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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, STS (serologic test for syphilis), MPX NAT and WNV MP NAT), blood typing (ABO/Rh), antibody screen (ABS), Chagas (T. Cruzi), Zika MP NAT and Babesia NAT.

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

PROCEDURE:

- A. 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. Anti-HTLV I/II
 6. ABO/RH
 7. ABS (antibody screen)
 8. STS (serologic test for syphilis),
 9. MPX NAT (HIV NAT/HCV NAT/HBV NAT)
 10. WNV MP NAT
 11. Zika MP NAT
 12. Chagas (T. Cruzi)
 13. Babesia NAT
 - b. Generate a "Request for Issue of Blood and/or Blood Components Prior to the Completion of Processing" form.

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- 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

FOR EMERGENCY USE ONLY	
ABO _____	Rh _____
ABS _____	STS _____
HIVNAT _____	WNVNAT _____
HCVNAT _____	HBVNAT _____
HCVAb _____	HBcAb _____
HBsAg _____	HIV1/2 _____
HTLV1/II _____	ZIKA _____
OTHER _____	

- 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 verification (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.

REPORTING & INTERPRETING RESULTS:


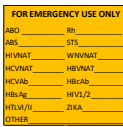
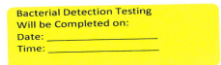
1. Any test result not completed at the time of release is to be telephoned to the receiving hospital as soon as the test is completed. Record tech, time and date on "Incomplete Processing Release" Log.
2. Unused units are to be returned to CBB for final labeling after completion of all processing. If the products are returned to CBB and re-labeled, place a ✓ in the 'Product Returned/Relabeled' column of the "Incomplete Processing Release" Log.
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.

REFERENCES:

1. AABB standard 5.8.5.1

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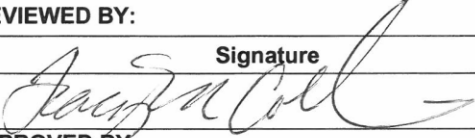
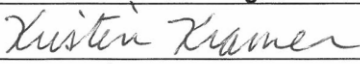

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Original Effective Date	Revised by	Revision	Supersedes Revision #
3.23.1982	D. Pirschel	Renamed SOP (prior-Emergency Release of Blood and/or components) Added incomplete BDS processing steps Updated and renamed forms: included addition of documentation of Medical Director approval.	1.001
	D. Pirschel	Remove BRD Union Square address	1.002
	D. Pirschel	Deleted: RPR Added: STS (serologic test for syphilis), Chagas (T. Cruzi)	1.003
	T. Collier	Added: MPX 2.0 NAT (HIV NAT/HCV NAT/HBV NAT)	1.004
	T. Collier	Deleted:  Added: AABB standard 5.8.5.1 the "Incomplete Processing Release" Log Zika ID NAT Anti-HTLV I/II Zika ID NAT 	1.005
3.23.1982	T. Collier	Deleted: Bacterial Detection Testing Label Bacterial Detection Testing (BDS) Incomplete Bacterial Detection Testing. 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 Detection Testing will be completed.  Documentation: Generate an "Incomplete Processing Release" Log Date Time the request was received. Requesting Hospital Name of person requesting components: hospital physician, laboratory director, etc. Contact CBB Medical Director or pathologist on call for CBB Medical Director for approval. Document on the "Incomplete Processing Release" Log. <i>This step is not required for Hospitals that are performing an FDA approved Bacterial Detection test.</i> Name of pathologist approving. Date and time of approval How the approval was received- verbal (face to face), phone, fax, email or other Once the approval has been received, Document on the "Incomplete Processing Release" Log: Donor Unit Number Component Code BDS under "Testing Not Completed" <input type="checkbox"/> 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": <input type="checkbox"/> Note: A "Request for Issue of Blood and/or Blood Components Prior to the Completion of Processing" form is not required.	1.006
3.23.1982	D. Pirschel	Deleted: ID Added: MP	1.007
3.23.1982	T. Collier	Deleted: 2.0 2.0	1.008
3.23.1982	K. Kramer	Added: , and Babesia NAT 13. Babesia NAT	1.009

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REVIEW/APPROVAL/IMPLEMENTATION

REVIEWED BY:			
Department Head	Name	Signature	Date
Technical Director	Tracy Collier		2-25-2020
APPROVED BY:			
Position	Name	Signature	Date
QA Director	Kristin Kramer		2-25-2020
Medical Director	Jeffrey A. Richmond MD		2-26-2020
IMPLEMENTATION DATE: APR 20 2020			

REVIEW			
MEDICAL DIRECTOR	DATE	MEDICAL DIRECTOR	DATE

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