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Implementation: To be determined by each Service

## **Change Notification UK National Blood Services No. 47 - 2020**

# **Platelets, Apheresis, Leucocyte Depleted, at Reduced Dose as a Contingency**

Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom 8<sup>th</sup> Edition 2013

**Please Note:** This is a specification to be used at the discretion of each blood service during the COVID-19 pandemic period and can be found in Annex 5: Blood Components for Contingency Use.

## **A5.2 Platelets, Apheresis, Leucocyte Depleted, at Reduced Dose as a Contingency**

A single-donor platelet component containing less than  $1 \times 10^6$  leucocytes.

### **A5.2.1: Technical information**

- Platelets, Apheresis, Leucocyte Depleted, at Reduced Dose as a Contingency 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.
- The volume of suspension medium must be sufficient to maintain the pH at  $\geq 6.4$  at the end of the shelf life of the component.
- 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 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, Leucocyte Depleted, at Reduced Dose as a Contingency should be administered through a CE marked transfusion set.

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### **A5.2.2: 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, 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

### **A5.2.3: 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 whether an open or closed system is used.
- Packs currently in use for this purpose allow for storage at a core temperature of  $22 \pm 2^{\circ}\text{C}$  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 requires either an assay to exclude bacterial contamination prior to transfusion or application of a licensed pathogen inactivation procedure.
- Where any manufacturing step involves an open system the platelets should be used as soon as possible after collection. If storage is unavoidable, the component should be stored at a core temperature of  $22 \pm 2^{\circ}\text{C}$  with continuous agitation and used within 6 hours.

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- 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.

#### A5.2.4: 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), a minimum of 75% of those components tested for the parameters shown in Table A5.2 shall meet the specified values.

**Table A5.2 Platelets, Apheresis, Leucocyte Depleted, at Reduced Dose as a Contingency – additional tests**

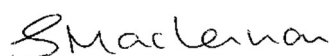
Parameter	Frequency of test	Specification
Volume*	1% or as determined by statistical process control	Within locally defined nominal volume range
Platelet count**	(if ≤10 components produced per month then test every available component)	≥ 150 × 10 <sup>9</sup> /unit
pH at end of shelf life***		≥ 6.4
Leucocyte count****	As per sections 6.3 and 7.1	<1 × 10 <sup>6</sup> /unit
* Units measured and found to be outside of the range 100 to 380 mL should not be issued for transfusion		
** Units tested and found to have <120 × 10 <sup>9</sup> /unit or more than the maximum recommended by the manufacturer of the storage pack, where stated, should not be issued for transfusion		
*** A minimum of 95% of components tested shall meet the specified value		
**** 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.

#### A5.2.5: 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.



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