NZBS BLOOD COMPONENT MONOGRAPH
PLATELET POOL, LEUCOCYTE - DEPLETED IN ADDITIVE SOLUTION

REASON FOR ISSUE: Update to include ISBT 128 component codes, and label changes.

Council of Europe Guide Monograph	Platelets, Recovered, Pooled, Leucocyte Depleted, in Additive Solution
eProgesa Component Name	Platelet Pool in Additive Solution Leucocyte Depleted
eProgesa Component Code	12130, E9483V00, E9484V00

1. DEFINITION and PROPERTIES:

Platelet Pool Leucocyte Depleted in Additive Solution (LD-AS) is a platelet component derived from four donations of fresh *Whole Blood* which contains most of the original platelet content in a therapeutically effective adult dose suspended in a mixture of plasma (30 – 40%) and an additive solution (60 – 70%).

Platelet Pool LD-AS contains a minimum platelet content of 2.4×10^{11} per pooled unit, thereafter referred to as a unit.

Platelet Pool LD-AS contains less than 5.0×10^{6} leucocytes per unit.

2. PREPARATION:

Platelet Pool LD-AS is prepared from buffy coats produced from *Whole Blood* anti-coagulated using an Acid-Citrate-Dextrose-Adenine solution (ACD-A). Pre-storage leucocyte depletion is performed by filtration and completed immediately post pooling.

A *Whole Blood* unit, stored in conditions validated to maintain a temperature between +20 and +24°C for up to 24 hours, is centrifuged so that the platelets are primarily sedimented to the buffy coat layer, together with leucocytes. The buffy coat is separated and further processed so that four blood group-compatible buffy coats are pooled in a sterile manner and suspended in 280mL of an approved platelet additive solution (SSP+, Macopharma).

After careful mixing, the buffy coat pool is centrifuged (soft-spin) so that the platelets remain in the supernatant, but the red cells and leucocytes are effectively sedimented to the bottom of the bag. The platelet-containing supernatant is immediately leucocyte depleted by filtration and transferred in a sterile manner into an approved platelet storage bag.

Platelet Pool LD-AS are collected and prepared in a functionally closed system.

3. RELEASE REQUIREMENTS and QUALITY CONTROL:

The tables below list the requirements to comply with *NZBS Manufacturing Standards 112P003 Standards for Infectious Marker Testing* and *112P004 Standards for Blood Group Serology*.

Bacterial contamination is monitored by taking a 7 – 10mL sample from all platelet components at ≥36 hours post collection and inoculating both aerobic and anaerobic culture bottles for a minimum incubation period of seven days.

NZBS BLOOD COMPONENT MONOGRAPH
PLATELET POOL, LEUCOCYTE - DEPLETED IN ADDITIVE SOLUTION

3.1 Release Requirements

Parameter	Requirements	Frequency of control
ABO, RhD	Grouping	All units
Red Cell Alloantibodies	Negative Antibody screen	
Anti-HIV 1 & 2	Negative by approved screening test	
HbsAg	Negative by approved screening test	
Anti-HCV	Negative by approved screening test	
Syphilis serology	Negative by approved screening test	
Anti-HTLV I / II[1]	Negative by approved screening test	
Nucleic acid test for HIV RNA, HCV RNA and HBV DNA	Negative by approved screening test	
Bacterial contamination	Sample taken for bacterial contamination testing (≥36 hours)	

1. Donor is tested on first occasion they donate only. A negative result accredits the donor for future donations.

3.2 Quality Monitoring Requirements

Parameter	Requirements	Frequency of control
Volume [2]	200 – 350 mL	As determined by SPC
Platelet Content [2]	≥ 2.4 x 10^{11} per pooled unit	
Albumin [2]	≥9 g / L	
Residual leucocyte content [3]	<5 x10^{6} per unit	
pH measured at 22º C at expiry [2, 4]	≥ 6.4	

2. A minimum of 90% of components tested must meet the specification
3. These requirements are deemed to have been met if there is 95% confidence that 99% of the units tested comply.
4. 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

Platelet Pool LD-AS must be stored under conditions which guarantee that their viability and haemostatic activities are optimally preserved.

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

The maximum storage time for *Platelet Pool LD-AS* is seven days.

4.2 Transport

During transportation, the temperature of *Platelet Pool LD-AS* 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 the recommended conditions.

5. LABELLING:

The following information must be shown on the label or contained in this component monograph, as appropriate:

name of the component: *Platelet Pool Leucocyte Depleted in Additive Solution*

- component code
- volume
- name of the Processing centre
- donation number*
- ABO group*
- Rh D group stated as positive or negative*
- number of platelets (average or actual as appropriate)
- date of collection
- date of expiry*
- name of the anticoagulant solution
- name of the approved platelet additive solution
- additional component information : irradiated, etc. (if appropriate)
- storage temperature
- a statement – “Agitate gently throughout storage”

* eye readable and barcode format

In addition the following instructions are included:

- always check that the recipient for this component is properly identified
- do not use if there are signs of deterioration or damage
- use a standard transfusion set
- this product carries the risk of adverse reaction / infection
- contact your Blood Bank for further information

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.

Platelet Pool LD-AS 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).