

Issued by JPAC: 04 May 2020

Implementation: To be determined by each Service

## **Change Notification UK National Blood Services No. 24 - 2020**

# **Cryoprecipitate for Neonates and Infants, Leucocyte Depleted**

**Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom 8<sup>th</sup> Edition 2013**

### **7.36: Cryoprecipitate for Neonates and Infants, Leucocyte Depleted**

The component represents a source of concentrated FVIII, and von Willebrand factor, fibrinogen, FXIII and fibronectin from a unit of fresh frozen plasma. The plasma from which the cryoprecipitate was produced contains less than  $1 \times 10^6$  leucocytes per component.

#### **7.36.1: Technical information**

- Section 7.21 provides general guidance on the requirements for components for use in neonates and infants under 1 year.
- 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 for Neonates and Infants, Leucocyte Depleted is the cryoglobulin fraction of plasma obtained by thawing a single donation of Fresh Frozen Plasma, Leucocyte Depleted (see section 7.15), fulfilling the requirements for neonates and infants, at  $4 \pm 2^\circ\text{C}$ .
- The component should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B. Testing for CMV antibodies is not required.
- 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 for Neonates and Infants, Leucocyte Depleted should be rapidly frozen to a core temperature of  $-25^\circ\text{C}$  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 for Neonates and Infants, Leucocyte Depleted should be administered through a CE marked transfusion set.

#### **7.36.2: Labelling**

For general guidelines, see section 6.6.

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The following shall be included on the component label:

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

- Cryoprecipitate for Neonates and Infants, 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 four 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

#### 7.36.3: Storage

For general guidelines, see section 6.7.

- The component should be stored at a core temperature of  $-25^{\circ}\text{C}$  or below for a maximum of 36 months.
- Although a storage temperature below  $-25^{\circ}\text{C}$  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  $37^{\circ}\text{C}$ ; temperatures between  $33^{\circ}\text{C}$  and  $37^{\circ}\text{C}$  are acceptable.

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- 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 used immediately. If delay is unavoidable, the component should be stored at ambient temperature and used within 4 hours.

#### 7.36.4: 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), a minimum of 75% of those components tested for the parameters shown in Table 7.36 shall meet the specified values.

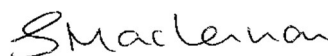
**Table 7.36 Cryoprecipitate, Leucocyte Depleted – additional tests**

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*	As per sections 6.3 and 7.1	<1 × 10 <sup>6</sup> /unit**
* Methods validated for counting low numbers of leucocytes must be used		
** Pre-freeze in starting component		

#### 7.36.5: 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.



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