Forms

CS-600-JA-01, Notification Recommendations
CS-600-F-02, Post Donation Information Notification/Withdrawal
HS-300-F-01, Product Return/Transfer Report

Supplies and Equipment

Computer with appropriate blood system access

Instructions

1.0 Blood Center notification of hospital consignee
- 1.1 CBC will request retrieval of all involved in-date components within 3 calendar days.
- 1.2 Consignee will be subsequently notified of all involved components utilizing form CS-600-F-02, Post Donation Information Notification/Withdrawal.

2.0 Hospital management of PDT information
- 2.1 Upon receipt of CS-600-F-02, determine the disposition of blood component(s) listed on the form.
  - 2.1.1 Blood component information listed includes donor identification number (DIN) and date product shipped from CBC.
  - 2.1.2 More than one blood component may be listed and more than one form may be received.
- 2.2 Document disposition of blood component(s) listed on the form.
  - 2.2.1 Check appropriate disposition box on PDT form to indicate component status(ex. transfused, discarded),
  - 2.2.2 Enter date and tech initials to complete documentation.
- 2.3 Fax form back to CBC as verification as soon as possible using the number listed at bottom of form.

3.0 Recipient Notification
- 3.1 Hospitals are responsible for notifying recipients according to institutional protocols.
  - 3.1.1 CBC provides recommendations for recipient (patient) notification based on current FDA guidance, however, Consignee should conduct notification according to internal protocols
  - 3.1.2 Reason for notification is indicated in upper half of the PDT form.
  - 3.1.3 Additional comments by CBC Associate Medical Director may be included in the appropriate box. Hospital Medical Director should contact CBC with any questions.

END

Post Donation Information Notification/Withdrawal

To: _____ Email: _____ Fax # _____ PDT # _____

Facility _____

Date of Initial Notification _____ ☐ by fax ☐ by e-mail Phone Verification of receipt _____

Community Blood Center/Community Tissue Services® is performing a withdrawal due to the following post donation information:

- ☐ Received human pituitary-derived growth hormone (1)
- ☐ Received a dura mater transplant (1)
- ☐ History of CJD in more than one blood relative (1)
- ☐ Diagnosed (or suspected) ☐ CJD (1) ☐ vCJD (1)
- ☐ Diagnosed with WNV infection (1)
- ☐ Diagnosed or suspected Zika (1)
- ☐ Post donation diagnosis of _____ (2)
- ☐ Post donation illness (2)
- ☐ Tattoo/piercing/needle stick (2)
- ☐ Malarial risk event (2)
- ☐ Medication _____ (2)
- ☐ Donor behavior / history or risk of_____ (2)
- ☐ Other: _____
- ☐ Ebola Risk _____(1)

Comments:

(1) FDA guidelines recommend the consignee inform physician or other qualified personnel responsible for the care of the recipient, so that medically appropriate notification and counseling may be performed at the discretion of health care providers.

(2) For components already transfused, conduct recipient notification per your facility Standard Operating Procedure

⇨ **UPON RECEIPT OF THIS FORM, PLEASE COMPLETE THE HIGHLIGHTED BOX BELOW AND FAX TO CBC.**
⇨ **KEEP A COPY OF THIS FORM FOR YOUR FILES.**
⇨ **DISCARD OR RETURN COMPONENTS IN INVENTORY TO CBC.**
⇨ **QUESTIONS MAY BE DIRECTED TO: Ghada Khalife, MD (937)461-3450**

Unit # ***DO NOT INCLUDE PATIENT NAME OR MR#***	**Component**	**Blood Type**	**Expiration Date**	**Disposition** (Hospital – check appropriate box and enter date of disposition and initials of staff completing form)	
				☐ Transfused ☐ Returned to CBC ☐ Expired and destroyed ☐ Transferred to: _____ ☐ Discarded ☐ Other (specify)	Date/Initials:
				☐ Transfused ☐ Returned to CBC ☐ Expired and destroyed ☐ Transferred to: _____ ☐ Discarded ☐ Other (specify)	Date/Initials:

Please fax completed form to 1-937-719-4389

**DO NOT INCLUDE PATIENT NAME OR MR#*

Forms

HLSM-010-F-04, Lookback Notification
HLSM-010-F-07, Import Lookback Notification Letter
HS-300-F-01, Product Return/Transfer Report

Definitions

Lookback is the identification of blood components from a donor with **prior** collections who now tests repeat reactive for one or more infectious disease markers.

Instructions

A. Blood Center Notification of Hospital Consignee:

1. **Within three calendar days** of a repeat reactive test result, CBC will identify blood components previously donated by the donor according to current FDA regulations.

    a. CBC will **immediately** identify any **in-date** components, both in-house and at hospital(s).

        1) Any in-date components identified in-house will be immediately quarantined according to CBC protocol to prevent shipping.

        2) Any hospitals that received in-date components will be directly contacted by phone to prevent transfusion of identified components.

            - CBC will immediately call hospital and request that identified product(s) be defaced and quarantined per hospital protocol.

            - CBC will schedule a courier to retrieve quarantined product(s).

2. CBC will subsequently notify Consignee (hospital) of all involved components from **prior** collections within FDA defined timelines.

    a. CBC will document all involved components received by an individual hospital on HLSM-010-F-04 and send by fax or email to the transfusion service supervisor **within 30 calendar days** after confirmation testing is received.

    b. CBC will document confirmation testing results on the form using current FDA guidelines for recipient notification recommendations.

3. CBC will notify Consignee of any **imported** components received by CBC from another blood center, shipped, and now involved in a targeted Lookback case.

    a. Upon notification by the Import blood center, CBC will complete HLSM-010-F-07 and send by fax or email to the receiving hospital transfusion service supervisor.

    b. CBC will also include additional paperwork requested by the Import blood center to be completed by the receiving hospital.

B. Hospital Management of Lookback Information:

1. Upon contact by CBC of in-date components that must be quarantined and returned, immediately follow blood center instructions to quarantine products in order to prevent transfusion.

   a. Document component(s) on the Product Return/Transfer Report (HS-300-F-01) and enter "**Lookback**" in comments.

   b. Include product return form when returning quarantined component(s).

2. Upon receipt of the **Lookback Notification** form (HLSM-010-F-04), review information provided and complete the **Disposition** box according to the instructions listed.

   NOTE: *Do not include recipient's name or medical record ID on the form*.

   a. Fax or email the form back to CBC as verification of receipt as soon as possible using the information listed on the form.

   b. Please note that more than one blood component may be listed and more than one form may be received.

3. Upon receipt of the **Import Lookback Notification Letter** (HLSM-010-F-07), review information provided and complete the form.

   NOTE: *Do not include recipient's name or medical record ID on the form*.

   a. Fax or email HLSM-010-F-07 form back to CBC as verification of receipt as soon as possible using the information listed on the form.

   b. Complete documentation as requested by the Import blood center and send according to their instructions.

C. Recipient Notification:

1. Hospitals are responsible for notifying recipients according to institutional protocols.

   a. CBC provides recommendations for recipient (patient) notification based on current FDA guidance. However, Consignee should conduct notification according to internal protocols.

   b. Additional comments by CBC may be included as needed in the Comments box.

   c. Hospital Medical Director should contact CBC with any questions. Refer to the **Lookback Number (LB #)** located in the upper right corner of the form when placing a call for more information.

END

To: _____ **Fax #** _____ **LB #** _____

Facility _____

Date of Initial Notification _____ ☐ **by fax** ☐ **by e-mail** **Tech:** _____

Community Blood Center/Community Tissue Services is performing Lookback notification of the following components:

DIN	Component	Donation Date	Expiration Date	Shipment Date	**Disposition** (Hospital – check appropriate box and enter date of disposition and initials of staff completing form)	
					☐ Transfused ☐ Returned to CBC ☐ Expired and destroyed ☐ Transferred to: _____ ☐ Discarded ☐ Other (specify)	Date/Initials:
					☐ Transfused ☐ Returned to CBC ☐ Expired and destroyed ☐ Transferred to: _____ ☐ Discarded ☐ Other (specify)	Date/Initials:

Reason for Lookback: on a subsequent donation (date), the donor tested:

Comments:

(1) FDA guidelines do not recommend recipient notification
(2) For transfused components, FDA recommends recipient notification following Hospital standard operating procedure

⇨ **THE UNIT SHIPPED TO YOU TESTED NEGATIVE FOR ALL INFECTIOUS DISEASE TESTS REQUIRED BY THE FDA**
⇨ UPON RECEIPT OF THIS FORM, PLEASE COMPLETE THE DISPOSITION BOX ABOVE
⇨ DISCARD OR RETURN COMPONENTS IN INVENTORY TO CBC
⇨ FAX COMPLETED FORM TO CBC @ 1-937-461-6950, Donor Testing Lab, ATTN: Connie Piekenbrock/Sharon Wing
⇨ KEEP A COPY OF THIS FORM FOR YOUR FILES.
⇨ QUESTIONS MAY BE DIRECTED TO: James Alexander, MD, Ghada Khalife, MD or James Gatton, MD @ 1-(937)461-3450

Reviewed By/Date: _____

Date

<Blood Bank Supervisor>
<Hospital>
<Address>
<City>, <State> <Zip>

Dear <Blood Bank Supervisor>,

Community Blood Center has received notification of a product, imported from an outside facility, which has been identified as being involved in **xxx** (positive tests) Lookback. Our records indicate this product was shipped to your facility,

DIN/WBN: _____

Product Code: _____

Date shipped: _____

Please complete this form and the enclosed paperwork as requested by the Import Center.

Fax all documents to 937-461-6950: Attention Record Review Specialist/HS Supervisor.

A copy of the paperwork should be retained by your facility.

I acknowledge the receipt of the Notification Letter sent by Community Blood Center/Community Tissue Services, Dayton, Ohio.

_____ _____

Signature / Title Date

Form

HLSM-013-F-01, Transfusion Transmission Disease Investigation

Instructions

A. The Hospital Transfusion Service is responsible for initiating a **Transfusion Transmission Disease Investigation** (HLSM-013-F-01) upon notification by a patient's clinician or the hospital's infection control process of a suspected transfusion-related infection.

1. Complete hospital and patient information requested at the top of the form, Page 1.

   NOTE: Documentation of risk factors is necessary for a complete investigation of TTD.

   Factors to consider and ask the patient and/or their clinician include: previous transfusion history (including other hospitals), lifestyle choices, contact with friends and family who are positive for infectious diseases or other known exposures.

2. Document all infectious disease testing available for the patient at the time of reporting in the Hospital Laboratory Results section on Page 1.

3. List blood products transfused to the patient on Page 2 of the form according to the criteria listed below.

   a. For **Hepatitis** cases, list products transfused up to 6 months prior to the onset of symptoms.

   b. For **HIV** cases, list all products transfused.

   c. For **WNV** cases, list products transfused within 120 days of the onset of symptoms.

4. The Transfusion Service Medical Director reviews all information collected to determine whether investigation is complete. Sign and date the form (Page 1) after review and include any additional notes or comments that may assist the investigation.

5. Send the completed form to CBC, attention: CBC HS Supervisor/Record Review Specialist through the CBC courier system.

B. CBC will return the completed **Transfusion Transmission Disease Investigation** to the hospital upon completion of the investigation.

1. CBC will contact all implicated donors to provide follow-up testing.

2. Upon receipt of subsequent donor testing, CBC will complete documentation and send TTD investigation results to the reporting hospital.

3. If, after 2 months, the donor cannot be contacted or is unable to provide a specimen for follow-up testing, CBC will complete documentation and send TTD investigation results to the reporting hospital.

4. CBC Medical Directors are available to answer questions on the TTD investigation process and results. Hospitals may call 937-461-3450 and ask for the medical director.

END

Hospital: _____ Date Form Completed: _____ Is Patient Currently Hospitalized? ☐ Yes ☐ No

Patient Name: _____ DOB: _____ Physician: _____

Disease Diagnosed/Date: _____

Period of Tx* From: _____ To: _____ Reason for Tx: _____

Other Risk Factors: _____

** List transfused blood products on page 2.*

Date Received at CBC:
_____

CBC Case No.:
_____

Date Case Closed:
_____

Hospital Laboratory Results:

Previous Infectious Disease Testing	Result	Date	Post-Transfusion / Current Serology Tests	Result	Date
HBsAg			HBsAg		
HIV			HIV		
HCV			HCV		
WNV			WNV		

Transfusion Service Medical Director: approval of documentation

Comments: _____

Transfusion Service Medical Director Signature: _____ Date: _____

SEND COMPLETED FORM TO CBC BY BLOOD COURIER - ATTN: HOSPITAL SERVICES SUPERVISOR/RECORD REVIEW SPECIALIST

For CBC Use Only:

CBC Medical Director's Conclusion: ☐ Probably Transfusion Related ☐ Probably Not Transfusion Related ☐ Investigation Inconclusive

Comments: _____

Medical Director's Signature: _____ Date: _____ Case Findings Mailed By/Date: _____

For Hospital Use Only[1]			*For CBC Use Only*
Donation # or Manufacturer/Lot #	**Product Code or Product**	**Transfusion Date (MM/DD/YY)**	**Subsequent Donation/Date/Test Result**

[1]*For **Hepatitis** Cases: List products transfused up to 6 months prior to the onset of symptoms.*
*For **HIV** Cases: List products transfused since 1978.*
*For **WNV** Cases: List products transfused up to 120 days prior to onset of symptoms.*

Forms

MIC-307-F-02, SDP Memorandum
HS-300-F-01, Product Return/Transfer Report

Instructions

I. Blood Center notification of hospital Consignee:

A. CBC will promptly retrieve all involved in-date blood components upon receipt of a positive bacterial detection test.

1. Any in-date components identified in-house will be immediately quarantined according to CBC protocol to prevent shipping.

2. Any hospital that may have in-date components will be directly contacted by phone to determine current disposition.

a. CBC will instruct hospital to return any identified in-date blood components to prevent transfusion.

b. Hospital must follow CBC instructions to return components with a completed Product Return/Transfer Report (HS-300-F-01).

3. If product(s) have been transfused, CBC will request the following information: patient name, date of transfusion, patient's physician name and phone number.

B. A CBC Medical Director will be promptly notified of any bacterial detection cases where the product has been transfused.

1. The CBC Medical Director will promptly review the bacterial detection case and contact the patient's physician or transfusion service medical director.

2. CBC will send a SDP Memorandum (MIC-307-F-02) by fax to the Hospital Transfusion Service Medical Director and the Transfusion Service Supervisor.

3. CBC will alert the transfusion service by phone that notification has been sent.

II. Hospital management of bacterial detection notification:

A. Hospitals are responsible for notifying recipients according to institutional protocols.

1. CBC Medical Director is available for consultation at 937.461.7557.

B. Hospitals are responsible for notifying CBC of any changes in contact information including name/title, email address, phone number, and fax number.

END

TO: Transfusion Service Medical Director

FROM: CBC/CTS Medical Directors

SUBJECT: Bacterial Detection Notification - SDP

CC: Transfusion Service Supervisor

In accordance with AABB Standards, CBC/CTS is currently screening Single Donor Apheresis Platelets (SDP) for bacterial contamination by culture using the BacT/Alert. Although these products are not released until after 12 hours of culture with no growth detected, the cultures are maintained until the outdate of the product.

Today's Date: _____ Hospital Name: _____ BDI Case Log #: _____

Our records indicate a patient at your institution received the following component.

Patient name: _____

Component: ☐ Apheresis Platelet ☐ RBC/LR RBC ☐ FFP

Unit number: _____ Date transfused: _____

Patient's Attending Physician: _____ Phone: _____

Subsequent to your patient's transfusion, the SDP manufactured from this unit tested positive for bacterial contamination using the BacT/Alert. However, at this time definitive gram stain and final culture results are not available to confirm or rule out true bacterial contamination. Final culture results will be available in approximately five days.

The clinical significance of these results is uncertain, given the possibility of a false positive result and the uncertainty about the presence of, or pathogenic quality of, any potential organism in the component transfused to the patient. The patient's clinical situation, immune status, concurrent antibiotic therapy are key considerations in evaluating any potential risk to the recipient. It is highly suggested that blood cultures be performed on the recipient; culture results can be faxed to (937) 461-2738 upon completion.

If you have questions, we would be happy to talk with you at any time. You can contact a CBC/CTS physician at (937) 461-3450. Thank you very much.

☐ Gram Stain Result: Faxed by/date/time: _____

☐ No organisms seen, culture to follow ☐ Organisms seen: _____

Final Culture Results: ☐ No growth after 48 hours ☐ Organism(s) identified: _____

Faxed by/date/time: _____