

**BLOOD COMPONENT MONOGRAPH
PLATELETS APHERESIS IN PLASMA LEUCOCYTE-DEPLETED CRYOPRESERVED**

REASON FOR ISSUE: Change in component code for the cryopreserved platelets manufactured via the WeLoc method to storage temperature of -65°C (BMSCR778).

Council of Europe Guide Monograph	Platelets, Cryopreserved
eProgesa Component Name	Platelets Apheresis in Plasma Leucocyte Depleted Cryopreserved
eProgesa Component Code	12880, 12881, 12882, 12883, E7324100, E73241A0, E73241B0, E73241C0, E7324V00, E7324VA0, E7324VB0, E7324VC0

1. DEFINITION AND PROPERTIES:

Platelets Apheresis in Plasma Leucocyte Depleted Cryopreserved is a component prepared by the freezing of platelet components within 48 hours of collection, using a cryoprotectant.

A thawed and reconstituted unit of *Platelets Apheresis in Plasma Leucocyte Depleted Cryopreserved* contains more than 40 % of the platelets in the original component. The method facilitates extended storage of platelets from selected donors and of autologous platelets.

2. PREPARATION:

Platelets Apheresis in Plasma Leucocyte Depleted Cryopreserved are prepared by secondary processing of *Platelets Apheresis in Additive Solution Leucocyte Depleted*. The component is cryopreserved as soon as possible after routine bacterial testing and within 48 hours of collection using a cryoprotectant. The method in use by NZBS for preparation of *Platelets Apheresis in Plasma Leucocyte Depleted Cryopreserved* utilises DMSO at 6% w/v.

Before use, the platelets are thawed and resuspended in plasma.

3. RELEASE REQUIREMENTS AND QUALITY CONTROL

Release requirements are as indicated for the primary component with the following quality monitoring requirements:

3.1 Quality Monitoring Requirements:

Parameter to be checked	Requirements	Frequency of control
Volume	50 – 200 mL	All units
Platelet content	>40% of the pre-freeze platelet content	

A thawed unit of *Platelets Apheresis in Plasma Leucocyte Depleted Cryopreserved* will not swirl.

BLOOD COMPONENT MONOGRAPH

PLATELETS APHERESIS IN PLASMA LEUCOCYTE-DEPLETED CRYOPRESERVED

4. STORAGE AND TRANSPORT:

Platelets in the frozen state must be constantly maintained at -65°C or colder, stored in an electric freezer for up to 12 months.

If transport in the frozen state is unavoidable, storage conditions must be maintained during transportation.

Thawed platelets must be used as soon as possible after thawing within a shelf life of 6 hours. The thawed component must be stored between $+20^{\circ}\text{C}$ and $+24^{\circ}\text{C}$.

Transportation of thawed platelets is limited by the short shelf-life of this component. During transportation the temperature of the thawed *Platelets Apheresis in Plasma Leucocyte Depleted Cryopreserved* must be kept as close as possible to the recommended storage temperature.

5. LABELLING:

The following information is shown on the label or contained in this component monograph:

- Name of the component – *Platelets Apheresis in Plasma Leucocyte Depleted Cryopreserved*
- Component code
- Volume (mL)
- Name of the processing centre
- Donation number*
- ABO group*
- RhD group stated as positive or negative*
- Name of any approved platelet additive solution used
- Date of collection
- Date and time of expiry*
- Name and volume (mL) of the cryoprotective solution
- The storage temperature
- The HLA and/or HPA type (if determined);
- Additional component information: Leucocyte depleted, irradiated, etc. (if appropriate);

(* 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

BLOOD COMPONENT MONOGRAPH

PLATELETS APHERESIS IN PLASMA LEUCOCYTE-DEPLETED CRYOPRESERVED

6. WARNINGS:

Residual cryoprotectant (DMSO) can be toxic.

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.

Adverse reactions include:

- Transfusion-associated circulatory overload;
- Haemolytic reaction due to anti-A, -B in case of incompatible transfusions when thawed platelets are re-suspended in plasma;
- Non-haemolytic transfusion reaction (mainly chills, fever and urticaria);
- Allo-immunisation against HPA antigens;
- Transfusion-related acute lung injury (TRALI);
- Post-transfusion purpura;
- Graft versus host disease (TA-GVHD);
- Sepsis due to inadvertent bacterial contamination;
- Viral transmission (hepatitis, HIV, etc.) is possible, despite careful donor selection and screening procedures;
- Syphilis transmission;
- Protozoal transmission (e.g., malaria) may occur in rare instances;
- Transmission of other pathogens that are not tested for or recognised.