

To: Transfusion Services Managers

From: Hospital Relations

Date: March 5, 2019

Re: Customer Service Manual updates

Please update the Customer Service Manual as indicated below.

Section 1.0 General Information

Please replace the organizational charts located at the back of the section due to the addition of the new director of operations for Tyler.

Section 7.0 Collections

The Arlington donor center has relocated and a new donor center will open on March 18, 2019, in the Alliance area; please replace page 7-2 for location information.

Section 8.0 Special Donations

Licensed Zika testing is now available; please replace page 8-4 and 8-8.

Section 9.0 Components and Testing

Verax Biomedical Platelet PGD[®] testing has been implemented to extend the expiration of eligible apheresis platelets. Please replace page 9-3.

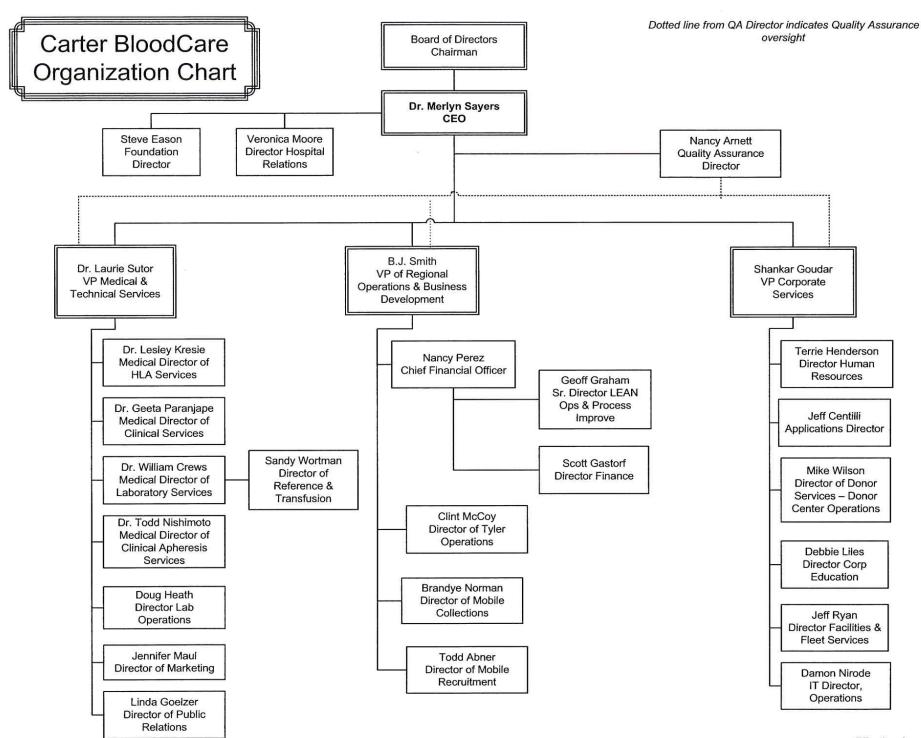
Section 12.0 Reference and Transfusion

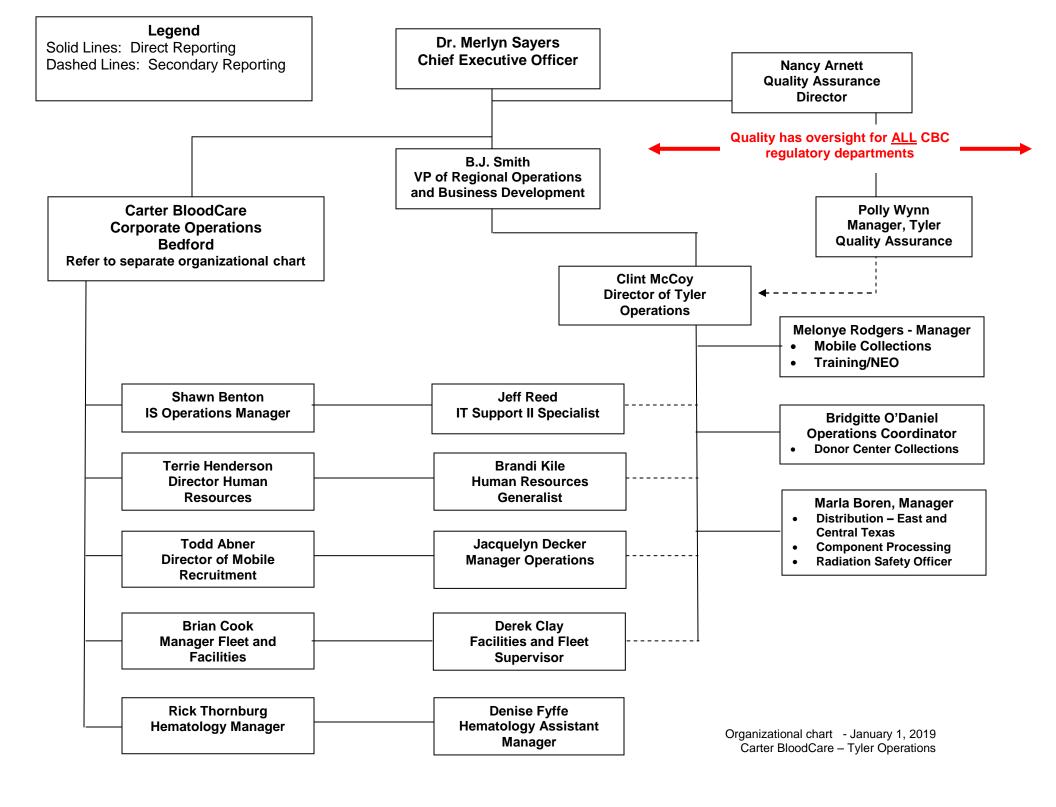
The following form and unit tags have been updated to include licensed Zika testing.

RTF214.03 Untested Product Release

RTL214.03A Previous Donation Results Label

RTL214.03B Testing Not Performed Label





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

Alliance

7260 Blue Mound Road Fort Worth, TX 76131 817-412-5917

Arlington *

4780 Little Road Arlington, TX 76017 817-274-0812

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 76104 817-335-4935

Fort Worth

4995 South Hulen Street Fort Worth, TX 76132 817-263-5810

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

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7.0 Collections Page 7 - 2

- Indirect Antiglobulin Test (IAT)
- Serological Test for Syphilis (STS)
- Anti-*T-Cruzi*,(Chagas'), one time testing per donor
- Nucleic Acid Amplification testing (NAT) for HIV-1, HCV, HBV
- Nucleic Acid Amplification testing (NAT) for West Nile Virus (WNV)
- Nucleic Acid Amplification (NAT) for Zika

Any abnormal test results are reported to your facility transfusion service and the patient's physician on form SDF802.01A, Autologous Blood with Abnormal Test Results Notification, prior to product shipment. A copy of the notification form is included in this section. The donor is also notified directly by Carter BloodCare of any clinically significant results or results that would cause the donor to be deferred.

Confirmatory or supplemental testing is automatically performed on any reactive viral marker tests. These test results will be provided to the patient's physician.

Autologous units with confirmed HBsAg, anti-HIV 1/2, anti-HTLV I/II and/or NAT, will <u>not</u> be routinely sent to your facility. Such units will be discarded unless the Transfusion Service physician requests delivery in writing. In the event that the unit tests positive for one or more of these tests, the Special Donations department will contact your facility to obtain approval for delivery or discard, unless a standing policy has previously been established. Units positive for NAT WNV will not be available for transfusion. Units positive for infectious disease markers sent to facilities for transfusion will be labeled with a Biohazard label.

Units with other positive tests will automatically be shipped to the patient's healthcare facility unless the facility Transfusion Service notifies Carter BloodCare's Special Donations department that the facility will not accept shipment of autologous units with specific reactive laboratory tests. Units with reactive viral marker test results will be labeled with a Biohazard label.

8.1.8 Special Considerations

In the event, for any reason, an autologous unit is not available to be shipped, the Special Donations department will notify your facility and the patient's physician as soon as possible.

8.1.9 Policy for Freezing Autologous Red Blood Cells

Carter BloodCare will freeze autologous red blood cells based on the following.

- The patient has a rare blood type or multiple alloantibodies or other serological problems.
- The patient will need blood for a procedure that cannot be scheduled (i.e., delivery of a baby or awaiting cadaveric renal transplantation).
- The patient has had surgery postponed and will be unable to donate again due to a medical condition (i.e. patient with infection).
- To salvage a unit that has been air-contaminated, if time permits (at no charge to the hospital).

- Hepatitis C Antibody (HCV)
- HIV-1/2 Antibody (HIV-1/2)
- HTLV-I/II Antibody (HTLV-I/II)
- Indirect Antiglobulin Test (IAT)
- Serological Test for Syphilis (STS)
- Anti-*T-Cruzi* (Chagas') , one time testing per donor
- Nucleic Acid Amplification testing (NAT) for HIV-1, HCV, HBV
- Nucleic Acid Amplification testing (NAT) for West Nile Virus (WNV)
- Nucleic Acid Amplification Test (NAT) for Zika

NOTE: Units with abnormal or reactive test results will not be released to the facility for transfusion.

8.2.9 Special Considerations

In the event, for any reason, that a directed unit is unavailable to be shipped, the Special Donations department will notify your facility and the patient's physician as soon as possible.

Directed red blood cells will not be frozen. Exceptions may be made in special circumstances if the unit qualifies under Restricted Donation criteria. Please refer to 8.3 Restricted Donations for more information.

8.2.10 Directed Unit Crossover

Directed units not used by the patient may be crossed over into regular stock inventory at the hospital's discretion or may be returned to Carter BloodCare to be placed into general inventory.

8.3 RESTRICTED DONATIONS

Restricted donations are directed components collected from donors who have not met regular donor eligibility requirements, but have been approved by Carter BloodCare's medical staff for collection and transfusion into an intended recipient. These units <u>are not crossed</u> over into regular inventory. Restricted components are tested, processed, and labeled the same as other directed components; however, an additional orange tie tag, stating the donation is "RESTRICTED" and should not be crossed over into regular inventory, is attached to the component bag. An example of a Restricted Donation tie tag is included at the back of this section. Restricted red blood cells may be frozen depending on the nature of the component and the medical condition (see 'Policy for Freezing Autologous Red Blood Cells' in the Autologous Policies Section).

Restricted blood donors must pay a handling fee for restricted units at the time of donation. Unfortunately, the fees will not be refunded if the unit(s) is not used for the patient.

- Rh (D) blood type
- Indirect Antiglobulin Test (IAT)
- Antibody Identification-performed by Carter BloodCare
- Serological Test for Syphilis (STS)
- Hepatitis B Core Antibody (HBc)
- Hepatitis B Surface Antigen (HBsAg)
- Hepatitis C Antibody (HCV)
- HIV-1/2 Antibody (HIV-1/2)
- HTLV-I/II Antibody (HTLV-I/II)
- Anti-*T-Cruzi* (Chagas'), one time testing per donor
- Nucleic Acid Amplification Test (NAT) for HIV, HCV, HBV, WNV, and Zika

9.3.2 Other Tests Performed as Indicated:

- Bacterial Detection Quality Control Testing for apheresis and Acrodose® platelets is performed at Carter BloodCare prior to distribution.*
 - Testing method utilized is BacT/Alert[®] and Verax Biomedical Platelet PGD[®] (as applicable)
 - o Random platelets are not bacterially tested prior to distribution
- Cytomegalovirus (CMV)
- Sickle cell trait (Hemoglobin S) (performed by Carter BloodCare).
- * QC testing may be incomplete in cases of emergent need of platelet component. Emergency release of platelet product with testing in progress requires physician approval.

9.4 Testing and Labeling

The Testing and Labeling department provides testing of some patient samples for hospitals and other facilities. Samples are routed through and results are provided by the Testing and Labeling department.

Available tests are listed in the Test Information Chart in this manual (see section 10.0). Tests implemented after the printing of this manual may not be listed. An example requisition form is located at the back of this section. For information on new or available tests, please call the Hospital Relations department.

Confirmatory testing is automatically performed on samples for "Processing Profiles" with positive or reactive infectious disease tests.



UNTESTED PRODUCT RELEASE

Patient Name	Identification Number	Facility	ABO/RH (if known)
Reason for Product Release:			
☐ Checked Test Procedu	ures Not Performed -		nor known to be Negative on ked Test Procedures
Anti-HIV 1/2	Anti-HTLV I	/II NAT - I	HIV1/HCV/HBV
HBsAg	STS (Syphil	is) NAT - WNV	
Anti-HBc	IAT	NAT – ZIKA	
Anti-HCV	CMV	Bacterial Detection (Platelets)	
Anti-T.cruzi (Chaç	gas') or Previously Tested		
UNIT NUMBER	PRODUCT CODE	PRODUCT DESCRIPTION	ON ABO/RH
Form Completed by:		Date:	
Current conditions dictate that these Carter BloodCare prior to shipment of		ent urgency to waive the pe	erformance of the above tests by
Requesting Physician or Medical Director Signature		Date:	

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RTF214.03 Version: 05 Effective Date: 02/11/2019 Collected from a donor known to be

negative on _

STS Anti-HIV-1/2 NAT ZIKA

HBsAg IAT Anti-HBc CMV

Anti-HCV NAT HIV-1/ HCV/ HBV

NAT WNV Anti-HTLV-I/II

Anti-T. cruzi (Chagas') Negative or Previously Tested

RTL214.03A

Version: 06

Effective Date: 02/11/2019

TESTING NOT PERFORMED

Anti-HIV-1 / 2 IAT HBsAg CMV

Anti-HBc NAT HIV-1/ HCV/ HBV

Anti-HCV NAT WNV Anti-HTLV-I/II NAT ZIKA

STS Bacterial Detection (Platelets)

Anti-T. cruzi (Chagas') Crossmatch, if applicable

RTL214.03B Version: 06

Effective Date: 02/11/2019