Guidelines for the Blood Transfusion Services

7.7.9: Fresh Frozen Plasma for Neonates and Infants, Leucocyte Depleted

http://aws-lon-jpac.targetservers.uk/red-book/chapter-7/7-7/7-7-9

7.7.9: Fresh Frozen Plasma for Neonates and Infants, Leucocyte Depleted

Fresh Frozen Plasma for Neonates and Infants, Leucocyte Depleted is plasma that has been obtained from whole blood or by apheresis. The plasma contains less than 1×10^6 leucocytes per component.

Using a closed system the component may be subdivided into approximately equal volumes and rapidly frozen to a temperature that will maintain the activity of labile coagulation factors.

7.7.9.1: Technical information

- Section 7.7 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.
- 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.
- The plasma should be separated before the red cell component is cooled to its storage temperature. Greater FVIII yields will be obtained when the plasma is separated as soon as possible after venepuncture and rapidly frozen to -25°C or below.
- The method of preparation should ensure the component has the maximum level of labile coagulation factors with minimum cellular contamination. The production process should be validated to ensure that components meet the specified limits for FVIII concentration.
- 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.
- Fresh Frozen Plasma for Neonates and Infants, Leucocyte Depleted should be transfused through a CE/UKCA/UKNI marked transfusion set.

7.7.9.2: Labelling

For general guidelines, see section 6.6

The following shall be included on the label:

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

- Fresh Frozen Plasma 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 should be used within 4 hours of thawing if maintained at 22 ±2oC or up to a maximum of 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

7.7.9.3: 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, and at the time of administration, 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 may be stored and should be used within 4 hours if maintained at 22 ±2°C, or up to a maximum of 24 hours if stored at 4 ±2°C.

- Transfusion of FFP should be completed within 4 hours of issue out of a controlled temperature environment.

7.7.9.4: 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), the component shall be free from clinically significant irregular blood group antibodies and high-titre anti-A and/or anti-B. Furthermore, a minimum of 75% of those components tested for the other parameters shown in Table 7.7.9 shall meet the specified values with the exception of FVIII.

Table 7.7.9 Fresh Frozen Plasma for Neonates and Infants, 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%
Total protein		>=50 g/L
Platelet count [1,2]		<30 × 10^9/L
Red cell count [2]		<6 × 10^9/L
FVIII [3,4]		Mean >=0.70 IU /mL
Leucocyte count [2,5]	As per sections 6.3 and 7.1.1	<1 × 10^6/unit
[1] Units with a residual platelet count >100 × 10^9/L should only be issued for transfusion under concessionary release		
[2] Pre-freeze in starting component		
[3] Units measured and found to have <0.30 IU/mL should only be issued for transfusion under concessionary release		
[4] A minimum of 90% of those components tested should have >=0.50 IU/mL		
[5] Methods validated for counting low numbers of leucocytes must be used		

7.7.9.5: 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.