Department of Health and Human Services, Food and Drug Administration

- FDA Biologics License number 1274

Centers for Medicare & Medicaid Services (CMS)

- CLIA certificate number 45D0486046 (Bedford)

Foundation for the Accreditation of Cellular Therapy

- (FACT does not provide accreditation numbers)

If you require a copy of any of these licenses or if you require a different license not listed above, please contact Hospital Relations.

1.5 Department Descriptions and Contact Directory

Carter BloodCare
2205 Highway 121
Bedford, TX 76021

Carter BloodCare
815 South Baxter Avenue
Tyler, TX 75701

1-800-DONATE4
carterbloodcare.org

Clinical Services

Peripheral blood stem cell collection, therapeutic apheresis procedures including plasmapheresis, cytoreduction and red cell exchange, photopheresis, lymphocyte collections, and granulocyte collections

Main number (972) 788-0650
Fax number (972) 661-9409

Granulocyte Orders Pager (817) 482-9446

Distribution/Hospital Services

Order, delivery and inventory inquiries, inventory management and consultation, autologous and directed unit deliveries

North Texas
Main number (817) 412-5700
Fax number (817) 412-5729

Howard Jenkins (817) 412-5714
Shift Operations Manager hjenkins@carterbloodcare.org

Doug Heath (817) 412-5715
Director of Laboratory Operations dheath@carterboodcare.org

Central Texas
Main number (254) 297-4100
Fax number (254) 399-6391

Marla Boren (903) 363-0433
Manager of Site Operations mboren@carterbloodcare.org

Josey Keep (254) 297-4101
Shift Supervisor jkeep@carterbloodcare.org

East Texas
Main number (903) 363-0404
Fax number (903) 363-0483

Marla Boren (903) 363-0433
Manager of Site Operations mboren@carterbloodcare.org

Jared Jordan (903) 363-0403
Operations Coordinator jjordan@carterbloodcare.org

Donor Notification

Donor notification of significant test results, transfusion-transmitted disease investigations, donor re-entry

Main number (817) 412-5603
Fax number (817) 412-5609

Pat Davenport, MT(ASCP)SBB (817) 412-5604
Manager of Special Donor Services pdavenport@carterbloodcare.org

Donor Recruitment

Blood drive recruitment and scheduling

Rhonda Cantrell (817) 412-5384
Administrative Assistant rcantrell@carterbloodcare.org

Todd Abner (817) 412-5385
Director of Mobile Recruitment tabner@carterbloodcare.org

East Texas
Jacquelyn Decker (903) 363-0432
Manager of Operations and Field Recruitment jsdecker@carterbloodcare.org

Finance and Billing

Fax number (817) 412-5136

Main contact for invoice or billing

Cheryl Stark
Accounts Receivable Coordinator (817) 412-5123
cstark@carterbloodcare.org

Nancy Perez (817) 412-5121
Chief Financial Officer nperez@carterbloodcare.org

Scott Gastorf (817) 412-5139
Director of Finance sgastorf@carterbloodcare.org

Hospital Relations

Customer service related, iWeBB activities, Customer Incident reporting and tracking, educational in-services, transfusion service mock audits, Service Manual information and updates

Veronica Moore, MBA, MT(ASCP) (817) 412-5328
Director of Hospital Relations Cell (817) 822-8956
vmoore@carterbloodcare.org

Judy Thornburg, MLT(ASCP) (817) 412-5719
Hospital Relations Advocate Cell (817) 343-3324
jthornburg@carterbloodcare.org

Andrea Sign (817) 412-5825
Manager of Client Relations Cell (817) 706-2447
asign@carterbloodcare.org

Note: Inquiries can be directed to hospitalrelations@carterbloodcare.org

Medical Services

Medical consultation

Main number (817) 412-5104
Fax number (817) 412-5117

Laurie Sutor, M.D. (817) 412-5601
Vice President Medical & Technical Services lsutor@carterbloodcare.org

Geeta Paranjape, M.D (817) 412-5612
Medical Director of Clinical Services gparanjape@carterbloodcare.org

Todd Nishimoto, M.D. (817) 412-5236
Medical Director of Clinical Apheresis tnishimoto@carterbloodcare.org

William Crews, M.D. (817) 412-5611
Medical Director of Laboratory Services wcrews@carterbloodcare.org

Lesley Kresie, M.D. (817) 412-5610
Medical Director of HLA Services lkresie@carterbloodcare.org

Quality Assurance

Lookback, product recalls, regulatory consultation

Main number (817) 412-5580
Fax number (817) 412-5659

Nancy Arnett (817) 412-5577
Director of Quality Assurance narnett@carterbloodcare.org

East Texas

Main number (903) 363-0419
Fax number (903) 363-0467

Polly Wynn (903) 363-0419
Manager of Quality Assurance pwynn@carterbloodcare.org

Immunohematology Reference Laboratory and Transfusion Services

Transfusion accounts, sample pick-up and receipt, transfusion inquiries, antibody identification, antigen screening, HLA platelet orders, platelet antibody orders, transfusion reaction notification, general transfusion and MD consultation, and flow cytometry

Main number (817) 412-5740
Fax number (817) 412-5749

Sandy Wortman, MT(ASCP),SBB (817) 412-5271
Director of Reference and Transfusion swortman@carterbloodcare.org

Pamela Boyd, MT(ASCP),BB (817) 412-5229
Manager Reference and Transfusion pboyd@carterbloodcare.org

Mike Newhouse, MT(ASCP),SBB (972) 566-4910
Manager Reference and Transfusion mnewhouse@carterbloodcare.org

Marie Becerra, MT(ASCP) (817) 702-2040
Manager Reference and Transfusion mbecerra@carterbloodcare.org

Molecular Services (AABB Accredited)

Donor and patient RBC genotyping/ predicted phenotype testing; discrepancy resolution and 24/7 consultation services.

Main number_____(817) 412-5740
Fax number_____(817) 412-5749

Preventative Maintenance Services

Pipette calibration and maintenance; digital timer calibration; and thermometer standardization.

Main number_____(903) 363-0469
Fax number_____(903) 363-0451

Special Donations

Autologous, directed and therapeutic unit scheduling, tracking and consultation.

***NOTE**: For delivery requests, please refer to Distribution/Hospital Services*

Main number_____(817) 412-5308
Toll free number_____1(866) 525-3378
Fax number_____(817) 412-5318

Stem Cell Laboratory Services

Peripheral blood stem cell collections, assistance with surgical harvest of bone marrow, processing, cryopreservation, storage, thawing and infusion of stem cells, CD34 selection

Main number_____(817) 412-5743
Fax number_____(817) 412-5746

Vincent Zost, MT(ASCP),SBB_____(817) 412-5743
Stem Cell Laboratory Manager vzost@carterbloodcare.org

Component Production and Testing and Labeling

Viral marker testing, viral marker test results, labeling and release of blood components

Main number_____(817) 412-5731
Fax number_____(817) 412-5748

Regina Collier, MT (AMT)_____(817) 412-5733
Component Production &Testing and Labeling Manager rcollier@carterbloodcare.org

Administration

Main number (817) 412-5000
Fax number (817) 412-5992

Merlyn H. Sayers, MB, BCh, PhD (817) 412-5101
Chief Executive Officer msayers@carterbloodcare.org

Shankar Goudar (817) 412-5344
Vice President of Corporate Services goudar@carterbloodcare.org

B.J. Smith (817) 412-5158
Vice President of Regional Operations & Business Development
bjsmith@carterbloodcare.org

Human Resources Job Hotline (817) 412-5150

East Texas
Main number (903) 363-0400

Carla Beck (903) 363-0443
Director of East Texas Operations cbeck@carterbloodcare.org

Central Texas
Main Number (254) 297-4000

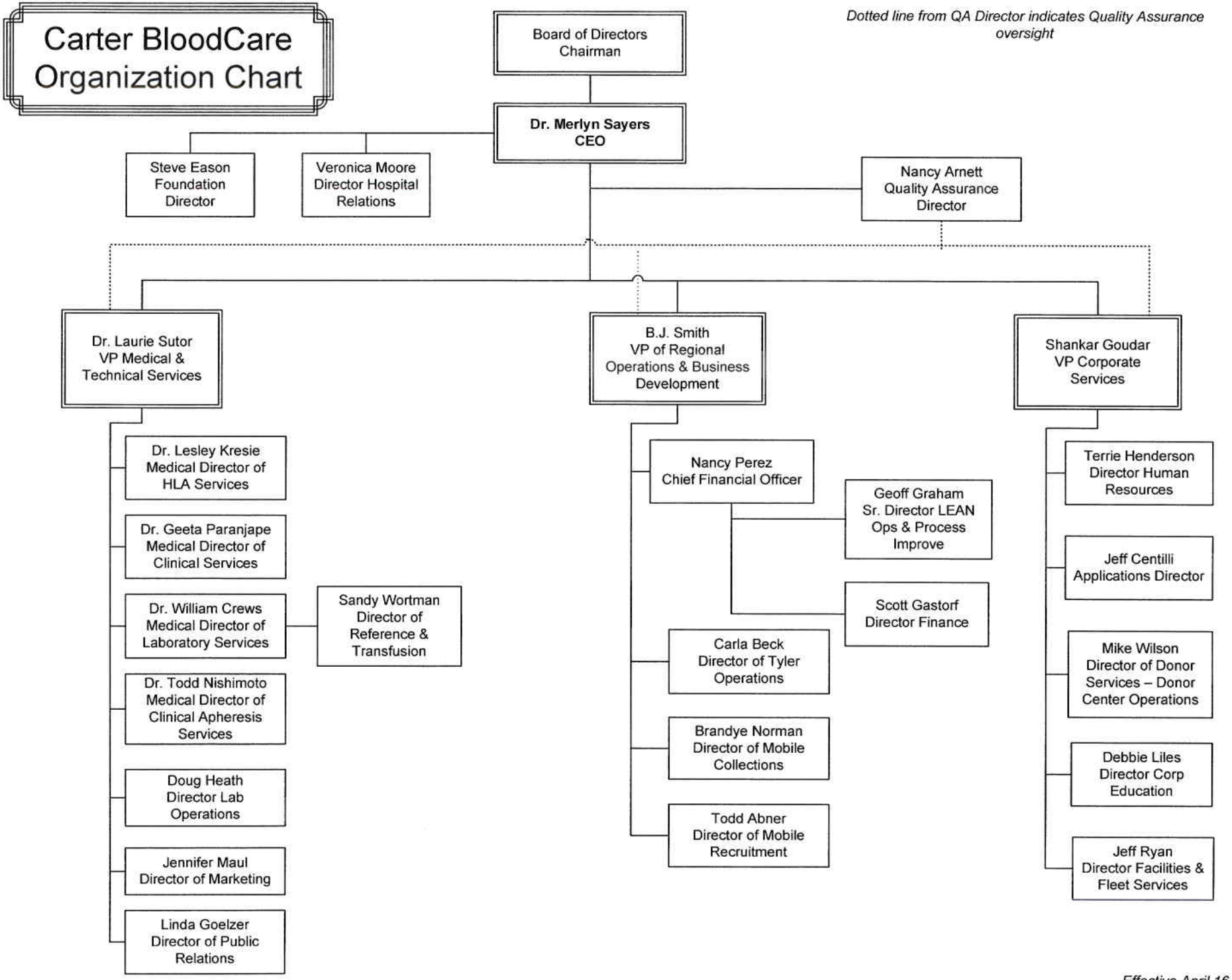
Vickie Carpenter (254) 297-4004
Manager of Recruitment Operations vcarpenter@carterbloodcare.org

1.6 Forms

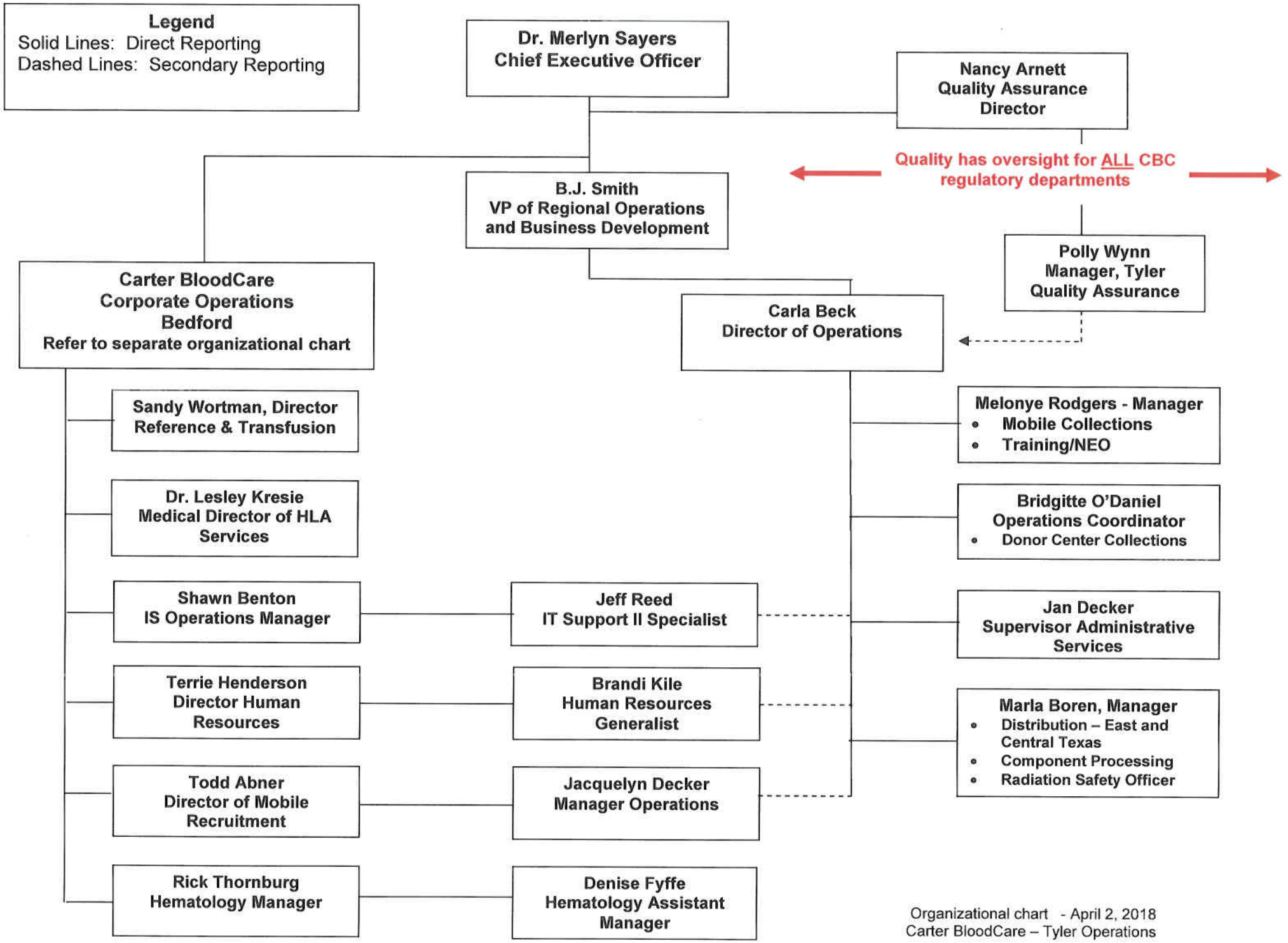
- Organizational Charts

Carter BloodCare Organization Chart

Dotted line from QA Director indicates Quality Assurance oversight



Effective April 16, 2018



Organizational chart - April 2, 2018
Carter BloodCare – Tyler Operations

((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

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 EIA = 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 _____

emergency/disaster situation. Carter BloodCare will immediately make the necessary contacts with the local, state and/or governmental agencies, coordinate with local hospitals that might be affected and contact all internal Directors/designees to insure a **coordinated direction of response.**

The facility in Bedford is designed to be self-sufficient to help maintain operations. The facility is equipped with the following **redundant systems:** air conditioning and heating, generated power, specially designed refrigeration equipment for blood storage, uninterrupted power sources, and **duplicated processes for many of our critical operations.** With the exception of a catastrophic disaster, directly to the campus, Carter BloodCare's facility in Bedford will be operational.

3.2 Blood Service Agreement Statement

Contact Information:

Hospital Relations
Carter BloodCare
2205 Highway 121
Bedford, TX 76021
Phone: (817) 412-5328
(817) 412-5825
(817) 412-5719
Fax: (817) 412-5991

Carter BloodCare is required by regulating agencies to have a signed, current Blood Service Agreement on file before providing blood products and services to any facility. To initiate a Blood Service Agreement or to obtain a copy of your current Blood Service Agreement, please contact the Hospital Relations department. It is highly recommended that you maintain a copy of your current Blood Service Agreement on file.

3.3 Finance and Billing Policies

Contact Information:

Accounting & Finance
Carter BloodCare
2205 Highway 121
Bedford, TX 76021
Phone: (817) 412-5123 or (817) 412-5139
Fax: (817) 412-5136

Phone: (817) 412-5328 – Hospital Relations Department
(817) 412-5825
(817) 412-5719

4.0 REPORTING SUSPECTED TRANSFUSION COMPLICATIONS

4.1 REPORTING ADVERSE REACTIONS

Contact Information:

Immunohematology Reference and Transfusion Services Laboratory
Carter BloodCare
2205 Highway 121
Bedford, TX 76021
Phone: (817) 412-5740
Fax: (817) 412-5749

4.1.1 Definition

The term "**transfusion reaction**" refers to a group of complications that may arise during or after the administration of blood components to a patient. The severity of these complications may range from mild discomfort to serious life-threatening hemolytic or septic reactions. Fatal transfusion reactions can occur in spite of technical perfection.

4.1.2 Types of Adverse Transfusion Reactions

Allergic Reactions

Mild allergic reactions may occur in 1-3% of transfused recipients. These reactions are usually caused by antibodies (IgE) in the recipient directed against foreign proteins in the transfused plasma. Mild symptoms of allergic reaction include urticaria (hives), rash and itching. Such reactions may be treated with an antihistamine medication and the transfusion resumed when symptoms subside. More serious signs or symptoms are swelling of the lips, face or tongue, itching of the throat, or difficulty breathing. These symptoms should cause immediate discontinuation of the transfusion and close attention to avoid anaphylactic shock. Units of blood involved in reactions with allergic symptoms other than mild skin reactions should not be used for further transfusion.

Febrile Non-hemolytic Reactions

Febrile non-hemolytic reactions are defined by a rise in body temperature of $\geq$ 1°C with no other known cause for fever. These reactions may occur in 0.5 – 1.5% of transfusion recipients and may be more common in frequently transfused patients. These reactions are usually caused by antibodies of the recipient directed against white blood cell antigens in the transfused blood component. These reactions are seldom dangerous,

REFERENCE AND TRANSFUSION SERVICES
TRANSFUSION REACTION INVESTIGATION
PRELIMINARY REPORT

Carter BloodCare

Patient Name:		Sample Collection Date & Source:	
ID Number:		Date Request Received:	
Requesting Facility:		Diagnosis:	
Ordering Physician:		Patient Date of Birth & Gender:	

UNIT INFORMATION

Unit Number: _____ Date/Time of Transfusion Reaction: _____

Component Involved: _____ Amount Transfused: _____ ml

REACTION DETAILS

	Chills present		Nausea/Vomiting	**Other listed below**
	Fever		Urticaria / Hives / Rash	
	Dyspnea		Hematuria	
	Shock		Back or Chest Pain	
	Jaundice			

INVESTIGATION FINDINGS

	Clerical checks were performed and found acceptable		Discrepancy noted in Clerical/Visual paper work check
	Visual inspection of the pre- and post-sample was normal		Hemolysis present in post transfusion sample
	Pre and Post transfusion sample testing resulted in no discrepancies		Discrepancy noted in sample testing
	There is no evidence of red cell incompatibility		Evidence of red cell incompatibility
			* Gram stain and culture results pending

Patient Pre-transfusion DAT:	POLY		IGG		C3	
Patient Post-transfusion DAT:	POLY		IGG		C3	

REACTION CLASSIFICATION

X	* Pending Medical Director Review

RECOMMENDATIONS and COMMENTS

X	* Pending Medical Director Review

COMMENTS: _____

Results called to:		Date / Time	
Testing performed by:		Date / Time	

"+m" = Microscopic "+w" = Weakly Positive NT = Not Tested Neg = Negative

CarterBloodCare
2205 HWY 121
Bedford, TX 76021
(p)817-412-5740
(f)817-412-5749
CLIA#45D0486046
AABB IRL #95

Carter BloodCare

REFERENCE AND TRANSFUSION SERVICES
TRANSFUSION REACTION INVESTIGATION
FINAL REPORT

Patient Name:		Sample Collection Date & Source:	
ID Number:		Date Request Received:	
Requesting Facility:		Diagnosis:	
Ordering Physician:		Patient Date of Birth & Gender:	

UNIT INFORMATION

Unit Number: _____ Date/Time of Transfusion Reaction: _____

Component Involved: _____ Amount Transfused: _____ ml

REACTION DETAILS

	Chills present		Nausea/Vomiting	**Other listed below**
	Fever		Urticaria / Hives / Rash	
	Dyspnea		Hematuria	
	Shock		Back or Chest Pain	
	Jaundice			

INVESTIGATION FINDINGS

	Clerical checks were performed and found acceptable		Discrepancy noted in Clerical/Visual paper work check	
	Visual inspection of the pre- and post-sample was normal		Hemolysis present in post transfusion sample	
	Pre and Post transfusion sample testing resulted in no discrepancies		Discrepancy noted in sample testing	
	There is no evidence of red cell incompatibility		Evidence of red cell incompatibility	
	Negative Gram stain (no organisms seen)		Positive Gram Stain	Date/Time
	Negative culture (no growth)		Positive Culture	Date/Time

Patient Pre-transfusion DAT:	POLY		IGG		C3	
Patient Post-transfusion DAT:	POLY		IGG		C3	

REACTION CLASSIFICATION

	Febrile		Allergic		Other, See Comments

RECOMMENDATIONS and COMMENTS

	Pre-medication with antipyretics to reduce the incidence of febrile non-hemolytic reactions may be indicated
	Pre-medication with antihistamine and/or steroids may be indicated
	Symptoms may be due to patient's underlying health conditions, clinical correlation is recommended

Comments _____

Results called to:		Date / Time	
Testing performed by:		Date / Time	
Record reviewed by:		Date / Time	
Report reviewed by the Medical Director on:	L.Sutor MD G.Paranjape MD W.Crews MD T. Nishimoto MD	Date	

"+m" = Microscopic "+w" = Weakly Positive NT = Not Tested Neg = Negative

CarterBloodCare
2205 HWY 121
Bedford, TX 76021
(p)817-412-5740
(f)817-412-5749
CLIA#45D0486046
AABB IRL #95

Carter BloodCare
We save lives by making transfusion possible.

TRANSFUSION REACTION INVESTIGATION

PATIENT INFORMATION	Patient Name _____ Identification Number _____ Facility Name _____ Ordering Physician _____ Diagnosis _____ _____
INFUSIONIST REPORT	Unit Number(s) _____ Component(s) Involved _____ Amount(s) Transfused _____ All forms, labels and patient identification have been verified. ☐ Yes ☐ No Date / Time Transfusion Started _____ Date / Time of Reaction _____ Date / time Transfusion Stopped _____ Infusionist_____ Person Completing Form _____ Date / Time _____

Pre-Transfusion	Post-Transfusion	Patient Symptoms
Temperature _____	Temperature _____	☐ Chills ☐ Nausea
Pulse _____	Pulse _____	☐ Fever ☐ Urticaria
Blood Pressure _____	Blood Pressure _____	☐ Dyspnea ☐ Hematuria
		☐ Shock ☐ Back or Chest Pain
		☐ Jaundice ☐ Other_____

INFUSIONIST INSTRUCTIONS

1. Immediately discontinue transfusion. Keep IV line open with normal saline (0.9% sodium chloride) or other FDA approved blood administration solution.
2. Check all forms, labels, and patient identification.
3. Notify attending physician and Carter BloodCare Reference and Transfusion Services.
4. Properly collect and label post-transfusion purple top (EDTA) anticoagulated specimen. Minimum 3 ml sample required.
5. Complete RTF215.01A Transfusion Reaction Investigation.
6. Send samples, blood component container with attached administration set and intravenous solutions, compatibility tag, and this completed form to Carter BloodCare Reference and Transfusion Services **STAT.**

1. Document the following in the "Patient Information" section (you may apply a patient sticker):
   - Patient name
   - Patient identification number
   - Requesting facility
   - Ordering physician
   - Patient Diagnosis
2. Document the following in the "Infusionist Report" section:
   - Unit number(s)
   - Component(s) involved
   - Amount(s) transfused
   - Mark "Yes" or "No" box appropriately, indicating whether or not all forms, labels and patient identification have been verified.
   - Date/time of reaction
   - Infusionist
   - Name of person completing the form
   - Date/Time the form was completed
   - Pre-transfusion
     - Temperature (including unit of measure ºF)
     - Pulse
     - Blood pressure
   - Post-transfusion
     - Temperature (including unit of measure ºF)
     - Pulse
     - Blood pressure
   - Place a checkmark (✓) or "X" next to the applicable patient symptoms associated with transfusion.
   - Send back to the blood bank

Carter BloodCare
2205 Highway 121
Bedford Texas 76021
(p) 817-412-5740
(f) 817-412-5749
CLIA# 45D0486046

Carter BloodCare
815 S Baxter
Tyler, Texas 75701
(p) 903-363-0406
(f) 903-363-0451
CLIA# 45D0483339

7.0 COLLECTIONS

Contact Information:

Collections Department
Carter BloodCare
2205 Highway 121
Bedford, TX 76021
Phone: 1-800-DONATE-4 – to schedule an appointment
Phone: 817-412-5380 – to schedule a blood drive or to schedule health fair activities through our Recruitment Department

Collections Department
Carter BloodCare
815 South Baxter Avenue
Tyler, TX 75701
Phone: 1-800-252-5584 - to schedule an appointment
Phone: 903-363-0400 - to schedule a blood drive or to schedule health fair activities through our Recruitment Department

Collections Department
Carter BloodCare
206 Archway Drive
Woodway, TX 76721
Phone: 1-800-DONATE-4 – to schedule an appointment
Phone: 254-297-4000

For the most up-to-date information regarding hours of operations, driving directions or to schedule a donation appointment, please call 1-800-DONATE-4 or visit our interactive web site at carterbloodcare.org.

7.1 Neighborhood Donor Centers

NORTH TEXAS LOCATIONS

Addison
3955 Belt Line Road
Addison, TX 75001
972-960-8895

Allen *
1328 W. McDermott Drive, Suite 250
Allen, TX 75013
214-509-0550

Arlington *
1618 W. Randol Mill Road
Arlington, TX 76012
817-274-0812

Cedar Hill
613 Uptown Boulevard, Suite 107
Cedar Hill, TX 75104
972-572-3917

Dallas*
4201 Gaston Avenue, Suite 110
Dallas, TX 75246
214-572-3917

Dallas*
12829 Preston Road, Suite 427
Dallas, TX 75230
972-980-9210

Denton
2215 South Loop 288, Suite 335
Denton, TX 76205
940-383-2055

Flower Mound
2601 Flower Mound Road
Flower Mound, TX 75028
972-219-1668

Fort Worth*
1263 West Rosedale
Fort Worth, TX 7104
817-335-4935

Fort Worth
4995 South Hulen Street
Fort Worth, TX 76132

Frisco
4350 W. Main Street, Suite 105
Frisco, TX 75033
214-217-5690

Garland
6850 N. Shiloh, Suite V
Garland, TX 75044
972-437-4483

Grand Prairie
4146 South Carrier Parkway, Suite 630
Grand Prairie, TX 75052
972-988-6051

Hurst-Euless-Bedford*
1731 W. Airport Freeway
Bedford, TX 76021
817-283-4787

Irving
7750 N. MacArthur Boulevard, Suite 115
Irving, TX 75063
972-258-0055

Keller
101 Town Center Lane, Suite 111
Keller, TX 76248
817-337-1520

Lockheed (Employees Only)
1 Lockheed Boulevard
White Settlement, TX 76108
817-762-1551

Mansfield
920 US Hwy 287N, Suite 210
Mansfield, TX 76063
817-539-0244

Mesquite*
1515 N. Town East Blvd. Suite 151
Mesquite, TX 75150
972-270-2185

Plano
4701 W. Parker, Suite 610
Plano, TX 75093
972-612-2098

Weatherford
116 East I-20, Suite 151
Weatherford, TX 76087
817-594-4251

EAST TEXAS

Longview*
3080 N. Eastman, Suite 112
Longview, TX 75605
903-663-2650

Tyler*
815 South Baxter Avenue
Tyler, TX 75701
903-363-0400

Paris*
3305 N.E. Loop 286, Suite E
Paris, TX 75460
903-785-9399

CENTRAL TEXAS

Woodway*
206 Archway Drive
Woodway, TX 7021
254-297-4150

*** Denotes Donor Centers accepting autologous, directed and therapeutic phlebotomy collections**

7.2 Blood Drive Information

Be a part of our community blood program!

Organizations may schedule blood drives with Carter BloodCare. Blood drives may be operated indoors, if the space meets the specific regulatory requirements or the blood drive may be held in one of our mobile buses.

If you are interested in scheduling a blood drive, one of our field consultants will visit with you to help with all necessary planning and promotion assistance. In addition, they are trained to provide in-services to your staff regarding blood donation.

If you are interested in scheduling a blood drive, please contact our Recruitment Department.

7.3 Health Fairs

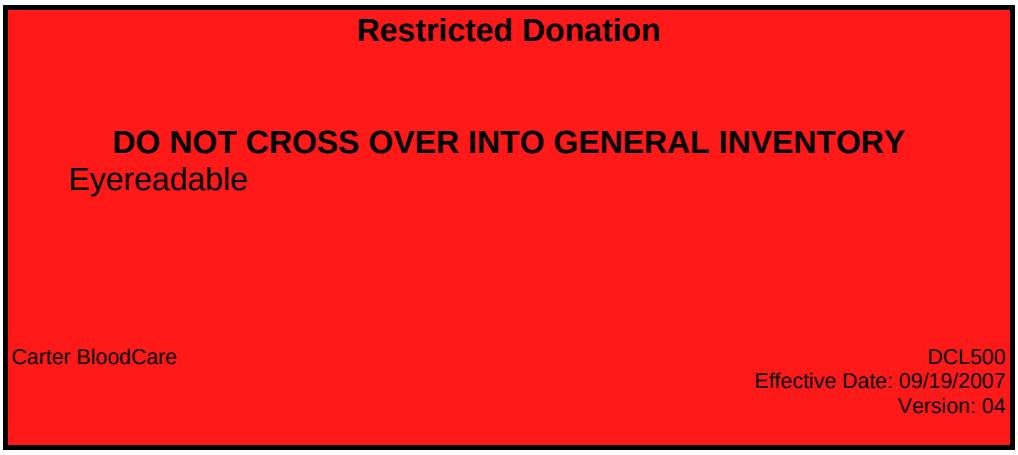
Carter BloodCare actively supports and participates in community health fairs.

If your organization is planning to host a health fair and would like Carter BloodCare to participate, please call our Recruitment Department.

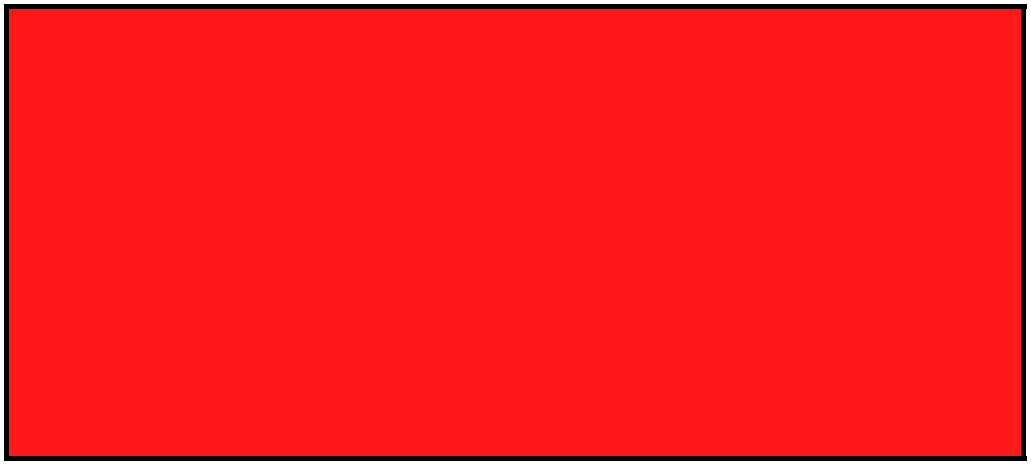
DCL500 Restricted Donation Tag

Color is Orange

Front



Back



11.11 Return Policy and Request for Quarantine

Blood components may be returned for full credit under the following conditions:

- As outlined in your Blood Service Agreement.
- The safety, potency or purity of the blood component is in question.
- The product has not been manipulated, altered or defaced by the facility.
- Prior approval has been obtained from Carter BloodCare.

In the event blood products will be returned to Carter BloodCare for investigational purposes, please complete DPF-300.03A, Return of Blood For Investigation. An example of this form is included in the forms section. Once completed, phone Carter BloodCare's Distribution department requesting the component (s) to be retrieved

A product quarantine request may be faxed to your facility to confirm the verbal request to quarantine and return or discard the component if available. The request will be generated by the Distribution department.

11.12 Forms

- DPF200.20A, Fax order and Inventory Form
- DPF200.05, Hand Ship Ticket
- DPF300.03, Hospital Report of Returned Blood Components
- DPF300.03A, Return of Blood For Investigation
- DPF400.20A, Quarantine Request Facsimile
- DPF400.20B, Quarantine Release Request Facsimile
- DPF400.20C Notification/Quarantine Request Facsimilie

Carter BloodCare

NOTIFICATION/QUARANTINE REQUEST FACSIMILE

Facility: _____ Contact: _____

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:

This fax is being sent as notification that your facility received a platelet product on _____ (date) which has now tested positive on the screening test for bacteria. If you have this product in inventory, it should be placed in quarantine for return to us at Carter BloodCare. If it has been transfused, we suggest notification of the transfusing physician of this finding.

Further testing will be done to determine if the platelet product is actually contaminated with bacteria or whether this is a false positive. Our sample has been sent for gram stain and secondary culture and possible bacterial identification. We will notify you of further information when we get the results.

Of note, this platelet product was testing culture negative at the time we shipped the unit to you, but the culture has subsequently turned positive in the intervening time.

If you or your medical staff has further questions, we can put you in touch with our medical director.

If these units are in your inventory, please quarantine them for return.

☐ Unit returned by facility

Unit Number	Product Code	Component Type	Blood Type	Ship Date

Fax received by: _____ Date: _____

Sign this form and fax it back to Carter BloodCare using the appropriate fax number shown above, indicating receipt of this notification.

12.0 REFERENCE AND TRANSFUSION SERVICES POLICIES

Contact and Shipping Information:

Immunohematology Reference Laboratory and Transfusion Services
Carter BloodCare
2205 Highway 121
Bedford, TX 76021

Phone:	(817) 412-5740
Fax:	(817) 412-5749
Emergency Phone(s):	(817) 685-1242
	(817) 684-7391
Emergency Fax:	(817) 283-1065

Distribution/Hospital Services
Bedford Phone: (817) 412-5700 Tyler Phone: (903) 363-0404

Hospital Relations
Phone: (817) 412-5328

NOTE: The Test Information Chart is in its own section of this manual.

12.1 GENERAL INFORMATION FOR PATIENT/REFERENCE TESTING SERVICES

Reference and Transfusion Services department staff are scheduled to provide coverage 24 hours a day, 365 days a year.

For quality control purposes, all incoming and outgoing calls of the Reference and Transfusion Services department are recorded.

The Reference and Transfusion Services department provides a wide range of services including:

- Provision of antigen negative units
- Crossmatch service
- Antibody identification (simple/complex)
- Platelet services (platelet antibody screen, crossmatch and/or HLA matched)

12.1.1 Contract

A contract is required to initiate reference services. A signed contract ensures all involved parties adhere to current regulatory requirements. Additionally, a contract

allows the client to exchange PHI with CBC and CBC to provide the client patient care results. To initiate a contract, please contact the Hospital Relations department.

12.1.2 Requisitions

The client is expected to utilize the appropriate requisition form. Requisition completion is detailed in the applicable parts of this section. Example copies of requisitions are included in the back of this section. Please contact the Reference and Transfusion Services department for questions regarding completing a requisition. Requisitions may be obtained from carterbloodcare.org or the Hospital Relations department.

Please complete the appropriate requisition fully. Accurate information is vital for test completion. It is helpful to provide as much detail as available to allow the laboratory to make a complete evaluation and report.

12.1.3 Specimen Collection and Preparation

Proper specimen collection and preparation is essential in order to provide a timely, accurate test result and is required by accreditation agencies. Please follow the sample collection requirements listed in the Test Information Chart. Please contact the Reference and Transfusion Services department for any questions.

Clearly label each specimen with the following information:

- Patient's full name as recorded in the medical record
- Patient's identification number (i.e., medical record number, birth date, or any other unique identification system utilized by the client)
- Collection date (month, day, year)
- Collection time
- Collector's initials
- Blood Bank ID number (if applicable)

Please inspect each sample tube to ensure:

- Information is clear and legible
- No defacement, tearing, or alteration of the label has occurred
- No broken or cracked tube
- The tube stopper is intact

It is important to follow manufacturer instructions for all drawing supplies. Please pay careful attention that anticoagulated specimens are properly mixed and are not hemolyzed.

12.1.4 Sample Shipping Requirements

Please notify Reference and Transfusion Services department in advance of sending a sample. Advance notice will help the department staff ensure the specimen and the request are handled more efficiently.

Samples for testing and the accompanying paperwork should Be delivered to:

Reference and Transfusion Services
Carter BloodCare
2205 Highway 121
Bedford, TX 76021

Samples may be delivered to Carter BloodCare by:

- Calling the Reference and Transfusion Services department to arrange for a sample pick up. There are additional charges associated with this service.
- Utilizing your own courier to deliver the samples.

Samples should be packaged in a leak-proof container. OSHA requires that all samples be marked as biohazards.

Samples may be delivered to the Reference and Transfusion Services department 24 hours a day, 365 days a year.

12.1.5 Unacceptable Specimens

IMPORTANT: As an AABB accredited laboratory, Carter BloodCare rejects incomplete or inaccurately labeled specimens. Specimens will be rejected without proper documentation. Proper identification of samples is essential if Carter BloodCare is to provide accurate laboratory results for the correct patient. The Reference and Transfusion Services department will not accept unlabeled specimens, even when accompanied by paperwork bearing the patient's name.

Sample integrity is crucial to achieving accurate test results. Samples cannot be compromised due to conditions during collection, transport, or storage. The most frequent causes of unacceptable samples are hemolysis, incorrect sample type, and insufficient sample volume.

If a sample is rejected for any reason, the client will be notified by phone. A follow up Specimen Rejection Report will be faxed or sent to the client noting the reason for specimen rejection. An example copy of the Specimen Rejection Report is included in the back of this section.

12.1.6 Available Tests

Available tests are listed in the Test Information Chart section 10.0 of this manual. Tests implemented after the printing of this manual may not be listed. For information on new or available tests, please call the Hospital Relations department.

12.1.7 Test Priority (Does Not Include Delivery Time)

STAT Order:

STAT describes a situation where unnecessary delay in testing would endanger the life of the patient.

If ordering specific blood products STAT, use of this term implies that no unit of blood exists within the hospital's assigned inventory suitable to meet the need.
The Reference and Transfusion Services department, in conjunction with the Distribution department, will utilize any means available to fill a STAT blood product order including use of short-dated units. In the event that units are not readily available, Carter BloodCare will go to any lengths necessary to obtain the desired units including:

- Testing units in stock inventory
- Obtaining units from hospital inventory
- Deglycerolizing frozen units
- Making arrangements to import units from other blood centers

The Reference and Transfusion Services department staff will provide the client with continual updates

Under normal circumstances, STAT turn-around-time is **2 HOURS** - that is, products ordered STAT will be *dispensed for shipment* within two hours from receipt of the order. Exceptions may apply if the order is for a large quantity of blood components, if the blood product must have special testing or manipulation prior to shipment including irradiation, washing, reconstitution, if blood products must be located from an outside source, or if the order involves a complex serological workup.

Because proper communication is essential during a STAT situation, Carter BloodCare will keep the client informed of all steps taken to provide the requested products. In turn, Carter BloodCare asks that it receives timely updates regarding the patient's status, especially if the situation is no longer determined to be STAT.

ASAP (As Soon As Possible) Order:

ASAP may be applied to any order, other than STAT, to notify the Reference and Transfusion Services department that routine testing turn-around-time will not be suitable due to specific, clinical time restraints. *Please specify the date and time of expected delivery.*

Under normal circumstances, ASAP turn-around-time is **4 HOURS** - that is, products ordered ASAP will be *dispensed for shipment* within four hours from receipt of the order. Exceptions may apply if the order is for a large quantity of blood components, if the blood product must have special testing or manipulation including irradiation, washing, or reconstitution prior to shipment, if blood products must be located from an outside source, or if the order involves complex serological workup.

Routine Order:

A Routine order is placed when there are no specific, clinical time restraints.

Routine order turn-around-time is **8 HOURS** from the time the order is received. That is, products included in a Routine Order will be dispensed for shipment within eight hours from receipt of the order.

Test Priority	***Target Turn-around time***
STAT	2 hours
ASAP	4 hours
Routine	8 hours

12.1.8 Test Cancellation

Tests may be canceled without charge if the cancellation notification is received prior to starting the test. If the test request is for profile (grouped) testing, the client will be charged for any test started before the test cancellation notification is received.

12.1.9 Results, Reports, Requests for Quarantine, Product Investigation Notification, and Requests for Historical Patient Antibody Testing Information

Verbal Report:

A telephoned verbal report is provided, if requested. The client will be notified when complex or difficult serological test cases necessitate a time delay. Information on anticipated turn-around time will be given on a case by case basis. Additional verbal reports will be provided upon request.

Preliminary Report:

A preliminary test result report and billing statement will be faxed upon completion of the testing or included with a shipment if blood products are requested.

Written Report:

A detailed written Immunohematology Report will be faxed after testing is completed. The detailed report includes all test results. If a final report is not received or there are questions concerning the final report, please contact the Reference and Transfusion Services Department.

Requests for Quarantine:

A product quarantine request may be faxed to your facility to confirm the verbal request to quarantine and return the component if available. The request may be generated by the Reference and Transfusion (R/T), the Records Audit and Data Entry (RADE) department and Distribution.

Requests for Historical Patient Antibody Testing Information:

Facilities may request information regarding previous antibody testing performed by Carter BloodCare. Complete patient information section of form RTF103.01A, Reference and Transfusion Service Patient Historical Record Check Request, and fax to 817-412-5749. The form will be completed and returned to your facility with any applicable historical information. A faxed request form is required to obtain information; verbal requests for historical information will not be accepted.

12.1.10 Emergency Release of Untested Components

In the event of an extreme emergency situation, Carter BloodCare may release components prior to completion of all testing. A Carter BloodCare physician must approve the shipment of any untested emergency released component. Incomplete results may include antigen screening and confirmation (for antigen negative RBCs), or infectious disease testing (for units still in processing). All emergency released untested components are ABO/Rh tested prior to release.

12.1.10.1 Requesting Emergency Released Untested Components

A written physician's statement of need must be completed in order for Carter BloodCare to emergency release untested components. In addition, the physician must complete Blood Release Form RTF214.03 and fax it to Reference and Transfusion. Upon receipt of the signed form, the Reference and Transfusion Services department staff will locate the requested components.

12.1.10.2 Labeling and Accompanying Paperwork for Emergency Released Untested Components

- Emergency released untested components are tagged with an Emergency Release Untested Component tie tag that specifically lists all pending tests.

- Blood Release Form RTF214.03 is sent with the labeled component *and must be completed and returned to CBC.*

12.1.11 Notification of Pending Test Completion

Upon completion of testing, the client will be notified by fax of the test results. If there are any reactive results the client will be notified immediately.

12.2 REFERENCE TESTING SERVICES – RED BLOOD CELLS

12.2.1 Serological Testing

The Reference and Transfusion Services department offers the following serological testing:

- ABO/Rh typing including Rh phenotyping
- ABO/Rh type discrepancy resolution
- Antigen typing
- Antibody screen and identification, routine and complex
- Compatibility testing
- Serological testing consultation

Sample Requirements for Serological Testing

Sample requirements for serological testing are described in the Test Information Chart.

Requisition for Serology Testing

Complete form RTF101.01A, Reference and Transfusion Services Request Form, with the following information:

- Patient's full name, as it appears in the medical records
- Patient identification used by requesting facility
- Requesting physician
- Sample collection information
- Requesting facility
- Patient information: diagnosis, gender, date of birth, transfusion history and pregnancy history (if applicable)
- Serological testing services requested
- Test priority: (Please ensure the appropriate test priority is indicated. Requisitions not marked with specific test priority will be assumed to be for routine testing.
- Results of known serological findings, if applicable.
- Special instructions, if applicable, for component(s) requested.

12.2.2 Red Blood Cell Antigen Screening

The Reference and Transfusion Services department will make every attempt to provide antigen negative red blood cell components for patients with clinically significant antibody(ies).

The Reference and Transfusion Services department maintains a special inventory of antigen negative liquid red blood cells. If the requested antigen negative blood is not readily available in the inventory, staff will screen units in regular inventory to find the requested antigen negative units. A frozen inventory of antigen negative units is also maintained. Frozen/deglycerolized antigen negative units may be substituted when no liquid antigen negative units are available. If no frozen or liquid units are available to fill the request, the Reference and Transfusion Services department staff will contact the client and make arrangements to import antigen negative units from outside sources.

Antigen screening of red blood cells for clinically insignificant antibodies will not be routinely performed. Carter BloodCare follows recommendations outlined in current transfusion medicine literature. Anti-A_1, anti-P_1, anti-M, anti-N, anti-Le^a, and anti-Le^b antibodies which are reactive at room temperature and/or at the complement phase of AHG testing are not considered to be clinically significant. A sample may be requested to verify the need for antigen negative units when associated with clinically insignificant antibodies or if the request requires the utilization of the American Rare Donor Program (ARDP).

ABO group compatible units will be provided.

If the request is for a **rare** unit, the Reference and Transfusion Services staff may request a sample of the patient's blood to reconfirm the antibody or to use for red blood cell screening.

Requisition for Serology Testing

Complete form RTF101.01A, Reference and Transfusion Services Request Form as described in Section 12.2.

12.2.3 Red Blood Cell Crossmatch Services

The Reference and Transfusion Services department performs crossmatching and blood component preparation as requested.

Requisition for Crossmatch Services

Complete form RTF101.01A, Reference and Transfusion Services Request Form as described in Section 12.2. The services requested would include the provision of crossmatched red blood cells.

In the top section of the form, record the Blood Bank ID # as it is noted on the patient identification armband if applicable. The ID # may be in any format used by the client, including Typenex numbers or Hollister numbers. Blood Bank ID armbands may be purchased from Carter BloodCare. An identification armband is required to be on the patient if crossmatching is to be performed by Carter BloodCare. Ask the Reference and Transfusion Services department for details on purchasing armbands.

Retain the yellow copy of the requisition form to include in the patient's chart.

Submit the top copy (white) with sample.

Patient Identification

Correct patient identification is a critical step in providing safe transfusion therapy. The following instructions are recommended for proper patient identification prior to blood sample collection. These instructions are recommended steps only. Be sure to follow all pertinent procedures at the transfusion facility.

NOTE: If platelets, plasma or cryoprecipitate are requested and the patient has been previously blood typed by Carter BloodCare, a blood sample does not need to be collected. For verification of sample collection, please contact the Reference and Transfusion Services department.

Recommended procedure for patient identification:

- The patient must be wearing an identification armband. The armband must not be removed from the patient after blood sample collection. Special Blood Recipient Identification armbands are designed for use in correlating positive identification of the blood recipient (patient), patient blood samples, the patient request form, and the blood components intended for the patient. These armbands are placed on the patient immediately before sample collection and must contain all required information.
- The phlebotomist or nurse must bring the completed Reference and Transfusion Services Request form to the patient's bedside or chair side when the blood sample is drawn to verify correct patient information. If the patient is alert and coherent, ask the patient to state his/her name. Be certain the patient is not under the influence of alcohol, mind-altering drugs, or strong analgesics. Verify that the name stated matches the name on the request form. Verify that the name and the patient identification number on the form match the name and patient identification number on the patient armband.
- Do not draw blood samples unless the patient's name and patient identification number on the armband exactly match the information recorded on the request form.
- Do not draw blood samples unless the name stated by the patient (provided the patient is alert and coherent) exactly agrees with the name on the request form.
- Do not use bed labels, patient's chart or door labels as patient identification.

- Note the date blood component(s) are requested on the request form.

Blood Sample Collection

- Samples for crossmatch should not be drawn more than **three days** in advance of the scheduled day of transfusion. Samples are valid for three days.
- Collect 15mls of patient sample in an EDTA tube.
- See Test Chart Information Section 10.0 for specific sample requirements.
    - Samples must be collected according to instructions listed previously in this section. See General Information.
    - Samples should not be hemolyzed.
    - Samples should not be collected from an intravenous infusion site.
    - Samples should not be drawn proximal to an intravenous infusion site.

Blood Sample Labeling Requirements

- Samples must be labeled with:
    - Patients full name
    - Patient's ID
    - Collection date (month, date, year)
    - Collection time
    - Collector's initials

      ** The above items **must be** on the sample tube**

- Labels must have clear, identical, legible information. Do not use markers or gel pens.
- The patient's blood samples must be labeled at the time of collection at the patient's bedside or chair side by the phlebotomist or nurse collecting the sample.
- If a Blood Recipient Identification Band is used, place one of the numbered stickers on the request form or hand write in the Blood Bank ID# box. Place a numbered sticker on each labeled tube submitted for testing.
- Send all additional blood bank stickers with the white copy of the completed Reference and Transfusion Services request form.

Completion and Delivery of the Crossmatch and Component Request by Carter BloodCare

- Upon receipt of the request form and blood sample tubes, all information will be carefully checked to ensure proper patient and sample identification is maintained.
- When the compatibility and crossmatch testing is complete, the units will be tagged with a Carter BloodCare Compatibility Tag (an example of the tag is included at the back of this section).
- If a Blood Recipient Identification Band was used and if the numbered stickers were sent with the patient's blood sample, a numbered sticker will be placed on each blood component intended for the patient. If the numbered stickers were not sent, the number will appear on the compatibility tag only and not on the product.

- The expiration of the crossmatch is **three days** from the date the blood sample for crossmatch was collected. Red blood cells crossmatched for a patient, but not transfused will be released when the crossmatch expires. NOTE: A crossmatch fee will be charged for red cells that are crossmatched but not requested for delivery or pick-up.
- Corresponding paperwork which will be sent with the crossmatched unit:
    - Pack List with each product shipment (see example in the Finance/Billing section of this manual).
    - Carter BloodCare Compatibility Tag.
- If Carter BloodCare has arranged the component delivery, a staff member at the facility will be asked to sign either the Pack List or the courier delivery ticket as verification of product receipt.

Component Delivery/Pick-Up

- Carter BloodCare does not deliver products directly to a patient's home for home transfusion.
- If a client is going to pick-up components from Carter BloodCare:
    - Carter BloodCare transport container will be utilized and the facility may be charged for the container. For questions regarding transport containers, please call the Distribution department.
    - Carter BloodCare staff will pack the component(s) according to regulations.

Crossmatched Product Return Policy

Carter BloodCare may accept return of unused crossmatched components under the following conditions:

- The component has been properly stored under approved storage conditions. Proof of appropriate storage conditions must be provided on Hospital Report of Returned Blood Components, DPF 300.03 (an example of the form is located at the back of Section 11.0)
- The component is in-date.
- Products must be approved in advance for return.

Instructions to Infusionist

Accurate identification of the recipient and donor unit is one of the most critical steps for a safe transfusion. The following instructions are recommended for proper patient identification prior to product infusion. These instructions are recommended steps only. Be sure to follow all pertinent procedures at the transfusion facility.

Before blood product administration, the nurse who will be administering the blood component must verify all information. Whenever possible, a second verification should

be performed by licensed personnel or according to internal policy. The following information must be verified:

- Patient's name and identification number on the armband exactly matches the patient's name and identification number on:
    - The yellow copy of the request form.
    - The Compatibility Tag attached to the blood component.
- If a discrepancy is noted, or if the patient's armband is not present, do not transfuse the component. Immediately notify the Reference and Transfusion Services department.
- Verify that the blood type and unit number on the blood component label matches the blood type and unit number on:
    - The Compatibility Tag attached to the blood component.
    - The information recorded on the Pack List.
- If a discrepancy is noted, do not transfuse the component. Immediately notify the Reference and Transfusion Services department.
- Verify the component is in-date and is not expired. Do not infuse the component if it is expired. Immediately notify the Reference and Transfusion Services department.
- Verify the numbered sticker on the blood component exactly matches the numbered sticker on the patient's Blood Recipient Identification Band. If a discrepancy is noted, do not transfuse the component. Immediately notify the Reference and Transfusion Services department.

Following Component Infusion

Following successful component infusion, complete the information on the Compatibility Tag attached to the blood component bag. Carter BloodCare automatically applies a presumed transfused final disposition; therefore, the Compatibility Tag should be retained by the facility for internal medical record use.

12.3 REFERENCE TESTING SERVICES – PLATELETS

Carter BloodCare provides HLA matched apheresis platelets, platelet crossmatches, and can send your patient samples to an outside HLA testing laboratory in the event you do not have an HLA type available on your patient.

A patient receiving multiple platelet components may become refractory as a result of immunization. The patient may require HLA-matched or crossmatch compatible apheresis platelet components to achieve a satisfactory increase in platelet counts.

Other causes of thrombocytopenia, i.e., fever, infection, splenomegaly, medications, bleeding, or DIC should be evaluated by a clinician. If these other causes of poor response to platelet transfusions exist, the ordering and transfusion of special platelet products cannot be expected to provide an appropriate transfusion response.

12.3.1 HLA matching

HLA typing is performed on Carter BloodCare apheresis donors for subsequent matching with a patient. The requesting Transfusion Service must provide the patient's HLA, class I (A & B) type in writing. The donor's HLA type is computer matched to the patient's HLA type. The best available match grade will be provided. Match grades of C or below are not routinely used.

Donor Classification	Description
A	All four antigens in donor identical to those in recipient
BIU	Three antigens detected in donor; all present and identical in recipient
BIX	Three donor antigens identical to recipient; fourth antigen cross-reactive with recipient
B2U	Two antigens detected in donor; both present and identical in recipient
B2UX	Three antigens detected in donor; two identical with recipient, third cross-reactive with recipient
B2X	Two donor antigens identical to recipient; third and fourth antigens cross-reactive with recipient
C	One antigen of donor not present in recipient and non cross-reactive with recipient
D	Two antigens of donor not present in recipient and non cross-reactive with recipient

If a donor with the required HLA type is not available at Carter BloodCare, Reference and Transfusion Services department staff will make every attempt, within reasonable means, to locate an acceptable HLA match. This includes, but is not limited to, calling specific donors to donate apheresis platelets or importing apheresis platelets from other sources.

Because of the difficulty in finding appropriate matches, it is highly recommended to notify the Reference and Transfusion Services in advance for the need of HLA matched platelets. This will allow time for donor recruitment, collection, and processing of an acceptable HLA matched product.

12.3.2 Platelet Antibody Screening and Crossmatching

Enzyme-Linked Immunoassay is used for screening of patient platelet antibodies. The presence of patient platelet antibodies directed against an antigen found on donor platelets would render ineffective or shorten the life expectancy of the transfused platelets. In platelet antibody screening, the patient's serum is tested against a routine panel of characterized platelets. The panel includes the following platelet glycoprotein serological specificities: HPA-1, HPA-2, HPA-3, HPA-4, and HPA-5. In addition, some antibodies directed toward some HLA specificities are detected by this method. A platelet antibody screen is recommended on a patient before crossmatching apheresis platelet components. Solid phase technology is utilized when crossmatching patient serum against apheresis donor platelets. It is recommended that the Reference and Transfusion Services department be notified in advance for the need for platelet testing.

12.3.3 Requesting Platelet Testing Services

Complete form RTF101.01A, Reference and Transfusion Services Request as described in Section 12.2.

- Please indicate special platelet components needed

If platelet testing services will be needed on specific dates, please note this on the requisition form.

12.3.4 Sample Requirements for Platelet Testing Services

Specific sample requirements:

Samples must be collected and labeled according to instructions listed previously in this section. See 12.1, General Information for patient/reference testing services.

- Please refer to Section 10.0, Test Information Chart, for specific sample requirements for platelet antibody screens, compatible platelet crossmatch and HLA testing.

NOTE: Serum separator tubes are not acceptable.

12.3.5 Platelet Labeling

HLA matched platelets are indicated as such on a yellow tie tag attached to the component. Information on the tag includes:

- Patient name
- Patient Identification number
- Hospital/Facility
- Unit Number
- Grade/interpretation of HLA match

Crossmatched platelet components are indicated as such by a manila tie tag attached to the component. Information on the tag includes:

- Patient name
- Patient Identification number
- Hospital/Facility
- “Platelet Crossmatched” circled on one side and stamped on the reverse side

12.4 MOLECULAR TESTING SERVICES (AABB ACCREDITED)

- Donor and Patient RBC genotyping/ Predicted phenotype testing (Common and Rare Antigen Systems)
- Discrepancy Resolution and 24/7 Consultation Services
- Handling of Specialized testing (i.e. RHCE and DNA sequencing)

12.5 PREVENTATIVE MAINTENANCE SERVICES

- Pipette Calibration and Maintenance
- Digital Timer Calibration
- Thermometer Standardization

12.6 Example Reports:

- RTF102.03, Immunohematology Final Report
- RTF102.04, Preliminary Report
- RTF104.15, Reference and Transfusion Specimen Rejection Report

12.7 Example Forms:

- APL100, Apheresis Product Tag
- APL100, Crossmatched Apheresis Product Tag
- RAF601.00, Request for Product Quarantine, Records Audit and Data Entry
- RTF101.01A, Reference and Transfusion Services Request Form(2 part carbonless)
- RTF103.01A, Reference and Transfusion Service Patient Historical Record-Bedford
- RTF120.11A, Request for Product Quarantine, Discard, or Retrieval
- RTF120.11D, Reference and Transfusion Suspected Component Contamination Notification
- RTF214.01, Uncrossmatched Product Release
- RTF214.03, Untested Product Release form
- RTL214.01, Emergency Release Uncrossmatched Blood Label
- RTL214.03A, Previous Donation Results Label
- RTL214.03B, Testing Not Performed Label
- RTL422.01, HLA Matched Tie Tag
- Non-Crossmatch Compatibility Tag
- Crossmatch Compatibility Tag
- RTL207.01A Confirmed Antigen Typing
- RTL207.01C Molecular Matched Antigen Typing

Carter BloodCare

REFERENCE AND TRANSFUSION SERVICES
IMMUNOHEMATOLOGY FINAL REPORT

Patient Name:		Sample Collection Date & Source:			
ID Number:		Date Request Received:			
Requesting Facility:		Test (s) Requested:			
Ordering Physician:		Patient Date of Birth & Gender:			

ABO/RH TYPE

ABO		Rho (D)		RH Phenotype	RH2	RH3	RH4	RH5	Probable Rh-hr
					C	E	c	e	Genotype

ADDITIONAL RED CELL ANTIGEN TYPE

MNS1	MNS2	MNS3	MNS4	KEL 1	KEL2	FY1	FY2	JK1	JK2	P1PK1	LE1	LE2							
M	N	S	s	K	k	Fy(a)	Fy(b)	Jk(a)	Jk(b)	P_1	Le(a)	Le(b)							

DIRECT ANTIGLOBULIN TEST

POLY		IgG		C3		ELUATE	

ANTIBODY(IES) IDENTIFIED

		LISS		PeG	Gel	Solid Phase	Comments
		37˚C	IgG	IgG	IgG	IgG	
Anti-	Reactive by						
Anti-	Reactive by						
Anti-	Reactive by						
Anti-	Reactive by						
Anti-	Reactive by						
Anti-	Reactive by						

ADDITIONAL DETAILS

TRANSFUSION RECOMMENDATIONS

Testing performed by:		Date & Time:	
Record reviewed by:		Date & Time:	
Report reviewed by the Medical Director on:	L.Sutor MD G.Paranjape MD W.Crews MD T. Nishimoto MD	Date:	

"m" = Microscopic "w" = Weakly Positive NT = Not Tested Pre/Prev = Previous

Carter BloodCare
2205 HWY 121
Bedford, TX 76021
(p)817-412-5740
(f)817-412-5749
CLIA#45D0486046
AABB IRL #95

Carter BloodCare

REFERENCE AND TRANSFUSION SERVICES
IMMUNOHEMATOLOGY FINAL REPORT

Patient Name:		Sample Collection Date & Source:		
ID Number:		Date Request Received:		
Requesting Facility:		Test (s) Requested:		
Ordering Physician:		Patient Date of Birth & Gender:		

ADDITIONAL DETAILS

TRANSFUSION RECOMMENDATIONS

Testing performed by:		Date & Time:	
Record reviewed by:		Date & Time:	
Report reviewed by the Medical Director on:	L.Sutor MD G.Paranjape MD W.Crews MD T. Nishimoto MD	Date:	

"+m" = Microscopic "+w" = Weakly Positive NT = Not Tested Pre/Prev = Previous

Carter BloodCare
2205 HWY 121
Bedford, TX 76021
(p)817-412-5740
(f)817-412-5749
CLIA#45D0486046
AABB IRL #95

Carter BloodCare

REFERENCE AND TRANSFUSION SERVICES

PRELIMINARY REPORT

Additional testing and review may be in progress.

Patient Name:		Sample Collection Date & Source:			
ID Number:		Date Request Received:			
Requesting Facility:		Test (s) Requested:			
Ordering Physician:		Patient Date of Birth & Gender:			

ABO/RH TYPE

ABO		Rho (D)		RH Phenotype	RH2	RH3	RH4	RH5	Probable Rh-hr
					C	E	c	e	Genotype

ADDITIONAL RED CELL ANTIGEN TYPE

MNS1	MNS2	MNS3	MNS4	KEL 1	KEL2	FY1	FY2	JK1	JK2	P1PK1	LE1	LE2							
M	N	S	s	K	k	Fy(a)	Fy(b)	Jk(a)	Jk(b)	P_1	Le(a)	Le(b)							

DIRECT ANTIGLOBULIN TEST

POLY		IgG		C3		ELUATE	

ANTIBODY(IES) IDENTIFIED

		LISS		PeG	Gel	Solid Phase	Comments
		37˚C	IgG	IgG	IgG	IgG	
Anti-	Reactive by						
Anti-	Reactive by						
Anti-	Reactive by						
Anti-	Reactive by						
Anti-	Reactive by						
Anti-	Reactive by						

ADDITIONAL DETAILS

TRANSFUSION RECOMMENDATIONS

Testing performed by:		Date & Time:		

"+m" = Microscopic "+w" = Weakly Positive NT = Not Tested Pre/Prev = Previous

Carter BloodCare
2205 HWY 121
Bedford, TX 76021
(p)817-412-5740
(f)817-412-5749
CLIA#45D0486046
AABB IRL #95

RTF102.04
Version: 10
Effective Date: 04/02/2018

Carter BloodCare

REFERENCE AND TRANSFUSION SERVICES

PRELIMINARY REPORT

Additional testing and review may be in progress.

Patient Name:		Sample Collection Date & Source:		
ID Number:		Date Request Received:		
Requesting Facility:		Test (s) Requested:		
Ordering Physician:		Patient Date of Birth & Gender:		

ADDITIONAL DETAILS

TRANSFUSION RECOMMENDATIONS

Testing performed by:		Date & Time:		

"+m" = Microscopic NT = Not Tested Pre/Prev = Previous

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REFERENCE AND TRANSFUSION SERVICE
PATIENT HISTORICAL RECORD CHECK REQUEST – BEDFORD

Patient's Name:_____ Alias *(if applicable)*: _____ DOB:_____

Blood Type *(if applicable):* _____ Other: _____

Requesting Facility:_____ Requested by:_____ Date Requested:_____

Facility Fax number: _____ Facility Phone number:_____

The section above is to be completed by the customer and faxed to the R&T Laboratory at: (817)412-5749

The section below is to be completed by the Carter BloodCare R&T Laboratory:

☐ No Historical Patient Record Found ☐ Historical Patient Record Found *(Refer to information below)*

☐ Positive Patient Identification Not Possible with Current Information

Blood Type (*if applicable*): _____ Historical Antibody(ies): anti-_____

☐ Serological ☐ Molecular

Red Cell Antigen Type:

RH2	RH3	RH4	RH5	MNS1	MNS2	MNS3	MNS4	KEL1	KEL2	FY1	FY2	JK1	JK2	P1	LE1	LE2
C	E	c	e	M	N	S	s	K	k	Fy^a	Fy^b	Jk^a	Jk^b	P_1	Le^a	Le^b

P = Positive N = Negative

Comments: _____

_____

Historical Patient Record Check Performed by: _____ Date: _____

Disclaimer:

All efforts were made to match the patient information listed above with our records; however, positive patient identification cannot be guaranteed. The results provided should only be used in correlation with your own facility's testing records.

The information contained in this facsimile message is privileged and confidential information intended only for the use of the individual or entity named above. If you have received this information in error, please notify us immediately by telephone at Reference and Transfusion Services Carter BloodCare phone (817)412-5740.

Carter BloodCare
2205 Hwy 121
Bedford, TX 76021
CLIA#45D0486046
AABB IRL #95

Carter BloodCare
We save lives by making transfusion possible.

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)

Carter BloodCare
We save lives by making transfusion possible.

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): _____

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 information is strictly prohibited. If you have received this message by error; please notify Carter BloodCare at (817)412-5740 immediately and destroy the related message.

13.0 Clinical Apheresis Services

Contact Information:

To initiate a contract or to inquire about procedures or services, please contact:

Clinical Apheresis Services
5550 LBJ Freeway, Suite 350
Dallas, TX 75240
Phone: (972) 788-0650

Christopher Edmond, RN,BSN
Manager, Cellular Therapy Collections
Cell: (817) 899-5765
ccedmond@carterbloodcare.org

Pamela Malvern, BSN,RN,CNN
Manager, Clinical Apheresis
Cell: (817) 716-3622
pmalvern@carterbloodcare.org

To schedule a therapeutic procedure 24/7, please call: (972) 788-0650.
For granulocyte orders 24/7, please call pager: (817) 482-9446.

13.1 Therapeutic Apheresis Services

Carter BloodCare provides mobile therapeutic apheresis procedures throughout the north Texas area, including Dallas/Ft Worth greater metroplex. This service is provided for hospitals that do not have apheresis programs, but also may serve as a back-up program for hospitals that do provide apheresis services but need assistance for rarely performed procedures or may require back-up in the event that hospital staff are not available to perform the procedures. A written physician order must be received by the Clinical Apheresis Services staff prior to the first procedure.

Carter BloodCare's therapeutic apheresis staff includes Registered Nurses and/or Hemapheresis Practitioners certified through the American Society of Clinical Pathologists, (ASCP) and apheresis technicians. All are trained in Basic Life Support/CPR (Cardiac Pulmonary Resuscitation).

All services listed below are provided by the Clinical Services department.

- Peripheral blood stem cell collection (processing and storage provided by Carter BloodCare stem cell laboratory if needed)
- Therapeutic Apheresis Procedures
  - Plasmapheresis/Therapeutic Plasma Exchange (TPE)
  - Cell depletion or exchange
  - Red cell exchange
  - Leukoreduction
  - Platelet depletion
  - Photopheresis
  - Inpatient Therapeutic Phlebotomy
  - Granulocyte collection

13.2 Diseases which may be treated by Apheresis

Plasmapheresis/Therapeutic Plasma Exchange (TPE)

- Bone marrow recipient receiving ABO incompatible marrow
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
- Eaton-Lambert Syndrome
- Goodpasture Syndrome
- Guillain-Barré Syndrome
- Hemolytic Uremic Syndrome
- Hyperviscosity Syndromes
- Multiple Myeloma (High Protein Load)
- Myasthenia Gravis
- Paraproteinemia (High Protein Load)
- Post -Transfusion Purpura
- Refsum Disease
- Thrombotic Thrombocytopenic Purpura
- Waldenstrom Macroglobulinemia
- Other situations, as determined after consultation with Carter BloodCare's medical staff

Cell Depletion or Exchange

- Sickle Cell Anemia:
  - Pre-operative
  - Refractory pain crisis
  - Acute chest syndrome
  - Priapism
- Acute leukemia with severe leukocytosis
- Essential thrombocythemia
- Severe Malaria or Babesiosis
- Life-threatening hemolysis from incompatible blood transfusion

Photopheresis

- Cutaneous T-cell Lymphoma, refractory to other therapies
- Mycosis Fungoides
- Sezary Syndrome
- Chronic Graft Versus Host Disease (hematopoietic stem cell transplant recipient)
- Cellular allograft rejection (lung or heart)
- Scleroderma (progressive systemic sclerosis), in some cases
- Rheumatoid Arthritis

13.3 Contract/Privileges

NOTE: Due to regulatory considerations, a current, signed therapeutic apheresis services contract is required to initiate these services.

If a signed contract is not in place, emergency privileges must be established for professional staff performing the procedures. A signed contract will be initiated as soon as possible.

13.4 Emergency Privileges

For emergency privileges several items must be completed prior to the procedure. A physician must agree to sponsor the professional staff. A facility administrator must give verbal approval for the procedure to be performed and provide basic billing information. To initiate emergency privileges, please contact Clinical Apheresis or a Carter BloodCare physician as soon as possible.

13.5 Granulocyte Orders

To initiate a granulocyte order, please use pager number (817) 482-9466. Once your facility has been contacted for initiation of the order, a completed CAF495, Granulocyte Order/Release Form, must be filled out completely and faxed to Clinical Apheresis at 972-661-9409 before donors can be collected.

13.6 Forms

- CAF495, Granulocyte Order/Release Form