Community Blood Bank
2646 Peach St. Erie, PA 16508

TITLE: RELEASE OF BLOOD/BLOOD COMPONENTS PRIOR TO COMPLETION OF PROCESSING

PURPOSE: To outline the steps to be taken when a physician requires release of blood or blood components prior to the completion of processing. Processing is to be defined as: completion of infectious disease testing (anti-HBc, HBsAg, anti-HTLV I/II, anti-HCV, anti-HIV, types 1 and 2, RPR, MPX NAT and WNV NAT), blood typing (ABO/Rh), antibody screen (ABS) or Bacterial Detection Testing (BDS)

MATERIALS:

Forms:

Incomplete Processing Release Log
Request For Issue Of Blood And/Or Blood Components Prior To The Completion Of Processing
Manual Consignment Sheet

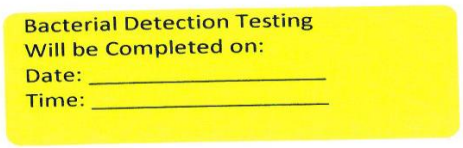
Labels:

For Emergency Use Only label
Bacterial Detection Testing Label

PROCEDURE:

A. Incomplete Bacterial Detection Testing.

1. On Products being sent to a hospital prior to the completion of Bacterial Detection Testing, place the Bacterial Detection Testing Label on the Consignment ticket with the date and time that Bacterial Dectection Testing will be completed.



2. Documentation:
   a. Generate an “Incomplete Processing Release” Log
      i. Date
      ii. Time the request was received.
      iii. Requesting Hospital
      iv. Name of person requesting components: hospital physician, laboratory director, etc.
   b. Contact CBB Medical Director or pathologist on call for CBB Medical Director for approval. Document on the“Incomplete Processing Release” Log. ***This step is not required for Hospitals that are performing an FDA approved Bacterial Detection test.***
      i. Name of pathologist approving,
      ii. Date and time of approval
      iii. How the approval was received- verbal (face to face), phone, fax, email or other
   c. Once the approval has been received,
      i. Document on the “Incomplete Processing Release” Log:
         1. Donor Unit Number
         2. Component Code
         3. BDS under “Testing Not Completed”

- **Note: If all infectious disease testing has been completed, label and ship the product per normal protocol. If not, follow the steps outlined in section “B:**
- **Note: A ““Request for Issue of Blood and/or Blood Components Prior to the Completion of Processing”” form is not required.**

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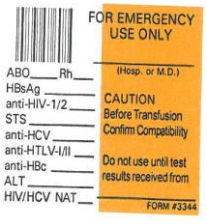
B. Incomplete Infectious Disease Testing, ABO/Rh or Antibody Screen Testing.

In the event of an emergency patient need for blood or blood components, the following must occur.

1. Upon request from a Hospital/Physician: Generate an "Incomplete Processing Release" Log
   a. Date
   b. Time the request was received.
   c. Requesting Hospital
   d. Name of person requesting components: hospital physician, laboratory director, etc.
   e. Contact CBB Medical Director or pathologist on call for CBB Medical Director for approval. Document on the"Incomplete Processing Release" Log
      i. Name of pathologist approving,
      ii. date and time of approval and
      iii. how the approval was received- verbal (face to face), phone, fax, email or other
2. Once the approval has been received,
   a. Document on the "Incomplete Processing Release" Log:
      i. Donor Unit Number
      ii. Component Code
      iii. List of tests not completed
         1. HBC (anti-HBc)
         2. HBS (HBsAg)
         3. HIVC (anti-HIV, types 1 and 2)
         4. HCV (anti-HCV)
         5. ABO/RH
         6. ABS (antibody screen)
         7. RPR (serologic test for syphilis)
         8. MPX NAT (HIV/HCV/HBV NAT)
         9. WNV NAT
   b. Generate a "Request for Issue of Blood and/or Blood Components Prior to the Completion of Processing" form.
      i. Populate: Donor Unit Number and Component Product Code.
      ii. Copy this form
3. Generate a Manual Consignment sheet (See example.):
   a. Record unit #'s
   b. Document "Emergency Issue".
4. Place a "For Emergency Use Only" label on each component to be sent



   a. Populate all tests that are completed (may be obtained from SafeTrace , =LA, TT, tab, Unit #). A 2nd Technologist will need to verify that the label is correct. Document label verfication (both tech 1 and tech 2) on the "Incomplete Processing Release" Log
   b. Populate hospital to be sent to.
5. Two copies of the"Request for Issue of Blood and/or Blood Components Prior to the Completion of Processing" Form are enclosed with the shipment. One signed copy must be returned to CBB by the receiving hospital.

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REPORTING & INTERPRETING RESULTS:

1. Any test result not completed at the time of release is to be telephoned to the receiving hospital as soon as the test is completed. Record tech, time and date in "Incomplete Processing Release" Log.

2. Unused units are to be returned to CBB for final labeling after completion of all processing. If the products are returned to CBB and re-labeled, place a ✓ in the 'Product Returned/Relabeled" column.

3. If reactive/positive results are detected and the unit has not been transfused, it should be recalled. If transfused, the CBB Medical Director should be notified immediately. The CBB Medical Director will then notify the attending physician.

4. If units have been transfused:
    a. Enter test results in computer
    b. Label product in computer
    c. Consign to hospital (Enter under comment: emergency issue yy/mm/dd)

5. Completed "Incomplete Processing Release" Log and manual consignment tickets should be given to the Technical and QA Directors for review.

6. Completed "Request for Issue of Blood and/or Blood Components Prior to the Completion of Processing" forms returned from the hospital will be given to the QA Director.

7. All forms will be kept on file in the QA department.