Guidelines for the Blood Transfusion Services

7.5.5: Cryoprecipitate, Pooled, Pathogen Reduced, Leucocyte Depleted

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

7.5.5: Cryoprecipitate, Pooled, Pathogen Reduced, Leucocyte Depleted

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

7.5.5.1: 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, Pathogen Reduced, Leucocyte Depleted is the cryoglobulin fraction of plasma obtained by thawing and pooling between 6 and 12 single Cryoprecipitate for Neonates and Infants, Pathogen Reduced, Leucocyte Depleted components.
- Plasma should be selected from male donors or screening of female donors for HLA/HNA antibodies should be considered, as a TRALI risk reduction strategy.
- For storage, Cryoprecipitate, Pooled, Pathogen Reduced, 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.
- Annual process validation is acceptable for leucodepletion quality monitoring purposes, provided that the primary components, Fresh Frozen Plasma, Pathogen Reduced, 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, Pathogen Reduced, Leucocyte Depleted components. A minimum of 75% of those components tested for the parameters shown at Table 7.5.5 below shall meet the specified values.
- A secure system must be in place to ensure a full audit trail and the correct identification number is put on the final component pack.
- Cryoprecipitate, Pooled, Pathogen Reduced, Leucocyte Depleted, should be administered through a CE/UKCA/UKNI marked transfusion set.

7.5.5.2: Labelling

The following shall be included on the component label:

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

- Cryoprecipitate, Pooled, Pathogen Reduced, Leucocyte Depleted * and volume
- the name of the PI system used
- 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 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 and allergy
to the compounds used for, or derived from, PI treatment.

7.5.5.3: Storage

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

- Protocols must be in place to ensure that the equipment is regularly cleaned and maintained to minimize 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.

7.5.5.4: 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 7.5.5 shall meet the specified values.

Table 7.5.5 Cryoprecipitate, Pooled, Pathogen Reduced, 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) Refer to Technical information (section 7.5.5.1) above	100 – 300 mL
Fibrinogen		>=700 mg /unit
FVIII		>=250 IU/mL
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		

7.5.5.5: Transportation

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