

Lookback

LOOKBACK FOR SUBSEQUENT DONATIONS FOR POSITIVE HIV & HCV TESTING

The US Department of Health and Human Services requires blood banks to notify hospitals of any *previously shipped product where testing was negative but subsequent donations now show positive testing for HIV or HCV*. Due to the window period (time between infection and positive testing), previous donations of the donor may still be infected. For that, and other reasons, a Lookback is required.

When a donor tests positive and there are previous donations, LifeStream will notify the hospital (via email) within 72 hours of the discovery. If the product has not been used, we will ask that it be returned to LifeStream. If the product has been transfused we will ask that you return the completed Product Retrieval Notification form (**SAMPLE #1**).

LifeStream is required to notify the hospital with results of confirmation testing within 45 days for HCV and within 30 days for HIV (**SAMPLE #2** and **SAMPLE #3**). If the confirmatory testing is positive LifeStream will send the hospital a "Packet."

The HIV/HCV Packet may contain (depending what testing was confirmed):

- Cover Letter stating that the test was confirmed positive (**SAMPLE # 4**).
- Transfusion Service Component Disposition Form, **Document 1432F5**
- Information for Physicians Regarding the HIV-1 Lookback Program of LifeStream, **Document 1432M5**.
- Information for Physicians Regarding the HIV-2 Lookback Program of LifeStream, **Document 1432M6**.
- Information for Physicians About the Significance of (RND) Reactive Non-Discriminated HIV-1, HCV, HBV (NAT) Nucleic Acid Test, **Document 1432M7**.
- Sample Letter from Transfusion Service Medical Director to Patient Attending Physician, **Document 1432F3**.
- Response from Physician to Transfusion Service, **Document 1432F2**.
- Hepatitis C Lookback: Information for Transfusion Services, **Document 1432M3**.

LOOKBACK FOR POST DONOR INFORMATION (PDI)

The FDA regulates how the blood bank handles post donor information. When a donor notifies the blood bank of information that was not available when the actual unit was drawn, the blood bank must inform the hospital. (Example of this would be the donor informing the blood bank after the product has been shipped stating that he has been in a malaria area.) (**SAMPLE # 5**.)