Change Notification for the UK Blood Transfusion Services

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

No. 24 – 2025

Provisional component specification:

Platelets, Apheresis, in Additive Solution and Plasma, 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. Platelets, Apheresis, in Additive Solution and Plasma, LD	○	○	○	○	○	○	●

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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

«A3.12: Platelets, Apheresis, in Additive Solution and Plasma, Leucocyte Depleted

A single-donor platelet component containing less than 1×10^6 leucocytes where the suspending medium comprises 30-50% plasma and 50-70% additive solution and anticoagulant.

A3.12.1: Technical information

- Platelets, Apheresis, in Additive Solution and Plasma, Leucocyte Depleted may be collected by a variety of apheresis systems using different protocols. Since platelet yields may vary, each procedural protocol must be fully validated, documented and specifications set accordingly.
- If a double or triple dose is collected, the platelet concentrate must be temporarily split, as a continuous part of the collection process, into the storage packs integral to the collection set so that the capacity of an individual pack is not exceeded.
- If filtration is used, the recommended capacity of the filter should not be exceeded.
- If the leucodepletion process transfers the final component into a pack that was not part of the original pack assembly, a secure system must be in place to ensure the correct identification number is put on the final component pack.
- The proportion of plasma carried over into the final component should be determined by validation and will depend upon the type of additive solution and platelet storage pack. Re-validation of the proportion of plasma carried over must be performed at least annually on a minimum of 25 units and after any changes to collection method.
- The volume of suspension medium must be sufficient to maintain the pH at ≥6.4 at the end of the shelf life of the component.
- The plasma from group O donors should be tested for high-titre anti-A and anti-B, and 'high-titre negative' units labelled. The testing method and acceptable limits should be defined (see also Chapter 9). Screening of female donors for HLA/HNA antibodies should be considered as a TRALI risk reduction strategy.
- Platelets, Apheresis, in Additive Solution and Plasma, Leucocyte Depleted should be administered through a CE/UKCA/UKNI marked transfusion set.

A3.12.2: Labelling

For general guidelines, see section 6.6.

The following shall be included on the label:

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

- Platelets, Apheresis in Additive Solution and 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 expiry date*
- the temperature of storage and a comment that continuous gentle agitation throughout storage is recommended
- the blood pack lot number*
- the name, composition and volume of the anticoagulant or additive solution.

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

A3.12.3: Storage

For general guidelines, see section 6.7.

- The storage period depends on a number of factors including the nature of the container, the concentration of platelets and on whether an open or closed system is used.

- Packs currently in use for this purpose allow for storage at a core temperature of 22 ±2°C with continuous gentle agitation for up to 5 days in a closed system. Appropriate pack and platelet concentration combinations may allow storage up to 7 days, but due to concerns over bacterial contamination would require either an assay to exclude bacterial contamination prior to transfusion or application of a licensed pathogen reduction procedure.

- If any production stage involves an open system, after preparation the component should be used as soon as possible. If storage is unavoidable, the component should be stored at a core temperature of 22 ±2°C with continuous agitation and used within 6 hours.

- Platelets should be gently agitated during storage. If agitation is interrupted, for example due to equipment failure or prolonged transportation, the components are suitable for use, retaining the same shelf life, provided that no single interruption lasts for more than eight hours, and the total length of all interruptions is no longer than 24 hours.

A3.12.4: Testing

In addition to the mandatory and other tests required for blood donations described in Chapter 9 and leucocyte counting (see section 6.3 and 7.1.1), a minimum of 75% of those components tested for the parameters shown at Table A3.12 shall meet the specified values.

Table A3.12. Platelets, Apheresis, in Additive Solution and Plasma, 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)	Within locally defined nominal range
Platelet count [2]		≥240 × 10^9/unit
pH at end of shelf life [3]	If less than 10 per month, every available component	≥6.4
Leucocyte count [4]	As per sections 6.3 and 7.1.1	<1 × 10^6/unit
[1] Units measured and found to be <150 mL or >380 mL should only be issued for transfusion under concessionary release		
[2] Units tested and found to have <160 × 10^9/unit, or more than the maximum recommended by the manufacturer of the storage pack where stated, should only be issued for transfusion under concessionary release		
[3] A minimum of 95% of components tested shall meet the specified values		
[4] Methods validated for counting low numbers of leucocytes must be used		

Note: Visual inspection of platelet components for the swirling phenomenon, clumping, excessive red cell contamination and abnormal volume is a useful pre-issue check.

A3.12.5: Transportation

For general guidelines, see section 6.11.

- Containers for transporting platelets should be equilibrated at room temperature before use. During transportation the temperature of platelets must be kept as close as possible to the recommended storage temperature and, on receipt, unless intended for immediate therapeutic use, the component should be transferred to storage at a core temperature of 22 ±2°C with continuous gentle agitation.

- Plastic overwraps should be removed prior to storage.»