Change Notification for the UK Blood and Tissue Services

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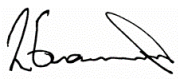
Effective date 19 August 2026
Implementation To be determined by each Service

CN 23-2026

Component specification:

Platelets, Apheresis, in Additive Solution and Plasma, Leucocyte Depleted

	Content changed	Type of change	Guidelines affected
1	Chapter 7.4: Platelet components	Updated chapter	**Red Book**



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Note: this document indicates inserted and ~~deleted~~ text. This formatting will not apply in the published text.

1. Chapter 7.4: Platelet components

Guidelines affected	Reason for change
Red Book	Specification moved to Chapter 7 as a blood component for routine use.

The following specification will be moved from Annex 3 to Chapter 7.4:

7.4.5 ~~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.

7.4.5.1: ~~A13.2.1~~: Technical Information

- Platelets, Apheresis, in Additive Solution and Plasma, Leucocyte Depleted (LD) may be collected by a variety of apheresis systems using different protocols. Since platelet yields may vary, each apheresis system and procedural protocol (i.e. single, double and triple collections) must be validated and shown to be compliant with the specification. ~~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, the target platelet yield/concentration 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, LD should be administered through a CE/UKCA/UKNI marked transfusion set.

7.4.5.2 ~~A3.12.2~~: Labelling

For general guidelines, see chapter 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"

7.4.5.3 ~~A3.12.3~~: Storage

For general guidelines, see chapter 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 8 hours, and the total length of all interruptions is no longer than 24 hours.

7.4.5.4 ~~A3.12.4~~: Testing

In addition to the mandatory and other tests required for blood donations described in chapter 9, and leucocyte counting (see chapter 6.3 and chapter 7.1.1), a minimum of 75% of those components tested for the parameters shown in Table 7.4.5 ~~A3.12~~ shall meet the specified values.

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

- Swirling phenomenon should be present
- Clumping or excessive red cell contamination should not be present

Table 7.4.5 ~~A3.12~~: Platelets, Apheresis, in Additive Solution and Plasma, LD – additional tests

Parameter	Specification	Frequency of test
Volume (1)	Within locally defined nominal volume range	1% or as determined by statistical process control (if ≤10 components produced per month then test every available component)
Platelet count (2)	≥240×10^9/unit	1% or as determined by statistical process control (if ≤10 components produced per month then test every available component)
pH at end of shelf life (3)	≥6.4	1% or as determined by statistical process control (if ≤10 components produced per month then test every available component) ~~If less than 10 per month, every available component~~
Leucocyte count (4)	<1×10^6/unit	As per chapter 6.3 and chapter 7.1.1

Notes on Table 7.4.5 ~~A3.12~~

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 those components tested shall meet the specified values.
4. Methods validated for counting low numbers of leucocytes must be used.

7.4.5.5 ~~A3.12.5~~: Transportation

For general guidelines, see chapter 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.