



Carter BloodCare

To:

Fax:

From: Distribution – Hospital Services Department

Office: Bedford: Phone: 817-412-5700 Fax: (817) 412-5729

Tyler: Phone: 903-363-0404 Fax: (903) 363-0483

Waco/Central Texas: Phone: 254-297-4100 Fax: (254) 399-6391

Date:

Total number of pages, including coversheet:

QUARANTINE REQUEST FACSIMILE

Unit returned by facility

COMMENTS:

This is to follow-up the telephone call requesting the disposition of the unit(s) listed below. If these units are in your inventory, please quarantine them for return.

Unit Number	Product Code	Component Type	Blood Type	Ship Date

IMPORTANT WARNING: This message is intended for the use of the person or entity to which is addressed and may contain information that is privileged and confidential, the disclosure of which is governed by state and federal laws. If the reader of this message is not the intended recipient, or the employee or agent responsible to deliver it to the intended recipient, you are hereby notified that any use, dissemination, distribution or copying of this message is strictly prohibited. If you have received this message by error, please notify Carter BloodCare at (817) 412-5000 immediately and destroy the related message.



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Total number of pages, including coversheet:

QUARANTINE RELEASE REQUEST FACSIMILE

COMMENTS:

You were recently notified to quarantine the component listed below. The issue that prompted the quarantine request has been resolved and the component may be released from quarantine. If you have any further questions concerning this unit, please call the Distribution – Hospital Services Department.

Unit Number	Product Code	Component Type	Blood Type	Ship Date

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SUSPECTED COMPONENT CONTAMINATION NOTIFICATION

Employee ID: _____ Date: _____ Q.A. File Number: _____
 Facility Name: _____

Please complete the Final Disposition and Date of Disposition fields in the table below and the bottom portion of this form. Direct any questions and send completed notifications via fax or email to the following Carter BloodCare Quality Assurance location:

- North/Central Texas – Phone: 817-412-5580 Fax: 817-412-5659 Email: ganotifications@carterbloodcare.org
 East Texas – Phone: 903-363-0419 Fax: 903-363-0467 Email: ganotifications@carterbloodcare.org

Reason for Notification:

- Bacterial detection testing for the unit(s) listed below resulted positive after distribution and continued incubation (negative at time of distribution).
 The unit(s) listed below are associated with another product that has a positive result for bacterial detection testing.
 The unit(s) listed below are associated with a transfusion reaction where possible bacterial contamination cannot be ruled out.

Bacterial Detection Testing or Transfusion Reaction Culture Results:

Gram stain results: Not Available No organisms seen Other: _____
 Gram stain results called to: _____ by _____ on (date/time) _____
 Final culture result: Not Available No growth Organism isolated: _____

DIN/BUN	Product Code	Product Type	ABO/Rh	Shipment #	Ship Date	Final Disposition	Date of Disposition

Disposition: T = Transfused D = Discard R = Returned to Carter BloodCare RNA = Record(s) Not Available O = Other

Comments: _____

 Name ([print] person completing form) _____ Date _____ Facility

 Signature _____ Title

COMPONENT RECALL/MARKET WITHDRAWAL NOTIFICATION

FACILITY NAME: _____

Q.A. FILE NUMBER: _____

Please complete the "Final Disposition" and "Date of Disposition" fields in the table below and document name, title, signature, and date on the bottom portion of this form. Send completed notifications via fax or email and direct any questions to the following Carter BloodCare Quality Assurance location:

- North Texas – Phone: 817-412-5580 Fax: 817-412-5659 Email: qanotifications@carterbloodcare.org
 East Texas – Phone: 903-363-0419 Fax: 903-363-0467 Email: qanotifications@carterbloodcare.org

The donor has subsequently reported the following information, indicated below, that would have made the donor ineligible for the donation(s) listed below. All infectious disease testing was negative/non-reactive for the unit(s) listed below.

Reason for Recall/Market Withdrawal Notification	Reported By	Date

DIN/BUN	Product Code	Product Type	ABO/Rh	Shipment #	Ship Date	Final Disposition	Date of Disposition

Disposition: T = Transfused D = Discarded/Outdated R = Returned to Carter BloodCare RNA = Records Not Available Other (Specify): _____

***If any component is in available inventory, immediately place it in quarantine. Contact Hospital Services/Distribution personnel for pick-up.**

 Name and Title ([print] person completing form)

 Signature (person completing form)

 Date

QUARANTINE/RELEASE NOTIFICATION

FACILITY NAME: _____

DATE: _____

REPORTED BY: _____

Please complete the "Final Disposition" and "Date of Disposition" fields in the table below and document name, title, signature, and date on the bottom portion of this form. Send completed notifications via fax or email and direct any questions to the following Carter BloodCare Quality Assurance location:

- North Texas – Phone: 817-412-5580 Fax: 817-412-5659 Email: qanotifications@carterbloodcare.org
- East Texas – Phone: 903-363-0419 Fax: 903-363-0467 Email: qanotifications@carterbloodcare.org
- QUARANTINE NOTICE – This is to follow-up the telephone call requesting the disposition of the component(s) listed below. If these component(s) are in your inventory, please quarantine them for return.
- RELEASE TO INVENTORY NOTICE – You were recently notified to quarantine the component(s) listed below. The issue that prompted the quarantine request has been resolved and the component(s) may be released from quarantine. If you have any further questions concerning the component(s), please contact the Quality Assurance Department indicated above.

Comments/Additional Information: _____

DIN/BUN	Product Code	Product Type	ABO/Rh	Shipment #	Ship Date	Final Disposition	Date of Disposition

Disposition: T = Transfused D = Discarded/Outdated R = Returned to Carter BloodCare RNA = Records Not Available Other (Specify): _____

***If any component is in available inventory, immediately place it in quarantine. Contact Hospital Services/Distribution personnel for pick-up.**

 Name and Title ([print] person completing form)

 Signature (person completing form)

 Date

CONSIGNEE NOTIFICATION RECORD

FACILITY NAME: _____

Q.A. FILE NUMBER: _____

The donor of the following unit(s) has subsequently tested reactive for the test(s) indicated below. All infectious disease testing was negative for the unit(s) listed below. Please complete the "Final Disposition" and "Date of Disposition" fields in the table below and document name, title, signature, and date on the bottom portion of this form. Send completed notifications via fax or email and direct any questions to the following Carter BloodCare Quality Assurance location:

North Texas – Phone: 817-412-5580 Fax: 817-412-5659 Email: qanotifications@carterbloodcare.org

East Texas – Phone: 903-363-0419 Fax: 903-363-0467 Email: qanotifications@carterbloodcare.org

Initial Repeat Reactive Test	Reported By	Date

Supplemental/Confirmatory Test	Result	Reported By	Date

FDA Lookback Requirement (HCV, HIV, Chagas)	CBC Lookback Number	Date of Last Negative Donation	Date of Positive Donation

DIN/BUN	Product Code	Product Type	ABO/Rh	Shipment #	Ship Date	Final Disposition	Date of Disposition

Disposition: T = Transfused D = Discarded/Outdated R = Returned to Carter BloodCare RNA = Records Not Available Other (Specify): _____

***If any component is in available inventory, immediately place it in quarantine. Contact Hospital Services/Distribution personnel for pick-up.**

Name and Title ([print] person completing form)

Signature (person completing form)

Date



REACTIVE NON-DISCRIMINATE MULTIPLEX HIV-1/HCV ASSAY NOTIFICATION

EMPLOYEE ID: _____

DATE: _____

Q.A. FILE NUMBER: _____

FACILITY NAME: _____

This is a request to retrieve the disposition of the unit(s) listed below. If the component(s) is in stock, place it in quarantine.

Contact Distribution and Product Management personnel at the following Carter BloodCare location for pick-up:

- North/Central Texas 817-412-5700
- East Texas 903-363-0404

The donor of the following unit(s) has subsequently tested reactive on a Multiplex (individual donor) Nucleic Acid Test (NAT) for HIV-1 and HCV. The unit(s) listed below was negative for all infectious disease testing.

Initial Test Results:

- Multiplex NAT HIV-1 and HCV = Reactive
- Anti-HCV ELISA = Non-Reactive
- Anti-HIV-1/2 EIA = Non-Reactive

Additional Test Results

- NAT HCV RNA _____
- NAT HIV-1 RNA _____

If discriminatory for HIV-1 or HCV, notification will become a lookback. Further notification will be performed on form QAF602.01 Consignee Notification Record.

Lookback: Recipient Notification **REQUIRED** for HIV and HCV

Date of Last Negative Donation: _____ Date of Positive Donation: _____ Reported By: _____ Date: _____

Please complete the form and fax it back to the following Carter BloodCare Quality Assurance location:

- North/Central Texas 817-412-5659
- East Texas 903-363-0467

DIN/BUN	Product Code	Product Type	ABO/Rh	Shipment #	Ship Date	Final Disposition	Date of Disposition

Disposition: T = Transfused D = Discarded/Outdated R = Returned to Carter BloodCare RNA = Records Not Available

Other (Specify): _____

Questions regarding this notification should be directed to the following Carter BloodCare Quality Assurance location:

- North/Central Texas 817-412-5580
- East Texas 903-363-0419

Name ([print] person completing form)

Date

Facility

Signature (person completing form)

Title



REQUEST FOR PRODUCT QUARANTINE, DISCARD OR RETRIEVAL

Date: _____ Facility: _____

Facility Contact: _____ Facility Fax: _____

From: Carter BloodCare – Reference & Transfusion Service Department _____
(Employee Name)

Phone: (817) 412-5740

Number of Pages: _____

This facsimile is to follow up the telephone notification you received from the R&T department requesting the disposition of the unit(s) listed below. If this unit(s) is currently in your inventory, please **immediately** quarantine and arrange return to Carter BloodCare through the Distribution department, unless otherwise instructed by a Carter BloodCare representative.

Unit Number(s): _____

Product Code(s): _____

Blood Type(s): _____

Date(s) Shipped: _____

To be completed by the customer and faxed back to the CBC Quality Assurance Department:

Fax: (817) 412-5659

If the facility was able to provide the below requested information to the R&T representative during the telephone conversation the R&T representative may have already completed the information below. In that case no further action is required by the facility at this time.

Status of the product (please mark applicable status and enter date(s), if applicable):

Available Transfused Date: _____ Discarded Date: _____

Completed by: _____ Date: _____
(Facility Name / Facility Representative Full Name)

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REFERENCE AND TRANSFUSION SUSPECTED COMPONENT CONTAMINATION NOTIFICATION

Date/Time: _____ Facility: _____

Facility Contact: _____ Facility Fax: _____

From: Carter BloodCare – Reference & Transfusion Service Department _____
(Employee Name)

Phone: (817) 412-5740

This facsimile is to follow up the telephone notification you received from the R&T or Distribution Department(s) requesting the disposition of the unit(s) listed below.

Unit Number(s): _____

Product Code(s): _____

Blood Type(s): _____

Date(s) Shipped: _____

Date/Time Transfused: _____

Patient Name (if applicable): _____ Patient MR# (if applicable): _____

Patient DOB (if applicable): _____

- This product tested positive for the screening test for bacterial detection after distribution (negative at the time of distribution.) Gram stain and culture results to follow.
- Other product(s) associated with the donation tested positive for the screening test for bacterial detection. Gram stain and culture results to follow.

Confirmatory Testing is as follows:

Gram Stain Results: No Organisms Seen Other _____

Gram Stain Results called to: _____ By: _____ on (Date/Time): _____

Final Culture Result: No Growth Organism Isolated

Final Culture Results called to: _____ By: _____ on (Date/Time): _____

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