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

A Guide to Product Visual Inspections
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
Resources used for this presentation

- Blood Component Visual Inspection Guide
- CBC KC SOPS and experience
“Normal” Products
“Normal” Products
“Normal” Products
“Normal” Products
“Normal” Products
“Normal” Products
Visual Anomalies

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

Percent Hemolysis
(Photograph for illustrative purposes only)
Hemolysis

Causes

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

Effects

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

- Some hemolysis is acceptable
- CBC uses $\leq 0.8\%$ hemolysis as compared to a color chart
Hemolyzed Platelets
Severe Hemolysis
Lipemic Plasma
Lipemia

Causes

- High fat meal
- Associated with disease state
e.g. hypercholesterolemia
Lipemia

Effects

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

- Does not affect safety of product
- Usually discarded for esthetics
Lipemic Segments
Hypertriglyceridermia
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
Clots remaining in primary bag after filtration
Green Plasma
## Discoloration

### Causes and Effects

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Possible Cause</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pale Green</td>
<td>Oral Contraceptive</td>
</tr>
<tr>
<td>Dark greenish brown</td>
<td>Icterus</td>
</tr>
<tr>
<td>Bright or fluorescent green</td>
<td>Drugs/bacteria contamination</td>
</tr>
<tr>
<td>Bright yellow to orange</td>
<td>Vitamins</td>
</tr>
<tr>
<td>reddish</td>
<td>RBCs /hemoglobin from incorrect preparation or equipment failure</td>
</tr>
</tbody>
</table>
Discoloration

Acceptability

- Pale to dark yellow
- Slight to green tinge
Particulate Matter

Includes

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

Causes

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

Effects

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

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
Aggregates

Effects

- Platelets – small whitish masses
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
Aggregate Size Chart/Metric Circle Chart

1 cm circle
Clumpy Platelet Examples: Unacceptable

Unacceptable: Large Aggregates (appearance of “egg drop soup”), > 1 cm circle
Unacceptable: > 40 Small Aggregates

The vast majority of the aggregates, if combined, 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.
Platelet Example with Clumps: Acceptable

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

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

Effects

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

Acceptability

- Suitability for release
White Particular Matter
Flocculent Plasma
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
Flocculent Material

Effects

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

Acceptability

- Suitable for release
CBC Experience

- Increasing number of “clotted” FFP reported by hospital
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
“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 37°C waterbath for 15-20 min to see if flocculation goes away
CBC Experiment

- 5 returned thawed FFP units placed in 37°C waterbath.

- In all 5 units, the flocculent material disappeared, confirming Fenwal’s theory that the “clots” are really cryo.
Cryoprecipitate Production

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

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

- **Causes**
  - Autoantibody that reacts with donor/patient's 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
Bacterial Contamination

Causes

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

Acceptability

- Not acceptable for release
Bacterial Contamination

Clot due to bacterial contamination
Foreign Objects

Definition

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

Causes

- Manufacturers defect
- Operator error
- Handling during transport
Foreign Objects

Acceptability

- Not acceptable for release
Blood lysis (dissolution) is the destruction of red blood cells, releasing hemoglobin, a red
pigment and the main component of hemoglobin. The red blood cells are surrounded by plasma (fluid portion) in the
reticuloendothelial system, in which some of the red blood cells are destroyed.

<table>
<thead>
<tr>
<th>WB RBC</th>
<th>Plasma</th>
<th>Platelets</th>
</tr>
</thead>
<tbody>
<tr>
<td>dark purple - black</td>
<td>pink to red in color</td>
<td>pink to red in color</td>
</tr>
<tr>
<td>less opaque</td>
<td>liquid state translucent</td>
<td>translucent</td>
</tr>
<tr>
<td>sheen</td>
<td>frozen, opaque</td>
<td>frozen, opaque</td>
</tr>
</tbody>
</table>

Chilled Acceptability

Based on guidelines of the Council on European Standards the
Red Cross has a limit of donor blood refrigeration temperature
at the upper limit of 4°C. After 4°C, the Red Cross uses a visual (qualitative) evaluation to determine
acceptability.

[Diagram of percent hemolysis]

Percent Hemolysis

(Photograph for illustrative purposes only)
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