Kim Peck
Vice President, Technical Services

Excuse Me, Sir, There's a Fly in my Plasma

A Guide to Product Visual Inspections

HAABB Meeting
April 29, 2014

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Our Mission:
To provide blood and support services that meet the needs of patients, donors, physicians and hospitals.

Today's Topics

- ❑ **Describe most common visual anomalies in products**
- ❑ **Discuss the cause of the anomalies**
- ❑ **Explain when it's acceptable to use the product & when it should be returned to the collection facility**

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Resources used for this presentation

- Blood Component Visual Inspection Guide
- CBC KC SOPS and experience

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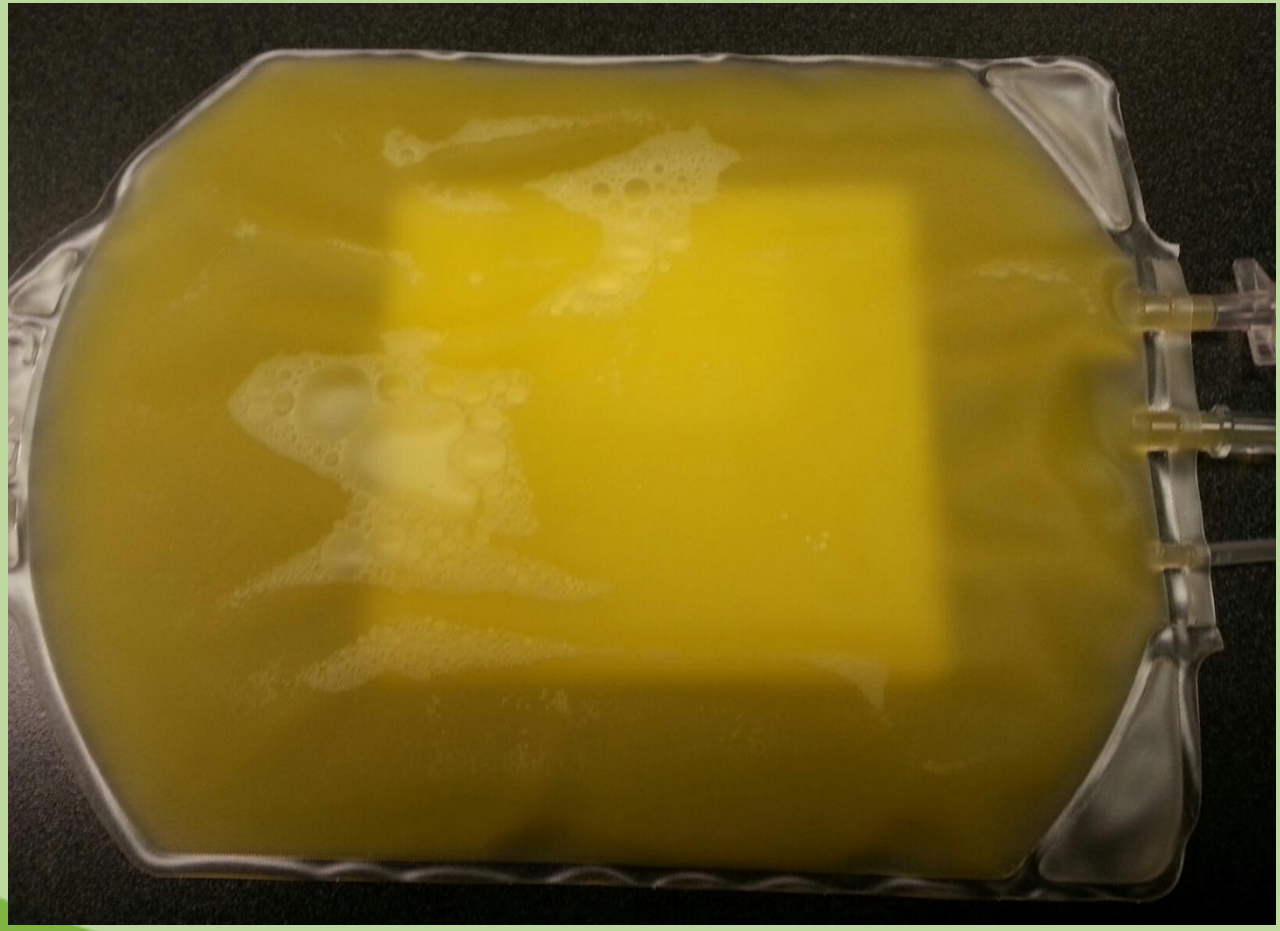
“Normal” Products



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“Normal” Products

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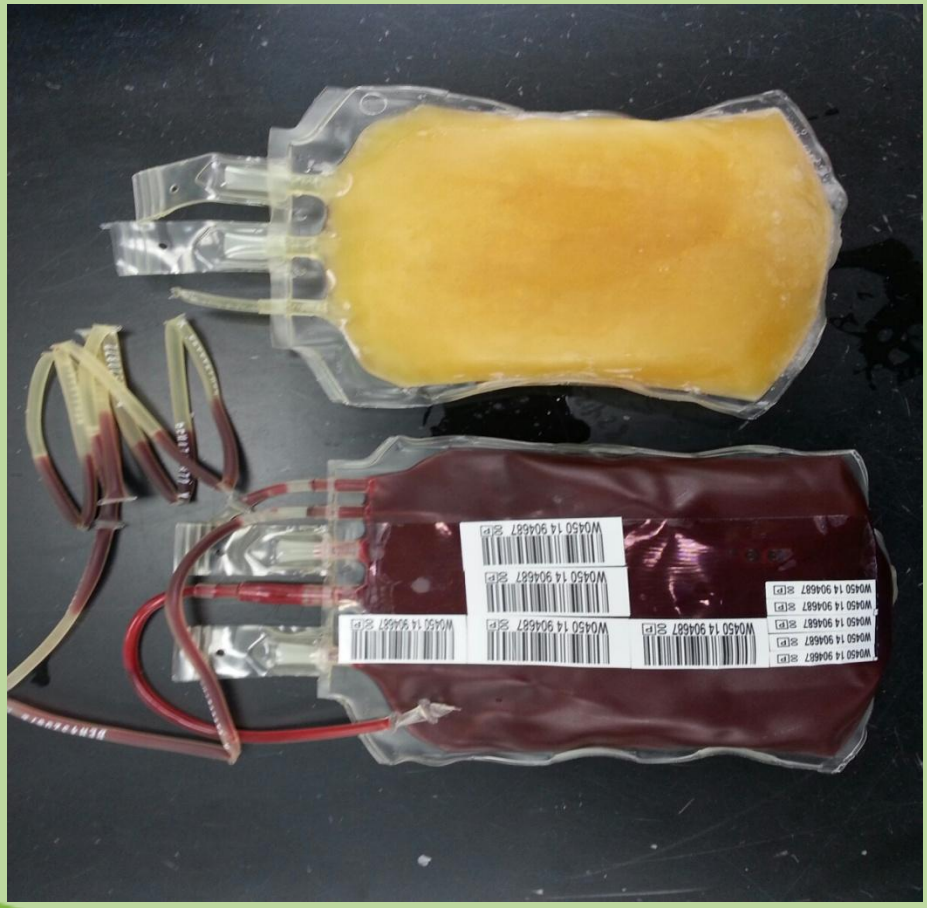
“Normal” Products



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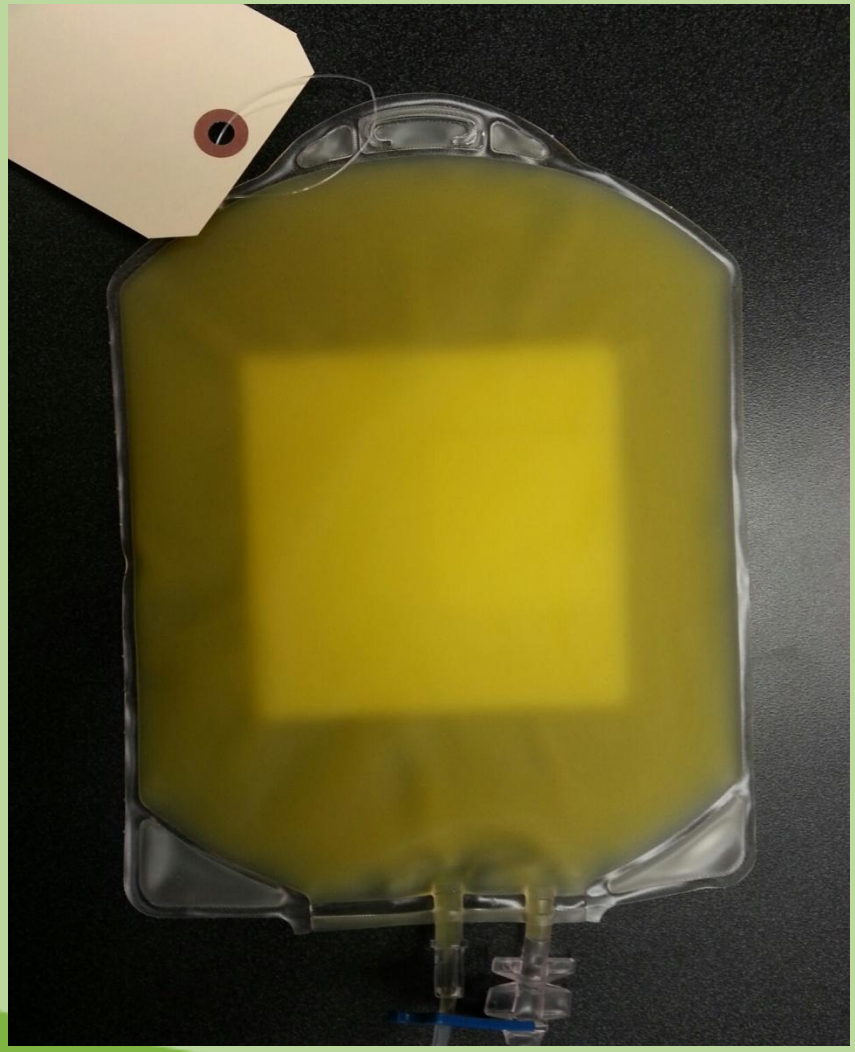

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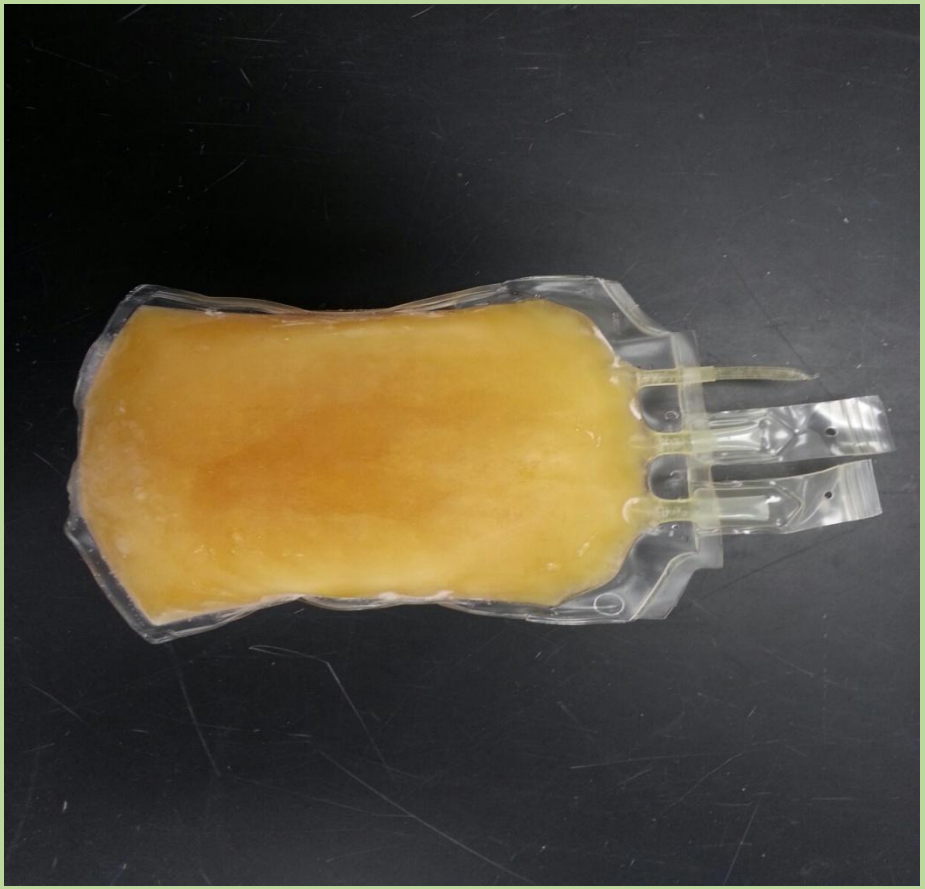

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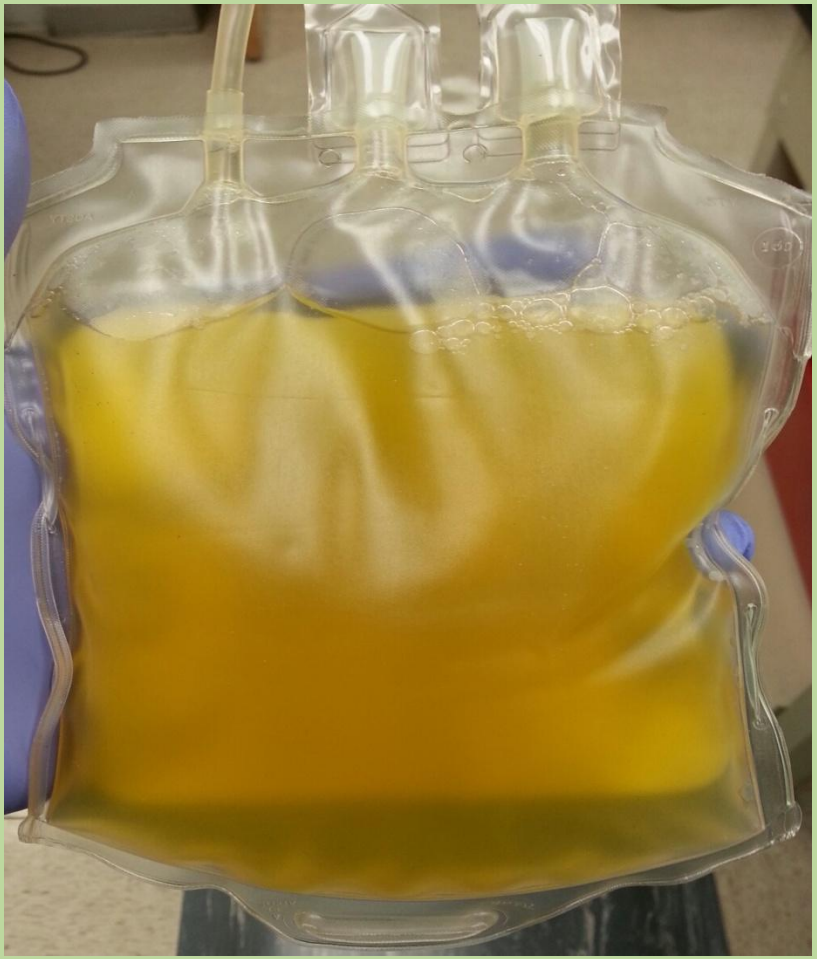

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Visual Anomalies

- ❑ Hemolysis
- ❑ Lipemia
- ❑ Clotted
- ❑ Discoloration
- ❑ Particulate Matter
- ❑ Bacterial Contamination
- ❑ Foreign Objects

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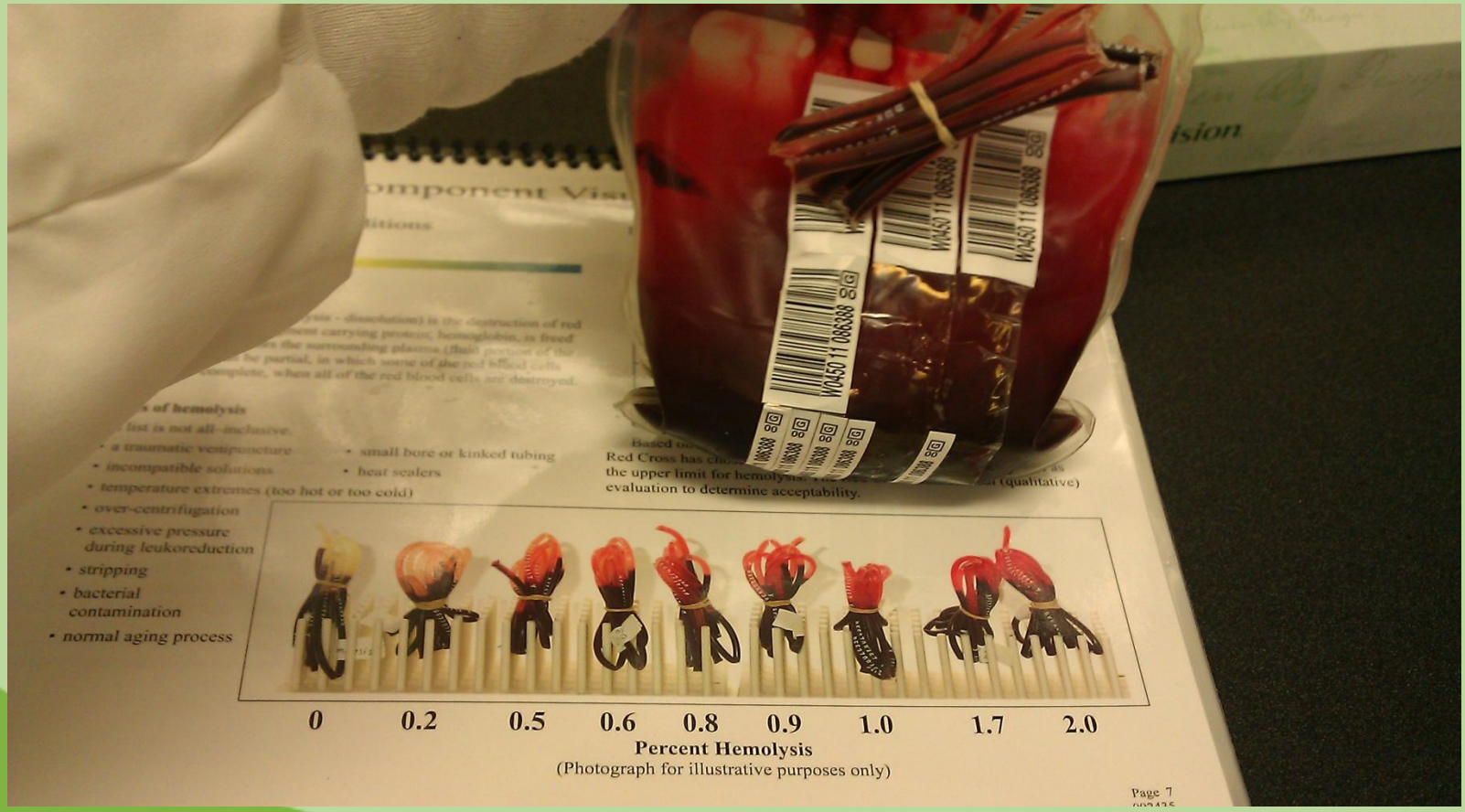
Hemolysis



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Hemolysis

Causes

- Traumatic venipuncture
- Temperature extremes during transport or storage
- Excessive pressure during leukoreduction
- Bacterial contamination
- Normal aging process

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Effects

- WB/RBC – dark purple/black
- Plasma/Platelets – pink to red translucent

Acceptability

- Some hemolysis is acceptable
- CBC uses ≤ 0.8% hemolysis as compared to a color chart

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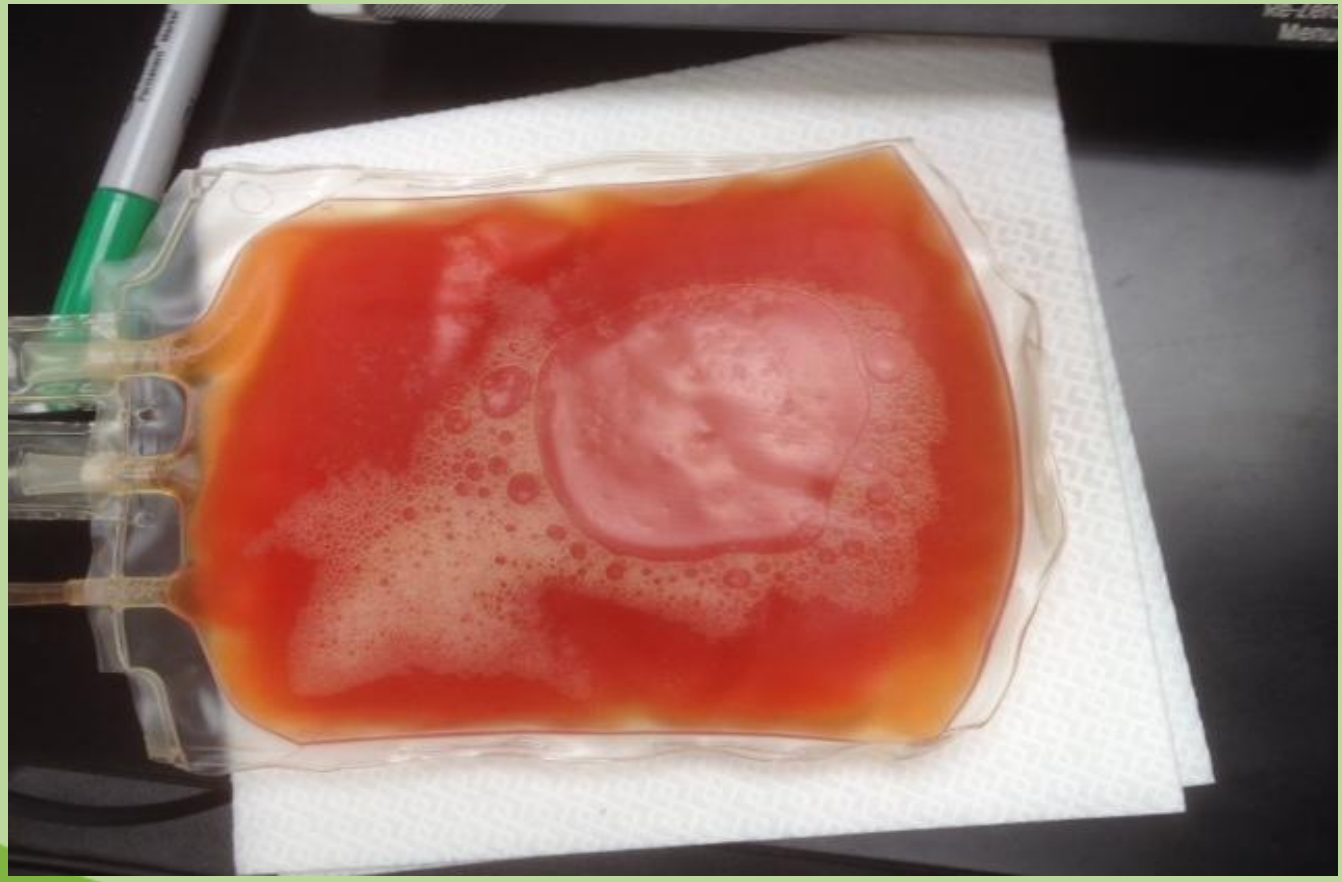
Hemolyzed Platelets



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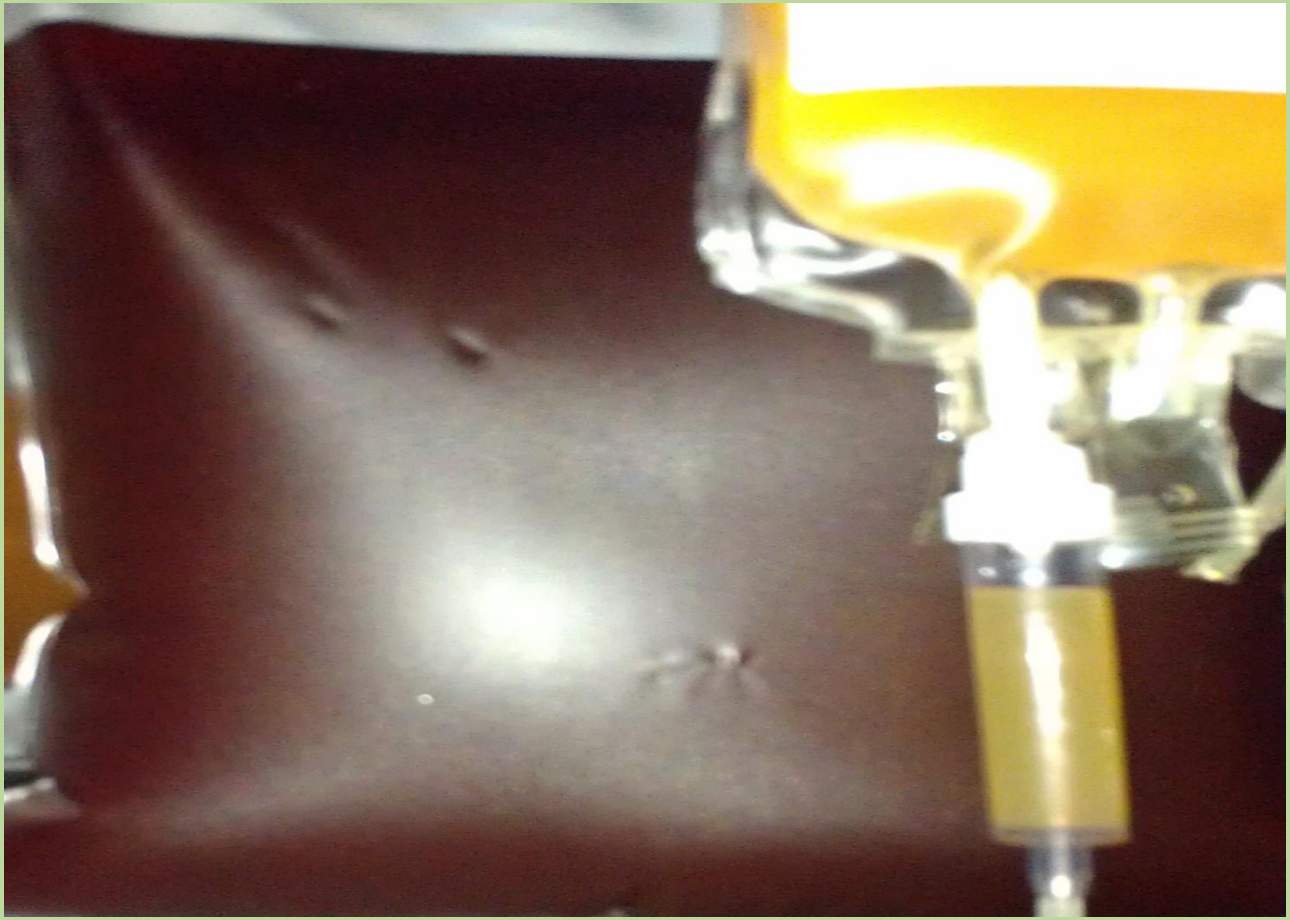
Severe Hemolysis



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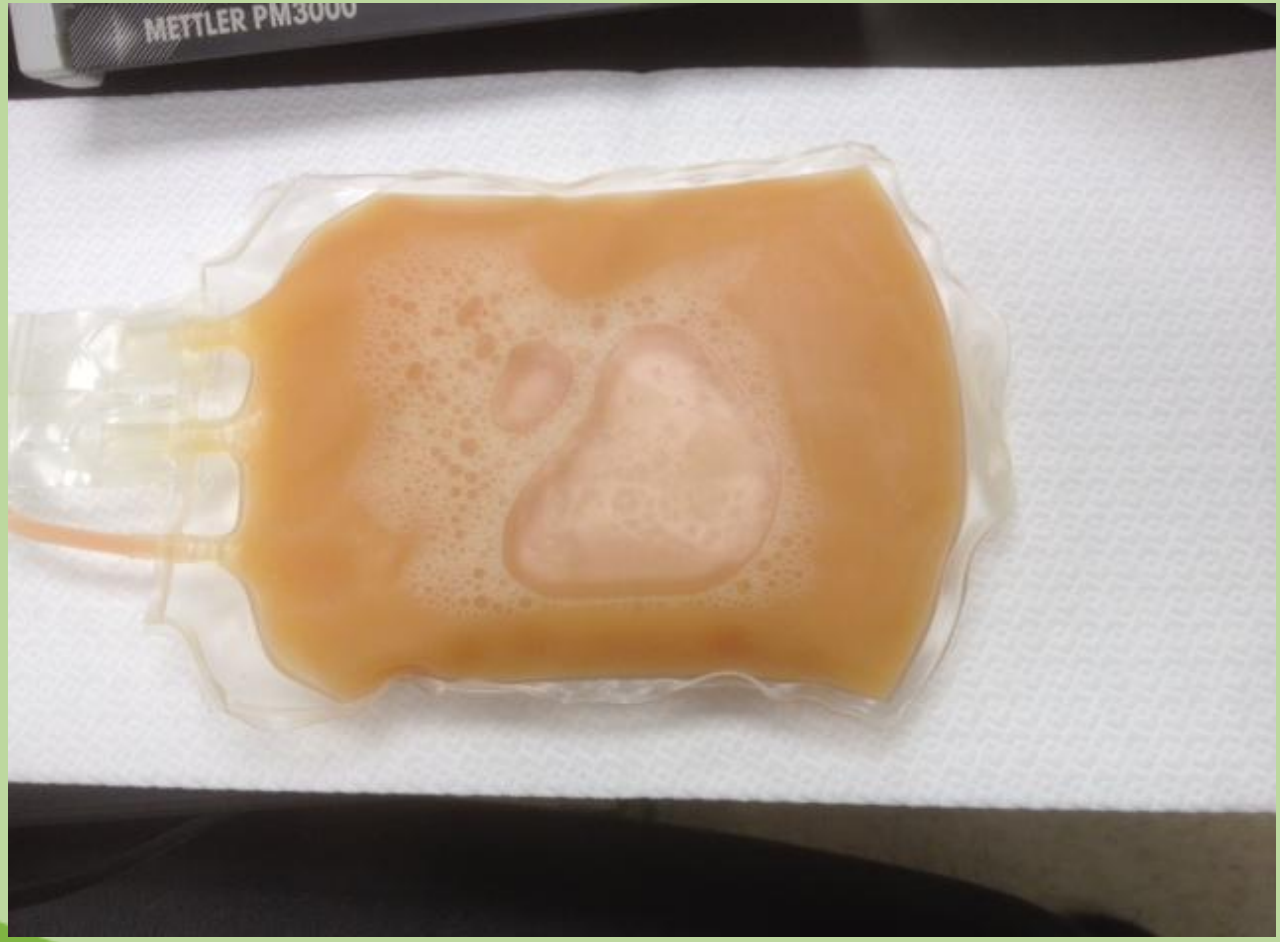
Lipemic Plasma



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Lipemia

Causes

- High fat meal

- Associated with disease state

e.g. hypercholesterolemia

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Lipemia

Effects

- WB/RBC – strawberry milkshake
- Plasma/Platelets – opaque, milky

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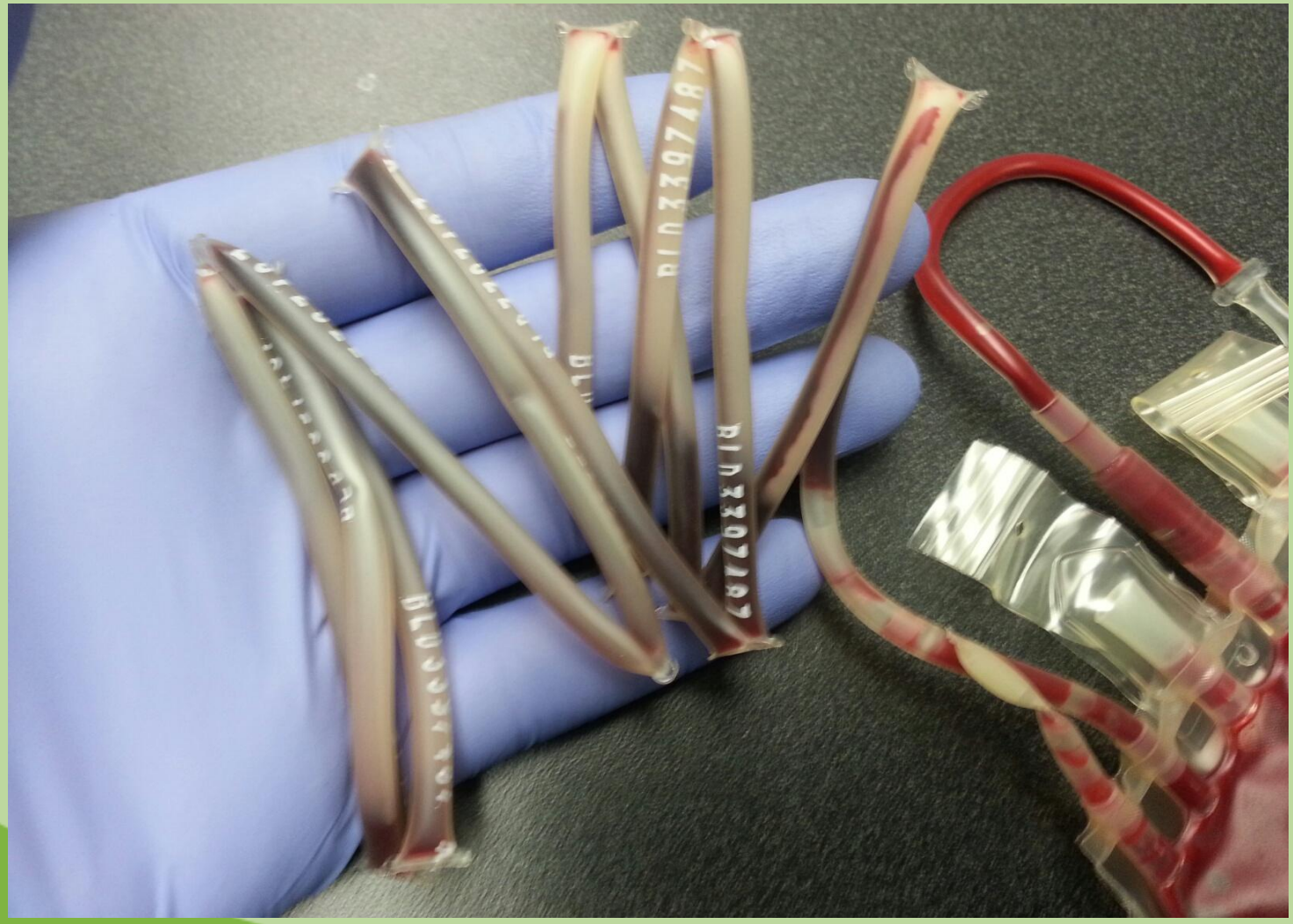
Acceptability

- Does not affect safety of product
- Usually discarded for esthetics

Lipemic Segments



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Hypertriglyceridemia

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Causes

- Traumatic venipuncture
- Insufficient mixing
- Insufficient volume of anticoagulant
- Bacterial contamination

Effects

- WB/RBC – dark purple/red masses
- Segments – red to black stringy mass
- Plasma containing products – thick, white opaque masses

Acceptability

- Small clots acceptable
- Less than a quarter size

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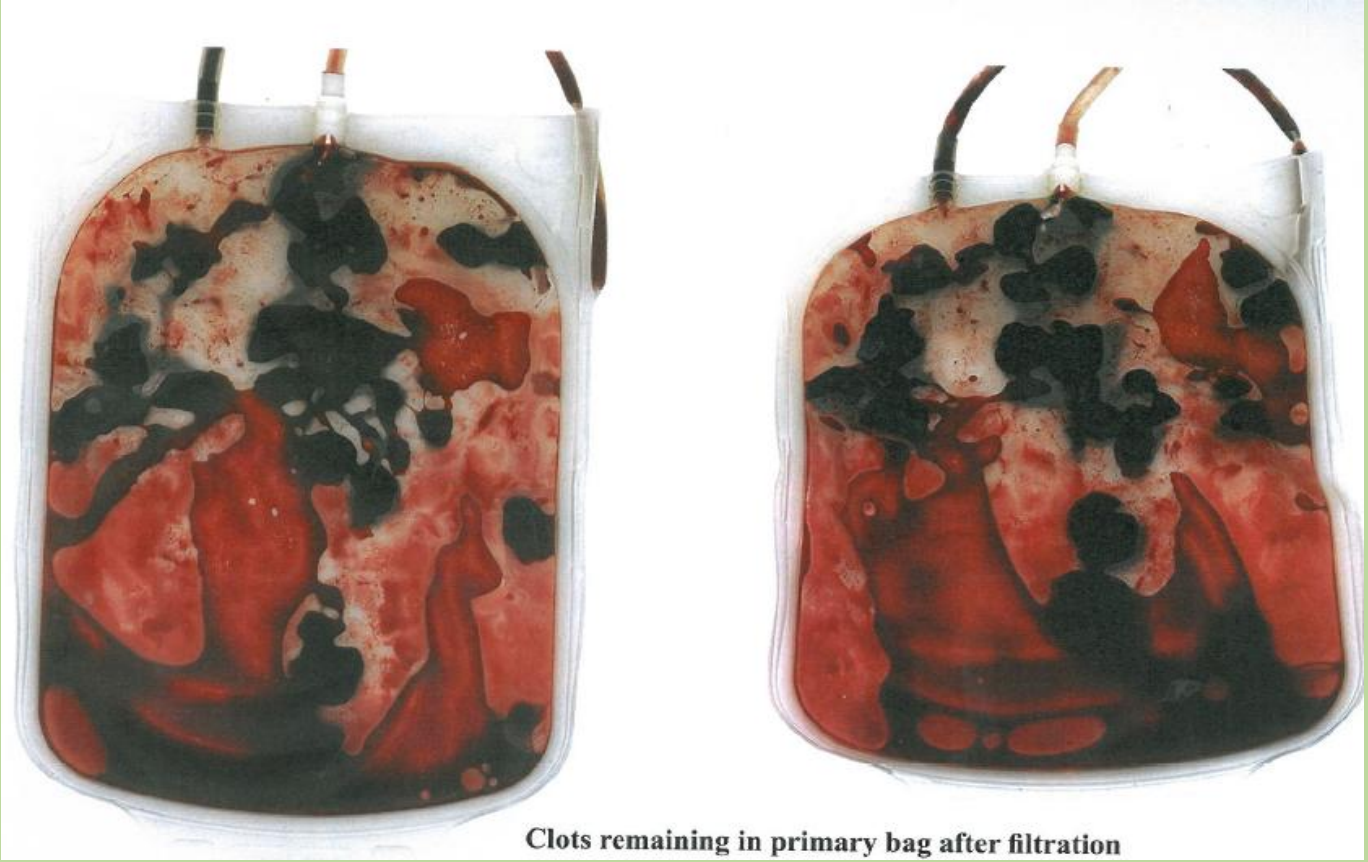
Clots



Clots remaining in primary bag after filtration

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Green Plasma

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Causes and Effects

Appearance	Possible Cause
Pale Green	Oral Contraceptive
Dark greenish brown	Icterus
Bright or fluorescent green	Drugs/bacteria contamination
Bright yellow to orange	Vitamins
Reddish	RBCs /hemoglobin from incorrect preparation or equipment failure

Discoloration

Acceptability

- Pale to dark yellow
- Slight to green tinge

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Wilsons

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Particulate Matter

Includes

- Fibrin strands
- Aggregates
- White particulate matter
- Flocculent material
- Cold agglutinins

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Fibrin Strands

Causes

- Traumatic venipuncture
- Insufficient mixing
- Insufficient volume of anticoagulent
- Bacterial contamination

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Fibrin Strands

Effects

- Any component-thin, whitish, thread-like strands

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Acceptability

- Probably ok if transfused through a filter

Aggregates

Causes

- Inadequate rest period post collection
- Environmental factors: e.g. cold countertop
- Improper storage
- Collection type
- Donor dependent variables

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Aggregates

Effects

- Platelets – small whitish masses

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Aggregates

Acceptability

- A few aggregates are ok
- CBC uses the following criteria
  - ✓Large in size - > 1 cm
  - ✓Many small clumps - > ~ 40
  - ✓All must fit within a 1 cm circle

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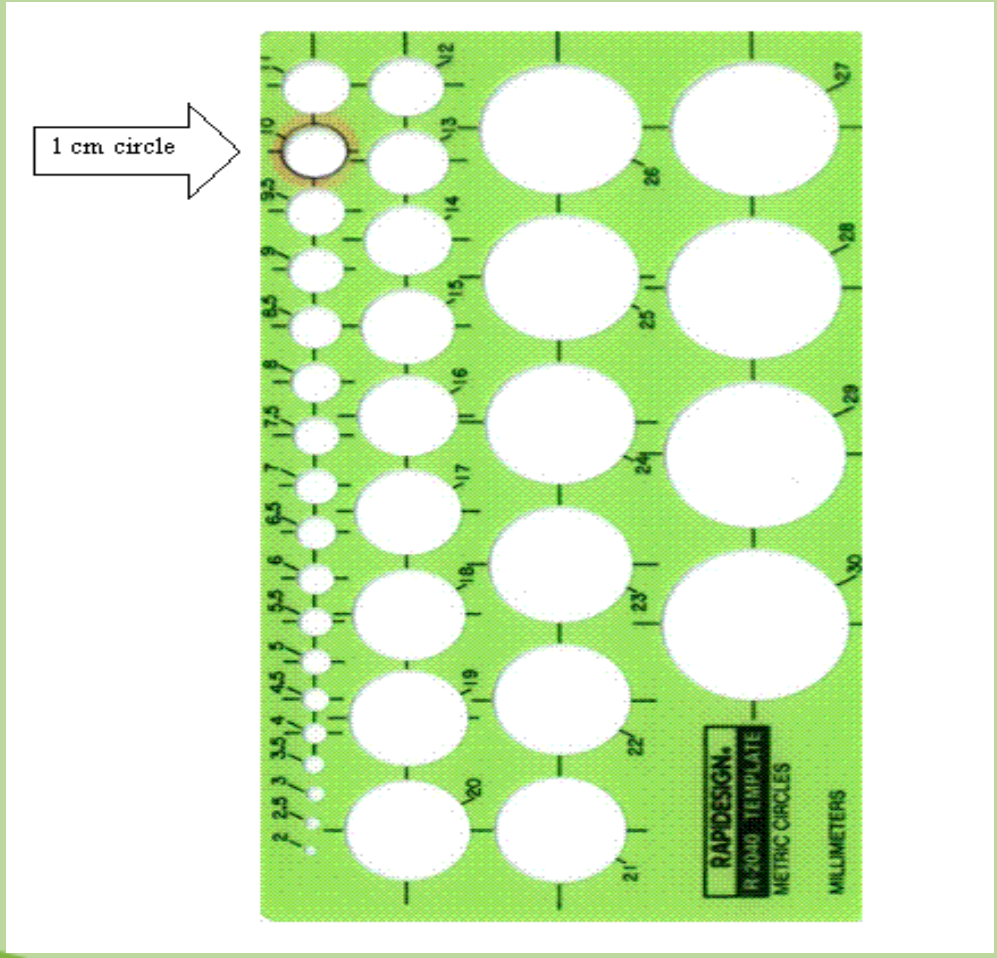
Aggregate Size Chart/Metric Circle Chart



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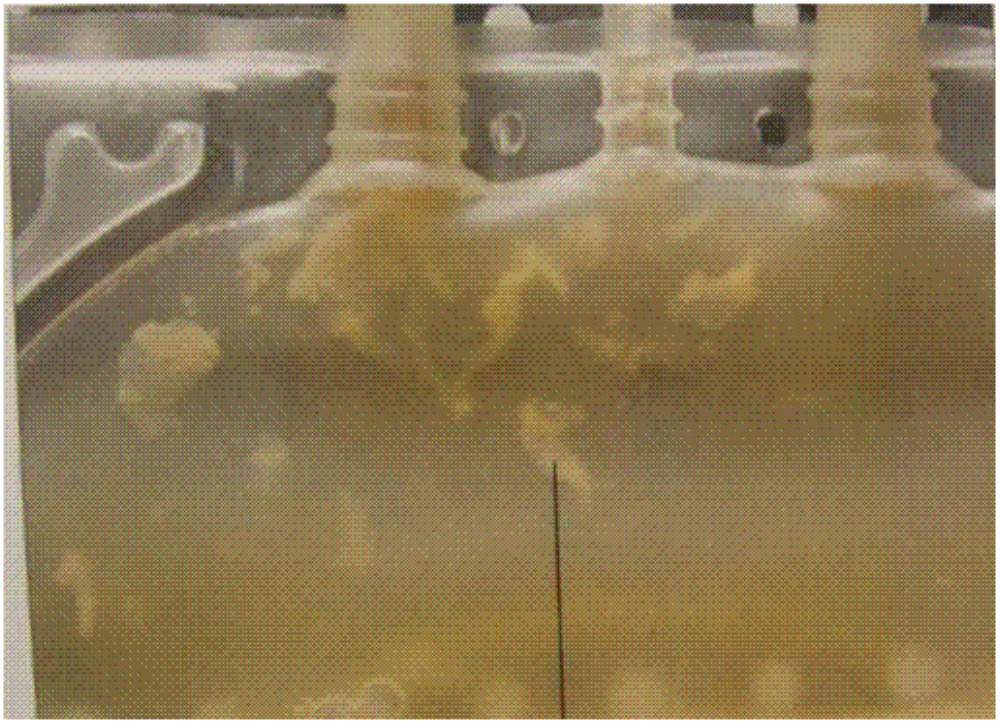
Clumpy Platelet Examples: Unacceptable

Unacceptable: Large Aggregates (appearance of "egg drop soup"), > 1 cm circle



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Clumpy Platelet Examples: Unacceptable

(continued)

Unacceptable: > 40 Small Aggregates

The vast majority of the aggregates, if combines would not fit within a 1 cm circle. In addition to the aggregates at the base of the bag, several have packed in the ports.

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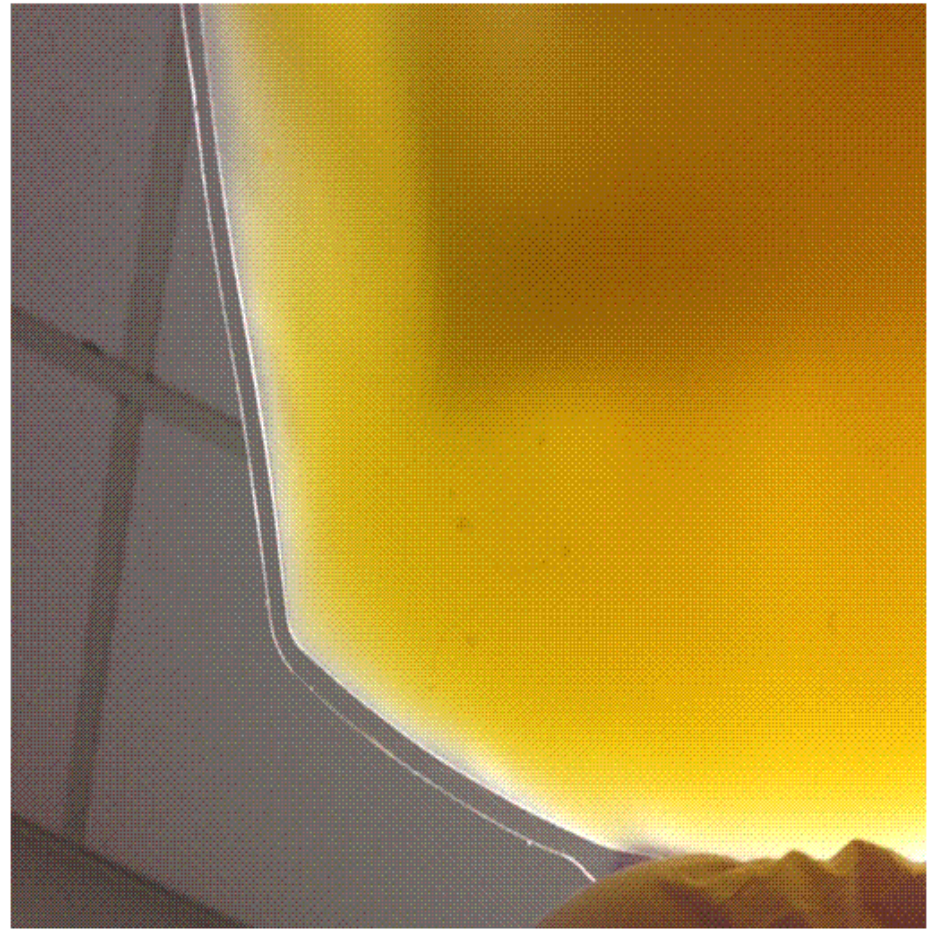
Platelet Example with Clumps: Acceptable

Acceptable: Small Clumps, Small in Number (<40), all aggregates fit within 1 cm circle



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White Particulate Matter

Causes

- Absence of leukocyte reduction
- Use of higher g-force in centrifugation
- Normal manufacturing process
- Normal storage process

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White Particulate Matter

Effects

- WB/RBC/Segments/Platelets
  - Crystalline material
  - Fatty material
  - Tissue
  - Waxy appearing globs
  - White specks

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White Particulate Matter

Acceptability

- Suitability for release

  See "FDA Update on Particulate Matter in Blood Bags", Oct 31, 2003

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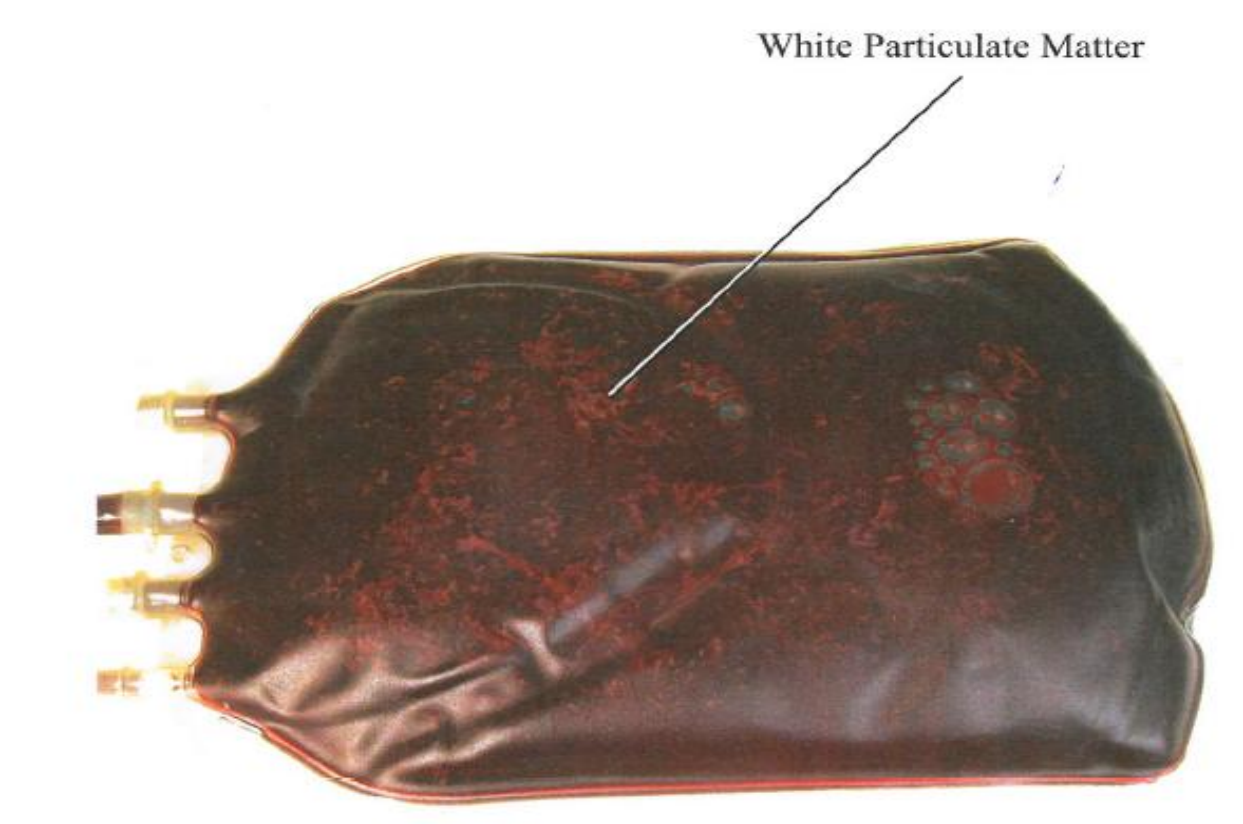
White Particular Matter



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Flocculent Plasma

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Flocculent Material

Causes

- Plasma is exposed to gradual or incomplete thawing
- Plasma is placed in refrigerator before being completely thawed
- Plasma is exposed to freeze, thaw, refreeze cycle

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Flocculent Material

Effects

- Plasma (Liquid) – cloudy, fuzzy, fluffy white precipitate; tissue paper-like appearance; disperses easlily

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Flocculent Material

Acceptability

- Suitable for release

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Flocculent Material

CBC Experience

- Increasing number of “clotted” FFP reported by hospital

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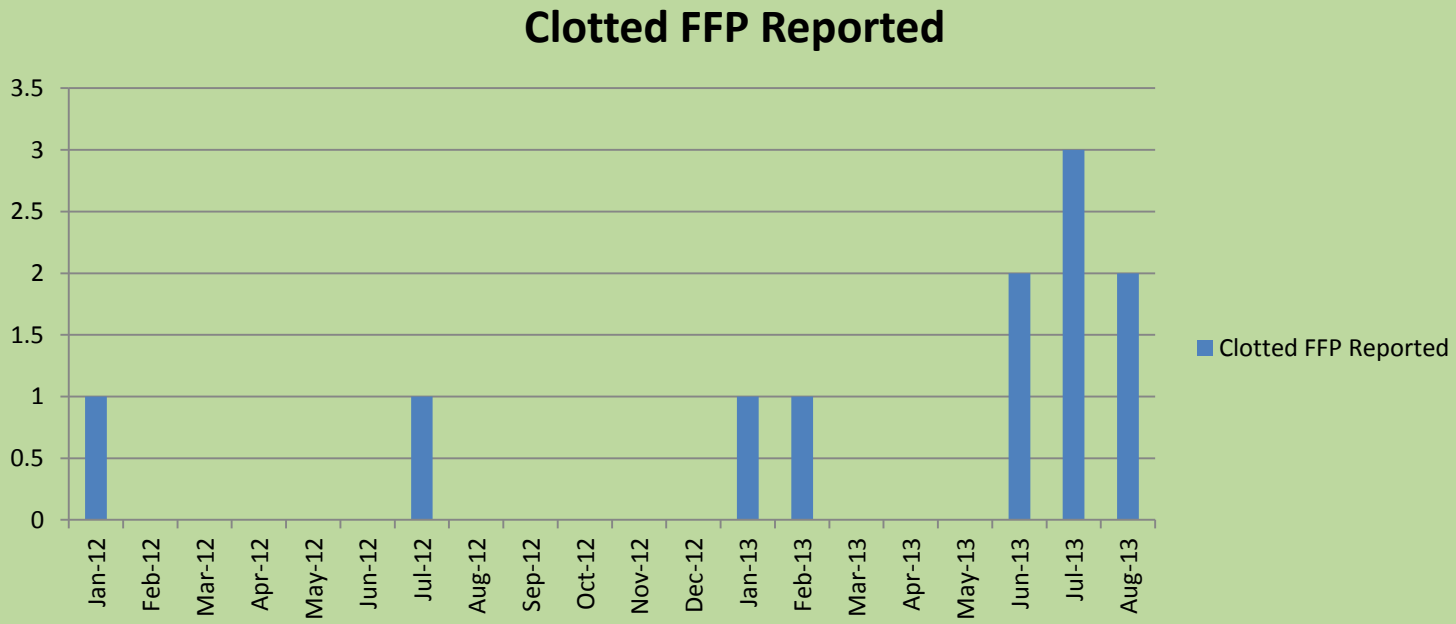
Clotted FFP Reported



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Investigation

- Determined the clots were not related to collection or manufacturing

- Contacted Fenwal
  - No problem reports from other centers
  - Did not appear to be bag lot related
  - Would forward to Fenwal Quality Engineer

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Fenwal Quality Engineer Report

- "Clots" may not actually be a clot
- Testing of material in returned units is consistent with cryoprecipitate & not clot formation
- To verify, place returned units in 37C˚ waterbath for 15-20 min to see if flocculation goes away

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CBC Experiment

- 5 returned thawed FFP units placed in 37C˚ waterbath.
- In all 5 units, the flocculent material disappeared, confirming Fenwal's theory that the "clots" are really cryo.

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Cryoprecipitate Production

- Freeze cryo rich plasma (CRP)
- Thaw CRP in 4˚ waterbath
- Cryo precipitates out
- Centrifuge unit & remove most of plasma, leaving cryo in bag

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Recommendations

- Ensure thawing is performed at 37C˚
- Verify that units are completely immersed in waterbath
- When thawing multiple units, ensure water bath temperature is maintained at 37C˚
- Verify units are thoroughly thawed before refrigeration
- During storage, avoid exposing plasma to temperatures that could result in a partial thaw

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Cold Agglutinins

- **Causes**
  - Autoantibody that reacts with donor/patients own cells at low temperature
- **Effects**
  - WB/RBC – may appear to have many small clots that look like coffee grounds or may be one large mass – all disperse when blood is warmed
- **Acceptability**
  - Not suitable for release

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Bacterial Contamination

Causes

- Donor with bacteremia
- Skin not properly cleaned prior to phlebotomy
- Collection kit sterility compromised

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Bacterial Contamination

Effects

- WB/RBC
  - Product darker than segments
  - Purple, brown
  - Unusual gas bubbles
  - Zone of hemolysis above RBC mass
  - Plasma is murky, purple, brown, red
  - Clots/fibrin strands
- Plasma/Platelets
  - Clots/fibrin strands
  - Murky
  - Unusual color

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Bacterial Contamination

Acceptability

- Not acceptable for release

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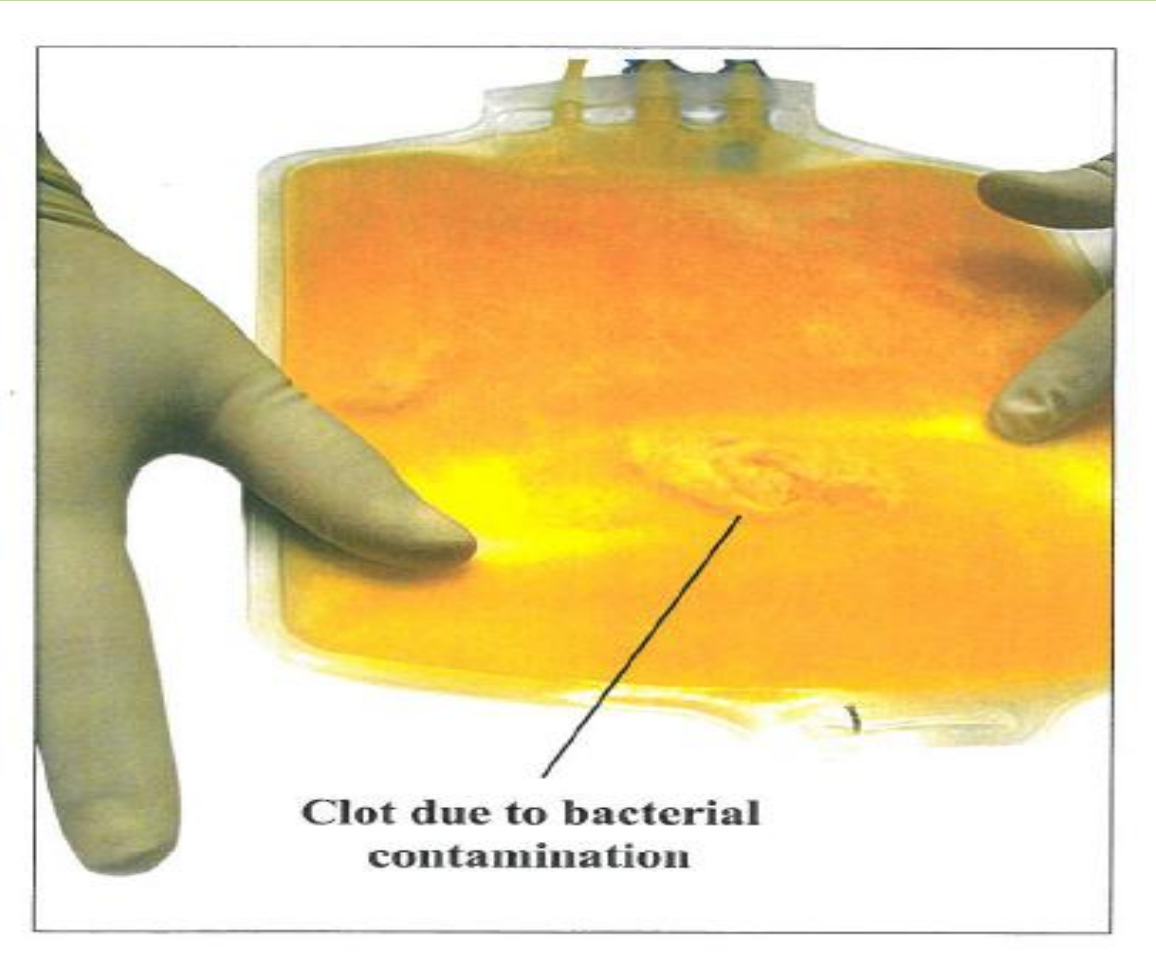
Bacterial Contamination



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Foreign Objects

Definition

- Part of collection set that's come loose within the container. Rarely, may be other object.

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Foreign Objects

Causes

- Manufacturers defect
- Operator error
- Handling during transport

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Foreign Objects

Acceptability

- Not acceptable for release

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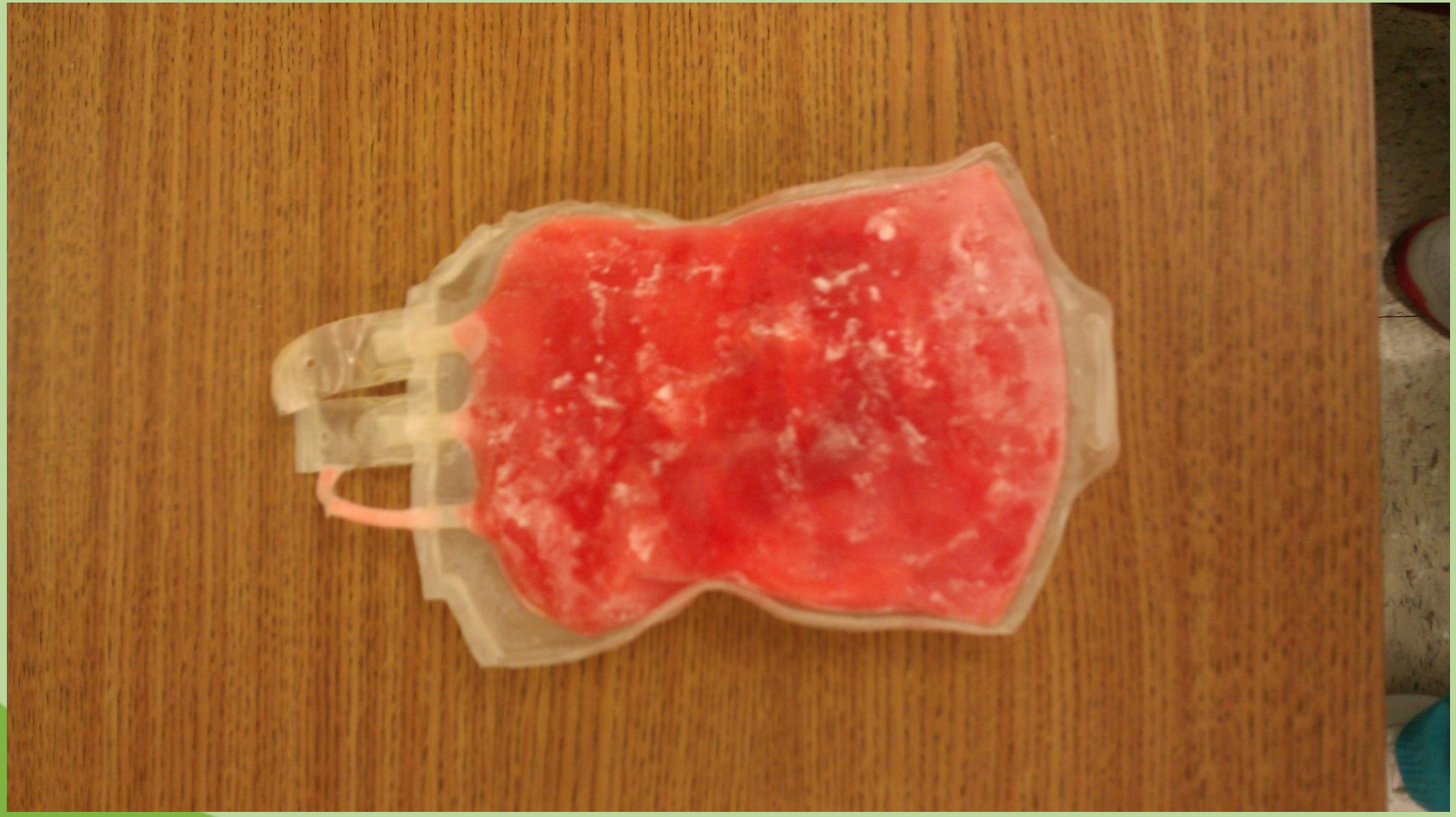

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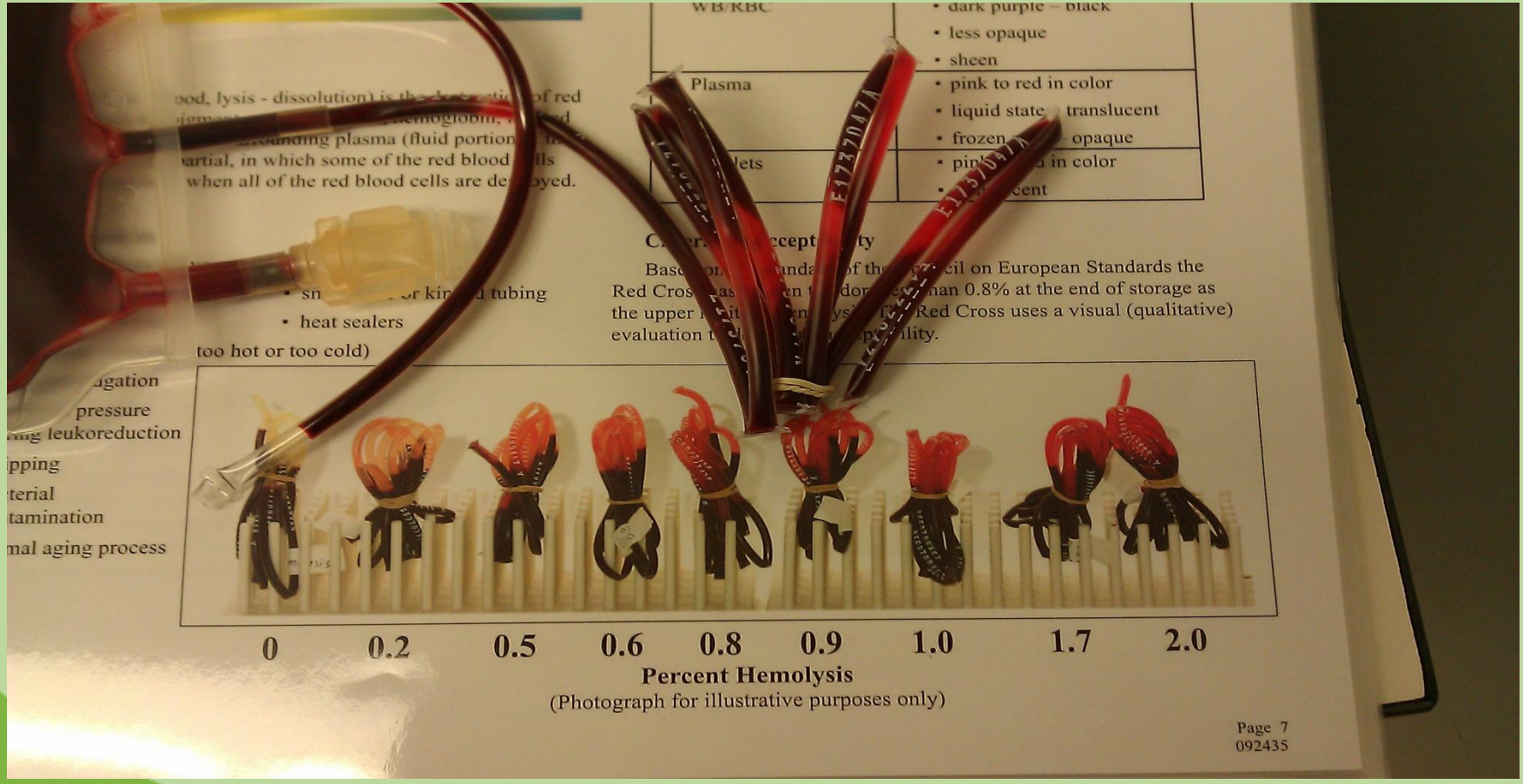
WB/RBC
• dark purple – black
• less opaque
• sheen
Plasma
• pink to red in color
• liquid state translucent
• frozen opaque
• heat sealers
too hot or kinked tubing
pressure
leukoreduction
0 0.2 0.5 0.6 0.8 0.9 1.0 1.7 2.0
Percent Hemolysis
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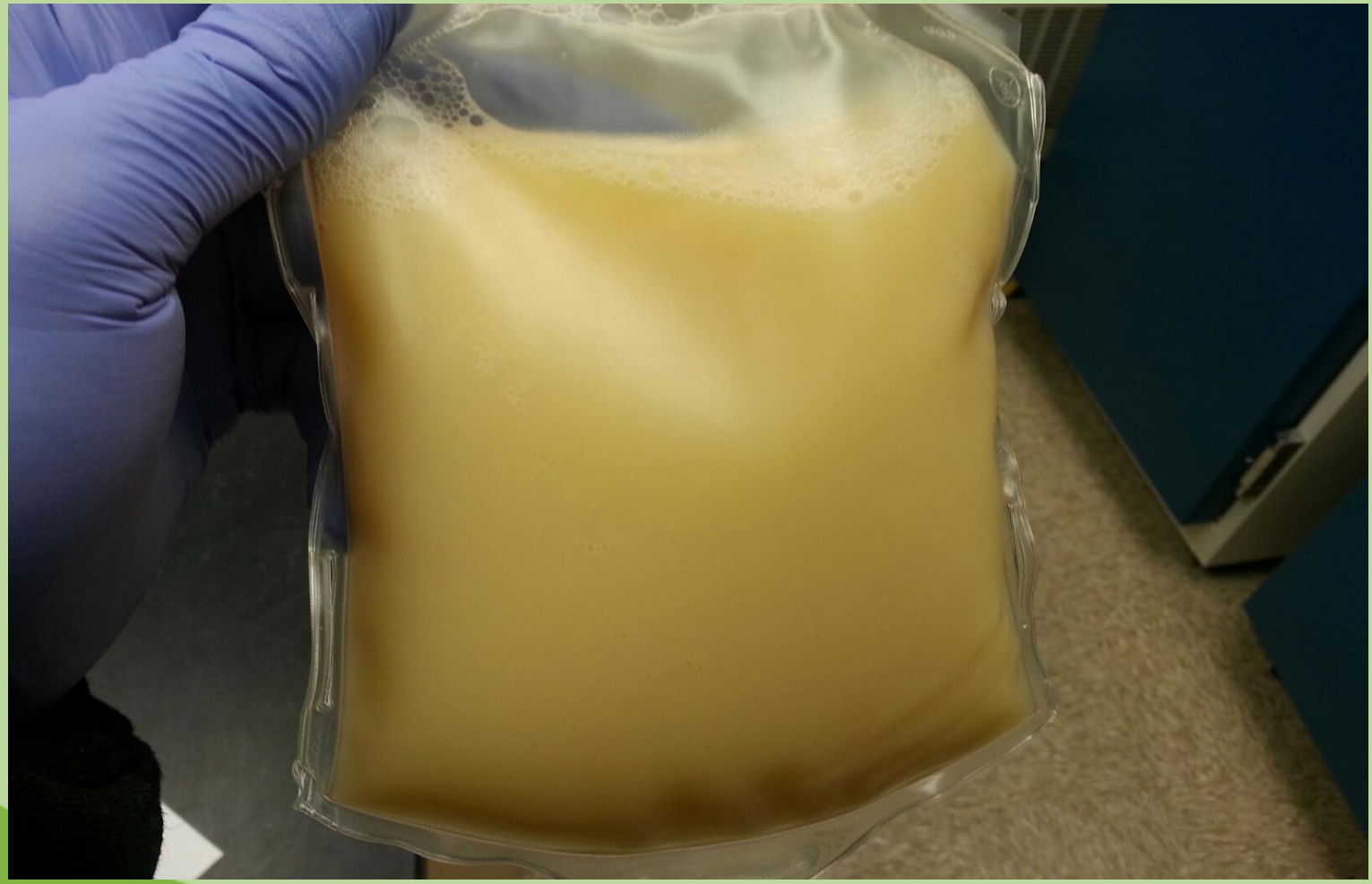

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What We've Covered Today

- Most common visual anomalies in blood products
- The cause of the anomalies
- When to use the product and when to send it back

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QUESTIONS?

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