NZBS BLOOD COMPONENT MONOGRAPH
PLATELETS APHERESIS in ADDITIVE SOLUTION LEUCOCYTE-DEPLETED

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

Council of Europe Guide Monograph	Platelets, Apheresis, Leucocyte Depleted, in Additive Solution
eProgesa Component Name	Platelets Apheresis in Additive Solution Leucocyte Depleted
eProgesa Component Code	12120, 12121, 12122, 12123, E9489V00, E9495V00, E9489100, E9495100, E9489VA0, E9495VA0, E94891A0, E94951A0, E9489VB0, E9495VB0, E94891B0, E94951B0, E9489VC0, E9495VC0, E94891C0, E94951C0

1. DEFINITION and PROPERTIES:

Platelets Apheresis in Additive Solution LD is a leucocyte depleted platelet component obtained by platelet apheresis of a single donor using automated cell separation equipment, which contains platelets in a therapeutically effective dose suspended in a mixture of donor plasma (30 - 40%) and an additive solution (60 – 70%).

Platelets Apheresis in Additive Solution LD contains a minimum platelet content of 2.4×10^{11} per unit.

Platelets Apheresis in Additive Solution LD contains less than 5.0×10^{6} leucocytes per unit.

2. PREPARATION:

To prepare *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 solution (ACD-A) and then the platelets are harvested. Platelets are stored in a combination of plasma and 500 mL of platelet additive solution (SSP+, MacoPharma). Pre-storage leucocyte depletion is performed either during the process by centrifugation or at the end of the process by filtration.

For use in neonates and infants, *Platelets Apheresis in Additive Solution LD* can be divided into satellite units under sterile conditions.

3. RELEASE REQUIREMENTS and QUALITY CONTROL

The tables below list the requirements. For details see the *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.

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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 [1]	180 - 400 mL	All units
Platelet Content [1]	≥ 2.4 x 10^{11} per unit	
Albumin [1]	≥9 g / L	As determined by SPC
Residual leucocyte content [2]	<5 x10^{6} per unit	
pH at expiry (measured at 22ºC) [1,3]	≥ 6.4	All units

1. A minimum of 90% of components tested must meet the specification
2. These requirements are deemed to have been met if there is 95% confidence that 99% of the units tested comply.
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 Apheresis in Additive Solution LD must be stored under conditions which guarantee that their viability and haemostatic activities are optimally preserved.

Storage temperature must be between +20 - +24ºC under constant agitation.

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

4.2 Transport

During transportation the temperature of *Platelets Apheresis in Additive Solution 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:

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

- name of the component – *Platelet Apheresis in Additive Solution – LD*
- component code
- volume
- name of the processing centre
- donation number*
- ABO group*
- Rh(D) group stated as positive or negative*
- name of the anticoagulant solution;
- name of the approved platelet additive solution used
- date of collection
- date of expiry*
- the 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.

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6. WARNINGS:

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

Platelets Apheresis in Additive Solution LD is not recommended in the case of:

- Plasma intolerance;

Adverse reactions include:

- transfusion-associated circulatory overload (TACO).
- haemolytic transfusion reaction due to anti-A, -B in the case of incompatible transfusions;
- anaphylaxis and allergic reactions;
- non-haemolytic transfusion reaction (mainly chills, fever and urticaria); the incidence is reduced by the use of pre-storage leucocyte depleted platelets;
- 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;