NZBS BLOOD COMPONENT MONOGRAPH
PLASMA, FRESH FROZEN LEUCOCYTE DEPLETED

Council of Europe Guide Monograph	Plasma, Fresh Frozen
eProgesa Component Name	Plasma, Fresh Frozen – Leucocyte Depleted
eProgesa Component Code	18170 or 18171 or 18172

1. DEFINITION and PROPERTIES:

Plasma, Fresh Frozen Leucocyte Depleted (FFP) is a component for transfusion prepared from either whole blood or from plasma collected by apheresis and 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.

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. FFP must contain less than 5×10^6 leucocytes per unit.

2. PREPARATION

From Whole Blood

Plasma is separated from *Whole Blood* that has been collected using a blood bag with integral transfer packs employing hard-spin centrifugation with freezing commenced within 8 hours of collection or within a timeframe validated to result in a component that meets specification.

Freezing must take place in a system that allows complete freezing within one hour to a temperature below -25°C.

By apheresis

FFP may be collected by apheresis. Freezing must commence within 8 hours of collection or within a timeframe validated to result in a component that meets specification. Freezing must take place in a system that allows complete freezing within one hour to a temperature below -25°C.

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.

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3.2 Quality Monitoring Requirements

Parameter to be checked	Requirements	Frequency of control[1]
Volume	180 – 340 mL	1%, minimum 10 per month
rWBC	$<5 \times 10^6$ / unit	1%, minimum 10 per month
Residual platelets	$<50 \times 10^9$/ L	1%, minimum 10 per month
Factor VIII[2]	Average (after freeze and thaw): ≥ 70 IU FVIII / 100 mL as determined by SPC on units in the first month of storage	1%, minimum 10 per month

1. Frequency of testing is determined by statistical process control methodology.
2. A minimum of 75% of components tested must meet the specification

4. STORAGE and TRANSPORT

The following storage times and temperatures are permitted:

- 24 months at below –25°C
- 3 months at between –18°C to –25°C

The storage temperature must be maintained during transport. Unless for immediate use, the packs must be transferred at once to storage at the recommended temperature.

Once thawed the component must be stored at 2 to 6°C and used within 24 hours. It must not be refrozen.

5. LABELLING

The following information must be shown on the label:

- Component Name: Plasma Fresh Frozen – Leucocyte Depleted*
- 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 24 hours of thawing” and “Store at 2-6°C after thawing”
- Blood pack lot number*

(* 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

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6. WARNINGS

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

FFP 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.