of cleanliness. Also, they should cover any cuts, sores, or abrasions. It does not appear that Hepatitis C virus can be transmitted through casual contact, and at this time, it is not known whether a baby can be infected by the mother during pregnancy or through breast milk.

What Should I Do Now?

First, I want to reassure you that the risk of your having any immediate serious repercussions from a Hepatitis C infection is extremely small, and the long-term risk for serious complications is not very great.
Still, I recommend that you see a physician as soon as possible. If you are having any symptoms of hepatitis (as noted above), I suggest that you see a physician immediately.

**Can I Donate Blood Again?**

**Autologous Donors:**

Some people donate blood for their own use during an upcoming scheduled surgery (this is called autologous donation). If you are currently an autologous donor, you can continue to donate and your blood will be used for you during your surgery. All people with positive Hepatitis C tests are still eligible to be autologous donors at UCLA in the future.

**Non-Autologous Donors:**

Hepatitis C virus is very easily spread through blood transfusion. Because of the significant risk that your blood carries hepatitis C virus, we were not able to transfuse your donated unit into another person. You must not donate again for transfusion to others. We maintain a confidential file of the names of donors who are no longer allowed to donate because their blood may be capable of transmitting infection.

We have added your name to this file. Information from this file is maintained confidentially and will not be released without your permission, except if required by law. You may examine your record at any time to make sure it is accurate.

If you prescheduled an appointment to return to donate, our donor center staff will automatically cancel that appointment.

Again, I want to thank you for your efforts in giving your blood, and express my regrets that you can no longer donate (except as an autologous donor). Should you or your physician need any further information, please feel free to call me.

Sincerely,

Medical Director of Transfusion Medicine
Dear NAME:

Thank you for your recent blood donation at the UCLA Blood and Platelet Center.

In order to assure the safety of the blood that we give to our patients, we perform numerous tests on samples of each donor’s blood. Before we go any further, please be assured that your test results are not related to AIDS.

Most of your blood test results were normal. However, your screening test for Hepatitis C virus antibody yielded a positive (i.e., abnormal) result. Because this very sensitive test sometimes gives incorrect results, we further tested your blood for Hepatitis C virus using a second, more accurate supplementary test. The results from this supplementary test were negative, indicating that you have almost certainly never been infected by the Hepatitis C virus, and that the positive screening test was probably a false result. This conclusion is further supported by the fact that a very sensitive Nucleic Acid Test (NAT), which directly looks for the presence of the HCV virus in your blood, was negative. In sum, it is extremely unlikely that you have ever had a Hepatitis C virus infection.

Your complete test results on your donated unit are as follows:

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</tr>
<tr>
<td>9. West Nile Virus Nucleic Acid Test (WNV NAT)</td>
<td>NEGATIVE</td>
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</tr>
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</table>

Although it is highly unlikely that you have been infected with the Hepatitis C virus, we’d like to give you some additional information about Hepatitis C.

**What is Hepatitis C Virus?**

Hepatitis C virus is a virus that can cause hepatitis. Hepatitis is best defined as an inflammation of the liver. Many people who are infected by the Hepatitis C virus will have no symptoms whatsoever, while others may have mild flu-like symptoms, and some may develop severe abdominal soreness, vomiting or a yellow coloration to the skin. A small but significant percentage of infected people may remain symptom-free for years but may develop severe liver disease over a long time interval.

**Are People With Hepatitis C Virus Contagious?**

It is not entirely certain how most people are infected by the Hepatitis C virus. Some people may have been infected through an infectious needle (i.e. people who used IV drugs) or through a blood transfusion (usually prior to 1990). Sexual contact with an infected individual may be a cause of Hepatitis C virus transmission, although the risk of infection through this mode appears remote. Hepatitis C infected individuals should not share razors or toothbrushes, and should practice the usual standards of cleanliness. Also, they should cover any cuts, sores, or abrasions. It does not appear that Hepatitis C can be transmitted through casual contact, and at this time, it is not known whether a baby can be infected by the mother during pregnancy or through breast milk.

**What Should I Do Now?** First, we want to reassure you that because you are almost certainly not infected by the Hepatitis C virus, the risk of you ever having any serious Hepatitis C related problems is extremely small. We recommend that, at your convenience, you make your doctor aware of these test results since
he/she might consider having you retested. Of course, if you are having any of the symptoms of hepatitis, we suggest that you see a physician immediately.

- Can I Donate Blood Again?

  Autologous Donors

  Some people donate blood for their own use during an upcoming scheduled surgery (this is called autologous donation). If you are currently an autologous donor, you can continue to donate and your blood will be used for you during your surgery. All people with positive screening tests for antibody to Hepatitis C are still eligible to be autologous donors at UCLA in the future.

  Non-Autologous Donors

  Because of your abnormal Hepatitis C virus screening results, we have been required by the U.S. Food and Drug Administration to destroy your donated unit. Furthermore, we are currently unable to reinstate you as a blood donor.

  We maintain a confidential file of the names of donors who are currently not allowed to donate because of abnormal test results. We have added your name to this file. Information from this file is maintained confidentially and will not be released without your permission, except if required by law. You may examine your record at any time to make sure it is accurate.

  If you prescheduled an appointment to return to donate, our donor center staff will automatically cancel that appointment.

  Again, we want to thank you for your efforts in giving blood, and express our regrets that you cannot donate anymore (except as an autologous donor). Should you or your physician need any further information, please feel free to call us.

  Sincerely,

  Medical Director of Transfusion Medicine
APPENDIX 3-C
SAMPLE LETTER SENT TO TRANSFUSION RECIPIENTS DURING A LOOK BACK

Dear MR. JOHN DOE:

We are writing to you to inform you that a unit of red cells that you received at the UCLA Medical Center on 1/1/2005 is the subject of a lookback investigation. This means that the donor of the unit has subsequently developed hepatitis C infection, and therefore the unit of blood that you received may have carried a risk for hepatitis C.

At the time this unit was transfused to you, the donor health history on file and all hepatitis test results were acceptable (negative). These tests included Hepatitis B Surface Antigen (HBsAg), Hepatitis B Core Antibody (HbcAb), and Hepatitis C antibody Screen (HCV ELISA). All other donor tests for infectious disease, including those for the HIV virus were also negative.

In May, 2006, however, we were contacted by the donor and told that hepatitis C virus was detected in the donor’s blood in testing done by the donor’s physician. Despite this information, it is important to note that the test for hepatitis C performed on red cell unit you received was negative.

Although the risk that this donor was infectious at the time of the prior donation is small, we cannot exclude the possibility that the donor was at a very early stage of infection before it could be detected by the screening test. We recommend that you get tested for hepatitis C for this reason.

Hepatitis C virus is a virus that can cause hepatitis, which is an inflammation of the liver. At the time of first infection with hepatitis C virus, many people will have no symptoms whatsoever, others may have mild flu-like symptoms, and some people may have serious symptoms such as severe abdominal soreness, vomiting, or a yellow coloration to the skin. Most persons who get hepatitis C carry the virus for the rest of their lives, and while they have some liver damage, many do not yet feel sick from the disease. Of every 100 persons infected with hepatitis C, about 15 persons will develop cirrhosis (scarring) of the liver which can lead to liver failure. This can take many years to develop.

It is important that you get tested for hepatitis C so you can be checked for liver disease and get treatment, if indicated. If you have hepatitis C, it is important that you learn what actions you can take in order to protect yourself by avoiding substances that can cause further harm to your liver (such as alcohol and certain medicines), and to avoid spreading this disease to others.

You can get tested for hepatitis C at no charge by providing the UCLA case number at the top of this letter. To arrange for this testing, contact Irene Stalcup at (310) 267-2686.

Enclosed is general information about hepatitis C and places you can contact to get more information. We will also be sending a letter to your physician, informing him of this investigation and that we have sent you a notification letter.

Should you or your physician need any further information, please feel free to call us.

Sincerely,

Medical Director
Transfusion Medicine