

ATTACHMENT D

OMB Control Number
Expiration Date
ID: <Sample ID>

2007 Nationwide Blood Collection and Utilization Survey

Your help is critical to assess the adequacy of our blood resources.

This biennial survey is the single best means of determining detailed accurate information about collection and utilization of blood and blood components for the United States. The data you contribute and the time you take to assure its accuracy are critical to the success of the survey and the interpretation of findings. In the past, we have asked questions about blood, blood components and cell therapy collection and utilization. This year, due to the needs of the blood banking and hospital blood resource providers, there are new questions regarding detailed utilization, therapeutic apheresis, biovigilance, human tissue collection and utilization and the practices related to these products and services. We look forward to seeing what unfolds and to sharing that report with you. Thank you in advance for your participation in this important National Survey. If you have any questions regarding the survey, while you are compiling the data or afterwards, please use our toll-free number: 800-793-9376.

Please return your completed questionnaire by September 15, 2007.

Statement on Confidentiality and Use of the Data:

The completed questionnaires will be processed and data compiled for analysis. No institutional data provided in response to this survey will be released that allows a facility to be identified directly or indirectly. De-identified data from this survey will be used by researchers throughout the blood community. Results will only be released in aggregate form. The de-identified data and the reports will be in the public domain, accessible to the public.



Advancing Transfusion and
Cellular Therapies Worldwide



Instructions: Please read carefully!

- Report all data for the calendar year 1/1/06 through 12/31/06 unless otherwise specified (some questions are about current practices only). If your institution is not on the calendar year 1/1/06 through 12/31/06, please report data for the most recent 12-month period that your institution has available.
- Answer all questions – **DO NOT LEAVE ANY ITEMS BLANK**, unless instructed to skip an item. If your answer is zero, it is important that you enter “0” rather than leaving a blank.
- Consult your records whenever possible to provide the most accurate information available. If records are not available, please provide your best estimate, or that of your most qualified co-worker. It may be necessary for you to forward this questionnaire on to another department for completion of some items.
- Before you begin, read the glossary on the inside back cover of this booklet.
- If you have any questions, please call the AABB toll-free Survey Helpline at 800-793-9376.
- Thank you in advance for your assistance with this important survey!

Section A. General Information

- A1. Provide the name, title, telephone number, and e-mail address of each person completing this survey:

Name	Title/Position	Telephone	E-mail
_____	_____	_____	_____
_____	_____	_____	_____

A2. Is your institution [choose one]:

- 1 A local or regional **blood center** (non-hospital) that collects blood from donors and supplies blood and components to other facilities?
- 2 A **hospital-based blood bank and transfusion service** that collects blood from donors (may be only autologous or directed) and provides blood and components for transfusion primarily to your own facility?
- 3 A **transfusion service** that provides blood and components for transfusion, but does not collect blood from donors?
- 4 A local or regional blood center that collects blood from donors and supplies blood, components, and crossmatched blood products to participating facilities (such as a **centralized transfusion service**)? In this category, the service is not limited to reference laboratory work, but includes routine transfusion service.
- 5 An independent facility that collects, processes, manufactures, stores, or distributes **cellular therapy** products?

For Institutions 1-4 above:

Does your institution collect, process, manufacture, store, and/or distribute hematopoietic progenitor cells (HPCs) or other cell therapy products? [If you only perform infectious disease testing, please check “No”.]

- Yes —————> BE SURE TO COMPLETE SECTION G
- No


Does your institution collect, process, manufacture, store, and or distribute human tissue for transplantation? [If you only perform infectious disease testing, please check “No”.]


- Yes —————> BE SURE TO COMPLETE SECTION F
- No

A3. List the official name, city, state, and zip code of every institution for which data are reported on this questionnaire. [If necessary, continue on the opposite page.]

a) Institution Name			
Street Address	City	State	Zip
b) Institution Name			
Street Address	City	State	Zip
c) Institution Name			
Street Address	City	State	Zip

A4. Does your institution serve as a transfusion service for other institutions?

Yes 

 No 

Which other institutions are served? [Please provide the official name, city, and state of every such facility, if different from your institution. Attach a separate sheet if needed.]

a) Institution Name			
Street Address	City	State	Zip
b) Institution Name			
Street Address	City	State	Zip
c) Institution Name			
Street Address	City	State	Zip

PLEASE GO TO SECTION B

Section B. Blood Collection, Processing, and Testing

B1. Does your institution collect blood from donors? [If you collect autologous units only, check “Yes” and complete this section.]

Yes —→ COMPLETE THIS SECTION.

No —→ SKIP TO SECTION C

B2. How many collection procedures (and for automated collections, how many products?) were successfully completed by your institution in each of the following categories in 2006? [If a breakdown is not available, put the total under “Allogeneic Whole Blood”. Do not count low volume or incomplete procedures.]

of Procedures

Manual Whole Blood Collections

- 1) Community (Non-Directed Allogeneic Donations)... _____
- 2) Autologous..... _____
- 3) Directed..... _____

of Procedures

of Products

Automated Collections

- 1) Red Cell Pheresis
 - a. Allogeneic red cells..... _____
 - b. Autologous red cells..... _____
 - c. Directed red cells..... _____
 - d. Concurrent plasma..... _____
 - e. Concurrent plasma – jumbo..... _____

- 2) Platelet Pheresis
 - a. Single Donor platelets..... _____
 - b. Concurrent plasma..... _____
 - c. Concurrent plasma – jumbo..... _____
 - d. Concurrent red cells..... _____

- 3) Plasma Pheresis
 - a. Source..... _____
 - b. Jumbo FFP (>400 ml)..... _____
 - c. FFP..... _____

B3. How many units were processed by your institution in each of the following categories in 2006?

a. Number of whole blood units processed for distribution as whole blood:
_____ units

b. Number of red cell units processed:
[Count double units resulting from double collections as two units. Exclude pediatric units. Include packed red cells plus units from red cell apheresis]
_____ units

B4. How many whole blood and red cells units (combined) were released for initial distribution? [Count double units resulting from double collections as two units. Units returned and released for distribution multiple times should only be counted once.]

TOTAL

B5. How many units of the following were produced from whole blood?

- a. FFP..... _____ units
- b. Plasma, frozen within 24 hours..... _____ units
- c. Plasma, cryoprecipitate reduced..... _____ units
- d. Jumbo size (> 400 ml)..... _____ units

B6. Of the following components, how many units were produced by your institution in 2006? [Count double or triple units resulting from double or triple collections or splits as two or three units.]

- a. Plasma for further manufacture..... _____ units
- b. Whole blood derived platelets _____ units
- c. Apheresis platelets from single collections [do not include autologous or therapeutic units] _____ units
- d. Apheresis platelets produced from double collections.... _____ units
- e. Apheresis platelets produced from triple collections _____ units
- f. Cryoprecipitate _____ units
- g. Granulocytes..... _____ units

B7. For each of the following categories, how many units did your institution collect/prepare/modify to achieve pre-storage leukoreduction in 2006?

- a. Red cells/whole blood _____ units
- b. Whole blood derived platelets _____ units
- c. Apheresis platelets _____ units
- d. Other component units, including pediatric units..... _____ units

B8. From how many of the following types of donors did you successfully collect blood products in 2006?

- a. First time allogeneic donors..... _____ donors
- b. Repeat allogeneic donors..... _____ donors

B9. In 2006, how many donors were deferred before donating?

_____ donors

B10. In 2006, how many donors were deferred before donating based on their response to the question regarding history of Chagas' disease?

_____ donors

B11. How many donations were from repeat allogeneic donors?

_____ donations

B12. How many severe donor adverse events did you have in 2006?

_____ events

B13. Are diversion devices used when collecting?

a. Apheresis platelets?

- Yes
- No
- Don't Know

b. Whole blood?

- Yes
- No
- Don't Know

B14. Do you issue blood to home transfusion services, free standing surgery centers, or other off-site non-hospital transfusion services, such as dialysis centers?

- Yes
- No
- Don't Know

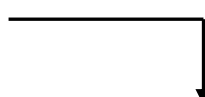


If yes, how many units of:

- a. RBCs _____ units
- b. Platelets _____ units
- c. FFP _____ units

B15. Do you issue blood for use by military installations?

- Yes
- No
- Don't Know



If yes, how many units of:

- a. RBCs _____ units
- b. Platelets _____ units
- c. FFP _____ units
- d. Cryoprecipitate _____ units

B16. What was the total number of allogeneic units (non-directed and directed combined) discarded in 2006 for any abnormal test results?

_____ units

B17. For all tested donations collected by your facility in 2006, indicate the number of repeat reactive and confirmed positive first- time allogeneic donors by infectious disease marker below:

Infectious Disease Marker	# of Repeat Reactive First-time Allogeneic Donors	# of Confirmed Positive First-time Allogeneic Donors
a. Anti-HIV-1/HIV-2		
b. Anti-HTLV-I/II		
c. Anti-HCV		
d. Anti-HBc		
e. HBsAg		
f. Serological test for Syphilis		
g. HIV-1 NAT (antibody negative)		
h. HCV NAT (antibody negative)		
i. Undifferentiated NAT (if HIV-1 and HCV discriminatory negative when applicable)		
j. WNV NAT		
k. HBV NAT		

B18. For all tested donations collected by your facility in 2006, indicate the number of repeat reactive and confirmed positive repeat allogeneic donors by infectious disease marker below:

Infectious Disease Marker	# of Repeat Reactive Repeat Allogeneic Donors	# of Confirmed Positive Repeat Allogeneic Donors
a. Anti-HIV-1/HIV-2		
b. Anti-HTLV-I/II		
c. Anti-HCV		
d. Anti-HBc		
e. HBsAg		
f. Serological test for Syphilis		
g. HIV-1 NAT (antibody negative)		
h. HCV NAT (antibody negative)		
i. Undifferentiated NAT (if HIV-1 and HCV discriminatory negative when applicable)		
j. WNV NAT		
k. HBV NAT		

PLEASE GO TO SECTION C

Section C. Blood Transfusion

C1. Is your institution directly involved in the transfusion of blood to patients or does it serve as a transfusion service for another institution that transfuses blood?

- Yes —————> COMPLETE THIS SECTION
- No —————> SKIP TO SECTION D

C2. In 2006, how many units of allogeneic whole blood and red cells (WB/RBCs) did your institution transfuse either directly or as a transfusion service for another institution? [Exclude directed units transfused to the intended patients.]

Total # of Units Transfused	Total # of Recipients

C3. Indicate below the total number of WB/RBC units transfused in each of the following categories and report the number of recipients of these units.

	Directed units transfused to the intended patient	Units transfused to pediatric patients (overlap possible)	Autologous units transfused to autologous donor
a. Number of units			
b. Number of recipients			

C4. In 2006, how many units of each of the following components did your institution transfuse, either directly or as a transfusion service for another institution?

- a. Whole blood derived platelets [Individual concentrates, not pools]..... units
- b. Apheresis platelet units – full dose ($\geq 3 \times 10^{11}$)..... units
- c. FFP..... units
- d. Plasma, frozen within 24 hours..... units
- e. Jumbo plasma (>400 ml) units
- f. Plasma cryoprecipitate reduced..... units
- g. Pediatric size (100ml) single donor and/or fresh frozen plasma units
- h. Cryoprecipitate AHF transfusion..... units
- i. Cryoprecipitate used for fibrin sealant units

j. Granulocyte unitsunits

C5. Indicate below how many irradiated, leukoreduced, and leukofiltered units of each of the following components your institution transfused, either directly or as a transfusion service for another institution in 2006:

	I. Components irradiated ▼	II. Components leukoreduced before or after storage (not at bedside) ▼	III. Components leukofiltered at the bedside ▼
a. WB/RBCs			
b. Whole blood derived platelets			
c. Apheresis platelets			
d. Other blood component units, including pediatric units			

C6. What percentage of blood usage by your facility went to the following departments in 2006?

- a. surgery - general _____%
- b. orthopedic surgery _____%
- c. cardiac surgery _____%
- d. trauma/ER _____%
- e. oncology _____%
- f. transplantation services _____%
- g. obstetrics/gynecology _____%
- h. pediatrics/neonatology _____%
- i. nephrology/dialysis _____%
- j. hematology _____%

C7. What is the average age of a unit transfused at your institution?

- a. Red blood cells....._____ days Don't know
- b. Whole blood derived platelets....._____ days Don't know
- c. 5 Day apheresis platelets....._____ days Don't know
- d. 7 Day apheresis platelets....._____ days Don't know

Calculated Average Estimate

C8. In 2006, how many therapeutic platelet doses were transfused?

a. As plateletpheresis products....._____doses

b. As whole blood derived platelets....._____doses

If you indicated a quantity above, what is the usual (most common) dosage at your institution of whole blood units from which the dose was derived? [Check one]

< 5 5 6 7 8 9 10 >10

C9. What volume of plasma is most commonly transfused during a single transfusion episode at your institution?

_____ ml

C10. How many grams of IVIG were used by your institution? [Include those issued by the pharmacy in your count.]

_____ grams

C11. What was the average dollar amount your institution paid per unit in 2006 for the following components? [Include discounts in your calculations. A response of \$0 should be entered as "NA" rather than 0.]

	Average amount paid ▼
a. Plasma, frozen within 24 hours of phlebotomy	\$
b. Red cells, leukofiltered	\$
c. Whole blood derived platelets, not leukoreduced, not irradiated	\$
d. Apheresis platelets, leukoreduced	\$
e. Cryoprecipitate	\$
f. Hematopoietic Progenitor Cells – Apheresis	\$
g. Hematopoietic Progenitor Cells – Marrow	\$
h. Hematopoietic Progenitor Cells – Cord	\$

C12. Does your institution have an established “bloodless” surgery program (with a dedicated coordinator)?

- Yes
- No
- Don't Know

C13. Does your hospital use intra-operative autologous blood recovery therapies?

- Yes
- No
- Don't Know

C14. How many days in 2006 was elective surgery postponed due to actual blood inventory shortages?

_____ days

If any, how many surgeries were postponed? [Do not count any single patient's surgery more than once.]

_____ surgeries

C15. On how many days in 2006 was your regular or standing order incomplete?

_____ days

C16. On how many days in 2006 were you unable to meet other non-surgical blood requests (e.g. red cells, platelets)?

_____ days

C17. How many WB/RBC crossmatch procedures were performed at your facility in 2006 by any method?

_____ procedures Don't know

If any:

a. **What percentage of crossmatch procedures performed would you estimate used electronic crossmatch?**

_____ %

b. **What percentage of crossmatch procedures would you estimate were performed serologically?**

_____ %

C18. How many transfusion-related adverse reactions were reported to the transfusion service in 2006? [Count the number of occurrences that required any diagnostic or therapeutic intervention.]

_____ events Don't know

If any events reported, complete the table below indicating how many of these were:

Event Description	# of Occurrences
a. Life threatening, requiring major medical intervention following the transfusion, e.g. vasopressors, blood pressure support, intubation or transfer to the intensive care unit?	
b. Transfusion Related Acute Lung Injury (TRALI)?	
c. ABO incompatibility?	
d. Transfusion Associated Circulatory Overload (TACO)?	
e. Acute Hemolysis?	
f. Delayed Hemolysis?	
g. Post Transfusion Sepsis	
h. Severe Allergic Reactions?	

C19. Do you have an electronic system for tracking events (i.e. unplanned, unexpected, and undesired occurrences)?

- Yes
- No

PLEASE GO TO SECTION D

Section D. Bacterial Testing

D1. Does your institution perform bacteria testing?

Yes → COMPLETE THIS SECTION

No → SKIP TO SECTION E

D2. Indicate what methods are used by your institution to limit/detect bacterial contamination?

[Check the applicable boxes.]

	Culture-Based Testing	Swirling	pH	Glucose	Other	None
a. Apheresis Platelets?						
b. WB Derived Platelets, singly?						
c. WB Derived Platelets, pooled?						

D3. How many confirmed positives and false positives were detected by method in 2006?

Method	Number tested	# Confirmed Positive	# False Positive
a. Culture-based Methods			
b. Alternative Method			

PLEASE GO TO SECTION E

Section E. Special Procedures and Product Disposition

This section should be completed by all respondents.

E1. Does your institution perform therapeutic apheresis procedures?

- Yes
 No → SKIP TO QUESTION E3

E2. How many therapeutic apheresis procedures were performed for the following indications in 2006?

	# of Procedures
a. Thrombotic Thrombocytopenia Purpura (TTP).....	_____
b. Guillain-Barré.....	_____
c. Multiple sclerosis.....	_____
d. Sickle cell disease.....	_____
e. Myasthenia gravis.....	_____
f. Hemochromatosis.....	_____
g. Chronic Inflammatory Demyelinating Polyradiculoneuropathy.....	_____
h. Goodpasture's Syndrome.....	_____
g. Other.....	_____

E3. In 2006, how many autologous and directed units of red cells and whole blood were crossed over to the community supply?

- a. Autologous..... units
b. Directed..... units

E4. How many total units of red cells, O positive red cells, and O negative red cells (allogeneic, non-directed) were outdated in 2006? Include only those units that were outdated while on your shelf. If you transfuse blood, include units outdated at your institution, as well as any other institutions for which you serve as a transfusion service.

- a. All Red Cell Units outdated..... units
b. O pos red cells outdated..... units
c. O neg red cells outdated..... units

E5. How many units in each of the following categories were outdated in 2006? Include only those units that were outdated while on your shelf. If you transfuse blood, include units outdated at your institution, as well as any other institutions for which you serve as a transfusion service.

- a. Whole blood _____ units
- b. Whole blood derived plasma _____ units
- c. Apheresis plasma _____ units
- d. Whole blood derived platelets _____ units
- e. Apheresis platelets _____ units
- f. Cryoprecipitate _____ units
- g. Directed units _____ units
- h. Autologous units _____ units

E6. At your facility, how many units of group O red cells do you use or ship on an average day?

_____ units

E7. What is the average number of units in your hospital's emergency trauma inventory (O positive and O negative units)?

_____ units N/A

E8. At your facility, what is the maximum number of units of group O positive and group O negative red cells in uncrossmatched inventory considered to be "critically low"?

_____ units

E9. At your facility, what is the minimum number of units of group O positive and group O negative red cells in uncrossmatched inventory considered to be "ideal"?

_____ units

PLEASE GO TO SECTION F

Section F. Cellular Therapy Products

Please give this section to the appropriate cellular therapy collection or laboratory personnel to complete!

F1. Does your institution collect, process, issue, or infuse hematopoietic progenitor cells (HPCs) or other cell therapy (CT) products?

- Yes → COMPLETE THIS SECTION
 No → SKIP TO SECTION G


F2. Choose which of the following best describes your program. Is your program a:

- Blood center performing HPC collections only
 Blood center.....collecting and processing and/or storing HPCs
 HPC collection facility within hospital
 HPC collection, processing, and storage facility within hospital
 Cord Blood collection facility only
 Other, please describe _____

OR

- Cord Blood processing/storage facility only (SKIP TO QUESTION F4)
 HPC processing/storage facility within hospital (SKIP TO QUESTION F4)

F3. Do you collect products for third party vendors (including cord blood banks NMDP, and other suppliers of cellular therapy products)?

- Yes
 No
- 

If yes, how many did you collect in 2006? [Check appropriate boxes below.]

	HPC-A Hematopoietic progenitor cells- Apheresis	HPC-M Hematopoietic progenitor cells - Marrow	HPC-C Hematopoietic progenitor cells - Cord	Other
<10 per year				
10-100 per year				
100-500 per year				
>500 per year				

F4. Are any CT products at your facility used for cardiology applications?

- Yes
- No
- Don't Know

F5. Does your program collect cord blood?

- Yes
- No

↓

Is your cord blood collected by:

- A nurse midwife/obstetrician
- Dedicated cord blood bank collector

F6. How many of each of the following product types were collected/processed at your institution in 2006? [For purposes of the survey, autologous cord blood refers to familial use in 1st or 2nd degree relatives]

	I.		II.
	COLLECTED		PROCESSED*
	Autologous ▼	Allogeneic ▼	<u>*See Glossary</u> ▼
a. Peripheral blood progenitor cell collections (HPC-A)			
b. Bone marrow collections (HPC-M)			
c. Cord blood collections (HPC-C)			
d. Donor Lymphocyte infusion (or unmanipulated non-mobilized peripheral blood mononuclear cells)			
e. Hematopoietic stem/progenitor cells, expanded			
f. Immunotherapies (natural killer cells, dendritic cells, T cells, other)			
g. Nonhematopoietic stem cells (mesenchymal stem cells (or multipotent stromal cells per ISCT recommendations), other)			
h. Other products			

F7. Indicate the number of infusion episodes and the number of patient recipients of cell therapies by product type at your institution in 2006. [For purposes of the survey, autologous cord blood refers to familial use in 1st or 2nd degree relatives]

	I. Autologous Infusions		II. Allogeneic Infusions	
	Total # of episodes ▼	Total # of patients ▼	Total # of episodes ▼	Total # of patients ▼
a. Peripheral blood progenitor cell products (HPC-A)				
b. Bone marrow products (HPC-M)				
c. Cord blood products (HPC-C)				
d. Donor Lymphocyte infusion(or unmanipulated non-mobilized peripheral blood mononuclear cells)				
e. Hematopoietic stem/progenitor cells, expanded				
f. Immunotherapies (natural killer cells, dendritic cells, T cells, other)				
g. Nonhematopoietic stem cells (mesenchymal stem cells (or multipotent stromal cells per ISCT recommendations) other)				
h. Other Products				

PLEASE GO TO SECTION G

Section G. Human Tissue

G1. Does your institution maintain an inventory of, or use human tissue for transplantation?

- Yes
- No → SKIP TO END

G2. What department(s) are responsible for ANY OPERATIONAL ASPECT OF HANDLING Human Tissue (i.e. ordering, receiving, storage, tracking, and/or issuance)? [Check all that apply]

- Operating Room
- Blood Bank
- Laboratory Medicine/Pathology
- Hospital in-house Tissue Bank
- Infection Control
- Cardiology
- Orthopedics
- Dermatology
- Ophthalmology
- Specialty Dept, Other

G3. What SINGLE department has the MOST responsibility for Human Tissue (i.e. ordering, receiving, storage, tracking, and/or issuance)? [Check only one]

- Operating Room
- Blood Bank
- Laboratory Medicine/Pathology
- Hospital in-house Tissue Bank
- Infection Control
- Cardiology
- Orthopedics
- Dermatology
- Ophthalmology
- Specialty Dept, Other

G4. In 2006, what was the total number of human tissue implants/grafts that your facility:
[Consult with Specialty Departments, if necessary, e.g. Orthopedics/ Dermatology/
Ophthalmology.]

- a. Used/implanted?..... _____
- b. Discarded? _____
- c. Returned?..... _____

G5. Do you maintain an inventory of human skin?

- Yes
 No

What was your average daily inventory of human skin in 2006?

_____ square feet

G6. In 2006 how many adverse events have been associated with human tissue implants/grafts?

_____ events

G7. If available: [Please direct to the appropriate department e.g.: risk management, quality assurance, etc.]

- a. **How many adverse events were related to viral transmission?** _____ events
b. **How many adverse events were related to bacterial infection?** _____ events
c. **How many adverse events were related to structural failure?** _____ events

Thank you very much for your help!

Please return the questionnaire in the enclosed postage-paid envelope.

**AABB
8101 Glenbrook Road Ste 1
Bethesda, MD 20814-9805**

Survey Glossary

Autologous: self-directed donations.

Collected: successful whole blood or apheresis collections placed into production (not QNS, or other removals).

Community: in this survey refers to those allogeneic donations not directed to a specific patient.

Directed: allogeneic donations intended for a specific patient.

Dose/Dosage: a quantity administered at one time, such as a specified volume of platelet concentrates.

Episode or Infusion Episode: infusion of one product type (e.g., peripheral blood stem cells) to a patient/recipient. The infusion episode may involve infusion of one or more containers of that product type.

FFP: fresh frozen plasma.

First time donor: first time at your center

Modify: used in this survey to refer to procedures applied by a blood center, hospital blood bank, or transfusion service that may affect the quality or quantity of the final product (e.g. irradiation, leukofiltration, or production of aliquots of lesser volume).

Plasma, frozen within 24 hours of phlebotomy: plasma separated from the blood of an individual donor and placed at -18°C or colder within 24 hours of collection from the donor. Sometimes also referred to as **FP24**.

Plasma, Jumbo: for the purposes of this survey FFP having a volume greater than 400 ml.

Processed: subjected, after collection, to any manipulation or storage procedure. One cellular therapy product can be divided and processed in more than one way and would be counted as one collection but as two or more products processed.

Released for Distribution: units that have fulfilled all processing requirements and are released for transfer to customers.

Severe Donor Adverse Events: adverse events occurring in donors attributed to the donation process that include, for example, major allergic reaction, arterial puncture, loss of consciousness of a minute or more, loss of consciousness with injury, nerve irritation, etc.

Source Plasma: the fluid part of human blood collected by plasmapheresis and intended as source material for further manufacturing use.

Transfusion Service: a facility that performs, or is responsible for the performance of, the storage, selection, and issuance of blood and blood components to intended recipients.

Tissue issuance: release of human tissue within a medical facility or institution.

Tissue recovery: the act of obtaining human cells and/or tissues intended for use in clinical implantation, transplantation, infusion, or transfer.

Tissue storage: the maintenance of human cells and tissue for future use.