BLOOD COMPONENT MONOGRAPH
GRANULOCYTES APHERESIS

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

Council of Europe Guide Monograph	Granulocytes, Apheresis
eProgesa Component Names	Granulocytes, Apheresis
eProgesa Component Codes	16435, E6201V00, E5934V00

1. DEFINITION AND PROPERTIES

Granulocytes, Apheresis is a component that contains granulocytes suspended in plasma and is obtained by apheresis of a single donor using automated cell separation equipment.

An adult therapeutic dose of *Granulocytes, Apheresis* contains between 0.15 – 0.30 x 10^9 granulocytes / kg body weight of the designated recipient.

Granulocytes, Apheresis has a significant content of red blood cells, lymphocytes and platelets.

Granulocytes, Apheresis must be irradiated.

IMPORTANT NOTICE

The clinical efficacy, indication and dosage of granulocyte transfusions have not been established. Potential donors of granulocytes need to receive medication before collection, and sedimenting agents are required during the apheresis procedure, both of which have potentially severe side-effects that are described below. Thus, it is essential to secure the informed consent of the donor. In addition to the recognised complications of routine donor apheresis, the following side-effects may occur.

• Hydroxyethyl starch (HES): acts as a volume expander. Donors who have received HES may experience headaches or peripheral oedema because of an expanded circulatory volume. HES may accumulate (which can result in pruritus) and allergic reactions are possible.

• Corticosteroids: may cause, for example, hypertension, diabetes, cataracts and peptic ulcer.

• G-CSF: The most common short-term complication after G-CSF administration in peripheral blood stem cell (PBSC) donors is bone pain though, on very rare occasions, splenic rupture or lung injury may occur. Concerns over acute myeloid leukaemia (AML) / myelodysplasia (MDS) development following G-CSF administration are based primarily on reports of increased rates of AML / MDS among women with breast cancer who received chemotherapy or patients with severe chronic neutropenia (SCN) who received G-CSF support. To date, registry data from Europe and the United States have not identified any increased risk of AML / MDS (including those based on the data of over 100 000 healthy individuals who donated PBSC and received G-CSF as pre-treatment). However, the median follow-up of these studies is less than 5 years.

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2. PREPARATION

Donors of *Granulocytes, Apheresis* require pre-treatment with corticosteroids and / or growth factors. *Granulocytes, Apheresis* are collected from a single donor by apheresis. To optimise collection yields the sedimenting agent Hydroxyethyl starch (HES) is used during the apheresis procedure.

3. REQUIREMENTS AND QUALITY CONTROL

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

Table 1: Release Requirements:

Parameter	Requirements	Frequency of control
ABO, RhD	Grouping	All units
Anti-HIV 1 & 2	Negative by approved screening test	
HbsAg	Negative by approved screening test	
Anti-HCV	Negative by approved screening test	
Volume[1]	< 500 mL	
Granulocytes[1]	≥ 10 x 10^9 per donation	
HLA *(when required)*	Typing	As required
CMV	Negative	

1. A minimum of 75% of components must meet the criteria

4. STORAGE AND TRANSPORT

Granulocytes, Apheresis are not suitable for storage and must be transfused as soon as possible after collection. If unavoidable, storage must be limited to the shortest possible period. The storage period must not exceed 24 hours.

The unit must be transported to the user in a suitable container at 22 ± 2 °C, but without agitation.

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5. LABELLING

The labelling must comply with the relevant national legislation and international agreements. The following information must be shown on the label or contained in this monograph as appropriate:

- Name of the component - *Granulocytes, Apheresis*
- Component code
- Volume
- Name of the Processing centre
- Donation number*
- ABO group*
- Rh(D) group stated as positive or negative*
- Date of collection
- Date of expiry (and time of expiry, when required)
- Name of the approved anticoagulant solution, additive solutions and / or other agents
- Storage temperature
- Additional component information: CMV antibody negative etc. (as appropriate)
- Number of granulocytes
- HLA type if determined
- A statement – “Do not agitate during 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

Because of the possibility of severe adverse effects associated with the collection (donor side-effects) and transfusion of granulocytes (recipient side-effects), the goals of granulocyte transfusion must be defined clearly before a course of therapy is initiated.

As there is a significant content of red blood cells, compatibility of donor red cells with the designated recipient must be verified by suitable pre-transfusion testing. Rh(D)-negative female recipients of child-bearing potential must not be transfused with granulocyte concentrates from Rh(D)-positive donors; if Rh(D)-positive concentrates have to be used, the prevention of Rh(D) immunisation by use of Rh(D) immunoglobulin must be considered.

Attention to HLA compatibility is also required for allo-immunised recipients.

Administration through a micro-aggregate or leucocyte-reduction filter is contraindicated.

The risk of adverse reactions is increased with concomitant administration of Amphotericin B.

Adverse reactions include:

- Non-haemolytic transfusion reaction (mainly chills, fever and urticaria);
- Allo-immunisation against red cell antigens, HLA, HPA and HNA;
- Transfusion-related acute lung injury (TRALI);
- Post-transfusion purpura;
- 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, toxoplasmosis) may occur in rare instances;
- Transmission of other pathogens that are not tested for or recognised;
- Citrate intoxication in neonates and in patients with impaired liver function;
- Accumulation of HES in multi-exposed patients.