Carter BloodCare

To: Transfusion Services Managers
From: Hospital Relations Department
Date: October 17, 2018
Re: Service Manual Updates

The Customer Service Manual has multiple updates. Please refer to the following.

Section 1.0 General Information: Organizational charts for both Carter BloodCare Bedford and Tyler are updated due to a recent retirement. Please replace the charts located at the back of the section.

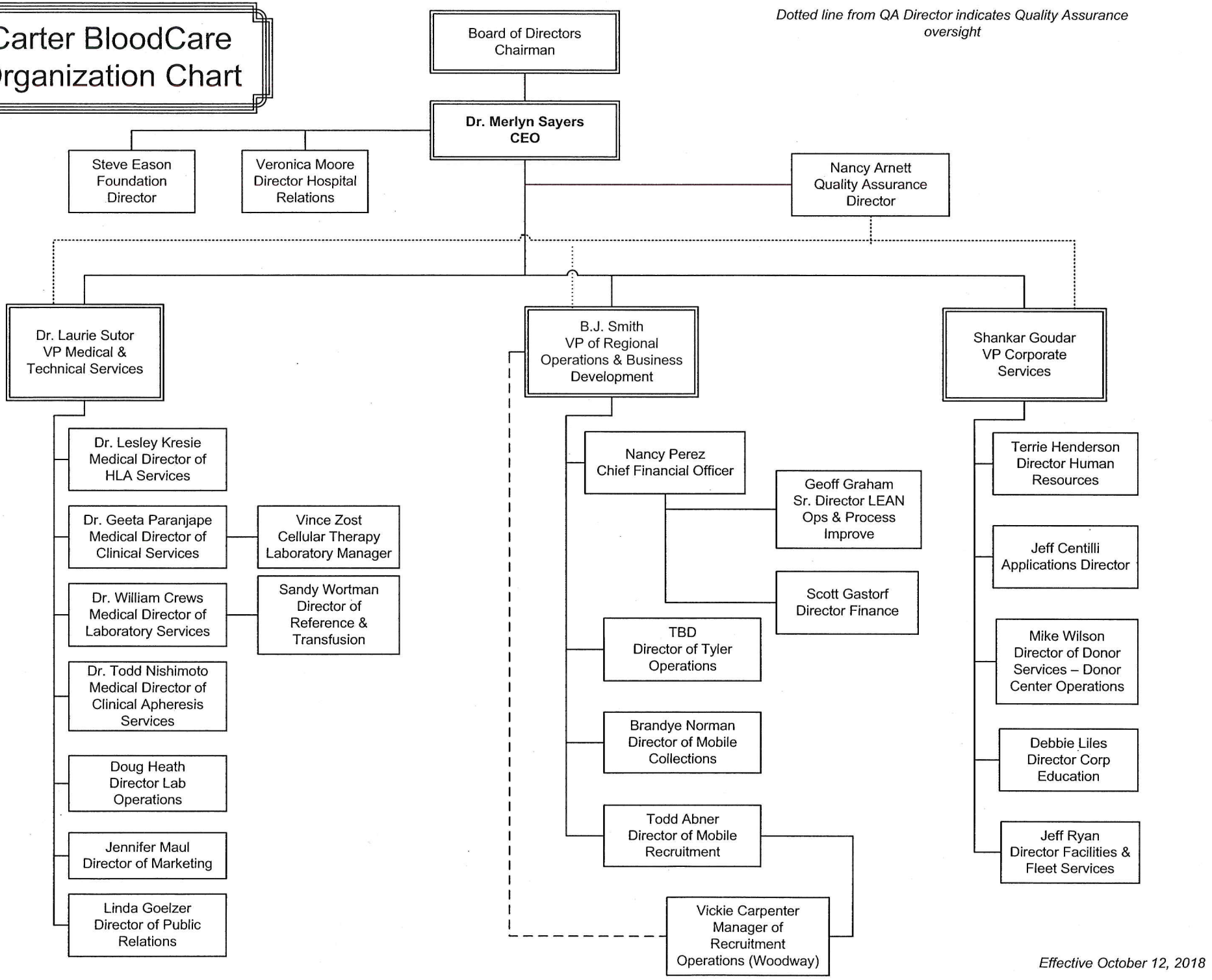
Section 2.0 Quality Assurance: The licensure of Zika testing has prompted Carter Blood Care to update this section. Additionally, the update will include contact information changes and revision of the Consignee Notification Record. Please replace pages 2-1 through 2-4 and also the Consignee Notification Record to clarify Anti-HIV-2 performed by EIA.

Section 6.0 Supplies: Please replace the section to clarify the supplies available from Carter BloodCare departments.

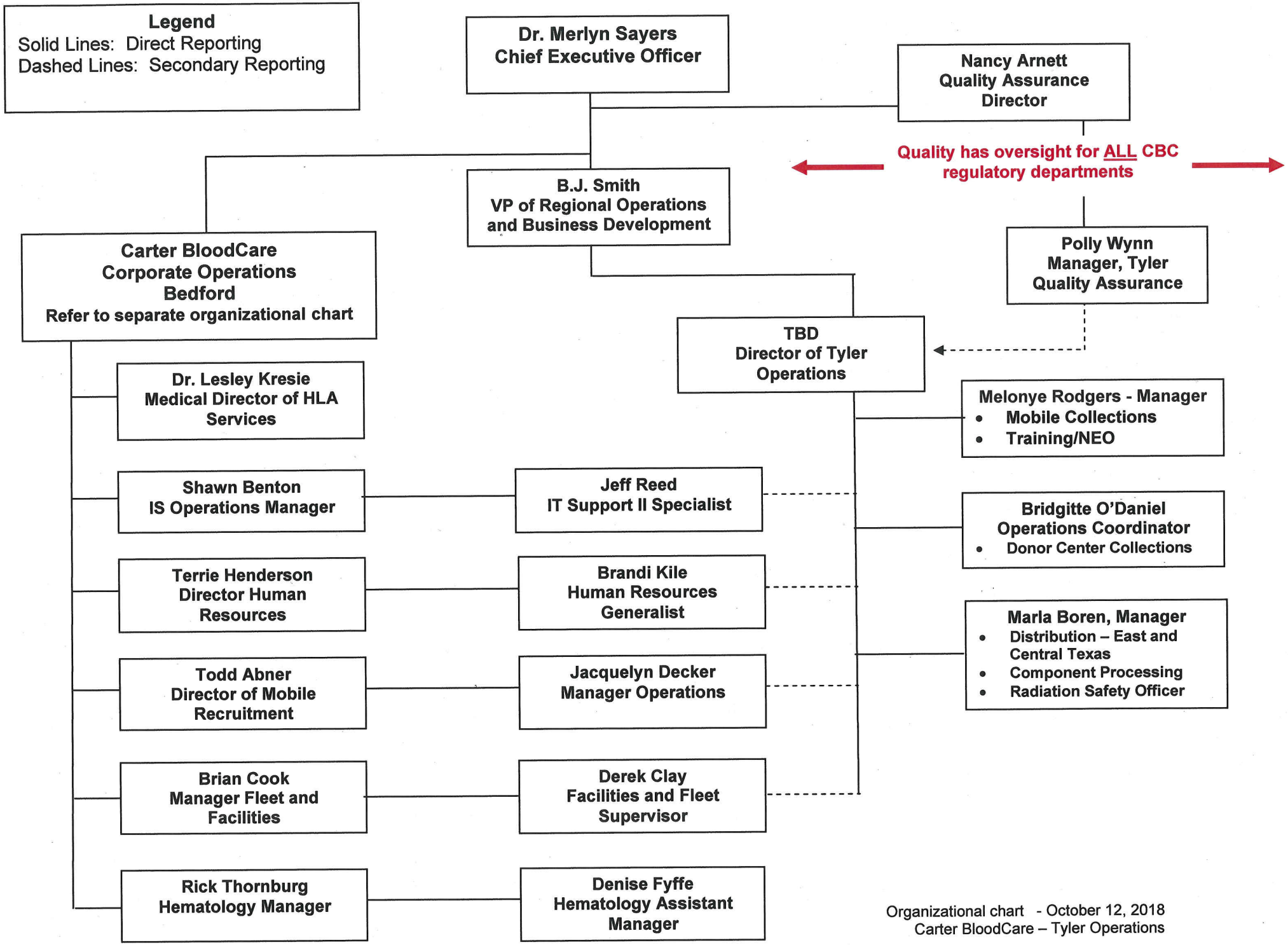
CarterBloodCare ▪ Hospital Relations ▪ 2205 Highway 121 ▪ Bedford, Texas 76021
Veronica Moore, Director of Hospital Relations vmoore@carterbloodcare.org 817-412-5328
Andrea Sign, Manager of Client Relations asign@carterbloodcare.org 817-412-5825
Judy Thornburg, Hospital Relations Advocate jthornburg@carterbloodcare.org 817-412-5719

Carter BloodCare Organization Chart

Dotted line from QA Director indicates Quality Assurance oversight



Effective October 12, 2018



Organizational chart - October 12, 2018
Carter BloodCare – Tyler Operations

2.0 Quality Assurance Policies

Contact Information:

Quality Assurances Department

Carter BloodCare
2205 Highway 121
Bedford, TX 76021
Phone: (817) 412-5580
Fax: (817) 412-5659

Carter BloodCare
815 South Baxter Avenue
Tyler, TX 75701
Phone: (903) 363-0419
Fax: (903) 363-0467

2.1 Quality Policy Statement

The Quality Policy of Carter BloodCare is to provide safe and efficacious blood and blood components in a manner that meets or exceeds the expectations of our internal and external customers.

Carter BloodCare maintains a quality management system to meet or exceed the minimum requirements of the Food and Drug Administration, AABB, and other accrediting organizations. Quality system essentials are defined in the Quality Plan. Quality Plan changes reflect the results of self-assessment activities, increasing maturity of the Quality Plan, organizational changes, and technical development.

Quality processes, products, and people are the foundation upon which the quality management system of Carter BloodCare is built. The quality management system supports the ideals set forth in the quality policy statement of Carter BloodCare. The quality management system monitors processes and operations by self-assessment audits, error management, and customer feedback. By conforming to regulatory standards, Carter BloodCare abides by the law. By conforming to requirements for accreditation, Carter BloodCare adheres to the high standards for quality established by the AABB and other peer-review organizations. By conforming to our customers' needs, Carter BloodCare practices the philosophy of continuous quality improvement.

2.2 Quarantine Notices

The Food and Drug Administration and the AABB have recommended the quarantine of previously donated blood components from donors currently testing repeatedly reactive for infectious disease markers, reactive for HCV-NAT(nucleic acid testing), HIV-1-NAT, HBV-NAT, WNV-NAT, Zika-NAT, Chagas' disease, and for donors responding

affirmatively to being at risk for Creutzfeldt-Jakob Disease (CJD) or vCJD. In-date blood components, meeting criteria as defined by FDA and AABB, are to be quarantined and returned to Carter BloodCare. In the event that a donation meets any of these criteria, you will be notified by a Quarantine Notice.

A Quarantine Notice may also be sent if a donor reports post-donation information that may affect the safety of the unit. Components are to be quarantined and returned to Carter BloodCare until our medical staff can evaluate the medical and regulatory implications of the information. The final component disposition of implicated components is determined on a case-by-case basis. Although most components will be discarded upon return, it is possible that further evaluation of the callback information may determine the component is acceptable for release back into regular inventory. This notice may be initiated by the Quality Assurance, Reference & Transfusion, Distribution, or Records Audit and Data Entry departments.

If your facility received blood components requiring quarantine, the Quality Assurance department will fax the Transfusion Service a Quarantine Notice (see example forms at the end of this section). The Quarantine Notice will be addressed to the Transfusion Service supervisor or the laboratory director.

If you receive a Quarantine Notice:

1) Immediately determine if the blood component is in your inventory.
2) If the blood component is in your inventory, the component should immediately be quarantined for return. Please call the Distribution department for blood component pick-up. **There is no charge to your facility for this pick-up.** Complete the appropriate section of the Quarantine Notice and fax as soon as possible to the Quality Assurance department.
3) If the blood component is not in your inventory, complete the appropriate section of the Quarantine Notice and fax as soon as possible to the Quality Assurance department.

If the completed Quarantine Notice is not received by the Quality Assurance department within approximately four (4) weeks, a second notice will be sent to the facility.

Quarantine notification is considered to be closed after written disposition of the blood component is received by the Quality Assurance department on the returned Quarantine Notice form or after the second notice is sent to the facility.

For additional information regarding quarantine notification, please contact the Quality Assurance department.

2.2.1 Quarantine/Lookback Notices

The Food and Drug Administration and the AABB have recommended lookback notification on previously donated blood components from donors who have subsequently tested confirmed positive for HIV, HCV, or Chagas by confirmatory or supplemental testing.

If your facility has received blood components implicated in a lookback investigation, the Transfusion Service Medical Director or the facility head will receive a Quarantine Notice with subsequent confirmatory test results as a certified letter detailing the reason for lookback. Each facility should determine what action to take when implicated blood components have been transfused. The FDA and CMS have published information regarding these lookback investigation requirements.

For additional information regarding lookback notification, please contact the Quality Assurance department.

2.3 Recall/Market Withdrawal Notices

Recall/market withdrawal is a method for removing components from inventory that do not meet the requirements of the Food and Drug Administration, AABB or Carter BloodCare. Reasons for recall/market withdrawal include, but are not limited to:

Manufacturer-directed withdrawal (e.g. phlebotomy bag withdrawn by manufacturer)

Variance from Carter BloodCare's Standard Operating Procedures

Recall/market withdrawal from an outside blood center for an imported product.

If the involved blood component is in-date, the receiving facility will be notified and requested to immediately quarantine and return the blood component.

If your facility received and used an involved blood component, the Transfusion Service Supervisor or Medical Director will be notified by fax detailing the reason for retrieval and the blood components involved. A Component Recall/Market Withdrawal form (see example form in this section) will be included for your facility to complete and return by fax to the Quality Assurance department.

Each facility should determine what steps to take when a recalled blood component has been transfused.

For additional information regarding Recall/Market Withdrawal notices, please contact the Quality Assurance department.

2.4 Quality Assurance Consultation Services

The Carter BloodCare Quality Assurance department staff is available to provide information to answer questions on FDA and AABB requirements for Transfusion Services. Additionally, the Quality Assurance department can assist you in the development of your Quality Plan.

Carter BloodCare license information and component quality control summary data are available for your review upon request.

Please contact the Quality Assurance department or the Hospital Relations department for more information.

2.5 Forms

QAF402.01A Quarantine Request Facsimile
QAF402.01B Quarantine Release Request Facsimile
QAF403.01 Suspected Component Contamination Notification
QAF601.01A Component Recall/Market Withdrawal
QAF601.01C Component Market/Withdrawal Notification
QAF601.01.01 Notice of Increased Risk of Transfusion-Transmitted Malaria
QAF602.01 Consignee Notification Record
QAF602.01.01 Reactive Non-Discriminate Multiplex HIV/HCV Assay Notification
QAF602.03.01B Creutzfeldt-Jakob Disease (CJD) Notice

Carter BloodCare

CONSIGNEE NOTIFICATION RECORD

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 or repeat reactive for the test(s) indicated below. The unit(s) listed below was negative for all infectious disease testing.

Repeat Reactive Test(s): ☐ Anti-HCV ChLIA ☐ Anti-HIV 1/2 ☐ HBsAg ☐ Anti-HBc[1] ☐ Chagas' EIA ☐ WNV NAT[1] ☐ Zika NAT[2] ☐ HTLV I/II

Additional Test Results:

☐ Anti-HCV EIA (Ortho) _____
☐ Anti-HIV-1 IFA _____
☐ Anti-HIV-2 2nd EIA _____
☐ HBsAg Neutralization[3] _____
☐ Chagas' ESA _____
☐ NAT HCV RNA _____
☐ NAT HIV-1 RNA _____
☐ NAT HBV DNA _____

[1] Supplemental testing was not performed on the currently reactive donation. This is the only notice.
[2] Informing the transfusion recipient's physician of record regarding potential need for monitoring and counseling recommended.
[3] Non-confirmed neutralization samples do not meet the criteria to be resulted as confirmed positive. This testing procedure does not allow for a definitive negative interpretation.

Additional Test Results: _____

Lookback: ☐ Recipient Notification *REQUIRED* ☐ Recipient Notification *NOT REQUIRED* ☐ Lookback *N/A*

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 _____

6.0 Miscellaneous Supplies

Contact Information:

Carter BloodCare Bedford
2205 Highway 121
Bedford, TX 76021
Distribution Department
Phone: (817) 412-5700
Reference and Transfusion Services
Phone: (817) 412-5740
Hospital Relations Department
Phone: (817) 412-5328 or (817) 412-5719

Carter BloodCare Tyler
815 South Baxter Avenue
Tyler, TX 75701
Phone: (903) 363-0404

This section contains information regarding products and services provided by Carter BloodCare. Because Carter BloodCare continually maintains top industry standards for products and services provided, some products and services may be in development and may not be listed. Some services may be tailored to meet your individual needs.

6.1 Circular of Information

The Circular of Information is an extension of the blood component label and should be used as a reference for product descriptions, storage requirements, and indications/contraindications for product use. Questions regarding the Circular of Information should be directed to Hospital Relations. Circulars of Information are available upon request from the Hospital Relations or the Distribution department and can be viewed on iWeBB.

6.2 Supplies Available through Carter BloodCare

Please order directly from Reference and Transfusion Laboratory Services

- Blood bank armbands
- Red blood cell transfusion sets
- Blood component transfusion sets

Please order directly from the Distribution department

- Therapeutic phlebotomy collection sets