

Preservation of a Safe & Adequate Blood Supply



Special Thanks — Bay Area Donor Centers

UCSF



**American
Red Cross**

**STANFORD
BLOOD CENTER**



Give blood for life!



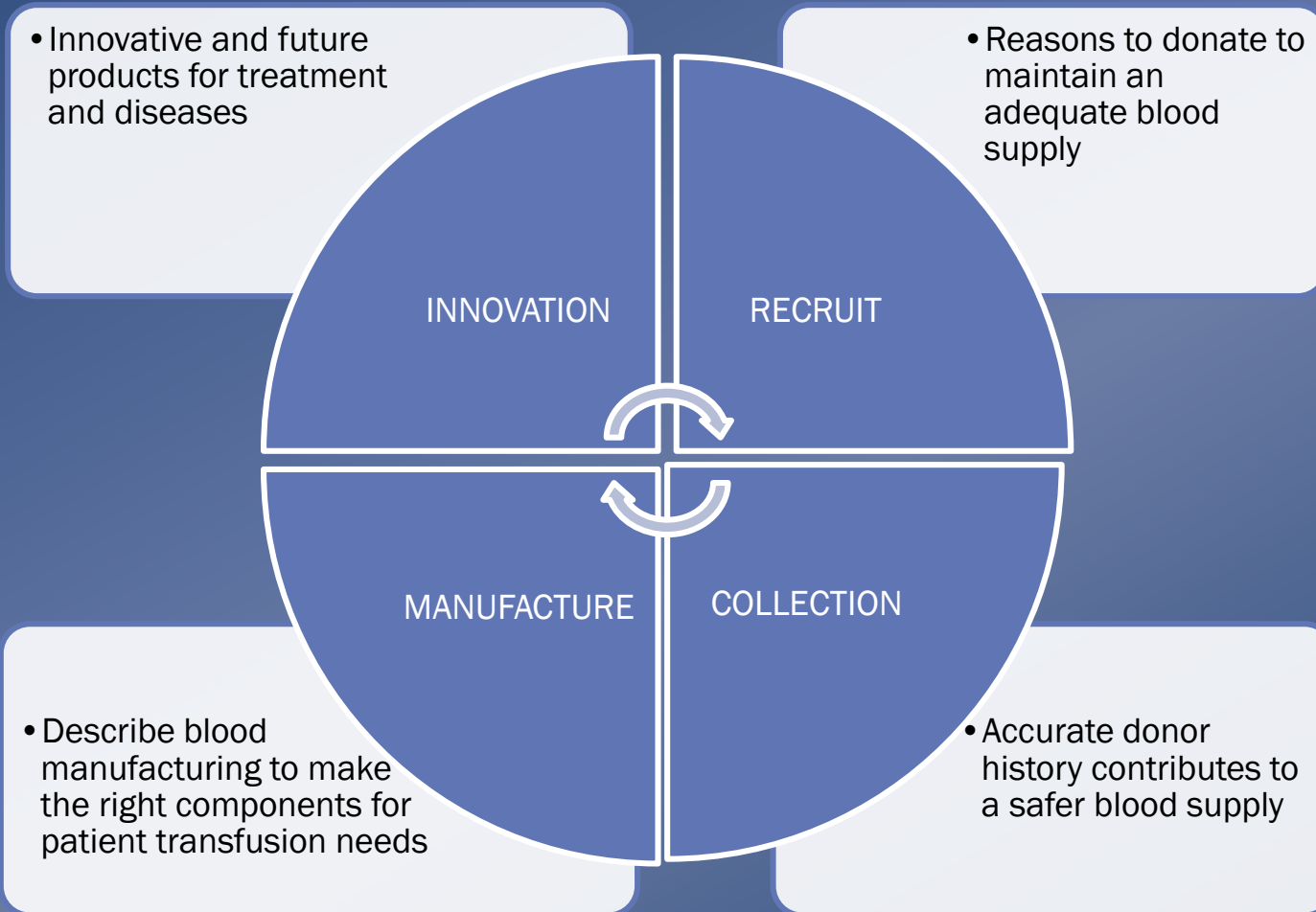
Transform a life,
and your own.
Give Blood.

vitalant 

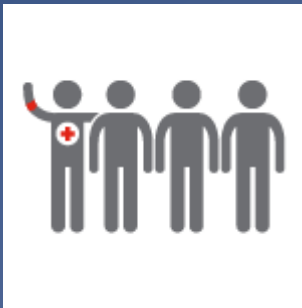
Goodies



OBJECTIVES



Donation Facts



1 donation
can
potentially
**save up to 3
lives**



Every **2
seconds**
someone in
the U.S.
needs blood



Estimated 38%
of the U.S.
population *is*
eligible to
donate *but*
**<10% do so
annually**



Blood **cannot
be
manufactured**,
it can only be
donated.

Blood Usage in the U.S.

☞ Daily usage in the U.S.

- Approximately 36,000 units of red blood cells. Average red cell transfusion is approximately 3 units.
- Nearly 7,000 units of platelets.
- Around 10,000 plasma.

☞ Sickle cell disease

- Affects 90-100,000 people in the U.S.
- Sickle cell patients can require blood transfusions throughout their lives.

☞ According to the American Cancer Society, about 1.7 million people are expected to be diagnosed with cancer in 2017.

- Many will need blood, sometimes daily, during their chemotherapy treatment.

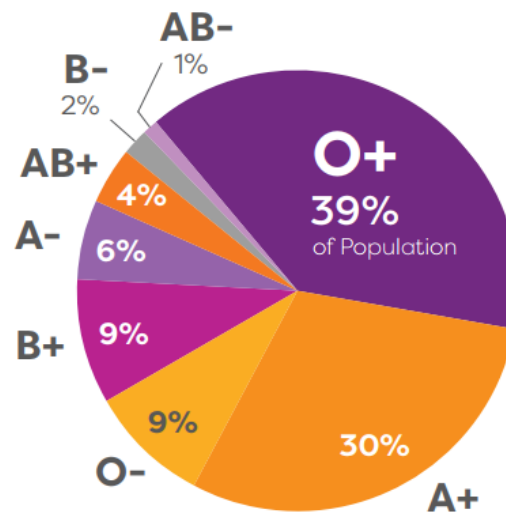
Donation Facts

THE HUMAN BLOOD TYPES

Blood is grouped into four types:

A, B, AB & O

Each type is also classified by an Rh factor—either positive or negative. Your ABO blood grouping and Rh factor are inherited from your parents.

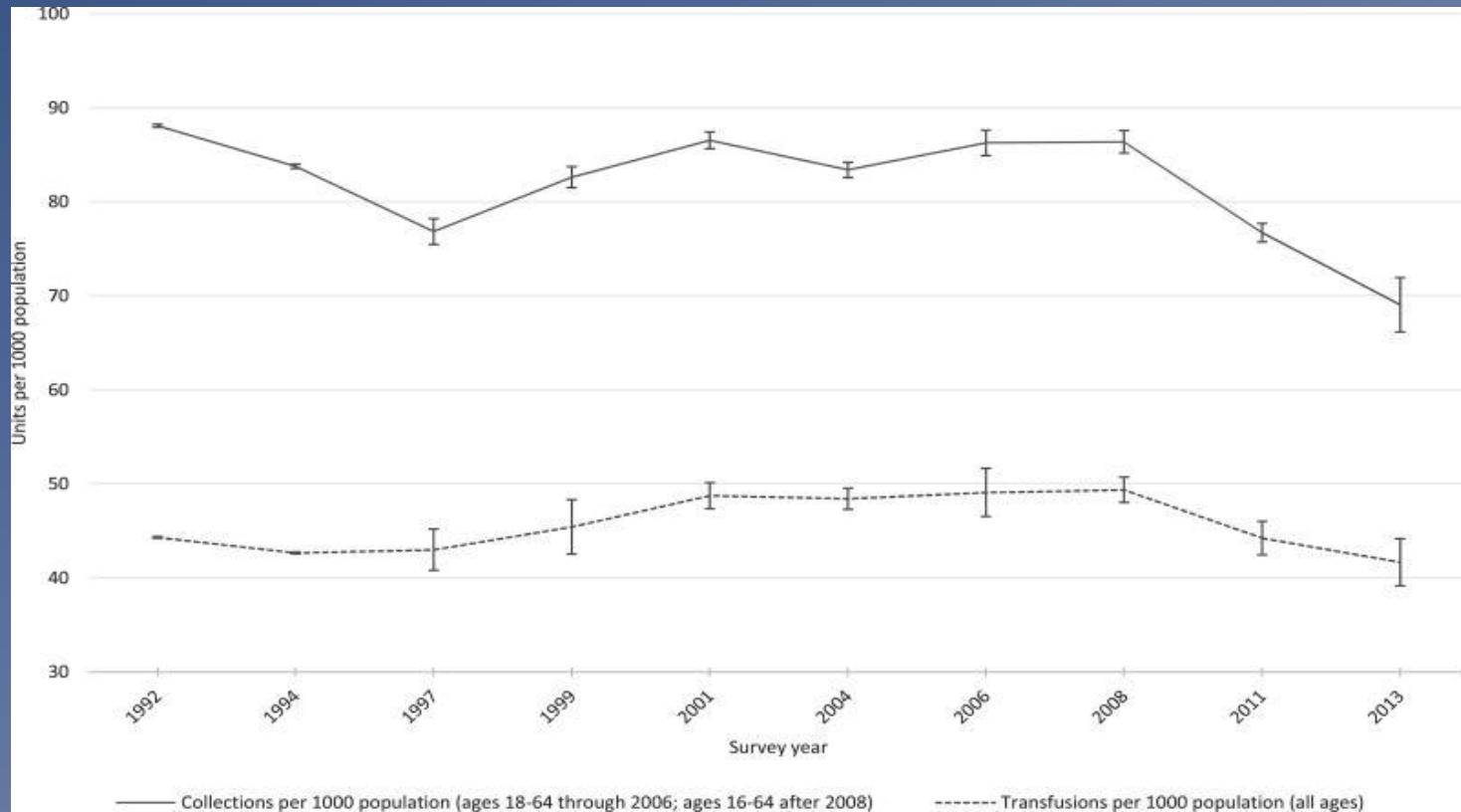


Universal RBC Donor :
Type O

Universal Plasma Donor :
Type AB

Collection-Transfusion Trend

AABB 2013 Survey Study



Downward trend for blood collections and

Transfusion

- Patient Needs (hospital)
- Industry Needs (biotechnology)

Manufacture

- Product availability

Donation

- Donor Blood Type
- Donor Donation Type

**Right Type
at the
Right Time**

Right Type at the Right Time - Action

Inventory	Production	Distribution																																																																													
<ul style="list-style-type: none"> Daily huddles Determine customer needs Determine availability 	<ul style="list-style-type: none"> Daily production orders 	<ul style="list-style-type: none"> Determine allocations 																																																																													
<table border="1"> <thead> <tr> <th colspan="7">Inventory</th> </tr> <tr> <th>RBC</th> <th colspan="2">SF</th> <th colspan="2">NB</th> <th colspan="2">SB</th> </tr> <tr> <th></th> <th>Stock</th> <th>Min</th> <th>Stock</th> <th>Min</th> <th>Stock</th> <th>Min</th> </tr> </thead> <tbody> <tr> <td>O+</td> <td>150</td> <td>200</td> <td>40</td> <td>50</td> <td>20</td> <td>20</td> </tr> <tr> <td>O-</td> <td>38</td> <td>50</td> <td>15</td> <td>15</td> <td>2</td> <td>2</td> </tr> <tr> <td>A+</td> <td>140</td> <td>150</td> <td>30</td> <td>30</td> <td>25</td> <td>10</td> </tr> <tr> <td>A-</td> <td>30</td> <td>40</td> <td>10</td> <td>10</td> <td>2</td> <td>2</td> </tr> <tr> <td>B+</td> <td>25</td> <td>30</td> <td>6</td> <td>6</td> <td>2</td> <td>2</td> </tr> <tr> <td>B-</td> <td>12</td> <td>20</td> <td>2</td> <td>2</td> <td>0</td> <td>0</td> </tr> <tr> <td>AB+</td> <td>8</td> <td>10</td> <td>2</td> <td>2</td> <td>0</td> <td>0</td> </tr> <tr> <td>AB-</td> <td>8</td> <td>10</td> <td>2</td> <td>2</td> <td>0</td> <td>0</td> </tr> </tbody> </table>	Inventory							RBC	SF		NB		SB			Stock	Min	Stock	Min	Stock	Min	O+	150	200	40	50	20	20	O-	38	50	15	15	2	2	A+	140	150	30	30	25	10	A-	30	40	10	10	2	2	B+	25	30	6	6	2	2	B-	12	20	2	2	0	0	AB+	8	10	2	2	0	0	AB-	8	10	2	2	0	0	<div style="border: 1px solid gray; padding: 10px;"> <p><i>Friday (2/28/20)</i> Production:</p> <p><i>O- : First 5 CPDA-1 RBC</i></p> <p><i>A-, B-, O- : RBC, FP24</i></p> <p><i>O+, B+, Unk: RBC, FP24</i></p> <p><i>A+ : RBC, RP</i></p> <p><i>AB+, AB- : RBC, FFP</i></p> </div>	<ul style="list-style-type: none"> STAT Orders ASAP Orders Stock Orders
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AB+	8	10	2	2	0	0																																																																									
AB-	8	10	2	2	0	0																																																																									

Right Type Collected to Produce the Right Products at the Right Time

Inventory

Inventory							
RBC	SF		NB		SB		
	Stock	Min	Stock	Min	Stock	Min	
O+	150	200	40	50	20	20	
O-	38	50	15	15	2	2	
A+	140	150	30	30	25	10	Transfer 10 A+ from SB to SF
A-	30	40	10	10	2	2	
B+	25	30	6	6	2	2	
B-	12	20	2	2	0	0	
AB+	8	10	2	2	0	0	
AB-	8	10	2	2	0	0	
FP24/FFP							
	SF		NB		SB		
	Stock	Min	Stock	Min	Stock	Min	
O	220	200	40	50	15	15	Transfer 10 O FFP/FP24 from SF to NB
A	200	150	50	40	15	10	
B	50	100	30	20	5	5	
AB	125	150	10	10	2	2	
Platelets							
	SF		NB		SB		
	Stock	Min	Stock	Min	Stock	Min	
O	55	60	8	8	1	2	Transfer 1 Plt (O) from NB to SB
A	42	60	8	4	0	0	
B	8	10	4	1	0	0	
AB	2	2	0	0	0	0	

Production

Friday (2/28/20)

Production:

O- : First 5 CPDA-1 RBC

A-, B-, O-: RBC, FP24

O+, B+, Unk: RBC, FP24

A+ : RBC, RP

AB+, AB- : RBC, FFP

Questions?

UCSF

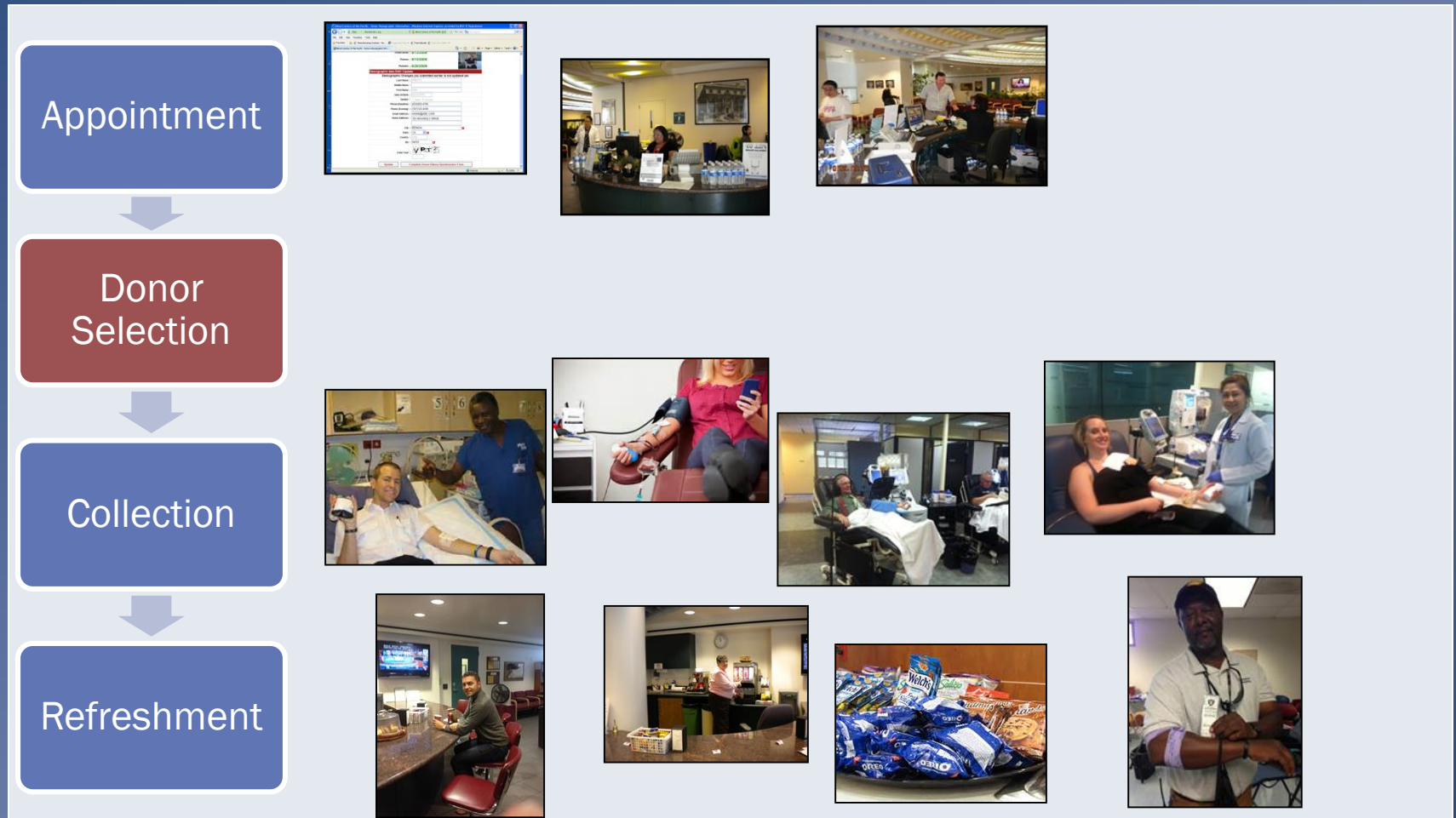


Donor Selection Criteria

- Protects the Recipient
- Protects the Donor



Donation Process



Donor Selection

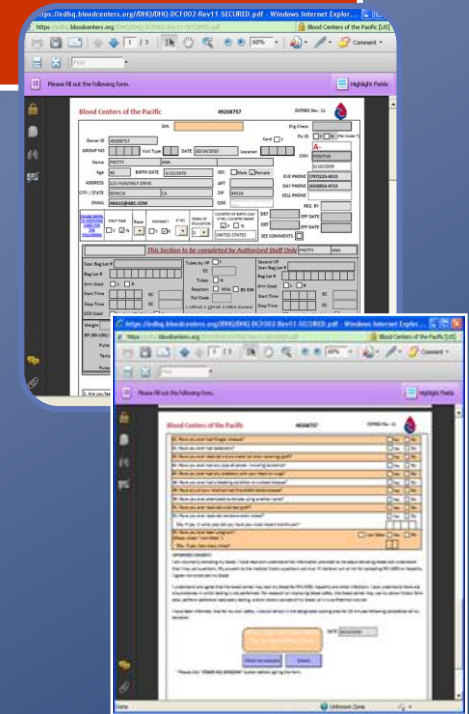
Registration



Physical



Donor History Questionnaire



Information & Instructions for Your Blood Donation



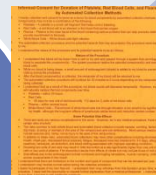
Use of Donor Information & Blood Samples in Research



Educational Material

Medication Deferral List

Informed Consent for Donations



∞ Donor Criteria regulated by:

- Food & Drug Administration (FDA)
- State of California
- American Association of Blood Banks (AABB)
- Local school districts



Donor Demographics

☞ Full name

☞ Address

☞ Phone

☞ E-Mail

☞ Picture ID

☞ Donor ID (Collection Institution)



Pre-Donation Eligibility

Required Day of Donation:

- Age: ≥ 16 years
16 years with parent consent
 ≥ 17 years without parent consent
- Weight: ≥ 110 lbs
- Blood Pressure (BP): Systolic (90-180)
Diastolic (50-100)
- Pulse: 50-100
- Temperature: $\leq 99.5^{\circ}\text{F}$ or $\leq 37.5^{\circ}\text{C}$
- RBC/Iron Indicator: Female: ≥ 12.5 g/dL (Hgb) or $\geq 38\%$ (Hct)
Male: ≥ 13.0 g/dL (Hgb) or $\geq 39\%$ (Hct)

Donation Intervals

☞ Whole Blood (WB)	8 weeks
☞ Double Reds (2RBC)	16 weeks
☞ Platelets (Pheresis)	7 days
☞ Plasma (Pheresis)	28 days

Aspirin

Question:

☞ In the past 48 hours, have you taken aspirin or anything that had aspirin in it?

- ☞ Platelet donor: Defer 48 hours*
- ☞ Whole Blood: Acceptable*



General Health

Question:



☞ *Are you feeling healthy and well today?*

☞ Headache without fever and feels well enough to donate?

☞ Allergies and feels well enough to donate?

Female Donors - Pregnancy



Question:

- ☞ *Female donors: In the past 6 weeks have you been pregnant or are you pregnant now?*
- ☞ Defer while pregnant
- ☞ Defer for 6 weeks following a term or third trimester delivery

Respiratory

Question:

☞ *Have you ever had any problems with your heart or lungs?*

Heart	Acceptable 1 year after asymptomatic and no medication for <ul style="list-style-type: none">• heart attack• angioplasty• angina• bypass surgery
Lung	Acceptable if asymptomatic

☞ Donors must be free of acute respiratory disease

Cancer

Question:

☞ *Have you ever had any type of cancer, including leukemia?*

Cancer	Deferral
<ul style="list-style-type: none">• leukemia• lymphoma• hodgkin's	Defer Permanently
<ul style="list-style-type: none">• basal cell• squamous cell• cervical• melanoma	Defer 1 year from completion of treatment

Current Infections



Questions:

- Are you currently taking an antibiotic?*
- Are you currently taking any other medication for infection?*
- Defer until last dose taken and no symptoms of infection.
- Prophylactic: Acceptable
- For acne: Acceptable except Accutane



Medication Deferral List

Question:

Are you now taking or have you ever taken any medications on the Medication Deferral List?

Trade Name	Drug	Deferral
Warfarin, Heparin	Anti-coagulants	<ul style="list-style-type: none">• Depends on reason• Verify with list or MD
	Anti-fungal	Acceptable
	Anti-hypertensive	Acceptable if BP meets standard
Accutane	Isotretinoin	Defer 1 month after last dose
Avodart	Dutasteride	Defer 6 months after last dose
Propecia, Proscar	Finasteride	Defer 1 month after last dose
Soriatane	Acitretin	Defer 3 years after last dose
Tegison	Etretinate	Defer Permanently

Vaccinations



Question:

- ☞ *In the past 8 weeks, have you had any vaccinations or other shots?*
- ☞ Receipt of live attenuated viral or bacterial vaccines – deferral period
- ☞ Receipt of toxoids, synthetic, or killed viral or bacterial vaccines – no deferral



Vaccinations — Live Virus

Vaccine	Type	Deferral
Hepatitis B	Live attenuated virus	Defer 1 week
Measles (rubeola)	Live attenuated virus	Defer 2 weeks
Rabies (no exposure)	Live attenuated virus	Defer 2 weeks
Chicken Pox (varicella zoster)	Live attenuated virus	Defer 4 weeks
German Measles (rubella)	Live attenuated virus	Defer 4 weeks
Shingles (zostavax)	Live attenuated virus	Defer 4 weeks
Rabies (after rabid animal bite)	Exposure to virus	Defer 1 year
Unlicensed Vaccine	Exposure unknown	Defer 1 year
HIV	Exposure to virus	Permanently

Vaccinations – Toxoid, Synthetic, Killed



Vaccine	Type	Deferral
Diphtheria	Toxoid, synthetic, killed	Acceptable
Hepatitis A	Toxoid, synthetic, killed	Acceptable
Influenza	Toxoid, synthetic, killed	Acceptable
Lyme Disease	Toxoid, synthetic, killed	Acceptable
Meningococcal	Toxoid, synthetic, killed	Acceptable
Pertussis	Toxoid, synthetic, killed	Acceptable
Pneumococcal	Toxoid, synthetic, killed	Acceptable
Polio (injection)	Toxoid, synthetic, killed	Acceptable
Rocky Mt Spotted Fever	Toxoid, synthetic, killed	Acceptable
Tetanus	Toxoid, synthetic, killed	Acceptable
Typhoid (injection)	Toxoid, synthetic, killed	Acceptable

Smallpox

Question:

- ☞ *In the past 8 weeks, have you had contact with someone who had a smallpox vaccination?*
- ☞ *Localized lesions?*
- ☞ *Scab spontaneously fell off?*



Minimize Transfusion Transmitted Disease

12 month deferral

UCSF

Questions:

- ☞ *In the past 12 months, have you had a blood transfusion?*
- ☞ *In the past 12 months, have you had a transplant such as organ, tissue or bone marrow?*
- ☞ *In the past 12 months, have you had a graft such as bone or skin?*
- ☞ *In the past 12 months, have you come in contact with someone else's blood?*
- ☞ *In the past 12 months, have you had an accidental needle-stick?*

- ☞ **Defer 12 months from event**
 - Transfusions: Autologous, Albumin and/or Plasma Protein acceptable
 - Organ/Graft: Autologous, Synthetic or Non-human acceptable

High Risk Activities: HIV Transmission

12 month deferral

UCSF

Questions:

- ☞ In the past 12 months, have you had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?*
- ☞ In the past 12 months, have you had sexual contact with a prostitute or anyone who takes money or drugs or other payment for sex?*
- ☞ In the past 12 months, have you had sexual contact with anyone who has ever used needles to take drugs or steroids or anything not prescribed by their doctor?*
- ☞ Defer 12 months from event*

High Risk Activities: HIV Transmission

12 month deferral

UCSF

Questions:

- ☞ *In the past 12 months, have you had sexual contact with anyone who has hemophilia or has used clotting factor concentrates?*
- ☞ *Female donors: In the past 12 months, have you had sexual contact with a male who has ever had sexual contact with another male?*

- ☞ **Defer 12 months from event**



High Risk Activities: Hepatitis Transmission

12 month deferral

UCSF

Questions:

- ☞ *In the past 12 months, have you had sexual contact with a person who has hepatitis?*
- ☞ In the past 12 months, have you lived with a person who has hepatitis?

- ☞ Defer 12 months from event



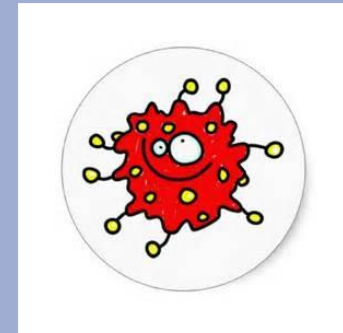
STD Transmission

12 month deferral

UCSF

Question:

☞ *In the past 12 months, have you had or been treated for syphilis or gonorrhea?*



☞ **Defer 12 months from completion of therapy**

High Risk Behavior

12 month deferral

UCSF

Question:

- ☞ *In the past 12 months, have you had a tattoo?*
- ☞ *In the past 12 months, have you had ear or body piercing?*
- ☞ *In the past 12 months, have you been in juvenile detention, lockup, jail or prison for more than 72 hours?*

- ☞ **Defer 12 months from event**
 - **Tattoo and Piercings: Acceptable if performed using single-use equipment**
- ☞ **Defer 12 months from correctional facility release**

Transfusion-Transmitted Disease: Malaria, Leishmania, etc.

Question:

☞ *In the past 3 years, have you been outside the United States or Canada?*

☞ Endemic areas: defer 12 months from departure



Transfusion Transmitted Disease: Creutzfeldt-Jacob Disease (CJD)



Defer Permanently

UCSF

Questions:

- ☞ *From 1980 through 1996, did you spend time that adds up to three (3) months or more in the United Kingdom?*
- ☞ *From 1980 through 1996, were you a members of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military?*
- ☞ *From 1980 to the present, did you spend time that adds up to five (5) years or more in Europe?*
- ☞ *From 1980 to the present, did you receive a blood transfusion in the United Kingdom or France?*

- ☞ **Defer Permanently**

Transfusion Transmitted Diseases

Defer Permanently

UCSF

Questions:

- ☞ Have you ever had hepatitis?*
- ☞ Have you ever had malaria?*
- ☞ Have you ever had Chagas' disease?*
- ☞ Have you ever had babesiosis?*

- ☞ Defer Permanently*



High Risk Activity : Transmission of Infectious Diseases

Defer Permanently

UCSF

Questions:

- ☞ *From 1977 to the present, have you received money, drugs or other payment for sex?*
- ☞ *Male donors: From 1977 to the present, have you had sexual contact with another male, even once?*
- ☞ *Have you ever had a positive test for HIV / AIDS virus?*
- ☞ *Have you ever used needles to take drugs, steroids, or anything not prescribed by your doctor?*

High Risk Conditions

Defer Permanently

UCSF

Questions:

- ☞ *Have any of your relatives had Creutzfeldt-Jakob disease?*
- ☞ *Have you ever received a dura mater (brain covering) graft?*
- ☞ *Have you ever had a bleeding condition or a blood disease?*
- ☞ *Have you ever used clotting factor concentrates?*
- ☞ **Defer Permanently**

Other reasons for Deferral:

The collection blood bank's Medical Director and associated staff physicians retain final authority on all matters concerning medical questions, standards and procedures.





Questions?

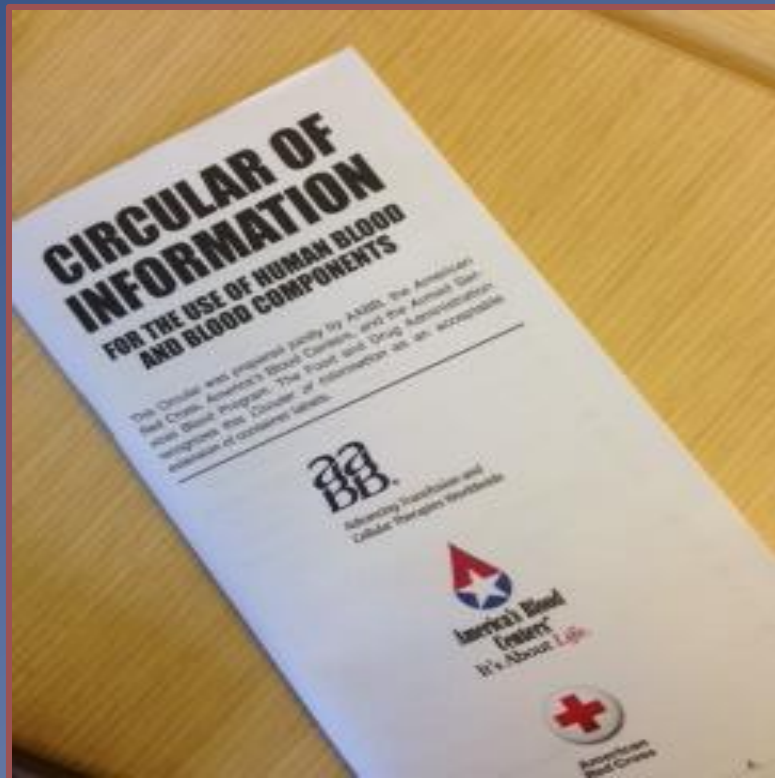
Blood Components and Therapy



Code of Federal Regulations (CFR)

Prescription Drug Regulations

Circular of Information



Blood Component Label

Presented by United Blood Services

Unique Donor Identification Number
W 1234 07
COUNTRY FACILITY YEAR

23456 **Z**
UNIQUE IDENTIFIER PROCESS CONTROL CHECK DIGIT

Black and White Print Only

Blood Type Bar Code

Expiration Date
22 Jan 2007
2 DIGIT DAY 3 LETTER MONTH 4 DIGIT YEAR

Collection Facility, Registration Number and License Number
BLOOD SYSTEMS
Scottsdale, AZ 85257
FDA Registration Number 2071464
US License Number 183

Special Testing Information
AB
Rh POSITIVE

Name of Facility that modifies original product
Special Testing Label goes here

Descriptive Product Code
E0316V00 0070222359
RED BLOOD CELLS
ADENINE SALINE (AS - 1) ADDED
From 500 mL CPD Whole Blood
Store at 1 to 6 C
Further Processing By label can be Placed here

18A04R1424 OM96B28044

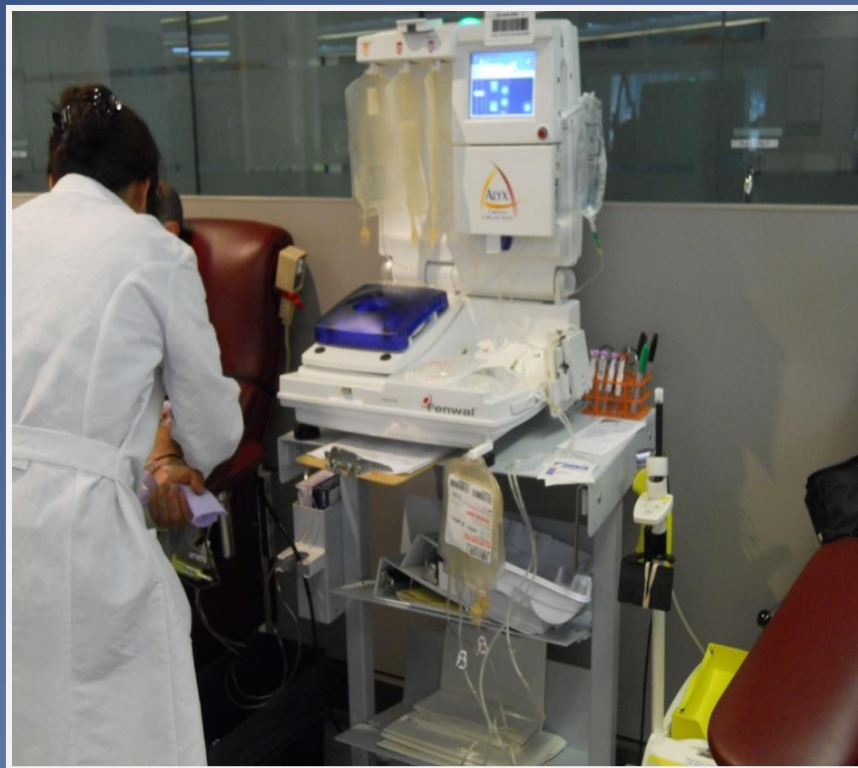
PRODUCT DESCRIPTION DONATION TYPE DIVISION TYPE
0316 V 00

Whole Blood Collections



Automated Collections

2RBC – Power Reds



Platelet/Plasma/RBC



Donation Types

AUTOLOGOUS

- ☞ Donate for self
 - Treat surgical blood loss
 - Compatible allogeneic blood is not available
- ☞ 30-50% Not Used; Unable to cross-over to the community
- ☞ Types:
 - Preoperative
 - Acute Normovolemic hemodilution
 - Intraoperative
 - Postoperative

DIRECTED

- ☞ Donate for a specific patient
- ☞ If blood relative, unit must be irradiated to prevent Graft-Versus-Host Disease (GVHD)
- ☞ Requirements are same as allogeneic donations
- ☞ Additional administrative cost
- ☞ Potential set-up for obligated donation

ALLOGENEIC

- ☞ Donate for the community
- ☞ 4.5 million Americans would die each year without life saving blood transfusions
- ☞ 38% of the US is eligible to donate, but less than 10% do on a yearly
- ☞ AB is the universal recipient and O is the universal donor

Centrifugation:



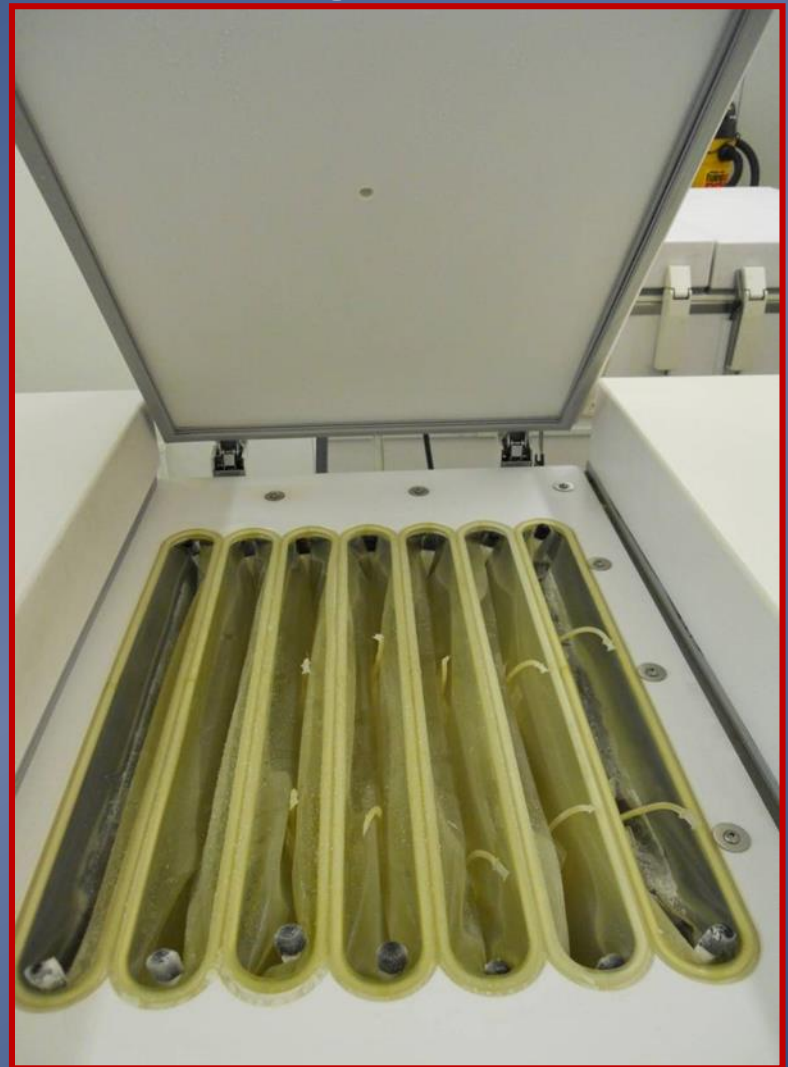
Separation:



Gravitational Separation:

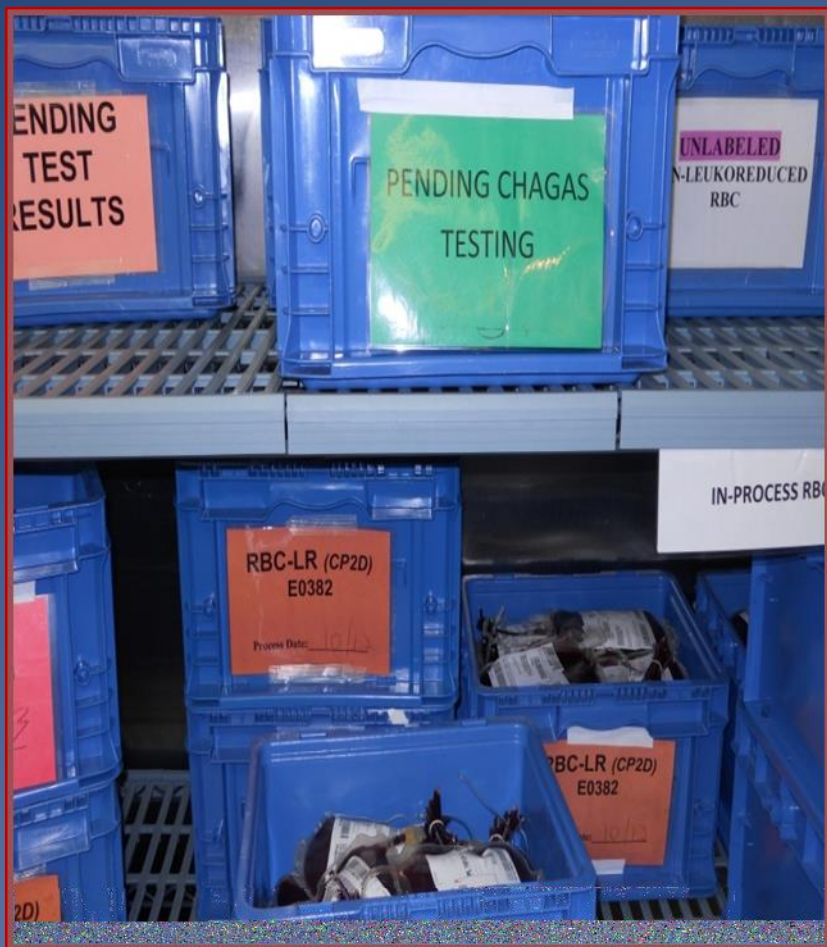


Blast Freezing:



STORAGE

Walk-In Refrigerator:



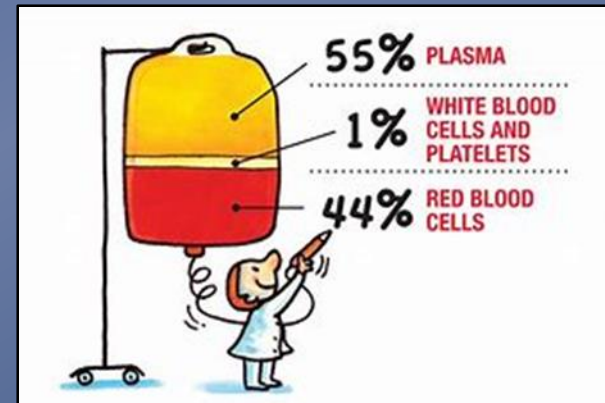
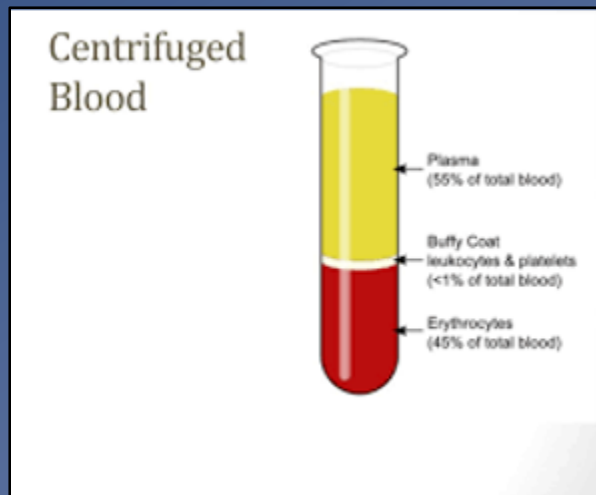
Walk-In Freezer:



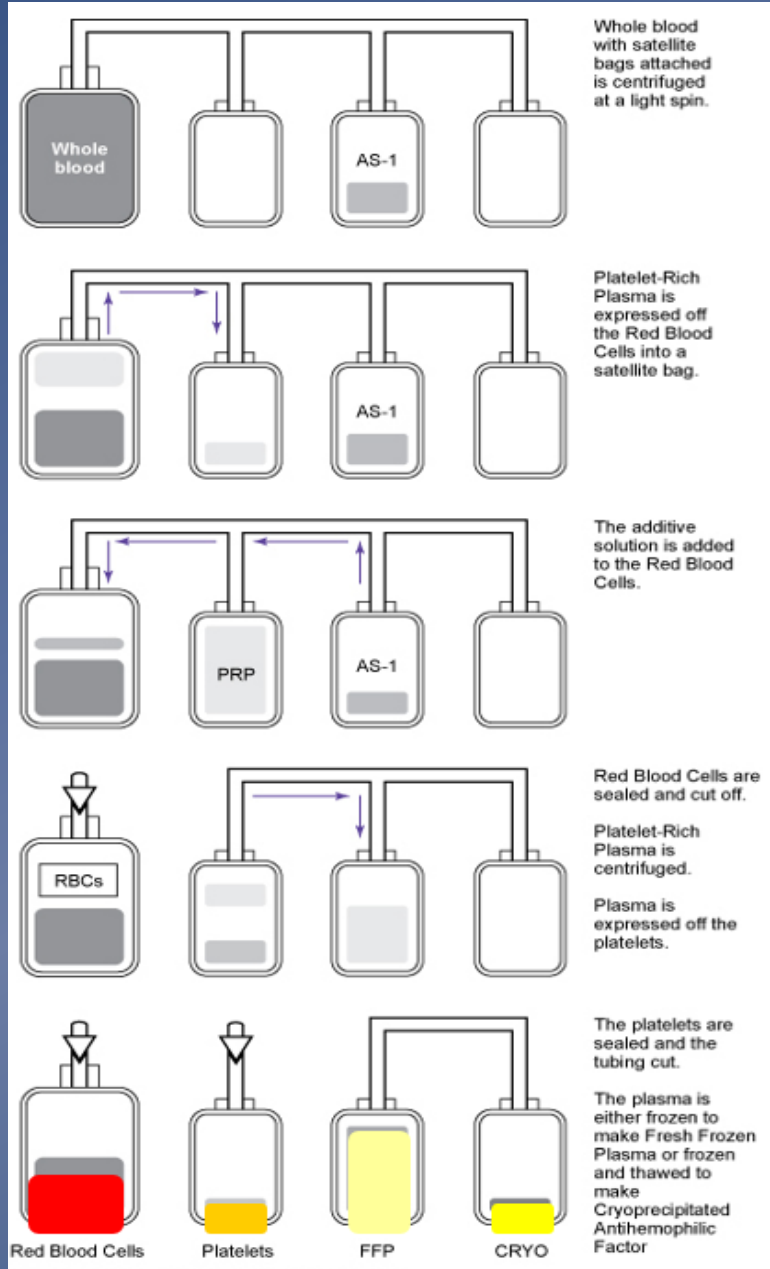
Component Manufacturing

- ∞ Produces blood components to specifically treat patients with product needs
- ∞ Allows optimum survival of each component
- ∞ Transfuse only component needed

Centrifuged Blood



Whole Blood Component Production

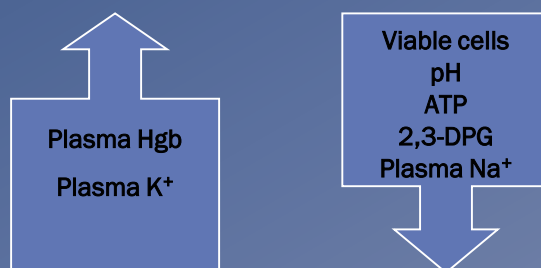


Red Cell Storage

∞ Shelf-Life = Expiration Date

- At least 75% of transfused cells remain in circulation 24 hours after transfusion.

∞ Storage Lesion = Biochemical changes which occur in 1-6 °C

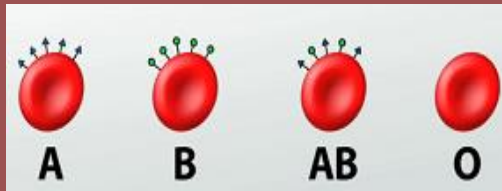


∞ Storage Period

- ACD, CPD, CP2D – 21 days
- CPDA-1 – 35 days

∞ Storage Temperature – 1-6 °C

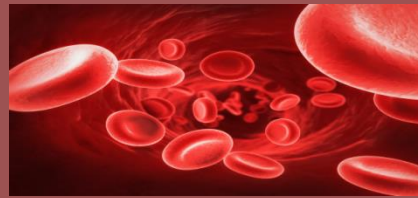
Whole Blood (WB)



- Content – Contains red cells, white cells and platelets suspended in plasma
- Indication – Symptomatic anemia with large volume deficit; trauma, shock, exchange transfusion
- Rarely used today, platelet non-functional, labile coagulation factors gone
- Must be ABO identical
- Storage Period
 - ACD, CPD, CP2D – 21 days
 - CPDA-1 – 35 days
- Storage Temperature – 1-6 °C
- Dosage (Adult 70 Kg) – 1 WB, hct 3% or hgb 1 g/dl



Red Blood Cells (RBC)



- ∞ Content – Red cells
- ∞ Indication – Symptomatic anemia; supports routine blood loss during surgery
- ∞ Storage period
 - ACD, CPD, CPD2 – 21 days
 - CPDA-1 – 35 days
 - Additive – 42 days
 - Note – If the seal is broken during processing, RBCs must be transfused within 24 hours and new expiration date and time must be on the label and in the records
- ∞ Storage Temperature – 1-6 °C
- ∞ Dosage (Adult 70 Kg) – 1 RBC, hct 3% or hgb 1 g/dl



Red Blood Cells, Leukocytes Reduced (RBC-LR)

- ∞ Content – Red cells, white cells reduced
- ∞ Indication – Symptomatic anemia, febrile reactions from leukocyte (WBC) antibodies
- ∞ Reduces reactions to WBC – cytokines, granulocyte antigens, micro aggregates and fragmentation
- ∞ May be considered CMV safe blood
- ∞ May be leukoreduced at collection, production or bedside
- ∞ Storage period
 - CPDA-1 – 35 days
 - Additive – 42 days
- ∞ Storage Temperature – 1-6 °C
- ∞ Dosage (Adult 70 Kg) – 1 RBC, hct 3% or hgb 1 g/dl



Rejuvenated Red Blood Cells

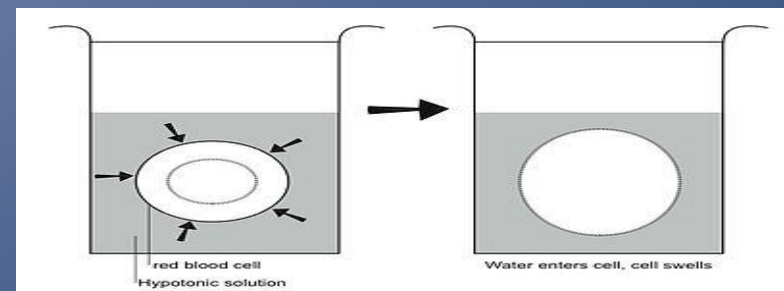
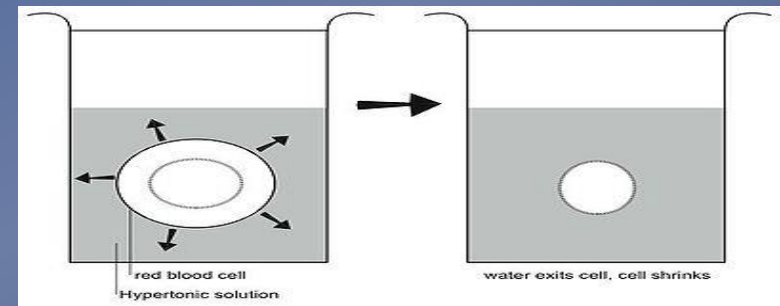
- ⌘ Content – Special solution added to expired RBCs up to 3 days after expiration to restore 2,3-DPG and ATP levels to pre-storage values.
- ⌘ Indication – Generally to extend the life of expired red cells for rare blood usage and/or freezing for storage
- ⌘ Storage period
 - 24 hours after unit has been entered
 - 10 years if frozen

Washed Red Blood Cells (W-RBCs)

- ⌘ Content – Red cells that has removed plasma proteins, platelets, WBCs and micro aggregates
- ⌘ Indication – IgA deficient patient with anti-IgA antibodies
- ⌘ Storage period
 - 24 hours after unit has been entered

Red Blood Cells, Frozen

- Content : Deglycerolized Red cells
- Indication: Symptomatic anemia
- Storage Temperature & Period
 - Frozen: - 65 °C or below for 10 years
 - Thawed: 1-6 °C for 24 hours
- Dosage (Adult 70 Kg) :
1 RBC, ↑hct 3% or hgb 1 g/dl



Fresh Frozen Plasma (FFP)

Content:

- Plasma prepared and frozen within 8 hours of WB phlebotomy
- contains plasma proteins and all coagulation factors

Indication: Deficient of labile and stable plasma coagulation factors

Storage Temperature & Period:

- Frozen: $-18\text{ }^{\circ}\text{C}$ or below for 1 year
- Thawed: $1-6\text{ }^{\circ}\text{C}$ for 24 hours



Frozen Plasma-24 Hours (FP24, PF24RT24)

Content:

- WB and Apheresis Plasma prepared and frozen within 24 hours of phlebotomy (FP24)
- Apheresis Plasma prepared within 24 hours after phlebotomy held at room temperature up to 24 hours after phlebotomy (PF24RT24)
- contains plasma proteins and non-labile coagulation factors

Indication: Deficient or defective plasma proteins and non-labile coagulation factors

Storage Temperature & Period:

- Frozen: -18°C or below for 1 year
- Thawed: $1-6^{\circ}\text{C}$ for 24 hours



Thawed (5 Day) Plasma

Content:

- Plasma prepared and frozen within 8 hours of WB phlebotomy, thawed and refrigerated, extended to 5 days from thaw.
- contains plasma proteins and non-labile coagulation factors

Indication: Primarily used for Massive Transfusion Protocols

Storage Temperature & Period:

- Thawed: 1-6 °C for 5 days from thaw

Solvent Detergent Plasma (SD-Plasma)

- ∞ Content – Plasma pools treated with chemicals to inactivate lipid-enveloped viruses.
 - Does not inactivate non-lipid envelope pathogens – parvo virus B19, hepatitis A, etc.
- ∞ Indication – Deficient of labile and stable coagulation factors with no need for Von Willebrand factor
- ∞ Storage Temperature & Period:
 - Frozen: -18 °C or below for 1 year
 - Thawed: 1-6 °C for 24 hours

Cryoprecipitated Antihemophilic Factor (AHF, Cryo)

∞ Content:

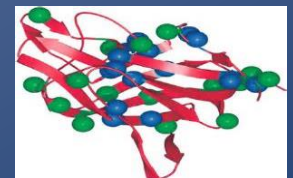
- cold insoluble precipitate from thawed FFP
- Rich in Factor VIII, XIII, vWF and Fibrinogen

∞ Indication:

- Hemophilia A
- von Willebrand's Disease
- Hypofibrinogenemia
- Factor XIII deficiency

∞ Storage Temperature & Period:

- Frozen: -18 °C or below for 1 year
- Thawed: RT for 6 hours or 4 hours if pooled



Plasma Cryoprecipitate Reduced

Content:

- Plasma residual from cryoprecipitate production and refrozen within 24 hours of thawing at -18°C or colder
- Deficient in fibrinogen, Factor VIII, Factor XIII and von Willebrand Factor (vWF)

Indication: provide clotting factors except fibrinogen, Factor VIII, Factor XIII and von Willebrand Factor (vWF); Plasma exchange for TTP (Thrombotic thrombocytopenic purpura)

Storage Temperature & Period:

- Frozen: -18°C or below for 1 year
- Thawed: $1-6^{\circ}\text{C}$ for 5 days



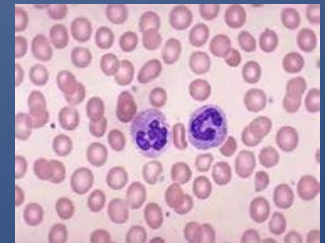
Platelets (PLT, PLC, SDP, PP)

- ∞ Content: Thrombocytes to help stop bleeding
- ∞ Indication: low platelet count or platelet function abnormality
- ∞ Storage Period: 5 days as a single unit, 4 hours if pooled
- ∞ Storage Temperature: 20-24 °C
- ∞ Dosage:
 - 1 Platelet Concentrate (bag)/10 Kg body weight
 - Adult dose = 5-6 platelet concentrates (PLT, PLC) or 1 Single Donor Platelets (SDP, PP)
 - 1 Platelet Concentrate, ↑ 5000-10,000/uL
 - 1 Platelet Pheresis, ↑ 30,000-60,000/uL



Granulocytes

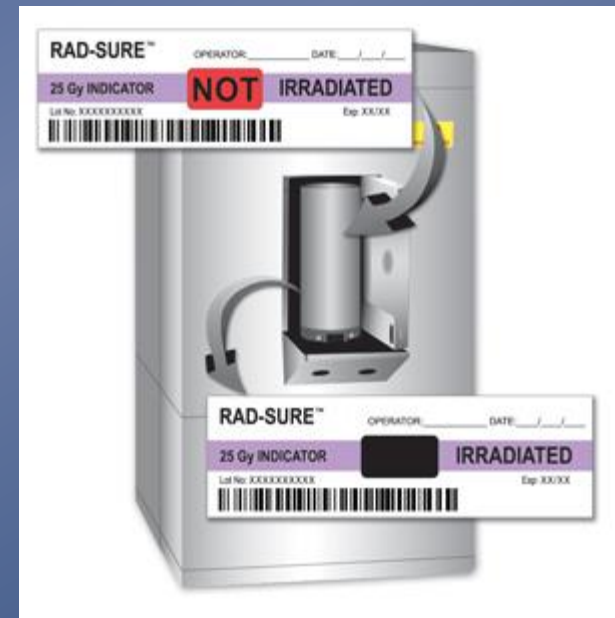
- ∞ Content: Concentrated leukocytes
- ∞ Indication: Neutropenia with gram negative infection and unresponsive to antibiotics
- ∞ Storage Period: Transfuse as soon as possible, within 24 hours of collections
- ∞ Storage Temperature: 20-24 °C



Irradiated Components

Whole Blood, Red Blood Cells, Platelets

- Function:
 - Stops the proliferation of White Blood Cells (WBC)
 - Treat components with WBCs
- Indication: Prevents “graft-vs-host” disease (GVHD) in patients with immunodeficiency
- Storage Period:
 - Expiration date will be 28 days from date of irradiation, but not more than the original expiration date
 - Irradiated Platelets will retain the original expiration date since it is only a 5 day product
- Storage Temperature: Retains applicable component storage temperature



Platelet Additive Solution (PAS)

UCSF



- ∞ Crystalloid nutrient media
- ∞ Replaces a portion of plasma in platelet components
- ∞ Lower risk for allergic transfusion reactions

Pathogen Reduction Technology (PRT)



- ∞ Treatment of platelets and plasma
- ∞ Reduces the infectious levels of disease-causing agents
- ∞ Pathogens inactivated by PRT
 - Viruses – enveloped and non-enveloped – CMV, Hepatitis, HIV, WNV
 - Bacteria – E coli, S aureus, K pneumonia
 - Parasites – Chagas, Babesiosis, Malaria
 - WBC – inactivation of white cell replication; alternative to irradiation

- ∞ Plasma derivatives are prepared by further manufacture of pooled, human plasma
- ∞ Production is at regulated manufacturing organizations
- ∞ Further manufacturing may include viral inactivation, heat, solvent-detergent treatment, nanofiltration, etc.
- ∞ Some derivatives
 - Factor VII , VIII, IX, XIII
 - Serum Globulin
 - Immune Globulin (Rhlg)
 - Volume Expanders – Crystalloids, Colloids

Donor Blood Testing - Required

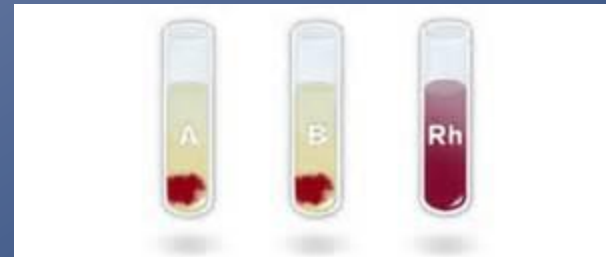
∞ ABO

- Cell Grouping (Forward)
- Serum Grouping (Reverse)

∞ Rh Typing

- Direct Agglutination
- Indirect Antiglobulin Test for Weak D

∞ Antibody Screen



Donor Blood Testing - Required

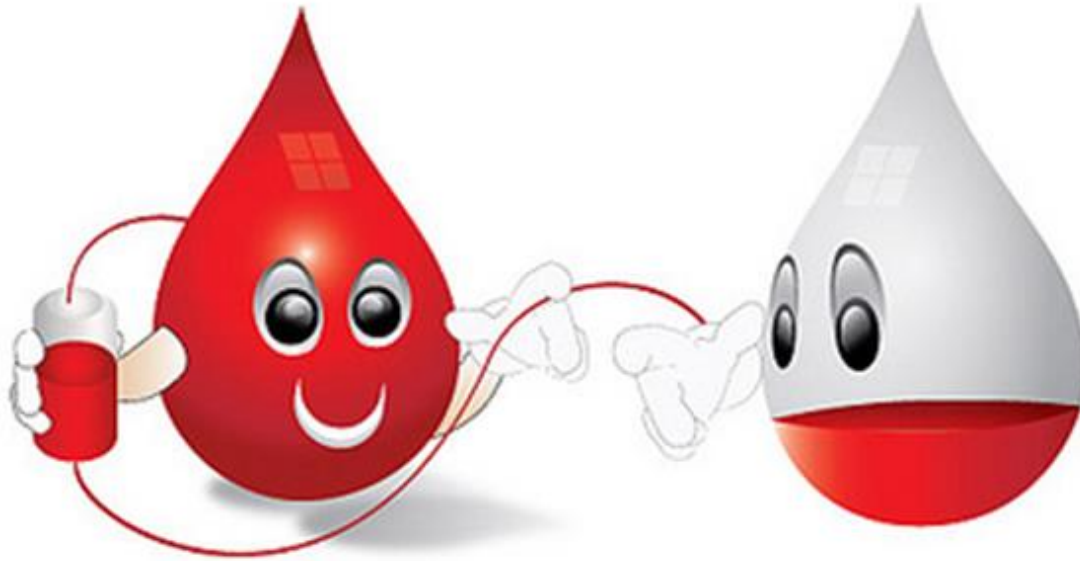
- ∞ Syphilis Serology
- ∞ Hepatitis
 - HBsAg
 - Anti-HBc
 - HCV (RNA) by NAT
- ∞ HIV
 - Anti-HIV 1/2
 - HIV (RNA) by NAT
- ∞ Anti - HTLV I/II
- ∞ WNV (RNA) by NAT
- ∞ Chagas (Anti-Trypanosoma cruzi)



Donor Blood Testing - Optional

- ⌘ Antigen Screening (K, Fy^b, E, etc)
- ⌘ Hemoglobin S
- ⌘ Anti-CMV

Questions?



Cellular Therapy & Advances



Baby Botulism

BABY BIG[®] IV (BIG-IV) Vaccine

- Infant botulism is a rare but serious gastrointestinal condition caused by exposure to *Clostridium botulinum* spores. Bacteria from the spores can grow and multiply in a baby's intestines, producing a dangerous toxin.
- While it's a rare condition, knowing the symptoms of infant botulism—the inability to suck, the constipation, the floppiness—can be lifesaving.
- About 100 babies a year in the United States will develop infant botulism
- Botulism immune globulin is a sterilized solution made from human plasma.

Production

- Healthy male donors are targeted
- Inoculate the healthy adult male donors with the recombinant botulism vaccine so high titer antibodies are made.
- After designated months, collection of the targeted donor Plasma is harvested for further vaccine manufacture.



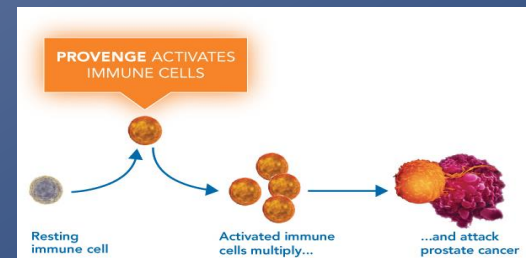
Prostate Cancer

Provenge®

- Provenge, known generically as sipuleucel-T, is an immunotherapy for prostate cancer.
- PROVENGE is not a chemotherapy, or hormone therapy. PROVENGE is an immunotherapy that works by stimulating the natural ability of immune cells already in the blood to attack prostate cancer cells, which may help your patients live longer.
- The treatment has been found to extend life by about 4.1 months.

Production

- Autologous leukapheresis collection
- Isolate patient's immune cells
- Expose patient's immune cells to proteins intended to stimulate and direct them against the patient's prostate cancer
- Reinfused
- A treatment is a total of 3X



Acute Lymphoblastic Leukemia (ALL)

Novartis Kymriah®

☞ KYMRIAHA is a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of pediatric patients up to young adults (25 years of age) with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse

☞ CAR-T cell therapy is a cutting-edge immunotherapy that uses specifically altered cells from your immune system to fight cancer in your blood.



Production

- ☞ ALL cancer patient is prepared to release autologous CD19 B Cells
- ☞ Autologous collection
- ☞ Isolate and concentrate the autologous CD19 B Cells
- ☞ Genetically modify the CD19 cells using a lentiviral vector to encode an anti-CD19 chimeric antigen receptor (CAR)
- ☞ Reinfuse into cancer patient so manufactured Car-T (target cells) attack cancer cells

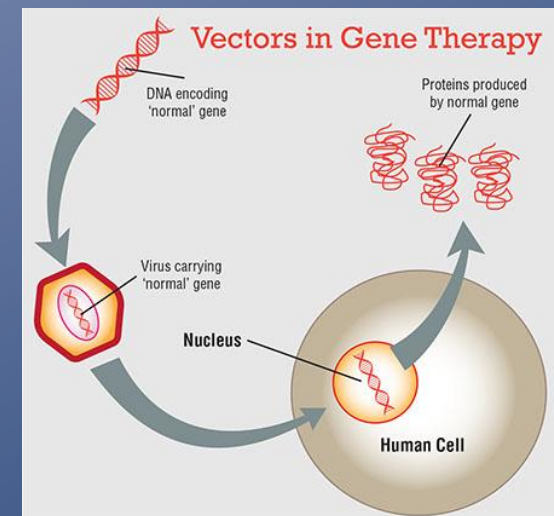
Severe Combined Immunodeficiency (SCID)

Gene Therapy for SCID

- Severe combined immunodeficiency (SCID) is a group of rare disorders caused by mutations in different genes involved in the development and function of infection-fighting immune cells.
- Infants with SCID appear healthy at birth but are highly susceptible to severe infections.
- The condition is fatal, usually within the first year or two of life, unless infants receive immune-restoring treatments, such as transplants of blood-forming stem cells, gene therapy, or enzyme therapy.

Production

- Autologous stem cells are obtained from the patient's bone marrow, the normal gene is inserted into the stem cells using a carrier known as a vector, and the corrected cells are returned to the patient.



Questions?



Thank You!

