

What's in the Bag?

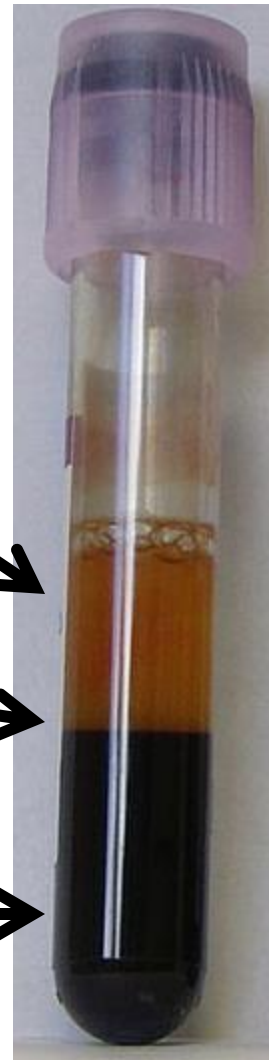
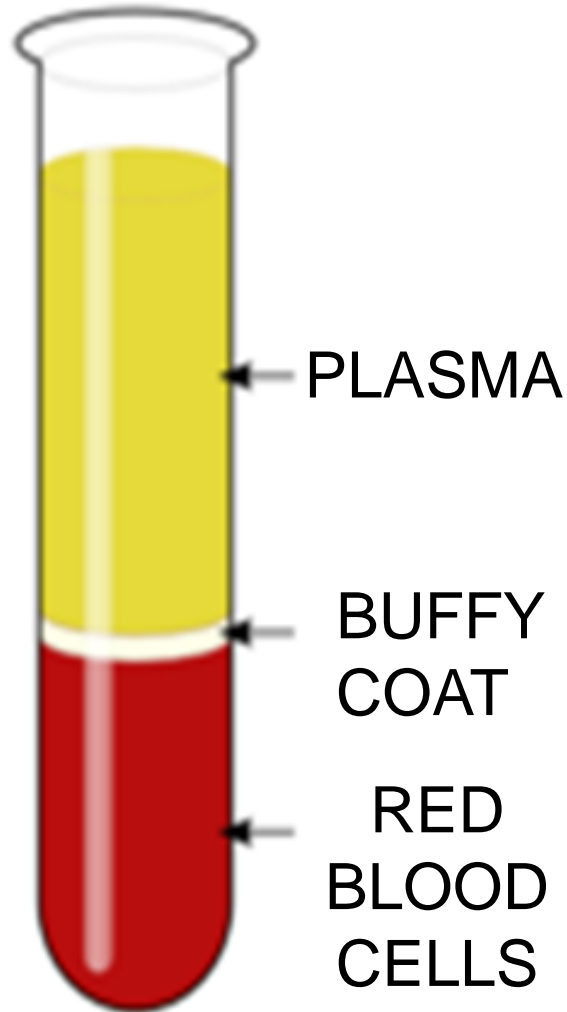
Theresa C. Stec, BA, MT(ASCP)
Biovigilance Program Manager
Surgical Services Administration

Objectives

- ❖ **To provide an overview of blood and blood products**
- ❖ **To provide an overview of regulations**
- ❖ **To provide possible quality assurance measures**

Blood Separation

Whole Blood



Blood and Blood Products

Whole blood centrifuged to separate red blood cells from plasma products



Blood and Blood Products

Red Blood Cells (RBCs)

Indication for use

- ❖ O₂-carrying capacity
- ❖ From pre transfusion values in average adult, one unit of RBCs
 - Increases hemoglobin by ~ 1 g/dL
 - Increases hematocrit by ~ 3%

Blood and Blood Products

Fresh Frozen Plasma (FFP)

Indication for use

- ❖ Replacement of plasma coagulation factors
- ❖ Reversal of warfarin
- ❖ Treatment of thrombotic thrombocytopenia purpura (TTP)

Blood and Blood Products

Platelets

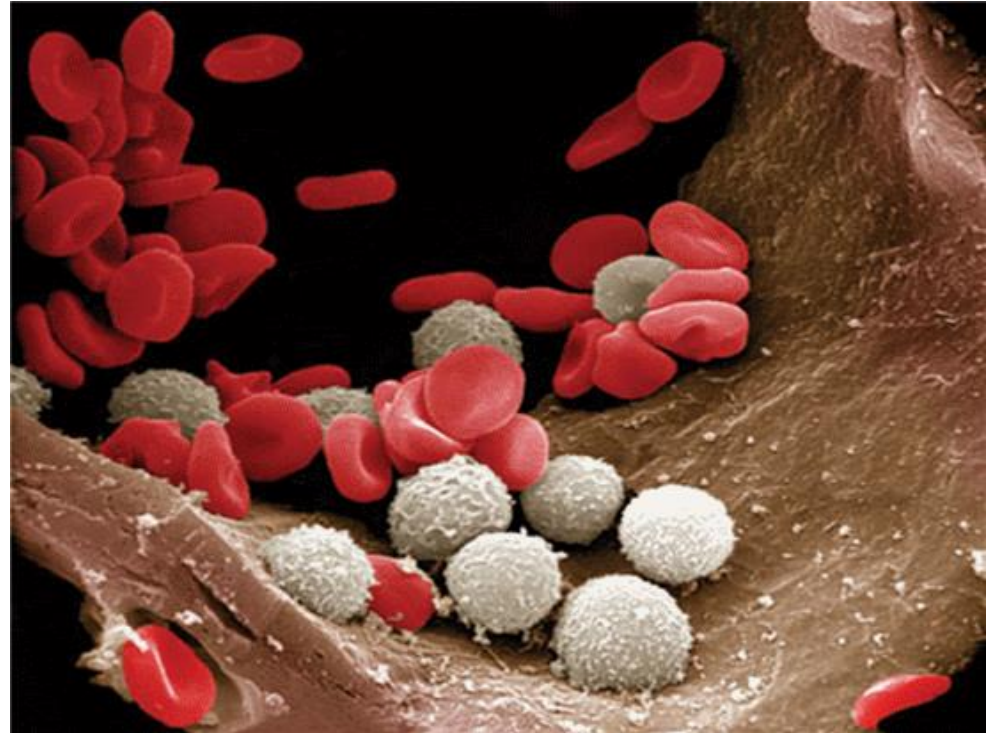
Indication for use is the treatment of patients with thrombocytopenic bleeding due to decreased count or function of circulating platelets

- Prophylactically used for cancer or chemotherapy patients ($< 10,000/\mu\text{L}$)
- Postoperative bleeding ($< 50,000/\mu\text{L}$)

Not indicated for transfusion in ITP or TTP patients unless life-threatening hemorrhage

Apheresis Blood Products

Apheresis
(Greek: “ to take away”)
Blood from a donor or patient is passed through an apparatus that separates out one particular constituent and returns the remainder to the circulation.



From Wikipedia, the free encyclopedia
<http://en.wikipedia.org/wiki/Apheresis>

Apheresis Blood Products

Apheresis derived products

- ❖ Single donor exposure
- ❖ One donation with multiple products
- ❖ Optimize donors
- ❖ Collect desired product
- ❖ Return donor cells and plasma

Apheresis Blood Products



Apheresis platelets contain $\geq 3.0 \times 10^{11}$ platelets per unit, possible for double or triple dose per donor



Apheresis plasma collected concurrently with platelets

Apheresis Blood Products

- ❖ Apheresis red blood cells

- 2 RBC units or



- 1 RBC & 1 FFP units

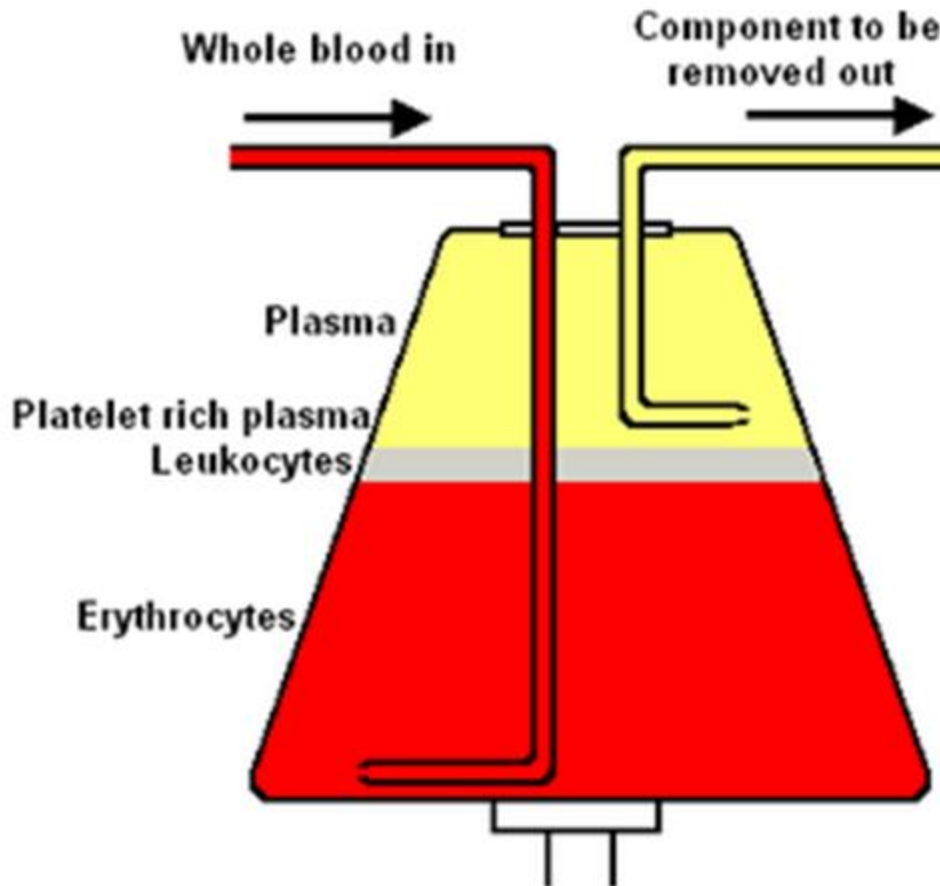


Apheresis Devices

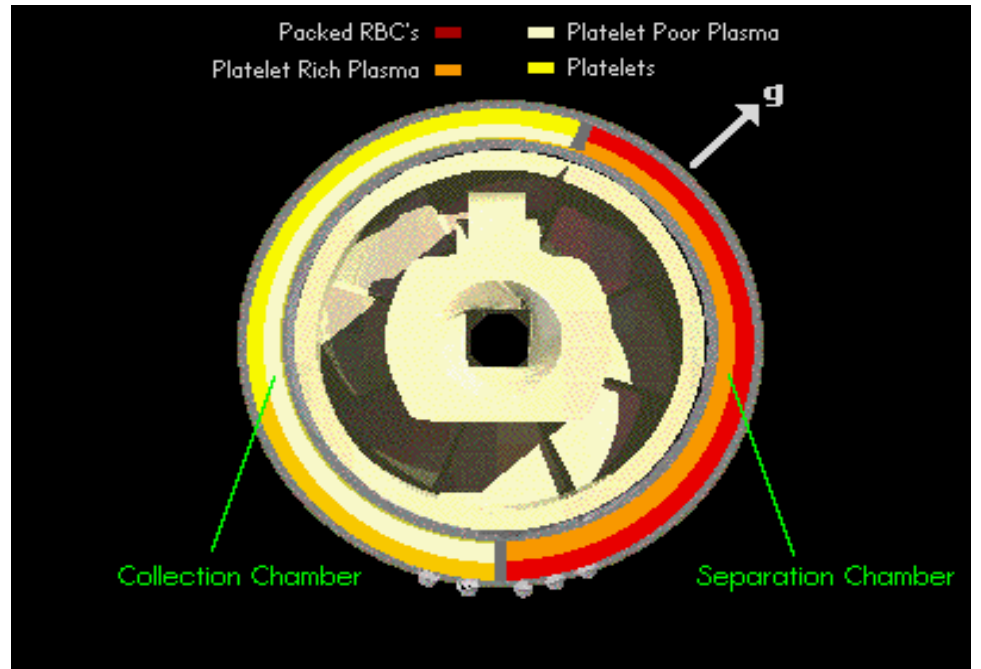
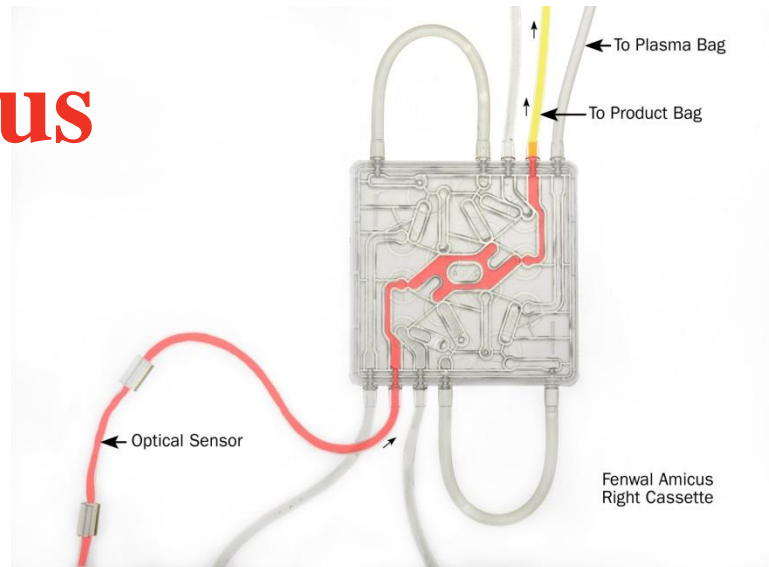


Blood Separation

Latham Bowl



Amicus



Spectra

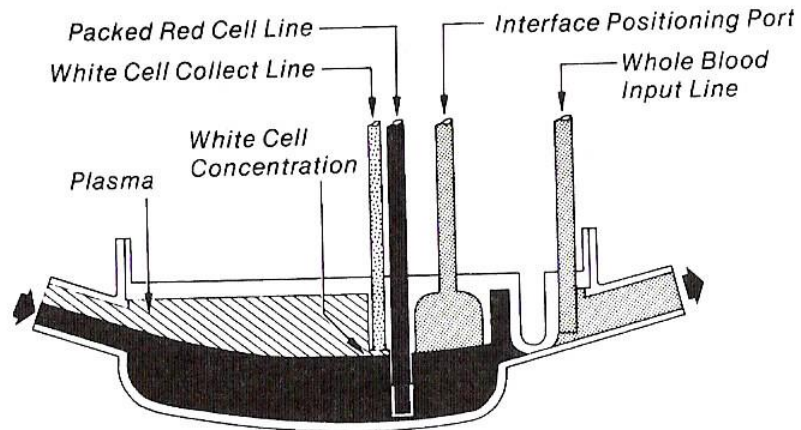
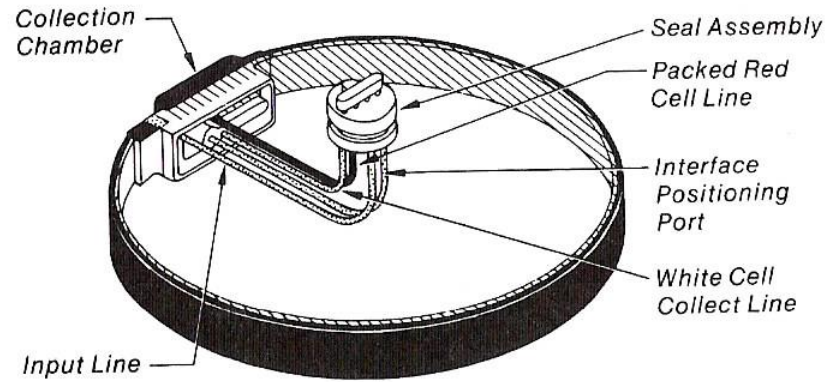
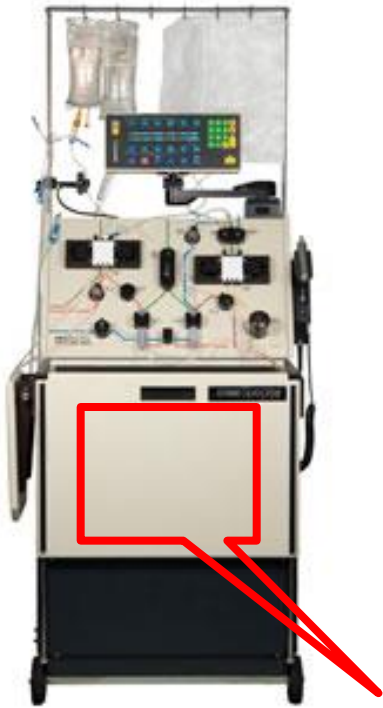


Figure 1-12. IBM 2997 single-stage channel and collection chamber. See text for structural and operational details. (Courtesy of Gambro BCT, Inc.)

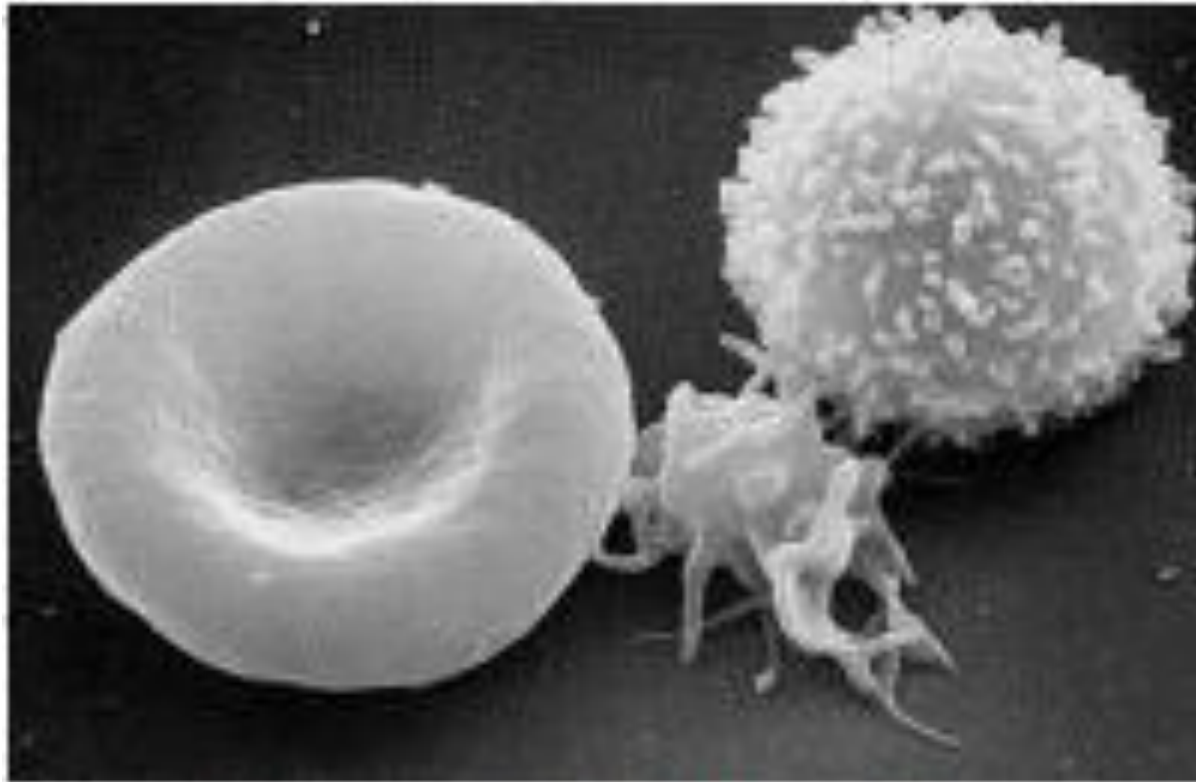
Apheresis Cellular Products

Spectra Lymphocyte Collection

Amicus Lymphocyte Collection



Cellular Components



erythrocyte (left), thrombocyte (center), and leukocyte (right)

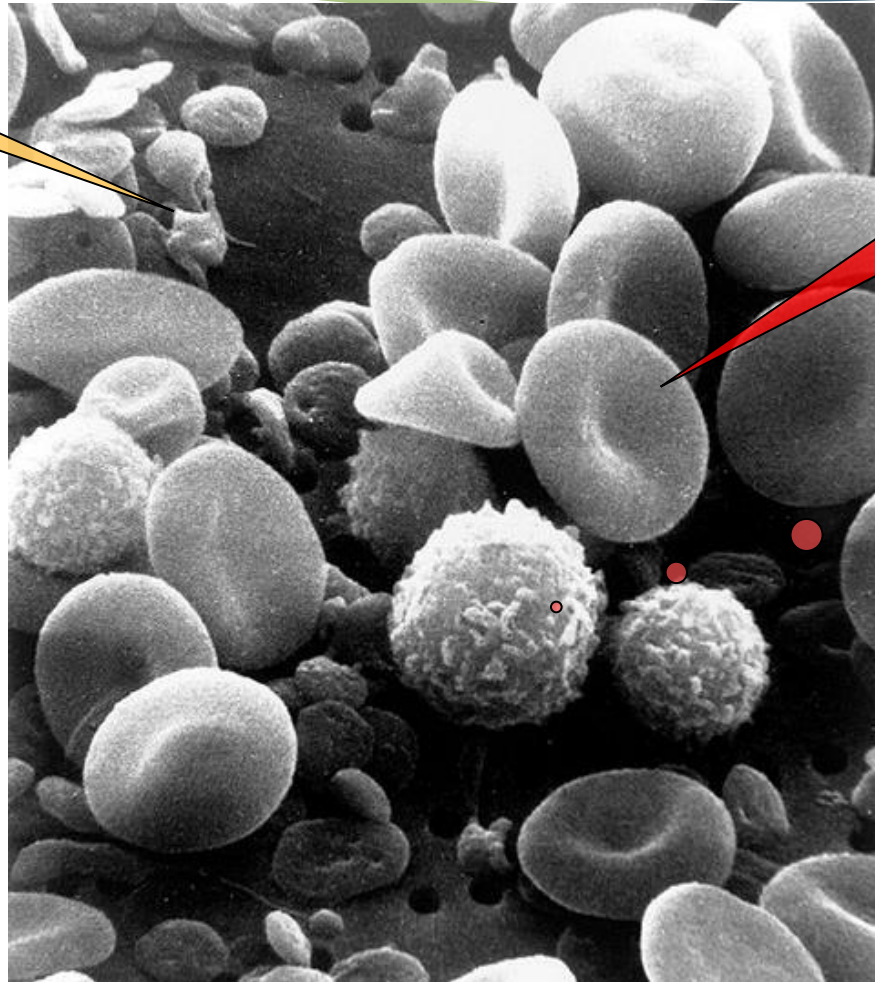
What is in the bag?

Platelets

RBCs

WBCs

All cells are
contained in
Plasma



Scanning electron microscope image from normal circulating human blood
Bruce Wetzel (photographer). Harry Schaefer (photographer)

Buffy Coat

Centrifugation

Density
(Specific Gravity)

1.025-1.029

Plasma

1.040

Platelets

1.070

Lymphocytes & Monocytes

1.087-1.092

Granulocytes

Reticulocytes

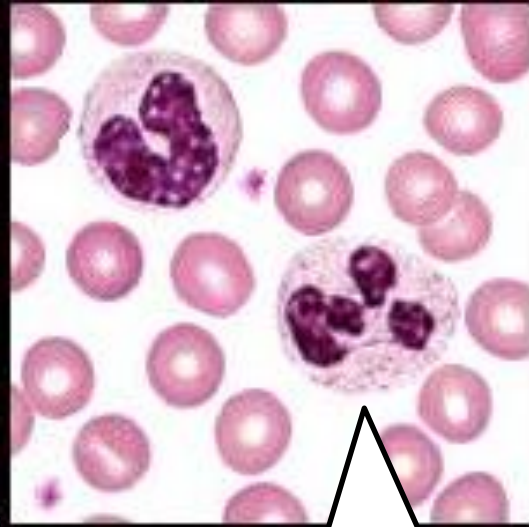
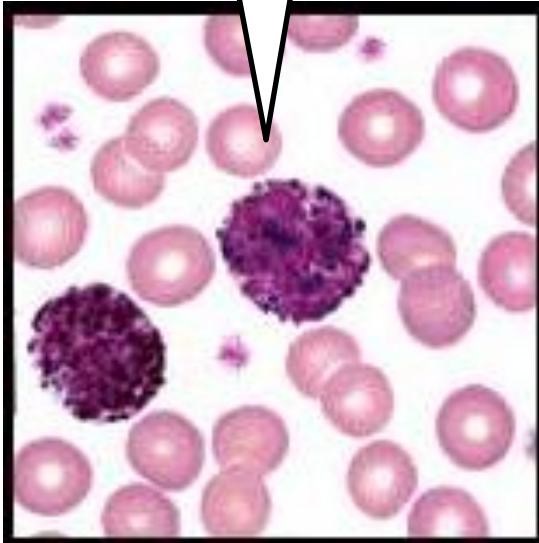
1.093-1.096

Packed Red Blood Cells

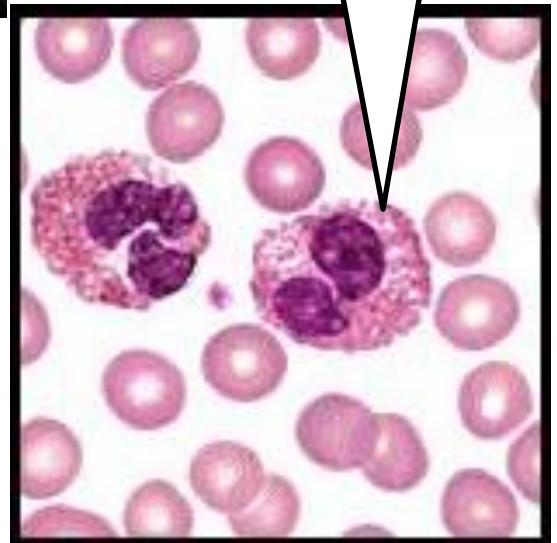


Mature Granulocytes

Basophils



Eosinophils



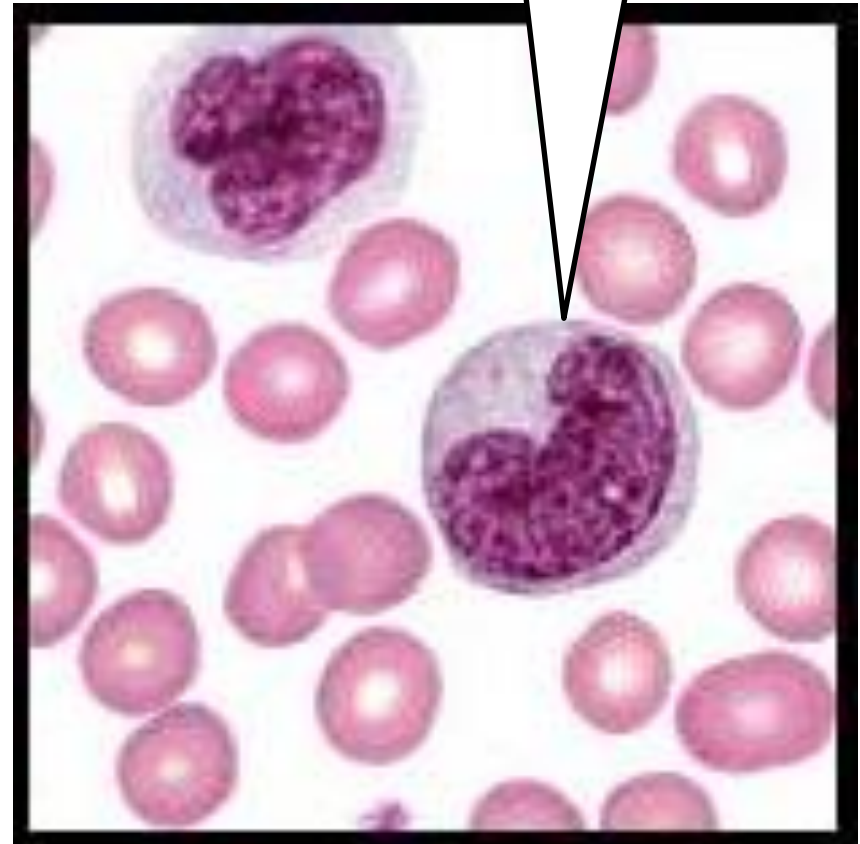
Neutrophils

Mononuclear Cells

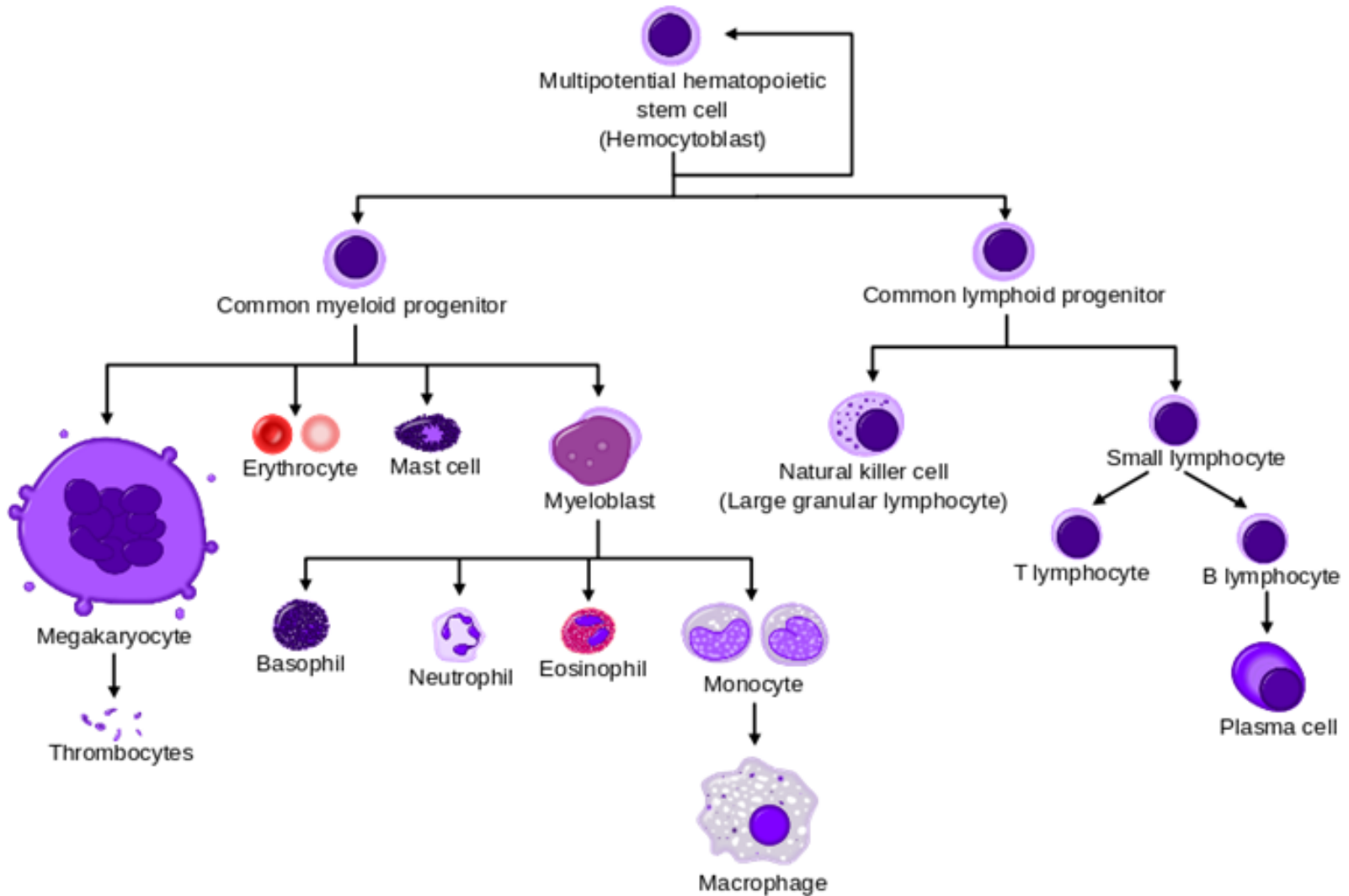
Lymphocytes



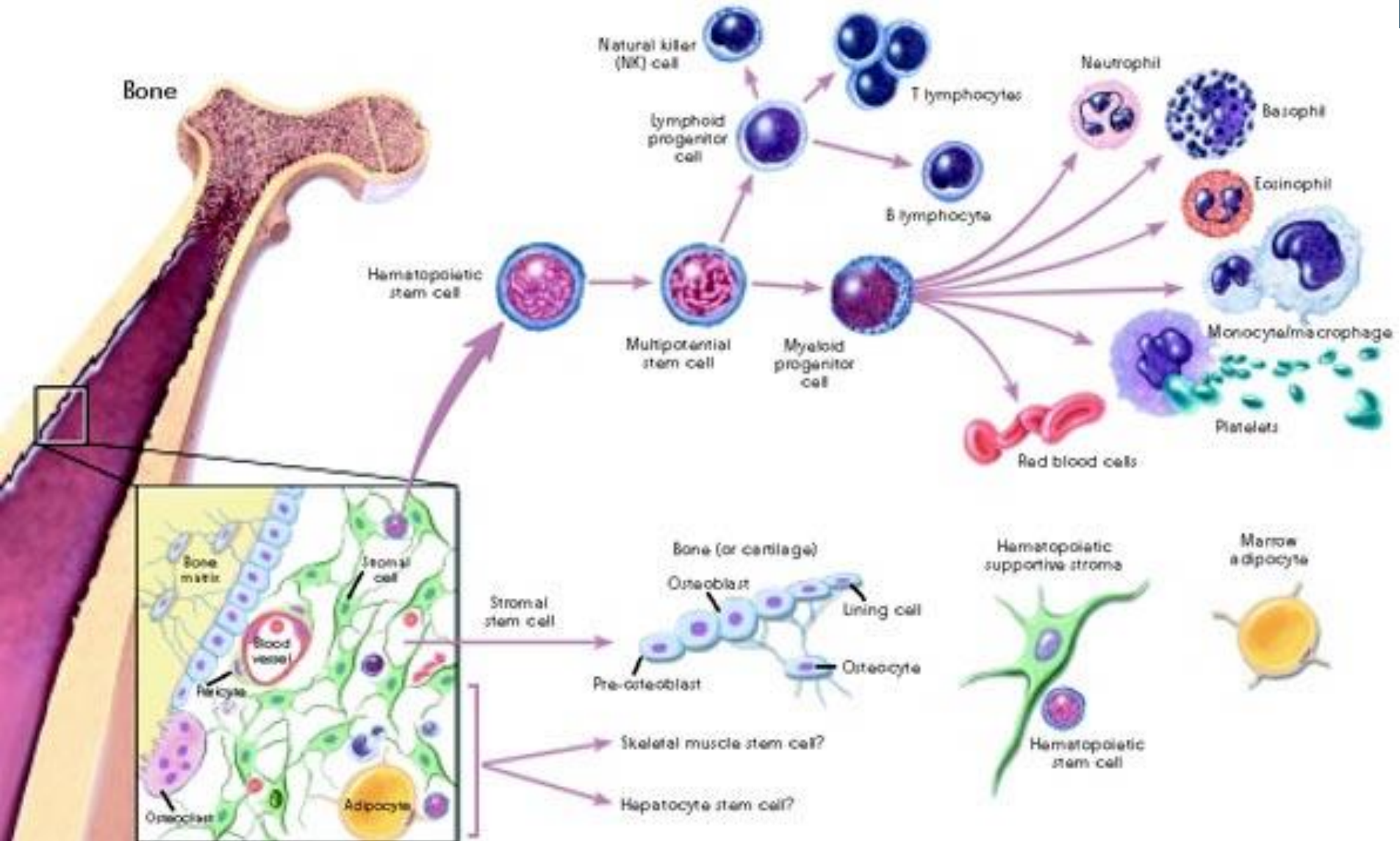
Monocytes



Hematopoiesis



Adult Stem Cells



What are adult stem cells?. In *Stem Cell Information* [World Wide Web site]. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2012 [cited Saturday, February 15, 2014] Available at <<http://stemcells.nih.gov/info/basics/pages/basics4.aspx>>

Calculations

Product volume =

$$\frac{\text{Weight of product} - \text{weight of product container}}{\text{Density of product}}$$

Density whole blood ~1.060 g/ml

Density plasma ~ 1.027 g/ml

Total cell count in product =

$$\text{Total product volume} \times \text{cell concentration of product}$$

% Recovery =

$$\frac{\text{Analyte concentration in final product}}{\text{Analyte concentration in original product}} \times 100$$

Quality Assurance

Apheresis RBC

- Mean collection of ≥ 60 g of hemoglobin or 180 ml red cell volume
- 95% of units sampled >50 g of hemoglobin or 150 ml red cell volume

Apheresis RBC Leukocyte Reduced

- Mean collection of ≥ 51 g of hemoglobin or 153 ml red cell volume and $< 5 \times 10^6$ residual leukocytes per unit
- 95% of units sampled >42.5 g of hemoglobin or 128 ml red cell volume

Quality Assurance

Apheresis Platelets

- 90% of units sampled contain a platelet concentration of $>3.0 \times 10^{11}$ platelets
- pH ≥ 6.2 at end of allowable storage

Apheresis Platelets Leukocyte Reduced

- 90% of units sampled contain a platelet concentration of $>3.0 \times 10^{11}$ platelets
- pH ≥ 6.2 at end of allowable storage
- 95% of units sampled contain $<5 \times 10^6$ residual leukocytes per unit

Quality Assurance

Apheresis Platelets

Platelet Additive Solution Added

Leukocytes Reduced

- Suspended in variable amounts of plasma and an approved platelet additive solution
- 90% of units sampled contain $\geq 3.0 \times 10^{11}$ platelets
- 95% of units sampled contain $< 5 \times 10^6$ residual leukocytes

Quality Assurance

Apheresis Granulocytes

- Minimum of 1.0×10^{10} granulocytes in 75% of units sampled
- Neonatal transfusion requirements defined by medical director

Quality Assurance

HPC, Apheresis Processing Tests

- Total nucleated cell count
- CD34 analysis or comparable assay
- Cell viability
- Microbial contamination at end of processing
 - Aerobic and anaerobic bacterial culture
 - Culture for fungal elements

ABO group and Rh typing by receiving or administering facility to compare to previous records

Quality Assurance

Cellular Therapy Products

- Relevant cell count
- Antigen expression analysis as appropriate
- Cell viability
- Microbial contamination at end of processing
 - Aerobic and anaerobic bacterial culture
 - Culture for fungal elements
- Potency assay as appropriate

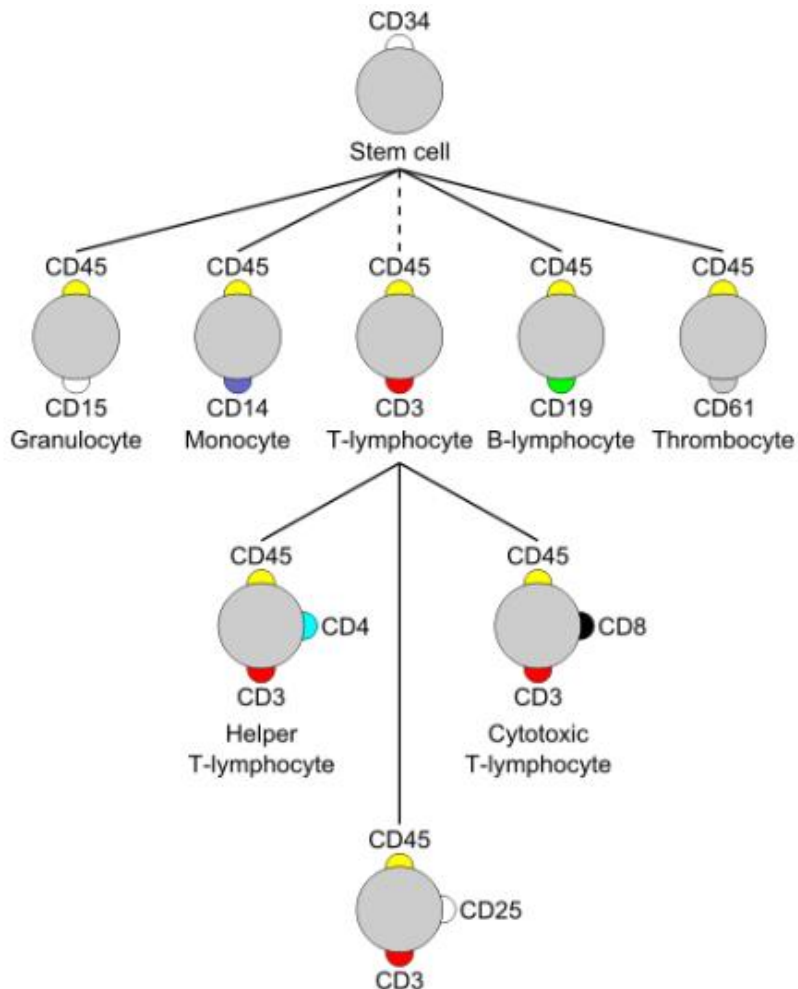
If final product contains RBCs,

- ABO group and Rh typing by receiving or administering facility to compare to previous records

Joint Commission Chart Audit Sample Size Recommendation

- ❖ 30-100 (charts, admissions, cases, etc.)
Sample Size for Audits should be 30 Charts
- ❖ 101-500 (charts, admissions, cases, etc.)
Sample Size for Audits should be 50 Charts
- ❖ >500 (charts, admissions, cases, etc.)
Sample Size for Audits should be 70 Charts

CD Markers

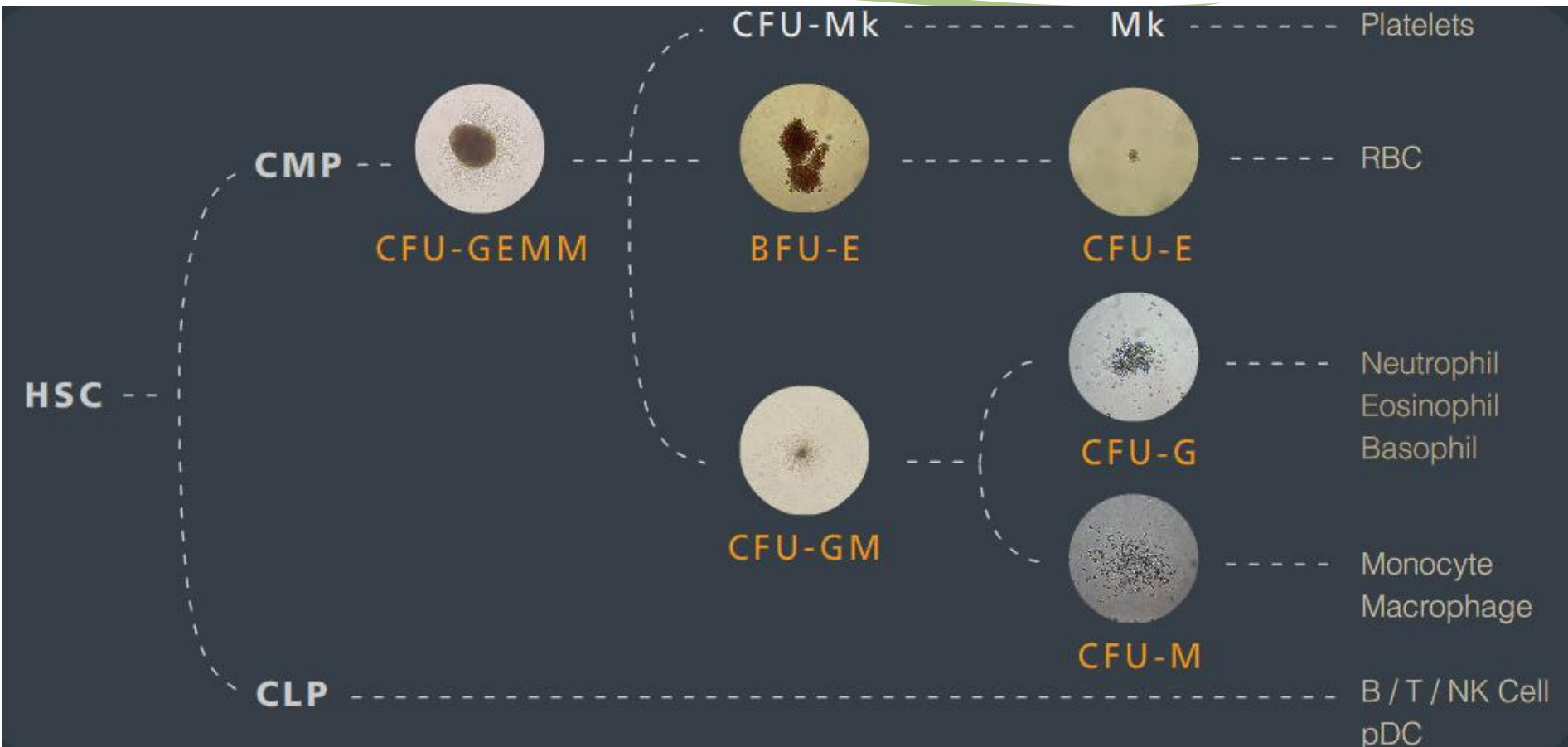


Cluster of differentiation
(cluster of designation)
known as CD
protocol for identification
of cell surface molecules
providing targets for
immunophenotyping of
cells.

CD Markers

Type of cell	CD markers
stem cells	CD34+, CD31-, CD117
all leukocyte groups	CD45+
Granulocyte	CD45+, CD11b, CD15+, CD24+, CD114+, CD182+ ^[6]
Monocyte	CD45+, CD14+, CD114+, CD11a, CD11b, CD91+, ^[6] CD16+ ^[7]
T lymphocyte	CD45+, CD3+
T helper cell	CD45+, CD3+, CD4+
T regulatory cell	CD4, CD25, and Foxp3
Cytotoxic T cell	CD45+, CD3+, CD8+
B lymphocyte	CD45+, CD19+ or CD45+, CD20+, CD24+, CD38, CD22
Thrombocyte	CD45+, CD61+
Natural killer cell	CD16+, CD56+, CD3-, CD31, CD30, CD38

CFU Lineage



What do you want in the bag?

- ❖ Cellular therapy product – end point defined by protocol
 - Stem cell product – minimum 2×10^6 CD34
- ❖ Know the best way to collect desired product
- ❖ Know who can support you with your collection issues
- ❖ Cell therapy manufacturers want as few granulocytes, platelets, and RBCs contamination as possible