January 19, 2023

«TSD»
«TSD_Title»
«Hospital_Name»
«Street»
«Street_2»
«City_State_Zip»

URGENT
RE: (HCV, HIV) RECIPIENT LOOKBACK INVESTIGATION

Lookback Case ID:
Unit Number: **ABO/Rh:** **Component:**
Date Shipped: **Expiration Date:**

Dear «TSD_Salutation_2»:

We are providing you with information regarding a Lookback Investigation we are now conducting. At the time of donation, the component was tested and found to be non-reactive for all required viral markers. On the donor was found to have the following positive test results:

☐ HIV-1 (Human Immunodeficiency Virus antibody)	☐ Confirmed by supplemental testing
☐ HIV-1 NAT (Nucleic Acid Test) (Considered confirmatory for HIV antibody)	
☐ HCV (Hepatitis C Virus antibody)	☐ Confirmed by Alternate Anti-HCV EIA Screening Test
☐ HCV NAT (Nucleic Acid Test) (Considered confirmatory for HCV antibody)	

The HHS and FDA regulations *require Lookback Investigation, which allows for proper management of patients who received prior transfusions from donors newly diagnosed with HIV or HCV infection.

Since it is not known when the donor may have become infected, previously donated units could have been infectious. Therefore, the recipient of the above component should be notified, counseled and tested. **The Code of Federal Regulations (610.46, 610.47, 610.48) requires that you make reasonable attempts to perform the notification within 12 weeks after receiving the supplemental (additional, more specific) test results for evidence of HIV or HCV infection or after receiving the donor's reactive screening test result for HIV or HCV if there is no available supplemental test that is approved for such use by FDA.**

The regulation suggests that the patient's attending physician assume this responsibility. However, if the patient's physician is unable or unwilling to perform this notification, it is the responsibility of the Transfusion Service. LifeStream is willing to assist you in locating patients who may be lost to follow-up.

Lookback cases are reportable to the Food and Drug Administration by LifeStream. We are asked to indicate the disposition of each involved blood component (discarded or transfused) in the report. Therefore, we request that you complete the attached form, specifying the final disposition of these blood components, and return it to us no later than 30 days from the date of this letter by fax. Thank you in advance for this information.

Please remember that if your investigation determines that the patient is infected, the case must be reported back to us a possible transfusion – transmitted infection, listing all of the components transfused.

We are enclosing information concerning (HCV, HIV) Lookback and transfusion – transmitted (HCV, HIV) that you should feel free to use in your interaction with attending physicians and patients. If you have questions regarding this matter, please do not hesitate to contact the Medical Surveillance Department or me at 1-800-879-4484 or (909) 885-6503.

Sincerely,

☐ HIV-1 LB Packet ☐ HCV LB Packet ☐ HIV-2 LB Packet

* 21CFR610.49; 21CFR610.47; 42CFR482