COMPONENT STANDARD
CRYOPRECIPITATE APERESIS – HIGH FIBRINOGEN

REASON FOR ISSUE: Document renumbered.

1. Component Name
Cryoprecipitate Apheresis – High Fibrinogen, Leucocyte Depleted

2. Component Description
This component is a concentrated source of Factor VIII, von Willebrand factor, fibrinogen and fibronectin prepared from a unit of plasma collected from a single donor using apheresis containing < 5 x 10^6 leucocytes per unit.

3. Technical Specifications

<table>
<thead>
<tr>
<th>Specification</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>80 – 120 mL</td>
</tr>
<tr>
<td>Leucocyte Count</td>
<td>&lt; 5 x 10^6/unit</td>
</tr>
<tr>
<td>Fibrinogen</td>
<td>≥ 750 mg/unit – 3 g/unit</td>
</tr>
<tr>
<td>Factor VIIIc</td>
<td>≥ 150 IU/unit</td>
</tr>
<tr>
<td>Anticoagulant</td>
<td>Sodium Citrate Solution 4% USP</td>
</tr>
</tbody>
</table>

4. Donor Specifications
Meets the requirements of the current edition of the Collection Standards.

5. Testing
Compliance with the WBC requirement in the starting unit will be monitored by statistical process control methods (SPC). A minimum of 75% of components tested must meet specifications for volume, Factor VIIIc and fibrinogen.

<table>
<thead>
<tr>
<th>Tests</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Volume</td>
<td>1%, minimum of 4 per month</td>
</tr>
<tr>
<td>Factor VIIIc</td>
<td>1%, minimum of 4 per month</td>
</tr>
<tr>
<td>Fibrinogen</td>
<td>1%, minimum of 4 per month</td>
</tr>
</tbody>
</table>

6. Storage and Expiry
The component should be stored at a temperature of -25°C or below for a maximum period of 24 months.

Once thawed the component should be stored at room temperature and be used within 4 hours. It must not be refrozen.

7. Transport
Every effort should be made to maintain the storage temperature of -25°C or below during transportation unless intended for immediate clinical use.

8. **Labelling**

The label should include:

- Name of the component – Cryoprecipitate Apheresis – High Fibrinogen Leucocyte Depleted*
- Volume
- Name of the collection centre*
- Donation number*
- ABO group*
- Rh(D) group stated as positive or negative*
- Date of expiry*
- The storage temperature
- A statement – “Use within 4 hours of thawing” and “store at ambient temperature after thawing”
- Blood pack lot number*

(* eye readable and barcode format)

In addition the following instructions are included:

- Check the identity of the recipient and the component
- Inspect the pack for deterioration or damage
- Risk of adverse reaction/infection