Change Notification for the UK Blood and Tissue Services

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Implementation To be determined by each Service

CN 22-2026

Component specification:

Cold-stored Platelets, in Additive Solution and Plasma, Leucocyte Depleted

	Content changed	Type of change	Guidelines affected
1	Annex 3: Provisional 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. Annex 3: Provisional components

Guidelines affected	Reason for change
Red Book	This is a new provisional component specification.

The following specification will be added to Annex 3:

A3.7: Cold-stored Platelets, in Additive Solution and Plasma, Leucocyte Depleted

A platelet concentrate derived from buffy coats or apheresis which contains less than 1×10^6 leucocytes and where the suspending medium comprises a mixture of platelet additive solution and plasma at a ratio of approximately 50–70% platelet additive solution to 30–50% plasma/anticoagulant.

A3.7.1: Technical Information

- Cold-stored platelet concentrates are intended for the treatment of bleeding.
- 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.
- Cold-stored Platelets, in Additive Solution and Plasma, Leucocyte Depleted (LD), should be administered through a CE/UKCA/UKNI marked transfusion set.
- Cold-stored platelets do not require agitation during storage.
- Swirling is not present in cold-stored platelets and is not required as a pre-issue visual check.

A3.7.1.1: Specific for cold-stored platelet concentrates from apheresis

- Platelets 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 split into the storage packs integral to the collection set prior to storage 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 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 additive solution is added aseptically to the platelet collection as part of a closed system. The proportion of additive solution carried over into the final component should be confirmed by validation and will depend upon the type of additive solution and platelet storage pack.

- 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.

A3.7.1.2: Specific for cold-stored platelet concentrates derived from whole blood buffy coats

- The component is manufactured as a primary component and not as a remanufactured secondary component.

- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for platelet production.

- The buffy coats must be prepared at ambient temperature from whole blood where the surface temperature of packs has not dropped below 18°C.

- Initial separation of buffy coats must occur within 24 hours of venepuncture (unless supported by additional validation), with a minimum buffy coat rest period of 2 hours before secondary pooling and processing of buffy coats to produce the final component, which is generally completed before the end of Day 1.

A3.7.2: Labelling

For general guidelines, see chapter 6.6.

The following shall be included on the label:

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

- Cold-stored platelets, in Additive Solution and Plasma, Leucocyte Depleted* and volume
- the blood component producer's name*
- the donation number or a unique pool number*
- the RhD group stated as positive or negative*
- the expiry date*
- the temperature of storage
- 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"

A3.7.3: Storage

For general guidelines, see chapter 6.7.

- The component may be stored for a maximum of 14 days at a core temperature of 4 ±2°C.
- Agitation is not required.
- Platelets should be placed into cold storage either within 8 hours from bleed for apheresis platelets or within 8 hours of manufacture for pooled platelets.
- Variation from the core temperature of 4 ±2°C must be kept to a minimum during storage and restricted to any short period necessary for examining, labelling or issuing the component.

A3.7.4: 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 A3.7 shall meet the specified values.

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

Table A3.7: Cold-stored Platelets, 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)
Leucocyte count (4)	<1×10^6/unit	As per chapter 6.3 and chapter 7.1.1

Notes on Table A3.7

1. Units measured and found to be <150 mL or >380 mL should only be issued for transfusion under concessionary release.
2. Units measured and found to have $<160\times10^9$/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.

A3.7.5: Transportation

For general guidelines, see chapter 6.11.

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
- plastic overwraps should be removed prior to storage
- 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