BLOOD COMPONENT MONOGRAPH
CRYOPRECIPITATE APHERESIS HIGH FIBRINOGEN LEUCOCYTE DEPLETED

REASON FOR ISSUE: DCR39128 - Update to include ISBT 128 component codes, and label changes.

Council of Europe Guide Monograph	Cryoprecipitate
eProgesa Component Name	Cryoprecipitate Apheresis High Fibrinogen Leucocyte Depleted
eProgesa Component Code	11090, E6300V00

1. DEFINITION and PROPERTIES

Cryoprecipitate Apheresis High Fibrinogen Leucocyte Depleted (LD) is a component containing the sedimented cryoglobulin fraction of plasma obtained by further processing of *Plasma, Intermediate Apheresis LD.*

It contains a major portion of the Factor VIII, von Willebrand factor, fibrinogen, Factor XIII and fibronectin prepared from a unit of plasma collected from a single donor using apheresis containing $< 5 \times 10^6$ leucocytes per unit.

2. PREPARATION

Plasma, Intermediate Apheresis LD is thawed using a two-stage process. Stage one is an overnight thaw at -5°C and stage two is an overnight thaw between 2 - 6°C. After thawing, the component is re-centrifuged using a hard spin at 2 - 6°C. The supernatant cryoprecipitate-poor plasma is then partially removed. The sedimented cryoprecipitate is then rapidly frozen.

3. REQUIREMENTS and QUALITY CONTROL

As indicated for *Plasma, Fresh Frozen LD* with the additional requirements given in the table below.

3.1 Quality Monitoring Requirements

Parameter	Requirements	Frequency of control
Volume	80 – 120 mL	All units
Fibrinogen	≥ 400 mg / unit	1 % of all units with a minimum of 4 units per month
Factor VIIIc [1]	≥ 150 IU / unit	

1. Only required if component used for treatment of haemophilia patients.

A minimum of 75% of components tested must meet specifications for volume, Factor VIIIc and fibrinogen.

BLOOD COMPONENT MONOGRAPH
CRYOPRECIPITATE APHERESIS HIGH FIBRINOGEN LEUCOCYTE DEPLETED

4. STORAGE and TRANSPORT

4.1 Storage

The stability of *Cryoprecipitate Apheresis High Fibrinogen LD* on storage is dependent on the storage temperature.

The component should be stored at a temperature of – 25°C or below for a maximum period of 24 months.

Before use, *Cryoprecipitate Apheresis High Fibrinogen LD* must be thawed in a properly controlled environment at +37°C immediately after removal from storage. Dissolution of the precipitate must be encouraged by careful manipulation during the thawing procedure. No insoluble cryoprecipitate must be visible on completion of the thaw procedure.

In order to preserve labile factors, *Cryoprecipitate Apheresis High Fibrinogen LD* must be used as soon as possible following thawing. It may be stored at ambient temperature and used within 4 hours of thawing. It must not be re-frozen.

4.2 Transport

The storage temperature must be maintained during transport. The receiving hospital blood bank must ensure that *Cryoprecipitate Apheresis High Fibrinogen LD* has remained frozen during transit. Unless for immediate use the *Cryoprecipitate Apheresis High Fibrinogen LD* must be transferred at once to storage at the temperature stated above.

5. LABELLING

The labelling must comply with the relevant national legislation and international agreements. The following information must be shown on the label or contained in this component monograph, as appropriate:

- component name; *Cryoprecipitate Apheresis High Fibrinogen LD*
- component code
- volume
- name of the Processing centre
- donation number*
- ABO group;
- RhD group stated as positive or negative*
- date of collection
- date of expiry*
- name of the approved anticoagulant solution
- storage temperature
- “Use within 4 hours of thawing”
- “N.B. Store at ambient temperature after thawing”

* eye readable and barcode format

After thawing, the date of expiry must be changed to the appropriate date (and time) of expiry.

In addition, the following instructions are included:

- always check that the recipient for this component is properly identified
- do not use if there are signs of deterioration or other damage
- use a standard transfusion set
- this product carries a risk of adverse reaction / infection
- contact your Blood Bank for further information

6. WARNINGS

Cryoprecipitate Apheresis High Fibrinogen LD is not recommended for patients with an intolerance to plasma proteins.

Adverse reactions include:

- non-haemolytic transfusion reaction (mainly chills, fever and urticaria);
- transfusion-related acute lung injury (TRALI);
- viral transmission (hepatitis, HIV, etc.) is possible, despite careful donor selection and screening procedures;
- sepsis due to inadvertent bacterial contamination;
- transmission of other pathogens that are not tested for or recognised;
- citrate toxicity in neonates and in patients with impaired liver function;
- transfusion associated circulatory overload;
- anaphylaxis and allergic reactions;