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Implementation: To be determined by each Service

Change Notification UK National Blood Services No. 31 - 2016

Liquid Plasma, Leucocyte Depleted

Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom 8th Edition 2013

Annex 3 Trial Components

This section contains information regarding trial components and can only be found on the JPAC website www.transfusionguidelines.org.uk

A3.3 Liquid Plasma, Leucocyte Depleted

Plasma that has been obtained from whole blood from a previously tested donor (as defined in section 7.3). The plasma contains less than 1×10^6 leucocytes per component

A3.3.1: 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 only.
- The plasma should be separated before the red cell component is cooled to its storage temperature.
- The method of preparation should ensure minimum cellular contamination. The plasma should be placed at 2-6°C as soon as possible after separation from the red cell component. The production process should be validated to ensure that components meet the specified limits for FVIII:C concentration at the end of expiry.
- Liquid Plasma, Leucocyte Depleted should be transfused through a 170–200 µm filter.

A3.3.2: Labelling

For general guidelines, see section 6.6.

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The following shall be included on the label:

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

- Liquid Plasma, Leucocyte Depleted* and volume
- the blood component producer's name*
- the donation number and, if divided, sub-batch number*
- the ABO group*
- the RhD group stated as positive or negative*
- the date of collection
- the expiry date of the component*
- the temperature of storage
- the blood pack lot number*
- 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

A3.3.3: Storage

For general guidelines, see section 6.7.

- The component should be stored at a core temperature of $4 \pm 2^{\circ}\text{C}$ for a maximum of 7 days
- The component must not be frozen and should be transfused as soon as possible. It should be borne in mind that the content of labile coagulation factors declines with the duration of storage.

A3.3.4: 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 A3.3 shall meet the specified values.

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Table A3.3 Liquid Plasma, 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		<0.2 × 10 ⁹ /L***
FVIII:C		≥X IU/mL****
Leucocyte count*	As per sections 6.3 and 7.1	<1 × 10 ⁶ /unit***
* Methods validated for counting low numbers of leucocytes must be used		
** Units measured and found to be outside of the range 200 to 360 mL should not be issued for transfusion		
*** Pre-freeze in starting component		
**** Units tested and found to have < 0.3 IU/mL should not be issued for transfusion		

(To be defined following operation validations)

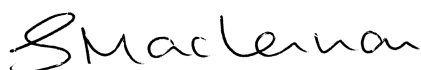
A3.3.5: Transportation

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 used straight away it should be transferred immediately to storage at the recommended temperature.

For liquid plasma components, transit containers, packing materials and procedures should have been validated to ensure the component surface temperature can be maintained between 2°C and 10°C during transportation. Additionally:

- the validation exercise should be repeated periodically
- if melting ice is used, it should not come into direct contact with the components
- dead air space in packaging containers should be minimised
- as far as is practicable, transit containers should be equilibrated to their storage temperature prior to filling with components
- transport time normally should not exceed 12 hours.



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