COMPONENT STANDARD

CRYOPRECIPITATE APHERESIS – 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 $< 5 \times 10^6$ leucocytes per unit.

3. Technical Specifications

Volume:	80 – 120 mL
Leucocyte Count:	$< 5 \times 10^6$/unit
Fibrinogen:	$\geq$ 750 mg/unit – 3 g/unit
Factor VIIIc:	$\geq$ 150 IU/unit
Anticoagulant:	Sodium Citrate Solution 4% USP

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.

Tests	**Frequency**
Volume	1%, minimum of 4 per month
Factor VIIIc	1%, minimum of 4 per month
Fibrinogen	1%, minimum of 4 per month

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