Change Notification for the UK Blood Transfusion Services

Date of Issue: 24 July 2025 **Implementation:** to be determined by each Service

No. 23 – 2025

Provisional component specification:

Dried Plasma, Leucocyte Deleted

This notification includes the following changes:

	BM-DSG Bone Marrow & Peripheral Blood Stem Cell	CB-DSG Cord Blood	GDRI Geographical Disease Risk Index	TD-DSG Tissue – Deceased Donors	TL-DSG Tissue – Live Donors	WB-DSG Whole Blood & Components	Red Book Guidelines for the BTS in the UK
1. Dried Plasma, LD	○	○	○	○	○	○	●

Ryan Evans
Chair, Standing Advisory Committee on Blood Components (SACBC)

Dr Stephen Thomas
Professional Director of JPAC

Changes are indicated using the key below. This formatting will not appear in the final entry.

original text	«inserted text»	~~deleted text~~

1. Changes apply to the **Red Book**

The following specification will be added to

Annexe 3: Provisional Components

«A3.11: Dried Plasma, Leucocyte Depleted

Plasma that has been obtained from whole blood or by apheresis (as defined in section 7.3). The starting plasma must be suitable for the production of FFP. The plasma contains less than 1×10^6 leucocytes per component and has been dried using a validated system demonstrated to maintain the activity of labile coagulation factors.

A3.11.1: Technical information

- Dried Plasma, Leucocyte Depleted is intended for the treatment of major haemorrhage currently only as part of clinical studies.
- Dried Plasma, Leucocyte Depleted should be manufactured from group A donations that are negative for high-titre anti-B antibodies.
- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable to produce 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.
- The plasma should be separated before the red cell component is cooled to its storage temperature. Greater FVIII:C 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:C concentration.
- Component samples collected for the quality monitoring assessment of FVIII:C should be representative of the distribution of ABO groups issued for clinical use.
- Dried Plasma, Leucocyte Depleted should be administered through a CE/UKCA/UKNI marked transfusion set.

A3.11.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

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

- Dried 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 dried component*
- the temperature of storage
- the blood pack lot number*
- a warning that the component must be used within 6 hours of rehydration if maintained at ambient temperature
- 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

A3.11.3: Storage

For general guidelines, see section 6.7.

- The component should be stored at a core temperature of 2-25°C for a maximum of 6 months.
- The component should be rehydrated with 200 mL sterile water for injection (SWFI) according to a validated procedure.
- After reconstitution, and at the time of administration, the content should be inspected to ensure that no insoluble plasma is visible and that the container is intact.
- Once rehydrated, the component must not be frozen and should be transfused as soon as possible. If delay is unavoidable, the component should be transfused within 6 hours.

A3.11.4: 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 A3.11 shall meet the specified values with the exception of FVIII:C.

Table A3.11. Dried Plasma, Leucocyte Depleted, for Clinical Studies – additional tests

Parameter	Frequency of test	Specification
Volume [1]	10 units per month of production	Within locally defined nominal range
Total protein		≥50 g/L
Platelet count [2,3]		<30 × 10^9/L
Red cell count [2,3]		<6 × 10^9/L
FVIII:C [4]		Mean ≥0.60 IU/mL
vWF:RiCof		Mean ≥0.40 IU/mL
Fibrinogen		Mean ≥2 g/L
Bacterial screening		Negative
Leucocyte count [2,3,5]	As per sections 6.3 and 7.1.1	<1 × 10^6/unit
[1] Units of starting plasma should meet the manufacturers specification of 265-285 mL		
[2] Residual cellular content need not be assessed if the starting material is already monitored		
[3] Pre-freeze in starting component		
[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		

A3.11.5: Transportation

For general guidelines, see section 6.11.

Every effort should be made to maintain the core storage temperature of ≤25°C during transportation.»