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

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	12590 or 12591 or 12592 or 12580

1. DEFINITION and PROPERTIES:

Platelets Apheresis in Additive Solution Leucocyte Depleted 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 (not less than 30%) and a platelet additive solution (PAS).

Platelets Apheresis in Additive Solution Leucocyte Depleted contains a minimum platelet content of 2.4×10^{11} per pooled unit, thereafter referred to as a unit

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

2. PREPARATION:

Platelets Apheresis in Additive Solution Leucocyte Depleted are prepared by the removal of whole blood from the donor using an apheresis machine. The blood is anti-coagulated using an Acid-Citrate-Dextrose–Adenine solution (ACD-A) and the platelets are harvested. Platelets are stored in a combination of plasma and platelet additive solution (SSP+). Leucocytes are removed during the processing of platelets by either centrifugation or filtration.

3. RELEASE REQUIREMENTS and QUALITY CONTROL

The tables below list the requirements. For details see the *NZBS Manufacturing Standards: Section 5 Standards for Infectious Marker Testing & Section 6 Standards for Blood Group Serology*.

3.1 Release Requirements:

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

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 to be checked	Requirements	Frequency of control[1]
Volume	180-400 mL [2]	All units
Platelet Content	≥ 2.4 x 10^{11} per unit [2]	All units
Albumin	≥9g/L [2]	1%, minimum of 4 per month
Residual leucocyte content	<5 x10^6 per unit [3]	1%, minimum of 4 per month
pH at expiry (measured at 22ºC)	6.4 – 7.4 [2, 4]	1%, minimum of 4 per month

1. Frequency of testing is determined by statistical process control methodology.
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.

4. STORAGE and TRANSPORT:

Platelets Apheresis in Additive Solution Leucocyte Depleted must be stored under conditions which guarantee that their viability and haemostatic activities are optimally preserved.

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

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

During transportation the temperature of *Platelets Apheresis in Additive Solution Leucocyte Depleted* 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 is shown on the label

- Name of the component – Platelet Apheresis in Additive Solution – Leucocyte Depleted
- Volume
- Name of the processing centre*
- Donation number*
- ABO group*
- Rh(D) group stated as positive or negative*
- Name of the approved platelet additive solution used
- Date of collection
- Date of expiry*
- The storage temperature
- A statement – “Agitate gently throughout storage”
- Blood pack lot number*

(* 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.

5. WARNINGS:

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

- Plasma intolerance;
- Rh (D) Negative female recipients of child bearing age or younger should preferably not be transfused with platelets from Rh (D) Positive donors.

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).