



Irish Blood Transfusion Service

Seirbhís Fuilaidriúcháin na hÉireann

Document Detail

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Title: **FRESH FROZEN PLASMA SUITABLE FOR NEONATAL USE**
Owner: 1066 KATE FITZGERALD
Status: CURRENT
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Expiration Date:

Review

Review: IBTS PMF REVIEW

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off By</u>
1	DIRECTOR OF QUALITY	MARIE O'CONNELL	MARIE O'CONNELL
1	QUALITY MANAGER MRTC	COLIN JOHNS	COLIN JOHNS
1	LABS HEAD OF PROCESSING IBTS	BERNIE QUIRKE	BERNIE QUIRKE
1	NATIONAL MEDICAL DIRECTOR	WILLIAM MURPHY	WILLIAM MURPHY

Change Orders

Changes as described on Change Order: Change Order No.

Change Orders - Incorporated

Changes as described on Change Order: Change Order No.
IBTS/CO/0328/15

IRISH BLOOD TRANSFUSION SERVICE

PRODUCT MASTER FILE

Title: Fresh Frozen Plasma Suitable For Neonatal Use

Name of Product: Fresh Frozen PLASMA Suitable For Neonatal Use

E Progesa Codabar Component Code: 18266

E Progesa ISBT-128 Component Code: C4048V00

General Description: Plasma obtained from a unit of whole blood, rapidly frozen to a temperature that will adequately maintain the activity of labile coagulation factors in a functional state. The majority of leucocytes are removed by filtration of the whole blood. The selected donors meet the additional criteria for neonatal use. Prepared from male donors only.

General Specification:

Parameter	Quality Requirement	Frequency of Control
Volume	220 - 300 ml	100 %
Factor VIIIc	> 0.7 IU/ml	10 per 3 months
Platelet Content	< 30 x 10 ⁹ /L	4 per month
Leucocyte Content	< 1 x 10 ⁶ /unit	4 per month
Red cell presence	Absent when examined macroscopically	100%
Total Protein	≥50g/l	10 per 3 months
ABO Agglutinins	No HighTitre Anti-A or Anti-B	100%
CMV	CMV ab negative	100%

Labelling: See Appendices 1 and 11

Storage: Fresh Frozen Plasma Suitable For Neonatal Use should be stored at a core temperature of $\leq -25^{\circ}\text{C}$ for a maximum of 12 months. Once thawed, Fresh Frozen Plasma Suitable For Neonatal Use must not be refrozen and should be used immediately. If delay is unavoidable, the component should be stored at ambient temperature and used within 6 hours.

Thawing: Thaw by placing in a 37°C controlled dedicated water bath in the plastic overwrap or by removing the overwrap and placing in a validated microwave plasma defroster.

Transportation: The air temperature of the transport container for units of Fresh Frozen Plasma Suitable For Neonatal Use should be maintained $\leq -25^{\circ}\text{C}$ during transportation from the Irish Blood Transfusion Service to the place where they are intended for use. Unless Fresh Frozen Plasma Suitable For Neonatal Use is to be thawed for immediate therapeutic use, it should be transferred immediately to storage at the recommended temperature, $\leq -25^{\circ}\text{C}$.

Indications for Use: Fresh Frozen Plasma Suitable For Neonatal Use may be used in coagulation disorders, particularly in those clinical situations in which a multiple coagulation deficit exists.

Fresh Frozen Plasma Suitable For Neonatal Use should not be used simply to correct a volume deficit in the absence of a coagulation deficit nor as a source of immunoglobulins.

Precautions In Use:

- Fresh Frozen Plasma Suitable For Neonatal Use should not be used in a patient with intolerance to plasma proteins.
- Blood group compatible Fresh Frozen Plasma should be used and where possible, women of child bearing age and younger should receive Rh D compatible plasma.
- Before use the component should be thawed in the vacuum pack in a properly controlled environment and the integrity of the pack should be verified to exclude any defects or leakages (see Appendices 1 and 11.). No insoluble cryoprecipitate should be visible on completion of the thaw procedure.
- Fresh Frozen Plasma Suitable For Neonatal Use should be infused intravenously through a set containing an inline 170-200 μm filter.
- No solution should be added to the bag or giving set.
- Fresh Frozen Plasma should not be used where a suitable viral inactivated alternative product is available.

Adverse Effects Include:

- Circulatory overload
- Haemolytic transfusion reaction due to transfusion of ABO-incompatible plasma in the component.
- Non Haemolytic transfusion reactions - chills, fever, hypersensitivity.
- Anaphylaxis
- Metabolic upset
 - Citrate toxicity in patients with impaired hepatic function or where large volumes are rapidly transfused.
- Immunological effects
 - Alloimmunisation to HLA and HPA antigens
 - Transfusion related Acute Lung injury (TRALI) by donor HLA/granulocyte antibodies
- Pathogen Transmission
 - Despite careful donor selection and laboratory screening procedures, infections including Syphilis, Viral Hepatitis, HIV, HTLV 1 & 11 and other viruses and protozoa (e.g. malaria) may, in rare instances, occur.
 - vCJD transmission
 - Transmission of other pathogens that are not tested for or recognised.
 - Acute sepsis due to bacterial contamination

Serious Adverse Reaction

Serious adverse reactions should be reported to:

National Haemovigilance Office
Irish Blood Transfusion Service
National Blood Centre
James's Street
Dublin 8

AND

Quality Assurance Manager
Irish Blood Transfusion Service

AT EITHER

National Blood Centre
James's Street
Dublin 8

OR

St Finbarr's Hospital
Douglas Road
Cork.

APPENDIX 1

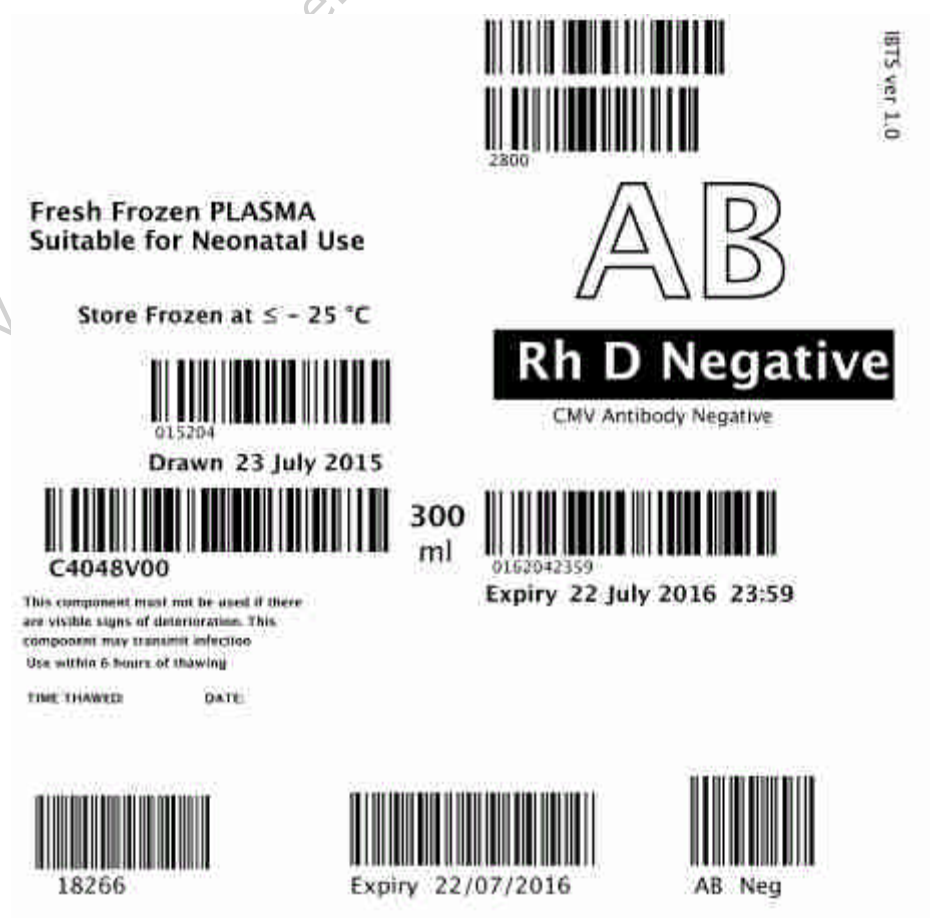
E Progesa Codabar Component Code : 18266

E Progesa ISBT -128 Component Code: C4048V00

Product Name
 Fresh Frozen PLASMA
 Suitable for Neonatal Use

Shelf Life
 365 days

Labelling and Barcode:
 (for illustration purposes only – barcodes not suitable for scanning – label not to scale)



APPENDIX 11

BT - 0196-9



Irish Blood Transfusion Service

Seirbhís Fuilaeistriúcháin na hÉireann

FRESH FROZEN PLASMA

National Blood Centre,
James's St,
Dublin 8
Tel. (01) 4322800

**Munster Regional
Transfusion Centre**
St. Finbarr's Hospital
Cork
Tel. (021) 4807400

Storage: Store the frozen plasma in this container
at $\leq -25^{\circ}\text{C}$.

Thawing: Place the component within its plastic overwrap in a
 37°C temperature controlled dedicated water bath or remove the
overwrap and place in a validated microwave plasma defroster
until thawed.

**IMPORTANT: ONCE THAWED, FROZEN PLASMA
SHOULD BE INFUSED WITHOUT DELAY BUT
NOT LATER THAN SIX HOURS AFTER THAWING.
THE THAWED PLASMA SHOULD BE HELD AT
AMBIENT TEMPERATURE.**

**UNDER NO CIRCUMSTANCES MAY
THAWED PLASMA BE REFROZEN**

Warning: Plasma must not be used if there are visible signs of
deterioration. This component may transmit infection.

August 2015

APPENDIX 111

BT – 0605-1

**Irish Blood
Transfusion Service**

Seirbhís Fuilaidriúcháin na hÉireann

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SUITABLE FOR NEONATAL USE**

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