Guidelines for the Blood Transfusion Services

7.5.3: Cryoprecipitate, Leucocyte Depleted

http://www.transfusionguidelines.org/red-book/chapter-7/7-5/7-5-3

7.5.3: Cryoprecipitate, Leucocyte Depleted

The component provides a concentrated source of FVIII, and von Willebrand factor, fibrinogen, FXIII and fibronectin. It is derived from a unit of Fresh Frozen Plasma, Leucocyte Depleted. The plasma from which the Cryoprecipitate, Leucocyte Depleted is produced contains less than 1×10^6 leucocytes per component.

7.5.3.1: Technical information

- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for the production of plasma components for direct clinical use.
- Cryoprecipitate, Leucocyte Depleted is the cryoglobulin fraction of plasma obtained by thawing a single donation of Fresh Frozen Plasma, Leucocyte Depleted (see section 7.5.1) at 4 ±2°C.
- Plasma should be selected from male donors or consideration should be given to screening female donors for HLA/HNA antibodies, as a TRALI risk reduction measure.
- For storage, Cryoprecipitate, Leucocyte Depleted should be rapidly frozen to a core temperature of –25°C or below within 2 hours of preparation.
- Component samples collected for the quality monitoring assessment of FVIII should be from an equal mix of group O and non-O donations due to the difference in FVIII levels between ABO blood groups.
- Cryoprecipitate, Leucocyte Depleted should be administered through a CE/UKCA/UKNI marked transfusion set.

7.5.3.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the component label:

(* = in eye-readable and UKBTS approved barcode format)

- Cryoprecipitate, Leucocyte Depleted* and volume
- the blood component producer’s name*
- the donation number*
- the ABO group*
- the RhD group stated as positive or negative*
- the date of collection
- the expiry date of the frozen component*

- the temperature of storage
- the blood pack lot number*
- a warning that the component must be used within 4 hours of thawing
- the name, composition and volume of the anticoagulant.

In addition, the following statements should be made:

INSTRUCTION
Always check patient/component compatibility/identity
Inspect pack and contents for signs of deterioration or damage
Risk of adverse reaction/infection, including vCJD

7.5.3.3: Storage

For general guidelines, see section 6.7.

- The component should be stored at a core temperature of –25°C or below for a maximum of 36 months.

- Although a storage temperature below –25°C improves the preservation of labile coagulation factors, lower temperatures increase the fragility of plastic. Particular care must be taken when handling such packs.

- The component should be thawed in a waterbath or other equipment designed for the purpose, within a vacuum-sealed overwrap bag according to a validated procedure. The optimal temperature at which the component should be thawed is 37°C; temperatures between 33°C and 37°C are acceptable.

- Protocols must be in place to ensure that the equipment is regularly cleaned and maintained to minimise the risk of bacterial contamination. After thawing, the content should be inspected to ensure that no insoluble precipitate is visible and that the container is intact.

- Once thawed, the component must not be refrozen and should be used immediately. If delay is unavoidable, the component should be stored at ambient temperature and used within 4 hours.

7.5.3.4: Testing

In addition to the mandatory and other tests required for blood donations described in Chapter 9, and leucocyte counting (see sections 6.3 and 7.1.1), a minimum of 75% of those components tested for the parameters shown in Table 7.5.3 shall meet the specified values.

Table 7.5.3 Cryoprecipitate, Leucocyte Depleted – additional tests

Parameter	Frequency of test	Specification
Volume	1% or as determined by statistical process control (if <=10 components produced per month then test every available component)	Within locally defined nominal range
Fibrinogen		>=140 mg/unit
FVIII		>=70 IU/unit
Leucocyte count [1,2]	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/unit
[1] Methods validated for counting low numbers of leucocytes must be used		
[2] Pre-freeze in starting component		

7.5.3.5: Transportation

For general guidelines, see section 6.11.

Every effort should be made to maintain the core storage temperature during transportation. Unless the component is to be thawed and used straightaway it should be transferred immediately to storage at the recommended temperature.