

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

Council of Europe Guide Monograph	Platelets, washed
eProgesa Component Name	Platelet Apheresis in PAS Washed Leucocyte Depleted
eProgesa Component Code	12596, 12597, 12598, 12607, EB120V00, EB120VA0, EB120VB0, EB120VC0

1. DEFINITION AND PROPERTIES

Platelet Apheresis in PAS Washed Leucocyte Depleted (LD) are derived from secondary processing of a platelet component involving sequential washing and re-suspension of platelets in platelet additive solution (PAS). Most of the plasma and leucocytes are removed. The amount of residual plasma depends on the washing protocol. A reduction in platelet count from the starting component of approximately 15% is to be expected.

Platelet Apheresis in PAS Washed LD contain a minimum content of $\ge 2.0 \times 10^{11}$ / unit of platelets.

Platelet Apheresis in PAS Washed LD contain a maximum of 5 × 10⁶ leucocytes.

2. **PREPARATION**

After centrifugation of the primary component and removal of the plasma or additive solution, the platelets are washed by sequential addition and removal of an additive solution.

3. **REQUIREMENTS AND QUALITY CONTROL**

Release requirements are as indicated for the source component with the following additional release requirement and quality monitoring standard:

3.1 Release Requirements

Parameter	Requirements	Frequency of control
HLA and / or HPA typing	As required	All units



3.2 Quality Monitoring Requirements

Parameter	Requirements	Frequency of control
Volume ¹	180 – 280 mL	
Platelet content ¹	≥ 2.0 × 10 ¹¹ per unit	
pH measured at + 22 °C at expiry	6.2 – 7.4	All units
Bacterial contamination	Sample taken for bacterial contamination testing \geq 36 hours	

1. A minimum of 90% of units tested should meet the required value.

2. Measurement of the pH in a closed system is preferable to prevent CO₂ escape. Measurement may be made at another temperature and then corrected.

Demonstration of the swirling phenomenon, which is based on light scattering by platelets in motion and of normal morphology, must be carried out prior to issuing this component. This is best done as close as possible before the time of transfusion.

4. STORAGE AND TRANSPORT

4.1 Storage

Platelet Apheresis in PAS Washed LD must be stored under conditions which guarantee that their viability and haemostatic activities are optimally preserved.

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

Platelet Apheresis in PAS Washed LD should be used within 24 hours of production. When an open system is used for washing, the storage time should be as short as possible after washing and must not exceed 6 hours.

4.2 Transport

During transportation, the temperature of *Platelet Apheresis in PAS Washed LD* must be kept as close as possible to the recommended storage temperature and, upon 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 monographas appropriate:

- Name of the component Platelet Apheresis in PAS Washed LD
- Component code
- Volume
- HLA and / or HPA type, if determined
- Name of the Processing centre
- Donation number*
- ABO group*
- Rh(D) group stated as positive or negative*
- Date of collection
- Date of expiry*
- Name of suspending or additive solution
- 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.

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;