Date of publication: 26 June 2013	**Implementation:** To be determined by each Service

Change Notification UK National Blood Services No. 12 - 2013

Platelets in Additive Solution and Plasma, Leucocyte Depleted, Pathogen-reduced

Applies to the Guidelines for the Blood Transfusion Services in the United Kingdom 8th Edition 2013

Annex 3 Trial Components

This section contains information regarding trial components and can only be found on the JPAC website www.transfusionguidelines.org.uk

A platelet concentrate, derived from buffy coats or apheresis, which contains less than 1×10^6 leucocytes and where the suspending medium comprises approximately 30-50% plasma and 50-70% additive solution. Subsequently the component is subjected to treatment using a licensed pathogen inactivation system prior to storage.

A3.1 Technical Information

- The primary platelet component prior to pathogen-reduction must meet the specifications set by the manufacturer of the pathogen-reduction system.
- Provided the pathogen reduction system used has been validated to inactivate lymphocytes, irradiation of the component to prevent transfusion-associated graft versus host disease is not required.
- The level of removal of the photo-sensitising agent prior to final storage should be validated, if such a step is included in the pathogen-reduction system.
- Provided the pathogen reduction system used has been validated to inactivate CMV, CMV testing of the component to prevent transfusion-associated CMV infection is not required.
- The component is manufactured as a primary component and not as a remanufactured secondary component.

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- Donations of whole blood where the bleed time exceeded 15 minutes are not suitable for platelet production.
- Where prepared from buffy coats, the buffy coats must be prepared at ambient temperature before the whole blood is cooled to below 20°C.
- Where prepared from buffy coats, initial separation of buffy coat 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.
- Screening of female apheresis donors for HLA/HNA antibodies should be considered as a TRALI risk reduction strategy.
- The volume of suspension medium must be sufficient to maintain the pH within the range 6.4–7.4 at the end of the shelf life of the component.
- Where the production 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 audit trail and the correct identification number is put on the final component pack.
- Platelets in Additive Solution and Plasma, Leucocyte Depleted, Pathogen-Reduced should be transfused through a 170–200 µm filter.

A3.2 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, (pooled or apheresis) in Additive Solution and Plasma, Leucocyte Depleted, Pathogen-Reduced (name of PR method)* and volume
- the blood component producer's name*
- a unique pool or batch number or the donation number of all contributing platelet units*
- the RhD group stated as positive or negative*
- the name, composition and volume of the anticoagulant and platelet additive solution
- the expiry date*
- the temperature of storage and a comment that continuous gentle agitation throughout storage is recommended
- the blood pack lot number*

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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

A3.3 Storage

For general guidelines, see section 6.7.

- The storage period depends on a number of factors including the nature of the pathogen inactivation system, additive solution and storage container.
- Systems currently in use for this purpose allow for storage at a core temperature of 22 ±2°C with continuous gentle agitation for up to 7 days in a closed system.
- 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.

A3.4 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), a minimum of 75% of those components tested for the parameters shown at Table A3.1 shall meet the specified values.

Table A3.1 Platelets in Additive Solution and Plasma, Pathogen-Reduced – additional tests

Parameter	Frequency of test	Specification
Volume	1% or as determined by statistical process control (if ≤10 components produced per month then test every available component)	Within locally defined nominal volume range
Platelet count		≥240 × 10^9/pool**
pH at end of shelf life	If less than 10 per month, every available component	6.4–7.4
Leucocyte count*	As per section 6.3 and 7.1	<1 × 10^6/pool*
*Methods validated for counting low levels of leucocytes must be used ** Units tested and found to have <160 x 10^9/pool should not be issued for transfusion.		

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

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A3.5 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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