BLOOD COMPONENT MONOGRAPH
PLATELETS NEONATAL APHERESIS LEUCOCYTE DEPLETED

REASON FOR ISSUE: Update to include ISBT128 component codes

Council of Europe Guide Monograph	Platelets Apheresis Leucocyte Depleted
eProgesa Component Name	Platelets Neonatal Apheresis Leucocyte Depleted
eProgesa Component Code	12221 - 12232, E9489VAa, E9495VAa, E9489VAb, E9495VAb, E9489Vac, E9495Vac, E9489VAd, E9495VAd, E9489VBa, E9495VBa, E9489VBb, E9495VBb, E9489VBc, E9495VBc, E9489VBd, E9495VBd, E9489VCa, E9495VCa, E9489VCb, E9495VCb, E9489VCc, E9495VCc, E9489VCd, E9495VCd

1. DEFINITION and PROPERTIES

Platelets Neonatal Apheresis Leucocyte Depleted (LD) is a leucocyte depleted platelet component, for neonatal transfusion, obtained from a single donor using automated cell separation equipment. *Platelets Neonatal Apheresis LD* contains platelets in a therapeutically effective dose suspended in approximately 30 - 40% plasma and 60 - 70% platelet additive solution (PAS).

Platelets Neonatal Apheresis LD contains a minimum content of 0.6×10^{11} platelets.

Platelets Neonatal Apheresis LD normally contains less than 5×10^{6} leucocytes per unit.

2. PREPARATION

Platelets Neonatal Apheresis LD are prepared from *Platelets Apheresis in Additive Solution LD. Whole blood* is removed from the donor by the apheresis machine, anti-coagulated using an Acid-Citrate-Dextrose-Adenine (ACD-A) solution and the platelets are then collected and stored in a mixture of donor plasma and 500 mL of PAS. Pre-storage leucocyte depletion is performed by filtration at the end of the collection process.

Where appropriate *Platelets Neonatal Apheresis LD* are HLA or HPA compatible.

3. RELEASE REQUIREMENTS and QUALITY CONTROL

Release requirements are as indicated for the source component with the following additional release requirements and quality monitoring standards;

3.1 Release Requirements

Parameter	Requirements	Frequency of control
HLA and / or HPA [1]	As required	All specified units
CMV Status [1]	Negative	All units

1. Testing is performed on the primary donation

3.2 Quality Monitoring Requirements

Parameter	Requirements	Frequency of control
Volume [2]	>40 mL per 60 x 10^9 platelets	As determined by SPC
Platelet Content [2]	≥0.6 x 10^{11} per neonatal pack	
pH measured at 22°C at expiry [2,3]	≥6.4	

2. A minimum of 90% of components tested must meet the specification
3. pH is measured in a closed system to prevent the escape of CO_2

The presence of swirling platelets is an indicator of adequate in-vivo platelet viability and can be visualized by holding the platelet bag in front of a light source. Demonstration of platelet swirl is performed and the result recorded, immediately prior to transfusion as a routine part of the blood bank component issue procedure.

4. STORAGE and TRANSPORT

4.1 Storage

Platelets Neonatal Apheresis LD must be stored under conditions which guarantee that their viability and haemostatic activities are optimally preserved.

The storage temperature must be between + 20 and + 24 °C under constant agitation.

Platelets Neonatal Apheresis LD are prepared in a functionally closed system. The maximum storage time for *Platelets Neonatal Apheresis LD* is seven days.

4.2 Transport

During transportation the temperature of *Platelets Neonatal Apheresis LD* must be kept as close as possible to the recommended storage temperature and on receipt, unless intended for immediate therapeutic use, the component must be transferred to storage under recommended conditions.

5. LABELLING

Additional and / or amended labelling requirements to those of the source component are:

- When components are split for use in neonates and infants, each split must have a unique unit identity number that allows traceability to the source donation;

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6. WARNINGS

Rh D negative female recipients of child-bearing age or younger should preferably not be transfused with platelets from Rh D positive donors. If unavoidable, administration of anti-D immunoglobulin should be considered.

Platelets Neonatal Apheresis LD is not recommended in the case of:

- Plasma intolerance;

Adverse reactions include:

- haemolytic transfusion reaction due to anti-A, -B in the case of incompatible transfusions;
- non-haemolytic transfusion reaction (mainly chills, fever and urticaria); the incidence is reduced by the use of pre-storage leucocyte depleted platelets;
- anaphylaxis and allergic reactions;
- allo-immunisation against red cell and HLA (very rarely after pre-storage leucocyte depletion) antigens;
- allo-immunisation against HPA antigens;
- transfusion-related acute lung injury (TRALI);
- post-transfusion purpura;
- graft versus host disease (GvHD);
- sepsis due to inadvertent bacterial contamination;
- viral transmission (hepatitis, HIV, etc.) is possible, despite careful donor selection and screening procedures;
- syphilis can be transmitted if component is stored for less than 96 hours at + 4°C;
- protozoal transmission (e.g. malaria) may occur in rare instances;
- transmission of other pathogens that are not tested for or recognized;
- citrate toxicity in neonates and in patients with impaired liver function;
- transfusion-associated circulatory overload (TACO).