Guidelines for the Blood Transfusion Services

7.7.10: Fresh Frozen Plasma for Neonates and Infants, Pathogen Reduced, Leucocyte Depleted

http://www.transfusionguidelines.org/red-book/chapter-7/7-7/7-7-10

7.7.10: Fresh Frozen Plasma for Neonates and Infants, Pathogen Reduced, Leucocyte Depleted

This component is plasma that has been obtained from whole blood or by apheresis, contains less than 1×10^6 leucocytes and has been treated with a pathogen inactivation (PI) system. The PI system must be approved (CE/UKCA/UKNI marked) for this use, and must have been validated by the Blood Service.

Following PI treatment, using a closed system the component may be subdivided into approximately equal volumes. The treated component is rapidly frozen to a temperature that will maintain the activity of labile coagulation factors.

7.7.10.1: Technical information

- Section 7.7 provides 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.
- Fresh Frozen Plasma for Neonates and Infants, Pathogen Reduced, Leucocyte Depleted, may be prepared from small pools of up to 12 individual donations if validated and risk-assessed by the blood service and if in accordance with the specifications of the manufacturer of the PI system.
- 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.
- It contains, on average, greater than 60% of the labile coagulation factors and naturally occurring inhibitors present in standard fresh frozen plasma.

- The PI system typically reduces the risk of infection from enveloped viruses (e.g. HBV, HCV, HIV) by at least one thousand-fold.

- 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.

- The level of removal of the photo-sensitising agent prior to final storage should be validated, if such a step is included in the PI system.

- Intact white blood cells in the plasma should be reduced to less than 1×10^6 per unit prior to the PI process.

- Fresh Frozen Plasma for Neonates and Infants, Pathogen Reduced, Leucocyte Depleted should be administered through a CE/UKCA/UKNI marked transfusion set.

7.7.10.2: 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, Pathogen Reduced, Leucocyte Depleted * and volume
- the name of the PI system used
- 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
- 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

7.7.10.3: 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 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.

7.7.10.4: 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 7.7.10 shall meet the specified values.

Table 7.7.10 Fresh Frozen Plasma for Neonates and Infants, 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)	Within locally defined nominal volume range and within any limits specified for the PI process used
Platelet count [1,2]		$<30 \times 10^9$/L
FVIII		>=0.50 IU/mL
Leucocyte count [2,3]	As per sections 6.3 and 7.1.1	$<1 \times 10^6$/unit
[1] Units with residual platelet count $>100 \times 10^9$/L should only be issued for transfusion under concessionary release		
[2] Pre-freeze in starting component		
[3] Methods validated for counting low numbers of leucocytes must be used		

7.7.10.5: 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.