Guidelines for the Blood Transfusion Services

A4.5 Plasma, Cryoprecipitate Depleted, Leucocyte Depleted

http://www.transfusionguidelines.org/red-book/annexe-4/a4-5

Redundant Component

A4.5: Plasma, Cryoprecipitate Depleted, Leucocyte Depleted

The supernatant plasma removed during the preparation of Cryoprecipitate, Leucocyte Depleted. The plasma from which the Plasma, Cryoprecipitate Depleted, Leucocyte Depleted was made contains less than 1×10^6 leucocytes per component and is derived from a previously tested donor.

A4.5.1: 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.
- 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.
- Plasma, Cryoprecipitate Depleted, Leucocyte Depleted should be frozen to a core temperature of –25°C or below within 2 hours of separation from its Cryoprecipitate, Leucocyte Depleted.
- Plasma, Cryoprecipitate Depleted, Leucocyte Depleted should be transfused through a 170–200 µm filter.

A4.5.2: 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)

- Plasma, Cryoprecipitate Depleted, 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 if maintained at 22 ±2°C, or 24 hours of thawing if stored at 4 ±2°C
- 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

A4.5.3: 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 cleaned daily and maintained to minimise the risk of bacterial contamination. After thawing, the content should be inspected to ensure that no insoluble cryoprecipitate 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 may be stored and should be used within 4 hours if maintained at 22 ±2°C or 24 hours if stored at 4 ±2°C, but it should be borne in mind that extended post-thaw storage will result in a decline in the content of labile coagulation factors.

A4.5.4: 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 A4.5 shall meet the specified values.

Table A4.5 Plasma, Cryoprecipitate Depleted, 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)	Stated volume ±10%
Platelet count		<30 × 10^9/L**
Red cell count		<6 × 10^9/L**
Leucocyte count*	As per sections 6.3 and 7.1.1	<1 × 10^6/unit**
* Methods validated for counting low numbers of leucocytes must be used		
** Pre-freeze in starting component (fresh frozen plasma)		

A4.5.5: 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.