Issued by JPAC: 26 November 2019	**Implementation:** To be determined by each Service

Change Notification UK National Blood Services No. 34 - 2019

Platelets in Plasma and Additive Solution for Neonatal Use, Leucocyte Depleted

This change applies to the Guidelines for the Blood Transfusion Services in the United Kingdom 8th Edition 2013

New Specification

7.34 Platelets in Plasma and Additive Solution for Neonatal Use, Leucocyte Depleted

An apheresis platelet component for neonatal use which contains less than 1×10^6 leucocytes per starting component and where the suspending medium comprises approximately 80% plasma and 20% additive solution.

7.34.1: Technical information

- The component should be free from clinically significant irregular blood group antibodies including high-titre anti-A and anti-B and should be negative for antibodies to CMV.
- The component is manufactured as a secondary component by splitting Platelets, Apheresis, Leucocyte Depleted (see section 7.10) after the sterile addition of a controlled volume of an approved platelet additive solution. Splitting must be performed using a closed system.
- The volume of additive solution added 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 / PAS must be performed at least annually on a minimum of 25 units and after any changes to production method.
- The volume of additive solution should be sufficient to maintain the pH ≥6.4 at the end of the shelf life of the component.
- The component should contain ≥40×10^9 platelets.

\Continued

Joint UKBTS Professional Advisory Committee (JPAC)
JPAC Office
NHS Blood and Transplant
Longley Lane, SHEFFIELD, S5 7JN

Tel: 0114 358 4903
Fax: 0114 358 4494
Email: caroline.smith@nhsbt.nhs.uk

- The component may be leucodepleted as part of an apheresis process or by subsequent filtration of the platelet component.
- Screening of female donors for HLA/HNA antibodies should be considered as a TRALI risk reduction strategy. If platelets are to be issued as HPA-matched (e.g. HPA-1a or HPA-5b negative) then donors should be screened and found negative for all clinically significant HLA and HPA antibodies (as defined in Chapters 16 and 18). This screening can be done on an initial sample and does not need repeating at each donation unless the donor has been transfused or pregnant since the last antibody screen.
- A record which demonstrates that the donor has not been transfused since the initial negative screen for antibodies and in the case of female donors that the donor has not been pregnant since the initial negative screen for antibodies needs to be maintained.
- Platelets in Plasma and Additive Solution for Neonatal Use, Leucocyte Depleted should be administered through a CE marked transfusion set.

7.34.2: 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 in Plasma and Additive Solution for Neonatal Use 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 date of collection
- 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 of the anticoagulant and additive solution

In addition, the following statements should be made:

\Continued

INSTRUCTION

Always check patient/component compatibility/identity
Inspect pack and contents for signs of deterioration or damage
Risk of adverse reaction/infection, including vCJD

7.34.3: Storage

For general guidelines, see section 6.7.

- The component should be stored at a core temperature of 22 ±2°C for up to 5 days. 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 inactivation procedure.

- Platelets should be 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 the interruption is for no longer than a total of 24 hours *and no single interruption lasts for more than eight hours.*

7.34.4: 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), the component shall be free from clinically significant irregular blood group antibodies and high-titre anti-A and/or anti-B, and antibodies to CMV.

Furthermore, a minimum of 75% of those components tested for the other parameters shown in Table 7.27 shall meet the specified values.

Table 7.27 Platelets in Plasma and Additive Solution for Neonatal Use, Leucocyte Depleted – 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 range
Platelet count *		≥40 × 10^9/unit
pH at end of shelf life **/***		≥6.4
Leucocyte count ****	As per sections 6.3 and 7.1	<1 × 10^6/starting component
* Units tested and found to have <40 × 10^9/unit, or more than the maximum recommended by the manufacturer of the storage pack, where stated, should not be issued for transfusion.		
** If producing low numbers, issue of most units is likely to make testing of outdated units impossible. In this situation periodic checks to ensure end-of-shelf-life quality should be undertaken with the combination of blood pack platelet concentration and storage conditions in routine use.		
*** A minimum of 90% of components tested shall meet the specified value.		
**** Methods validated for counting low levels 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.

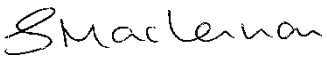
\Continued

7.34.5: 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°C with continuous gentle agitation.

- Plastic overwraps should be removed prior to storage.



Dr Sheila MacLennan
Professional Director - Joint UKBTS Professional Advisory Committee
☎ Direct Dial: (0113) 820 8638 ✉ sheila.maclennan@nhsbt.nhs.uk