Guidelines for the Blood Transfusion Services

7.5.4: Cryoprecipitate, Pooled, Leucocyte Depleted

http://www.transfusionguidelines.org/red-book/chapter-7/7-5/7-5-4

7.5.4: Cryoprecipitate, Pooled, Leucocyte Depleted

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

7.5.4.1: 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, Pooled, Leucocyte Depleted is the cryoglobulin fraction of plasma obtained by thawing and pooling five single Cryoprecipitate, Leucocyte Depleted components or pooling five single Cryoprecipitate, Leucocyte Depleted components immediately after production from thawed fresh frozen plasma.
- 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 Pooled, 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.
- Initial process validation must ensure that for a minimum of 20 tested Cryoprecipitate, Pooled, Leucocyte Depleted components a minimum of 75% of those components tested for the parameters shown in Table 7.5.4 shall meet the specified values.
- Annual process validation is acceptable for quality monitoring purposes, provided that the primary components, Fresh Frozen Plasma, Leucocyte Depleted and/or Cryoprecipitate, Leucocyte Depleted are separately monitored as part of monthly testing. If this is not the case, test monthly 1% or as determined by statistical process control (if <=10 components produced per month then test every available component), of Cryoprecipitate Pooled, Leucocyte Depleted components. A minimum of 75% of those components tested for the parameters shown in Table 7.5.4 shall meet the specified values.
- A secure system must be in place to ensure a full audit trail and that the correct identification number is put on the final component pack.

- Cryoprecipitate Pooled, Leucocyte Depleted should be administered through a CE/UKCA/UKNI marked transfusion set.

7.5.4.2: 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, Pooled, Leucocyte Depleted* and volume
- the blood component producer's name*
- a unique pool or batch number or the donation number of all contributing units*
- the ABO group*
- the RhD group stated as positive or negative*
- 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 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

7.5.4.3: 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 vacuumsealed 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 transfused as soon as possible. If delay is unavoidable, the component should be stored at ambient temperature and used within 4 hours.

7.5.4.4: 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 at Table 7.5.4 shall meet the specified values.

Table 7.5.4 Cryoprecipitate, Pooled, 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)	100 – 250 mL
Fibrinogen	Refer to Technical information (section 7.5.4.1) above	>=700 mg/unit
FVIII		>=350 IU/unit
Leucocyte count [1]	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/unit in the starting component
[1] Pre-freeze in starting component		

7.5.4.5: 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.