Change Notification for the UK Blood Transfusion Services

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

No. 02 – 2025

New component specification:

Human Plasma for Fractionation, Cryoprecipitate Depleted, Leucocyte Depleted

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. Chapter 7.5 Plasma Components	○	○	○	○	○	○	●

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Chair of 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**

Chapter 7: Specifications for blood components

(no changes to 7.1 – 7.4)

7.5: Plasma Components

(no changes to 7.5.1 – 7.5.6)

«7.5.7: Human Plasma for Fractionation, Cryoprecipitate Depleted, Leucocyte Depleted

Plasma which has been obtained from whole blood and subsequently recovered from the preparation of Cryoprecipitate, Leucocyte Depleted. The plasma from which the Plasma, Cryoprecipitate Depleted, Leucocyte Depleted was made contains less than 1×10^6 leucocytes per component.

UK derived plasma may be used for the manufacture of immunoglobulins and albumin for domestic use provided all relevant vCJD risk mitigation measures currently in place for blood components for transfusion are applied and manufacturers submit an application to the MHRA to register the use of UK-sourced plasma including a product specific risk assessment. Manufacture of other blood products such as clotting factors is not currently permitted.

7.5.7.1: Technical information

- All aspects of collection and manufacture, testing and storage should satisfy the requirements defined in the current British Pharmacopoeia monograph on Human Plasma for Fractionation.
- See chapters 3, 4, 5, 9 and 12 for specific details on donor selection, care and testing for Human Plasma for Fractionation, Cryoprecipitate depleted, Leucocyte Depleted.
- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for the production of plasma components for clinical use.
- Human Plasma for Fractionation, Cryoprecipitate Depleted, Leucocyte Depleted should be held at ambient for no more than 4 hours after processing before being rapidly frozen to a core temperature of –25°C or below, following locally validated processes.

7.5.7.2: Labelling

For general guidelines, see section 6.6. The following shall be included on the label in eye readable format:

(* = also in UKBTS approved barcode format)

- Human Plasma for Fractionation, Cryoprecipitate Depleted, Leucocyte Depleted*
- Recovered or Source plasma
- the component volume
- the blood component producer's name
- the donation number and, if divided, sub-batch number*

- the date of collection
- the expiry date of the frozen component*
- the temperature of storage
- the blood pack lot number*
- the name, composition and volume of the anticoagulant.
- Not for transfusion

7.5.7.3: Storage

For general guidelines, see section 6.7.

- The component should be stored at a core temperature of –20°C or below for a maximum of 36 months.

- Although frozen storage temperatures improve the preservation of labile and non-labile proteins, lower temperatures increase the fragility of plastic. Particular care must be taken when handling such packs.

7.5.7.4: Testing

- In addition to the mandatory and other tests required for blood donations for Human Plasma for Fractionation, Cryoprecipitate Depleted, Leucocyte Depleted described in Chapter 9, and leucocyte counting (see sections 6.3 and 7.1.1), components should be tested for the parameters shown in Table 7.5.7.

- Total protein testing will be undertaken according to the British Pharmacopeia 2021 – Plasma for Fractionation (*Human Plasma for Fractionation, Ph. Eur. 10.3 monograph 0853*) or using equivalent, validated assays.

- There is no requirement for FVIII testing.

Table 7.5.7 Human Plasma for Fractionation, Cryoprecipitate Depleted, Leucocyte Depleted – additional tests

Parameter	Frequency of test	Specification
Volume [1]	1% or as determined by statistical process control (if ≤10 components produced per month then test every available component)	Stated volume ±10%
Total protein		Mean ≥50 g/L
Platelet count [1,2]		<50 × 10^9/L
Red cell count [1,2]		<6 × 10^9/L
Leucocyte count [2,3]	As per sections 6.3 and 7.1.1	<1 × 10^6/unit
[1] A minimum of 90% of units tested should meet the required value		
[2] Pre-freeze in starting component		
[3] Methods validated for counting low numbers of leucocytes must be used		

More than 90% of leucocyte-depleted components from relevant processes must have less than 1 × 10^6 leucocytes per unit and more than 99% of components must contain less than 5 × 10^6 leucocytes per unit, both with 95% confidence.

Where Human Plasma for Fractionation, Cryoprecipitate Depleted, Leucocyte Depleted is collected into one container for final frozen storage the specification must be assessed based on locally set minimum and maximum volumes.

7.5.7.5: Transportation

For general guidelines, see section 6.11.

The frozen Human Plasma for Fractionation, Cryoprecipitate Depleted, Leucocyte Depleted should be stored and transported under conditions validated to maintain a temperature of –20°C or below. Temperature fluctuations in the plasma should be kept to a minimum during storage or transportation. A plasma temperature record during storage and transit of frozen plasma shall be available for inspection.

Short excursions of up to 30 minutes whilst preparing Human Plasma for Fractionation, Cryoprecipitate Depleted, Leucocyte Depleted for shipping are permissible.

Exceptional temperature deviations above –20°C, e.g. in the case of equipment failure, on one or more occasions are acceptable so long as the following conditions are met:

- the total period of time above –20°C does not exceed 72 hours
- the temperature does not exceed –15°C on more than one occasion
- the temperature does not exceed –5°C

Where Human Plasma for Fractionation, Cryoprecipitate Depleted, Leucocyte Depleted has been subject to temperature deviations during storage or transportation, this must be recorded and reported to any third party receiving the Human Plasma for Fractionation, Cryoprecipitate Depleted, Leucocyte Depleted.»

(no changes to 7.6 – 7.7)