Blood Component Production

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Canadian Blood Services
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Learning Objectives

• Describe the different blood components CBS produces
• Describe how the blood components are produced and their quality attributes
• Describe how many blood components are produced annually and the associated costs
Canadian Blood Services Enterprise Map
What does CBS produce?

It seems simple:

• Red Blood Cells
• Platelets
• Plasma Components
Red Blood Cells

• Red Blood Cells, Leukoreduced (LR)
  – Divided Red Blood Cells
  – Low Volume Red Blood Cells
  – Unfiltered Red Blood Cells

• Subsequent Production
  – Wash
  – Freeze/Deglycerolize
  – Irradiate
Platelets

• Pooled Platelets, LR
• Apheresis Platelets

• Subsequent Production
  – Irradiate
Plasma Components

- Frozen Plasma
- Fresh Frozen Plasma
- Divided Plasma
- Cryoprecipitate
- Cryosupernatent Plasma
- Recovered Plasma
- Source Plasma
Collection Sources

• Whole Blood … a process where whole blood is collected into a multi bag system which allows for the production of specific cellular and plasma components.

• Apheresis … a process by which blood being removed from a subject is continuously separated into component parts, usually to allow a desired component (or components) to be retained while the remainder is returned to the subject\(^1\).

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Whole Blood Collection

• Two Bag configurations
  – Platelet production
  – Non platelet production

• Two vendor strategy
B1 Bag – Platelet Production

Top / Bottom tubing system

- Bottom tubing connects to Red Cell Container with in line Red Cell Filter
- Top tubing connects to the Plasma container
- Buffy Coat in original collection bag
- Room temperature supply chain
Why Room Temperature?

- Temperatures \(< 20^\circ C\) activate platelets
- Active platelets clump (form thrombi)
Why Room Temperature?

- The closer to body temperature, the better bacteria grow
At the Clinics - Cooling Trays

- 24 hours allowed for component production through the use of a rapid cooling technique

- Improves availability of platelets
Production Site

- Next day production benefits
  - white blood cells hunt down any bacteria and other antigens
  - better platelet recoveries
  - production line
Centrifugation is DIFFERENTIAL: “more dense” settle before “less dense”

Hard Spin creates a buffy coat layer
Compomat – automated simultaneous extraction of Red Cells and Plasma

• Computer-controlled extraction allows for increased process control
  ⇒ better quality product
  ⇒ more consistent recoveries therefore more consistent platelet dose
  ⇒ higher percentage of platelets recovered per donation
The red cells are ready for filtration...
Red Blood Cell Filtration
Buffy Coat

Platelet recovery is much better if the platelets can rest and de-activate
Compodock - sterile docking

- 4 buffy coats pooled with one liquid plasma
- Product is pooled in plasma from male donors to reduce the risk of TRALI
Pooling Process

2nd Spin (soft spin)
Extraction of the Platelet Concentrate

Leukoreduction filter
B2 Bag – Non Platelet Production

Top / Top tubing system

- Tubing connects Whole Blood Collection Container to the filter
- Red Cell and plasma Storage Container + 1 extra storage bag
- Cold Chain
- Used when conditions are not suitable for Buffy Coat Method.
Whole Blood Filtration, then Centrifugation
Automated extraction of Red Blood Cells and Plasma – B2
Red Blood Cells

Storage Requirements
• Store at 1-6°C
• Expires at 42 days

QC Requirements

<table>
<thead>
<tr>
<th>Test</th>
<th>Acceptance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematocrit</td>
<td>≤ 0.80 L/L in 90% units tested</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>≥ 40 g/unit in 90% units tested AND ≥ 35 g/unit in all units tested</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>&lt; 0.8% in all units tested</td>
</tr>
<tr>
<td>Residual WBC Count</td>
<td>&lt; 5 x 10⁶/unit in all units tested</td>
</tr>
<tr>
<td>Volume</td>
<td>± 10% labelled volume in all units</td>
</tr>
<tr>
<td>Sterility</td>
<td>No growth</td>
</tr>
</tbody>
</table>
Pooled Platelet

Storage Requirements
- Store at 20-24°C with continuous agitation
- Expires at 5 days

QC Requirements

<table>
<thead>
<tr>
<th>Test</th>
<th>Acceptance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platelet Yield</td>
<td>&gt; 240 x 10⁹/unit in ≥ 75% of units tested</td>
</tr>
<tr>
<td>Volume</td>
<td>± 10% labelled volume in all units</td>
</tr>
<tr>
<td>pH</td>
<td>6.4 – 7.8 in all units</td>
</tr>
<tr>
<td>Residual WBC Count</td>
<td>&lt; 5 x 10⁶/unit in all units tested</td>
</tr>
<tr>
<td>Sterility</td>
<td>No growth</td>
</tr>
</tbody>
</table>
Bacterial Detection of Platelets

- Pooled platelets and apheresis platelets tested by Canadian Blood Services using the BacT/ALERT method prior to release to hospital
Frozen Plasma

**Storage Requirements**
- Store at $\leq 18^\circ C$
- Expires at 12 months

**QC Requirements**

<table>
<thead>
<tr>
<th>Test</th>
<th>Acceptance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>FVIII</td>
<td>$\geq 0.52$ IU/mL in $\geq 75%$ of units tested</td>
</tr>
<tr>
<td>Volume</td>
<td>$\pm 10%$ labelled volume in all units</td>
</tr>
<tr>
<td></td>
<td>$\geq 100$ mL in all units</td>
</tr>
</tbody>
</table>
First Stage Cryoprecipitate

Frozen Plasma units are hung overnight in the fridge.
Cryoprecipitate/ Cryosupernatant

Storage Requirements:
- Store at ≤ 18°C
- Expires at 12 months

QC Requirements

<table>
<thead>
<tr>
<th>Test</th>
<th>Acceptance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fibrinogen</td>
<td>• ≥ 150 mg/unit in ≥ 75% of units tested</td>
</tr>
<tr>
<td>Volume</td>
<td>• 5-15 mL</td>
</tr>
<tr>
<td></td>
<td>• ± 10% labelled volume in all units</td>
</tr>
</tbody>
</table>

QC Requirements

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<th>Acceptance Criteria</th>
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</thead>
<tbody>
<tr>
<td>Volume</td>
<td>• ± 10% labelled volume in all units</td>
</tr>
<tr>
<td></td>
<td>• ≥ 100 mL in all units tested</td>
</tr>
</tbody>
</table>
Cell Washer – Washed/Deglycerolized

Storage Requirements
• Store at 1-6C
• Expires at 24 hours

QC Requirements

<table>
<thead>
<tr>
<th>Test</th>
<th>Acceptance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematocrit</td>
<td>• ≤ 0.80 L/L in 90% of units tested</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>• ≥ 35 g/unit in 90% of units tested</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>• &lt; 0.8% in 90% of units tested</td>
</tr>
</tbody>
</table>
Irradiator

Storage Requirements
• Same temperature
• RBC expires at 28 days

QC Requirements
• No additional criteria
Apheresis Collections

• Two Bag configurations
  – Platelet Collection
  – Plasma Collection
Apheresis – multi-component devices
Fresh Frozen Plasma

Storage Requirements
• Store at ≤ 18°C
• Expires at 12 months

QC Requirements

<table>
<thead>
<tr>
<th>Test</th>
<th>Acceptance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>FVIII</td>
<td>• ≥ 0.70 IU/mL in 75% of units tested</td>
</tr>
</tbody>
</table>
| Volume  | • ± 10% labelled volume in all units
         | • ≥ 100mL in all units tested                           |
Apheresis Platelets

Storage Requirements
- Store at 20-24°C with continuous agitation
- Expires at 5 days

QC Requirements

<table>
<thead>
<tr>
<th>Test</th>
<th>Acceptance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platelet Yield</td>
<td>≥ 300 x 10^9/unit in ≥ 75% of units tested</td>
</tr>
<tr>
<td>Volume</td>
<td>± 10% labelled volume in all units</td>
</tr>
<tr>
<td>pH</td>
<td>6.4 - 7.8 in all units</td>
</tr>
<tr>
<td>Residual WBC Count</td>
<td>&lt; 5 x 10^5/unit in all units tested</td>
</tr>
<tr>
<td>Sterility</td>
<td>No growth</td>
</tr>
</tbody>
</table>
How Much Is Produced?

<table>
<thead>
<tr>
<th>Blood Component</th>
<th>Annual Production (2011-12)</th>
<th>Cost per Unit April 2011</th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Blood Cells</td>
<td>881,647</td>
<td>$425</td>
</tr>
<tr>
<td>Frozen Plasma</td>
<td>103,005</td>
<td>$39</td>
</tr>
<tr>
<td>Cryoprecipitate</td>
<td>55,249</td>
<td>$136</td>
</tr>
<tr>
<td>Cryosupernatant Plasma</td>
<td>55,249</td>
<td>$34</td>
</tr>
<tr>
<td>Recovered Plasma</td>
<td>628,167</td>
<td></td>
</tr>
<tr>
<td>Pooled Platelets</td>
<td>93,716</td>
<td>$280</td>
</tr>
<tr>
<td>Apheresis Platelets</td>
<td>43,045</td>
<td>$603</td>
</tr>
<tr>
<td>Apheresis Fresh Frozen Plasma</td>
<td>40,233</td>
<td>$358</td>
</tr>
<tr>
<td>Total Production</td>
<td>1,900,311</td>
<td></td>
</tr>
</tbody>
</table>
What is On Our Shelves?

<table>
<thead>
<tr>
<th>Snapshot of CBS Inventory - July 27, 2012</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Red Blood Cells</td>
<td>21,072</td>
</tr>
<tr>
<td>FP/FFP</td>
<td>10,740</td>
</tr>
<tr>
<td>Cryoprecipitate</td>
<td>3,227</td>
</tr>
<tr>
<td>Cryosupernatant Plasma</td>
<td>4,676</td>
</tr>
<tr>
<td>Platelets</td>
<td>425</td>
</tr>
</tbody>
</table>
Additional resources

- [www.transfusionmedicine.ca](http://www.transfusionmedicine.ca)
- [www.blood.ca](http://www.blood.ca)
  - CBS Circular of Information
  - Clinical Guide to Transfusion
  - Visual Assessment Guide
  - Customer Letters