SAN ANTONIO, TX

NATIONAL WHOLE BLOOD ACADEMY

Blood Center Notifications:

- Handling a donor with a newly reactive testing result
- Handling post-donation information

South Texas Blood & Tissue

Viral Marker Testing- Initial Screening

- Hepatitis B
- Hepatitis C
- HIV-1/2
- Human T-Lymphotropic Virus Types I & II
- Trypanosoma cruzi (T. cruzi) (Anti-T. cruzi Assay)
- West Nile Virus (WNV)

**Supplemental testing performed if the screening test is reactive

https://www.fda.gov/vaccines-blood-biologics/infectious-disease-tests

FAX Consignee Notification

Date: _____
2nd Notification: _____
3rd Notification: _____

To:	
Ph:	Fax:
Attn: Blood Bank Supervisor	

From: Guadalupe Mendoza
Quality Assurance Department
South Texas Blood & Tissue Center
6211 Interstate 10 West at First Park Ten
San Antonio, TX 78201
Phone # (210) 731-5555 ext 2737
(800) 292-5534 ext 2737
Fax # (210) 249-4447

CONFIDENTIAL

Please enter the final disposition of product if it is no longer in inventory. Sign below, date and fax this form back to the number above.

☑ Blood Product ☐ Tissue Product

Reason for Notification:

Product ID	Product Name	Blood Type	Draw or Procurement Date	Date of Discovery	Disposition of Product (Discarde/Returned/ Transfused) & Date

This notice is being sent to comply with FDA requirements. Notification of the recipient is at the discretion of the facility.

Confirmatory Results:

☐ Not applicable ☐ Pending ☐ Unreadable
☐ Negative ☐ Positive ☐ Indeterminate

Comments (give details):

Date: _____ Signature: _____

THIS FAX IS A **PRIVILEGED** AND **CONFIDENTIAL** COMMUNICATION AND IS TRANSMITTED FOR THE EXCLUSIVE INFORMATION AND USE OF THE ADDRESSEE. PERSONS RESPONSIBLE FOR DELIVERING THIS COMMUNICATION TO THE INTENDED RECIPIENT ARE ADMONISHED THAT THIS COMMUNICATION MAY NOT BE COPIED OR DISSEMINATED EXCEPT AS DIRECTED BY THE ADDRESSEE. **IF YOU RECEIVE THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY TELEPHONE AND MAIL THE COMMUNICATION TO US AT OUR LETTERHEAD ADDRESS.** FURTHER, IF THE READER OF THIS TRANSMITTAL IS NOT THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY REVIEW, DISSEMINATION, OR COPYING OF THIS FAX OR THE INFORMATION CONTAINED HEREIN IS PROHIBITED. THANK YOU.

- Consignee notification
  - Sent for outdated products
  - Let us know the disposition
  - Examples of when we may send:

    1. We will send this document within 3 days of a donor testing repeat reactive for HIV, HCV, HTLV I/II, HBsAg, Hep B core antibody, Chagas- repeat reactive (supplemental pending)
       - If supplemental testing is negative, we will send an updated form with the confirmatory result checked off
       - Patient/Transfusing patient notification up to MD discretion
    2. Post Donation information
       - Travel and medication history most commonly
       - Patient/Transfusing patient notification up to MD discretion

FAX Recall

Date:_____
2nd Notification: _____
3rd Notification: _____

To:	
Ph:	Fax:
Attn:	

From: Guadalupe Mendoza
Quality Assurance Department
South Texas Blood & Tissue Center
6211 Interstate 10 west at First Park Ten
San Antonio, TX 78201
Phone # (210) 731-5555 ext 2737
(800) 292-5534 ext 2737
Fax # (210) 249-4447

CONFIDENTIAL

In reference to FDA Memorandum dated July 19. 1996, regarding the Quarantine and Disposition of Units from prior collections from donors with repeatedly reactive screening test and/or FDA Memorandum dated December 10, 1993, regarding Post-Donation Information, the following product(s) was (were) shipped to your facility.

☒ **Blood Product** ☐ **Tissue Product**

Reason for Notification:

Product ID	Product Name	Blood Type	Draw or Procurement Date	Date of Disposition

Confirmatory Results:

☒ Not applicable ☐ Pending ☐ Unreadable
☐ Negative ☐ Positive ☐ Indeterminate

If the above product(s) is (are) in inventory, deface the product, quarantine and Return to South Texas Blood & Tissue Center (Attention: Quality Assurance Department).

Comments (give details):

Date: _____ Signature: _____

Sent for in-date products

Quarantine

Examples of when we may send:

1. We will send this document within 3 days of a donor testing repeat reactive for HIV, HCV, HTLV I/II, HBsAg, Hep B core antibody, Chagas- repeat reactive (supplemental pending)
   - If supplemental testing is negative, we will send an updated form with the confirmatory result checked off
   - Patient/Transfusing patient notification up to MD discretion
2. Post Donation information
   - Travel and medication history most commonly
   - Patient/Transfusing patient notification up to MD discretion

QUALITY ASSURANCE DEPARTMENT
6211 IH-10 WEST AT FIRST PARK TEN
SAN ANTONIO, TX 78201
PHONE: (210) 731-5555 EXT 2737
PHONE: (800) 292-5534 EXT 2737
FAX: (210) 249-4447
PRODUCTCOMPLIANCEGROUP@BLOODNTISSUE.ORG

BioBridge GLOBAL

HCV LOOKBACK FORM

Consignee & Testing Information				
Notification Date:	☐ First Attempt: _____ ☐ N/A ☐ Second Attempt: _____ ☐ N/A ☐ Third Attempt: _____ ☐ N/A			
Quality Event:	_____	**Discovery Date:**	_____	
Consignee:	_____	**Fax:**	_____	
Attn:	☐ Blood Bank Supervisor	☐ Medical Director	☐ Other: _____	
Donor Tested Reactive For:	**HCV EIA:** ☐ Yes	☐ No	☐ N/A	
	HCV NAT: ☐ Yes	☐ No	☐ N/A	
	ELISA: ☐ Yes	☐ No	☐ N/A	

The following component was prepared from a previous donation and sent to your facility. Unit listed below tested negative for all viral markers. Please complete the form below and return to South Texas Blood & Tissue Quality Assurance.

Unit Number	Draw Date	Blood Type	Component Type	Expiration Date	Disposition (& Date) *(e.g., transfused, in inventory, discarded, expired, or returned)*

Please check the appropriate response(s) below:

☐ The patient was notified by letter — **Date:** _____

☐ The patient as notified by telephone — **Date/Time:** _____

☐ The patient could **not** be notified because:
- ☐ Patient is deceased
- ☐ Patient cannot be located
- ☐ Patient is a minor (I have notified the patient's relative or legal representative)
- ☐ Patient is incompetent (I have notified the patient's relative or legal representative)

☐ Patient notification is **not** required

☐ The patient was **not** notified because the patient has already been tested for anti-HCV and is known to be:
- ☐ Positive
- ☐ Negative

Information Provided By: _____ **Date:** _____

A lookback investigation, a subset of consignee notification responses, is initiated by the blood supplier when the consignee notification suggests a potential risk of transmitting infection from a donor to a recipient.

***Patient notification is required except in the case of HCV NAT and ELISA negative-This is at MD discretion

South Texas Blood & Tissue Center

HIV Look Back Notification

Notification Date:	Quality Event: STBTC-NCMR-
Consignee:	Fax:
Medical Director: Blood Bank Supervisor	
Donor Confirmed Positive for: HIV HIV NAT Reactive RHIV: Reactive Geenius Assay: HIV-1 Positive	Discovery Date:

The following component(s) was prepared from a previous donation and sent to your facility. Unit(s) listed below tested negative for all viral markers.

Unit Number	*Draw Date*	*Blood Type*	*Type of Component*	*Expiration Date*

Please check the appropriate response(s) below:

☐ The patient was notified by letter dated _____/_____/____

☐ The patient was notified by telephone on _____ @ _____ AM / PM

☐ The patient could not be notified because:

- ☐ Patient is deceased
- ☐ Patient can not be located
- ☐ Patient is minor. I have notified or attempted to notify the patient's or legal representative
- ☐ Patient is incompetent (I have notified or attempted to notify the patient's relative or legal representative)

☐ The patient was not notified because the patient has already been tested for anti- _____ and is known to be ☐ positive ☐ negative.

Information Provided by:	Date:

Please complete this form and return within 60 days of receipt to address listed below:

Thank you for your cooperation.

Quality Assurance Coordinator
South Texas Blood & Tissue Center
6211 IH 10 West
San Antonio, Texas 78201 Fax: (210) 249-4447

No MD discretion, patient notification required

CODE OF FEDERAL REGULATIONS COMPLIANT		
Infectious Disease	**Lookback Period**	**Recipient/Patient Notification**
Hepatitis C virus (HCV)[3] or HIV[4]	12 months prior to the donor's most recent nonreactive licensed multiantigen screening test or NAT-reactive	Notify recipients or their physician of record of the increased risk of HCV or HIV infection from prior blood collections, and the need for recipient HIV or HCV testing and counseling. Notify the recipient's legal representative or relative for minors, those adjudged incompetent, deceased, or competent individuals under state law allowing representation. Make reasonable attempts to notify within 12 weeks of receiving HIV or HCV test results or donor's reactive screening, as per FDA guidelines

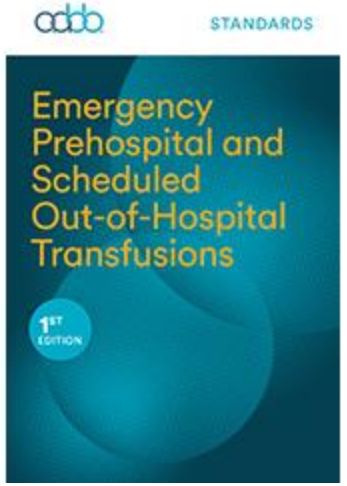
HCV
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-610/subpart-E/section-610.47
HIV
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-610/subpart-E/section-610.46

FDA/AABB GUIDANCE

Infectious Disease	Lookback Period	Recipient/Patient Notification
Babesiosis[5]	12 months prior to the date of the reactive index donation	Encourage consignees to have a discussion with the recipient's physician of record about a possible risk of transfusion-transmitted babesiosis, particularly if the involved component(s) had not been tested or pathogen reduced.
Trypanosoma cruzi (Chagas Disease)[6]	10 years or 12 months prior to the most recent negative test result (whichever is the lesser time period).	Encourage consignees to notify the recipient's physician of record of a possible increased risk of *T. cruzi* infection. Notification should be done within 12 weeks.
West Nile Virus (WNV)[7]	For donors with a medical diagnosis of WNV, recipients of donations from -14 to +120 days from illness onset For donors as the likely source of transfusion transmitted WNV infection, recipients of units donated from -120 days to +120 days from the infectious donation should be notified.	May consider notifying treating physicians of prior recipients of blood and blood components collected from that donor.

1st Edition Standards: *Emergency Prehospital and Scheduled Out-of-Hospital Transfusions (EPSOHT Standards)*

- Effective July 1, 2025 and will have a 2-year effective period
- "will maintain and enhance the quality and safety of services provided by prehospital transfusion services (EMS services)"
- Topics-
  a. Administration of blood in the prehospital setting
  b. Transfusion Administration Service (TAS): service provider responsible for receiving and transmitting orders of blood for transfusion, transporting blood to the transfusion site, performing the transfusion, monitoring the patient during transfusion, reporting outcomes, and ensuring the traceability of the unit is maintained
  c. Requirements for uncrossmatched blood



https://www.aabb.org/aabb-store/product/standards-for-emergency-prehospital-and-scheduled-out-of-hospital-transfusions-1st-edition-print-19188206

LTOWB Info Tag

SAFE-T-Vue 10 Device

- BIA development
- Targeted Recruitment- Focused on developing a program to engage donors
  - Special scripting
  - Engagement- Donors committed to donating only ITOWB

- Heroes in Arms
  - Inclusion of women
    - Never pregnant females
    - Women with a history of a livebirth and negative HLA antibody testing

- Donor Engagement
  - Patient stories
  - Partner Engagement

https://www.facebook.com/groups/hiastbt/

HEROES IN ARMS Celebration Event

https://youtu.be/0qb_dc1poAY?si=KkZhu13zAsr2wnHT

STBT Obligations:

1. Provide scheduled delivery service for Low Titer O Whole Blood (referred to herein as "LTOW Blood"), and other supplies or materials furnished by STBT, the quantities of which will be mutually determined from time to time by ESP management and STBT, subject to availability. Delivery fees, if any, are set forth on Exhibit A hereto.

2. Provide the reference and consultation services listed on Exhibit A hereto.

3. Conduct periodic blood banking educational programs and in-services for ESP personnel as reasonably requested, at mutually agreeable dates and times.

4. Provide literature and other support material for community relations concerning blood banking and donor recruitment, physician and medical staff education, and general blood banking information, as reasonably requested.

5. Notify ESP within three calendar days after STBT determines that it has supplied LTOW Blood collected from a donor who tested negative at the time of donation and subsequently tests reactive for Human Immunodeficiency Virus ("HIV") or Hepatitis C Virus ("HCV") infection on a later donation, or subsequently is determined to be at increased risk for transmitting HIV or HCV.

ESP Obligations:

1. Store and handle LTOW Blood in accordance with the laws, regulations, and standards set forth by the Center for Biologics Evaluation and Research of the Food and Drug Administration ("FDA") and the AABB (formerly known as the American Association of Blood Banks).

2. Use LTOW Blood products delivered to it for transfusion to its patients, in connection with ESP ground services medical program. ESP will not sell, distribute or transfer any of STBT's LTOW Blood products to any person or entity, business or individual, other than one of its patients undergoing transfusion treatment.

3. Allow periodic inspection of ESP blood service by STBT, at mutually agreed upon dates and times.

4. Make available to STBT copies of its Standard Operating Procedures ("SOP") for transfusion of LTOW Blood.

5. Perform blood utilization reviews in accordance with the requirements set forth by the AABB.

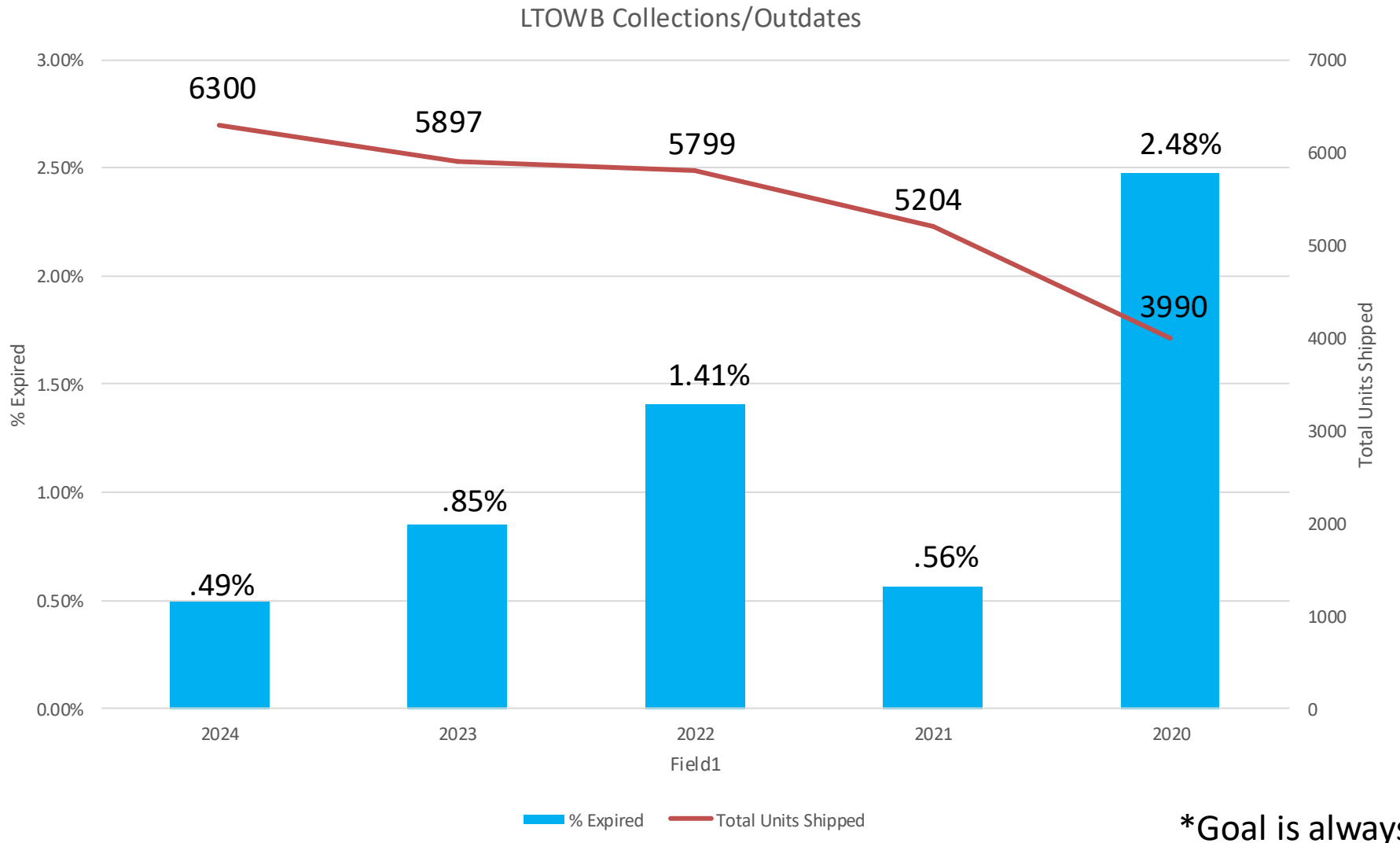
STB&T LTOWB STATUS:			
Scheduled Appointments	Inventory		In-Process
25 Monday	67		11
19 Tuesday	3 DOS	2 DOS	1 DOS
15 Wednesday	60	40	20
26 Thursday	* DOS= Days of Supply		

Whole Blood Rotation Status — Monday, July 7, 2025 14:00 — STRAC

Total On Hand	Today	Within 3 Days	Within 7 Days	Within 14 Days
66	3	17	17	29

Unit Name	Blood Unit Number	Rotation Date	Days to Rotation
Fredericksburg Fire/EMS	W14092506397300	07/07/2025	0
La Salle Co EMS	W14092506335300	07/07/2025	0
La Salle Co EMS	W14092505578500	07/07/2025	0
Acadian 4024	W14092506326600	07/09/2025	-2
Acadian 4025	W14092506123100	07/09/2025	-2
Acadian 4202	W14092504282300	07/09/2025	-2
Acadian 4300	W14092505582300	07/08/2025	-1
AirCare 2 (AE 147)	W14092506341100	07/08/2025	-1
AirEvac 48	W14092506036100	07/09/2025	-2
AirEvac 48	W14092505615800	07/09/2025	-2
AirEvac 71	W14092506014100	07/09/2025	-2
AirEvac 71	W14092504288600	07/09/2025	-2
DPS EPB	W14092506759800	07/10/2025	-3
DPS EPB	W14092506003800	07/10/2025	-3
Gonzales EMS	W14092505592300	07/09/2025	-2
Leon Valley Fire/EMS	W14092506156800	07/10/2025	-3
New Braunfels MOF-1	W14092506761900	07/10/2025	-3
SAFD Medic 45	W14092506372200	07/10/2025	-3
Wilson Co ESD 3	W14092505617100	07/09/2025	-2
Wilson Co ESD 4	W14092506477100	07/10/2025	-3

2025: 0.16%
2026 YTD: 0.05%



*Goal is always to stay under 2% expiration rate

Collection Information *(through 06/30/2026)*

Heroes in Arms units collected since program inception: **45168**

Heroes in Arms units collected in 2026: **5035**

Heroes in Arms units from male donors in 2026: **3781**

Heroes in Arms units from female donors in 2026: **1254**

Heroes in Arms units collected in June 2026: **904**

Heroes in Arms units collected in June from male donors: **695**

Heroes in Arms units collected in June from female donors: **209**

Donor Information

Total number of Heroes in Arms donors since program inception: **9112**

Total number of Heroes in Arms female donors since program inception: **1681**

Total number of Heroes in Arms male donors since program inception: **7431**

Total number of active Heroes in Arms donors (12 Months): **4107**

University Hospital Distribution

LTOWB units sent to University Hospital since program inception: **17142**

MCI Information Sheet

South Texas Blood & Tissue | HEROES IN ARMS

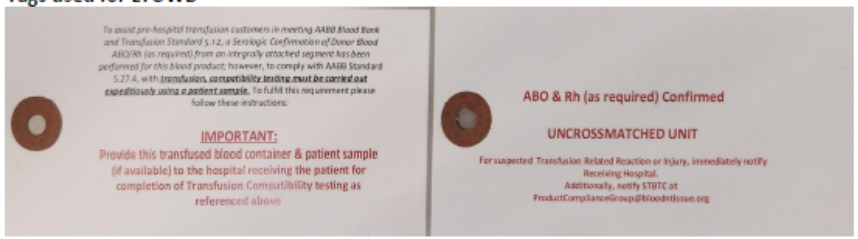
Low Titer O Whole Blood

What is low titer O positive whole blood (LTOWB)?
LTOWB is type O-positive whole blood that has low levels of anti-A and anti-B antibodies (titer < 1:256). LTOWB can be transfused to patients of any blood type. LTOWB is collected in a CPDA-1 bag allowing for a 35-day shelf life. LTOWB is unmodified and contains rbcs, platelets and plasma. LTOWB is non-leukoreduced and averages around 500 mLS. (Source AABB)

Low Titer O Whole Blood facts:

- 35-day (CPDA-1) Shelf Life
- Non-leukoreduced
- Volume 500 mLs (approx)
- Titer of <1:256
- ISBT Product Code E0068V00

Tags used for LTOWB



In order to facilitate compliance with 5.27.4, the tie tag instructs transfusing agency to provide blood container (with integrally attached segments to receiving facility/transfusion service.)

How to store and return LTOWB?
If you did not order this product, you are able to return the unused bag if stored correctly. Once removed from the shipping container, whole blood must always be kept in a temperature-controlled refrigerator between 1°C and 6°C.

For additional information please call 210-731-5550


METHODIST

https://youtu.be/ZFaf3rriAvo

QUESTIONS?

- TRALI Mitigation
  *Transfusion Associated Acute Lung Injury
  * Per AABB, Blood centers are required to TRALI mitigate high volume plasma products Plasma, Apheresis Platelets and **Whole Blood**

  - Should only be collected from males, never pregnant females or females who have been pregnant but have been tested and found negative for HLA antibodies

South Texas Blood & Tissue