9.0 CROSSMATCH SERVICES POLICIES

Contact and Shipping Information:

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

Emergency Phone: **(817) 685-1242**
(817) 684-7391
Emergency Fax: **(817) 283-1065**

NOTE: The Test Information Chart is in section 8.0 of this manual.

9.1 General Policies

Carter BloodCare provides blood products and testing as an outsourced service to facilities that do not have an in-house blood bank. The transfusing facility Medical Director is responsible for ensuring the transfusing facility remains compliant with applicable AABB Standards. All crossmatch facilities will be required to have their medical director review and sign the HRF100.01A, Transfusing Facility Medical Director Checklist initially and each year that service is provided. This checklist requires that written procedures are approved and staff are trained and continue to be trained for the following: patient identification including the use of a validated electronic patient identification system (as applicable) to reduce the risk of patient misidentification, specimen collection and labeling, return and re-issue of blood components, blood administration, and the recognition and reporting of infectious and noninfectious adverse events. The Annual Medical Director Checklist also outlines the transfusing facility's responsibilities for monitoring blood component ordering practices, patient identification, sample collection and labeling, infectious and noninfectious adverse events, near-miss events, usage and discard, appropriateness of use and blood administration.

If the transfusing facility requests to store blood components storage equipment, on-site, pre-approval must be granted by Carter BloodCare. The blood component storage equipment and associated policies and procedures are subject to inspection. The transfusing facility must have the equipment inspected by the hospital relations department prior to the beginning of delivery and annually thereafter. HRF100.01A Transfusing Facility Medical Director Checklist and HRF100.01B Annual Storage Checklist are provided at the end of this section for your review.

The Reference and Transfusion Services laboratory provides coverage 24 hours a day, 365 days a year.

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

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

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

9.1.1 Contract

A contract is required to initiate crossmatch services. A signed contract ensures all involved parties adhere to current regulatory requirements. Additionally, a contract allows you to exchange Protected Health Information (PHI) with Carter BloodCare to subsequently provide you with patient care results. To initiate a contract, please contact the Hospital Relations department.

9.1.2 Sample Shipping Requirements

Carter BloodCare utilizes a courier service to pick up specimens at your facility to be delivered to the Reference and Transfusion Services laboratory for testing. Please call Reference and Transfusion Services to request a sample pickup. Facility name, status, patient name and testing will be needed at the time of the call. There are additional charges for sample retrievals. **Your facility may elect to use its own courier service for sample delivery. Therefore, please document on your request form if your facility has provided the courier service**. Advance notice will help the department staff ensure the specimen and the request are handled more efficiently. Samples may be delivered to the Reference and Transfusion Services laboratory 24 hours a day, 365 days a year at the following addresses:

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

9.1.3 Order Deliveries

Carter BloodCare utilizes primarily a contracted courier service to make deliveries. Deliveries are coordinated to effectively optimize drivers; therefore, deliveries of routine and ASAP orders may be bundled together, with one driver making multiple deliveries.

STAT order deliveries are not bundled unless a delay would occur if utilizing a second courier. In urgent situations where a courier service may not be sufficient, Carter BloodCare will use all reasonable means available to ensure timely order delivery, including but not limited to use of police and other emergency services.

Carter BloodCare does not deliver products directly to a patient's home for home transfusion.

You may choose to pickup products from Carter BloodCare (see **Section 10.0 Crossmatch Services Procedures**).

Carter BloodCare packs the blood products according to Texas Department of Transportation and other licensing agency regulations. Products are packaged at the appropriate temperatures in sealed Carter BloodCare transport containers. These sealed containers are validated to maintain appropriate shipping conditions for 24 hours.

9.1.4 Sample Rejection

Proper identification of samples is essential if Carter BloodCare is to provide accurate laboratory results for the correct patient. The Reference and Transfusion Services laboratory will not accept unlabeled specimens, even when accompanied by paperwork bearing the patient's name. Due to our accrediting and licensing agency restrictions, Reference and Transfusion Services will not allow corrections to be made to improperly labeled specimens.

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 leading to sample rejection are:

- incomplete or missing information:
    - no patient name
    - no identification number
    - no collection date or incomplete date
    - no collector's initials
    - unlabeled sample including the omission of the blood bank armband
- illegible information
- non-identical information on sample and paperwork
- hemolysis
- incorrect sample type
- insufficient sample volume

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

9.1.5 Results and Reports

Verbal Report:

A telephoned verbal report is provided, if requested. You 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.

Crossmatch Account Report

A Crossmatch Account Report, RTF102.07D or RTF102.07B and billing statement will be faxed upon completion of the testing or sent with the delivery if blood products are ordered. Please retain the report and billing for your records.

Faxed Preliminary Report:

If an antibody screen is positive, a reference work-up will be performed to identify the unexpected antibody. A detailed preliminary report and a debit memo will be faxed upon completion of testing or if products are requested, will be sent attached to the blood products when delivered.

Final Written Report:

A detailed written Immunohematology Report, (example copy included in the back of this section) will be faxed after the Medical Director review 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 laboratory.

Retrospective Medical Director Review

Each facility will periodically receive data for you to use for blood utilization review.

9.1.6 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.
- The component is in-date.
- Products must be approved in advance for return.
- Complete and fax the Request for Pick-up of Units for Return form, DPF300.03B.

Approved Blood Component Storage Devices

If your facility chooses to use a blood bank storage device for storing blood products specifically red blood cells received from Carter BloodCare, a Carter BloodCare representative must inspect your equipment prior to the first shipment, and annually thereafter, in order for red blood cells to be approved for return. **The following criteria must be met:**

- Storage devices for blood components shall have audible alarms.
- Remote alarm monitoring 24/365 if facility is not staffed at all times.
- For storage of blood components, the temperature shall be monitored continuously and documented at least every four (4) hours.
- The alarm shall be set to activate under conditions that allow proper action to be taken before blood components reach unacceptable conditions.
- Return and re-issue of blood components – blood components can only be re-issued if the following criteria are met:
    - Primary container has not been opened
    - Appropriate temperature has been maintained
        - Red cells and thawed plasma at 1°C- 10°C
        - Platelets and thawed cryoprecipitate at 20°C- 24°C
    - Records indicate that the blood components have been inspected and they are acceptable for re-issue to patient care areas.
- Corrective action policies must address the following:
    - Process for the management of blood components when temperature cannot be maintained.
    - Process to review the temperature chart and/or CTMS records on a weekly basis for temperature deviations.
    - Documentation of the reason(s) for any temperature deviations and corrective action (s) should be included in the policy.
    - Document written explanation, corrective action, and disposition of component (if applicable) for any temperature deviation outside of acceptable range.
- Quality control(QC) procedures should be approved and must be conducted according to AABB standards and manufacturer recommendations:

    - Daily QC:
        - Records must be kept for daily manual (digital or liquid-in-glass) and chart recorder temperatures.
        - Verification that the alarm system is powered ON.
        - Records may be kept in the form of a daily temperature log sheet to include areas to record all daily QC temperature checks.
        - Manual temperatures and chart recordings are not required when continuous centralized or computerized temperature monitoring system (CTMS) is in use.
        - Retain records according to AABB standards.

    - Weekly QC:
        - Replace temperature chart every 7 days. Temperature chart must be labeled with start and stop dates. Charts must also be labeled to identify the facility, the specific storage device, and the person changing and reviewing the chart.
        - Review chart for any temperature deviation and provide a written explanation beside the deviation. Document corrective actions.
        - Retain charts.

- Chart is not required when CTMS is in use.

The following QC requirements apply only when a centralized or computerized temperature monitoring system (CTMS) is in use:

- Review of the previous week's temperature recordings and documentation of review.
- Manual thermometer in place to be utilized for backup and for alarm and temperature deviation investigation
- Accessibility to the CTMS temperatures.
- Retain records according to AABB standards.

- Quarterly QC:
  - Perform and record alarm activation testing to ensure that high and low alarms are operating as intended. Low and high alarms should be set to activate before the storage device reaches a critical temperature (i.e. high alarm set at 5.5°C; low alarm set at 1.5°C).
  - Check and record that the electrical source for the alarm system is functioning adequately (battery check or independent circuit operation check).
  - Retain records according to AABB standards.

- Annual Thermometer QC:
  - Thermometers must be calibrated against an NIST-certified or traceable standard or replaced annually.
  - CTMS use requires temperature comparison between secondary (manual internal thermometer) thermometer and computerized temperature monitoring system temperature. Acceptable variance is +/- 1˚C.

9.1.7 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, your facility will be charged for any test started before the test cancellation notification is received.

9.2 Test Priority and Turn-Around-Time (TAT):

It is important to consider the various steps that are involved in completing the patient's order, from initiation to final receipt of the blood product(s). This section provides guidance on determining acceptable test priorities and the associated turn-around-times (TAT), under normal circumstances.

NOTE: Normal circumstances would be defined by a situation in which the patient's antibody screen is negative and no additional serological investigation is required.

9.2.1 Sample Shipping and Delivery TAT:

Samples should be delivered to Reference and Transfusion for testing and order completion. Samples should be packaged in a leak-proof container. OSHA requires that all samples be marked as biohazards.

Please consider the urgency of the need for the blood product(s) when determining the acceptable turn-around-times for sample pickup and delivery to Reference and Transfusion. The following methods may be used for sample pick up.

- Call the Reference and Transfusion Services department to arrange sample pick up. There are additional charges associated with this service, as explained in the contract. Please refer to the following table for target turn-around times.

Sample Pick Up Priority	Courier Service Target TAT for Sample Pick Up
STAT	1 hour after dispatch (Dispatched w/in 15 minutes of receiving request)
ASAP	Within 3 hours
Routine	Variable (based on courier availability)

NOTE: Response times vary according to distance from Carter BloodCare, construction, traffic, and weather conditions

- Send the samples using your own courier or driver of choice. It is recommended that acceptable turn-around-times be established with your selected courier service or driver.

9.2.2 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 your inventory 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 you with periodic updates.

Under normal circumstances, STAT turn-around-time for Reference and Transfusion testing is **2 HOURS** - that is, products ordered STAT will be dispensed for shipment within two hours from receipt of the order (or sample) in Reference and Transfusion.

NOTE: *Exceptions to the STAT turn-around-time may apply if the order is for a large quantity of blood components, if the blood product must have special testing prior to shipment, if blood products must be located from an outside source, or if the order involves a complex workup.*

Under normal circumstances, Distribution will dispatch STAT orders **within 30 minutes** of product availability. This is calculated from the time the product is made available to Distribution by Reference and Transfusion. The following table summarizes expected turn-around-times for **STAT** order.

STAT ORDER:		
Courier Service Sample Pick-Up TAT	**Reference & Transfusion Target TAT**	**Distribution Target Dispatch Time**
1 hour after dispatch; Dispatched w/in 15 minutes of receiving the request	2 hours from order or sample receipt (whichever is later)	Dispatched w/in 30 minutes of product availability

NOTE: *Delivery response times may vary according to in-house availability of the specific blood product requested, distance from Carter BloodCare, construction, traffic and weather conditions.*

9.2.3 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.

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 (or sample) in Reference and Transfusion. You are required to indicate the date and time for receipt of the order on the requisition.

NOTE: Exceptions to the ASAP turn-around-time may apply if the order is for a large quantity of blood components, if the blood product must have special testing prior to shipment, if blood products must be located from an outside source, or if the order involves complex serological workup.

Under normal circumstances, Distribution will dispatch ASAP orders **prior to the desired arrival time**, as specified by you on the requisition. The following table summarizes expected turn-around-times for ASAP orders.

ASAP ORDER:		
Courier Service Sample Pick-Up TAT	**Reference & Transfusion Target TAT**	**Distribution Target Dispatch Time**
Within 3 hours	4 hours from order or sample receipt (whichever is later)	Prior to specified arrival time

NOTE: Delivery response times may vary according to in-house availability of the specific blood product requested, distance from Carter BloodCare, construction, traffic and weather conditions.

9.2.4 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 (or sample) is received by Reference and Transfusion. That is, products included in a Routine Order will be dispensed for shipment within eight hours from receipt of the order or sample.

For Distribution, routine orders will be **dispatched within 12 HOURS** of receiving the blood product(s) from Reference and Transfusion. The following table summarizes expected turn-around-times for Routine orders.

ROUTINE ORDER:		
Courier Service Sample Pick-Up TAT	**Reference & Transfusion Target TAT**	**Distribution Target Dispatch Time**
Variable; based on courier availability	8 hours from order or sample receipt (whichever is later)	12 hours

9.2.5 Test Priority Turn-Around-Time Summary Table

The following table provides an overview of the expected turn-around-times associated with each test priority. Please take into consideration your location from Carter BloodCare when determining expected delivery times.

Test Priority	***Reference & Transfusion: Target TAT (from order or sample receipt)**	**^Distribution: Normal Dispatch Time (from product availability)**
STAT	2 hours	Within 30 minutes
ASAP	4 hours	Prior to specified time
Routine Order	8 hours	12 hours

*****The Reference & Transfusion target turn-around time is calculated from the time the order (or sample) is received in the department.

^The Distribution dispatch time is calculated from when the component is made available to Distribution by Reference and Transfusion Services. If an in-house driver is unavailable to make the delivery, an outside courier service will be utilized by Carter BloodCare.

NOTE: *Delivery response times vary according to distance from Carter BloodCare, construction, traffic, and weather conditions.*

9.3 Example Reports:

- RTF102.03 Immunohematology Final Report
- RTF102.04 Preliminary Report
- RTF102.07B Crossmatch Account Report
- RTF102.07D Crossmatch Account Report (electronic report)
- RTF104.15 Reference and Transfusion Specimen Rejection Report

Example Forms:

- DPF-300.03B Request for Pick-up of Units for Return
- HRDF100.01A Transfusing Facility Medical Director Checklist
- HRDF100.01B Initial and Annual Storage Checklist