



HIV LOOKBACK, QUARANTINE AND NOTIFICATION

CBCNJ RESPONSIBILITIES:

1. **LOOKBACK PROCEDURES** – Community Blood Council of New Jersey, Inc. complies with all FDA requirements for HIV and HCV lookback notification as specified in the Code of Federal Regulations Title 42, section 482.27 and the requirements for infectious disease marker testing not subject to the lookback regulations in 21CFR 610.46 and 610.47 (including but not limited to Hepatitis B, West Nile Virus and Chagas Disease).
2. **QUARANTINE AND NOTIFICATION** – CBCNJ shall within 72 hours of discovering any infectious blood or blood components, take the following actions:
 1. Will promptly notify the hospital and recall all in-dated products from any donor who tested non-reactive at the time of donation, but tests repeatedly reactive for the disease marker on a later donation; and
 2. Will provide to the hospital results of the FDA-licensed, more specific test or other follow up testing recommended or required by the FDA for the disease marker, which will be completed within thirty (30) calendar days after the donor's repeatedly reactive screening test.

HOSPITAL RESPONSIBILITIES:

1. **QUARANTINE** – Within 72 hours of notification by CBCNJ, the hospital shall determine the disposition of any potentially infectious blood or blood products in inventory. These units shall be placed into quarantine and returned to CBCNJ when possible.
2. **DISPOSITION OF UNITS** – After the hospital has been notified of the results of the licensed, more specific test for HIV-1 or the second screening test for HIV-2, it may choose to do one of the following:
 1. If the result of the specific test (or other follow up test) is positive, the hospital is responsible for notifying patients as described in 42 CFR 482.27.
 2. If the result of the specific test is negative, the hospital may choose to return or discard any quarantine units.
 3. The hospital shall not return any potentially infectious units(s) to CBCNJ. If the unit is discarded, the hospital may request credit from in writing.
3. **NOTIFICATION OF PATIENT AND PHYSICIAN** – The hospital shall be responsible for notifying the physician and patient in a timely manner as described in 42 CFR 482.27 (6) – (7). If the hospital has contracted with a third party for patient notification, testing and counseling, the hospital will retain the responsibility for notification and referral of patients.