NZBS BLOOD COMPONENT MONOGRAPH
PLASMA, FRESH FROZEN – LEUCOCYTE DEPLETED, EXTENDED LIFE

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

Council of Europe Guide Monograph	Plasma, Fresh Frozen
eProgesa Component Name	Plasma, Fresh Frozen – Leucocyte Depleted, Extended Life
eProgesa Component Code	18170, 18171, 18172, E4004VA0, E4004VB0, E4004VC0

1. DEFINITION AND PROPERTIES:

Plasma Fresh Frozen – Leucocyte Depleted, Extended Life (ELP) is a component for transfusion prepared from *Plasma Fresh Frozen – Leucocyte Depleted*, which is prepared either from whole blood or from plasma collected by apheresis, frozen within 8 hours to a temperature that adequately maintains the labile coagulation factors in a functional state.

FFP used for clinical transfusion must comply with the specifications listed in the Requirements and Quality Control section below.

Once thawed it must contain, on average, 70% or more of the value of the freshly collected plasma unit and at least similar quantities of the other labile coagulation factors and naturally occurring inhibitors.

It must not contain irregular antibodies of clinical significance. It must be leucocyte-depleted to contain less than 5 x 10^6 per unit of leucocytes per unit.

2. PREPARATION:

Plasma Fresh Frozen – Leucocyte Depleted is transformed in eProgesa upon thawing to *Plasma Fresh Frozen – Leucocyte Depleted, Extended Life*.

Thawed *Plasma Fresh Frozen – Leucocyte Depleted, Extended Life* must be used within five days of being thawed, but it should be borne in mind that extended post-thaw storage will result in a decline in the content of labile coagulation factors. Thawed plasma must not be refrozen.

3. REQUIREMENTS AND QUALITY CONTROL

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

3.1 Release Requirements:

Parameter to be checked	Requirements	Frequency of control
ABO, RhD	Grouping	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[1]	Negative by approved screening test	All units
Nucleic acid test for HIV RNA, HCV RNA and HBV DNA	Negative by approved screening test	All units

1. Donor is tested on first occasion they donate only. A negative result accredits the donor for future donations. \

NZBS BLOOD COMPONENT MONOGRAPH
PLASMA, FRESH FROZEN – LEUCOCYTE DEPLETED, EXTENDED LIFE

3.2 Quality Monitoring Requirements:

Parameter to be checked	Requirements	Frequency of control[1]
Volume[1]	180 – 340 mL	1%, minimum 10 per month
rWBC[1]	<5 x 10^6 / unit	1%, minimum 10 per month
Residual Platelets	<50 x 10^9 L	1%, minimum 10 per month
Factor VIII[2]	Average (after freeze and thaw) not less than 70 IU of Factor VIII per 100 mL as determined by SPC within the first month of storage	1%, minimum 10 per month

1. ELP is a secondary product derived from Plasma Fresh Frozen – Leucocyte Depleted. This parameter is monitored on the primary product
2. A minimum of 75% of components tested must meet the specification

4. STORAGE AND TRANSPORT:

The storage temperature for thawed *Plasma Fresh Frozen – Leucocyte Depleted, Extended Life* is between 4 ± 2 °C.

The storage temperature must be maintained during transport. Transport time should not exceed 24 hours. Unless for immediate use, the packs must be transferred at once to storage at the recommended temperature.

5. LABELLING:

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

- Component Name: Plasma Fresh Frozen– Leucocyte Depleted Extended Life
- Component Code
- Volume
- Name of the collection centre
- Donation number*
- ABO group*
- Rh(D) group stated as positive or negative*
- Date of collection
- Date of expiry*
- The storage temperature
- A statement – “Use within 120 hours of thawing” and “Store at 2-6°C after thawing”

(* eye readable and barcode format)

In addition, the following instructions are included:

- Check the identity of the recipient and the component
- Inspect the pack for deterioration or damage
- Risk of adverse reaction/infection

NZBS BLOOD COMPONENT MONOGRAPH
PLASMA, FRESH FROZEN – LEUCOCYTE DEPLETED, EXTENDED LIFE

6. WARNINGS:

Transfusion of ABO blood group-incompatible plasma may result in haemolytic transfusion reaction.

ELP must not be used in a patient with an intolerance to plasma proteins.

Before use, the component must be thawed in a properly controlled environment and the integrity of the pack must be verified to exclude any defects or leakages. No insoluble cryoprecipitate must be visible on completion of the thaw procedure.

Adverse reactions include:

- Non-haemolytic transfusion reaction (mainly chills, fever and urticaria);
- Transfusion-related acute lung injury (TRALI);
- Viral transmission (hepatitis, HIV, etc.) is possible, despite careful donor selection and screening procedures;
- Sepsis due to inadvertent bacterial contamination;
- Transmission of other pathogens that are not tested for or recognised;
- Citrate toxicity in neonates and in patients with impaired liver function;
- Transfusion-associated circulatory overload;
- Anaphylaxis and allergic reactions.

Plasma Fresh Frozen – Leucocyte Depleted, Extended Life is not recommended:

- For patients with congenital factor V or VIII deficiencies
- For neonatal patients
- Where specific factor concentrates or an alternate specific therapy is available