Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

Document Detail

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Review

Review: IBTS PMF REVIEW

Level	Owner Role	Actor	Sign-off By
1	DOCUMENT CONTROLLER	REBECCA WALDEN	REBECCA WALDEN
2	QUALITY ASSURANCE WRITER IBTS	REBECCA WALDEN	REBECCA WALDEN
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4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS

Review: IBTS DOC PERIODIC REVIEW

Level	Owner Role	Actor	Sign-off By
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3	COMPONENTS HEAD OF DEPT MRTC	AINE FITZPATRICK	AINE FITZPATRICK
4	DIRECTOR OF QUALITY	KAREN BYRNE	KAREN BYRNE
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Review: IBTS DOC PERIODIC REVIEW

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3	MEDICAL & SCIENTIFIC DIRECTOR	ANDREW GODFREY	ANDREW GODFREY
3	SSCD HEAD OF DEPT IBTS	AILEEN FARRELLY	AILEEN FARRELLY
4	DIRECTOR OF QUALITY	KAREN BYRNE	KAREN BYRNE
4	QUALITY ASSURANCE REVIEWER IBTS	KAREN BYRNE	KAREN BYRNE

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Document Detail

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/0167/21

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Printed By: **Date:**

IRISH BLOOD TRANSFUSION SERVICE

PRODUCT MASTER FILE

TITLE: FRESH FROZEN PLASMA SUITABLE FOR NEONATAL USE

Change Description:
Revise IBTS/PMF/SPEC/0203 – 0218, 0220, 0221, 0224, 0226, 0227, 0232, 0236 to update the product labels in the appendices for each product.

Reason for Change:
Fix to the labels as part of the semester patch reference CC 126/19/IBTS and reference IBTS/QA/IQ/0600 Deviation 008

Change order No.:
IBTS/CO/0167/21

Referenced Documents
BT – 0196
BT - 0605

SmartSolve Roles
N/A

Training Type
N/A

SmartSolve Document Category

Category	Mobile	Cryobiology	Website	GDP
Yes / No	No	No	Yes	No

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 I, II and III

Storage: Fresh Frozen Plasma Suitable For Neonatal Use should be stored at a core temperature of ≤-25°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 ≤ -25°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, ≤ -25ºC.

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 reaction (mainly chills, fever and urticaria). The risk is reduced by leucodepletion.
- Anaphylaxis
- 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.
  - The risk of CMV transmission is minimal as the components are leucodepleted
  - Sepsis due to bacterial contamination (reduced but not eliminated by bacterial screening)
- Metabolic upset
  - Citrate toxicity, especially in neonates and in patients with impaired hepatic function.
- Immunological effects
  - Alloimunisation to HLA and HPA antigens
  - Post Transfusion purpura (PTP),especially in parous female recipients
  - The risk of Graft vs Host Disease (GvHD) in immuno compromised recipients is eliminated by irradiation
  - Transfusion related Acute Lung injury (TRALI) by donor HLA/granulocyte antibodies

Serious Adverse Reaction
Please inform the IBTS immediately about any event relating to suspected bacterial sepsis/ transfusion associated bacterial sepsis

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

Munster Regional Transfusion Centre
St Finbarr's Hospital
Douglas Road, Cork

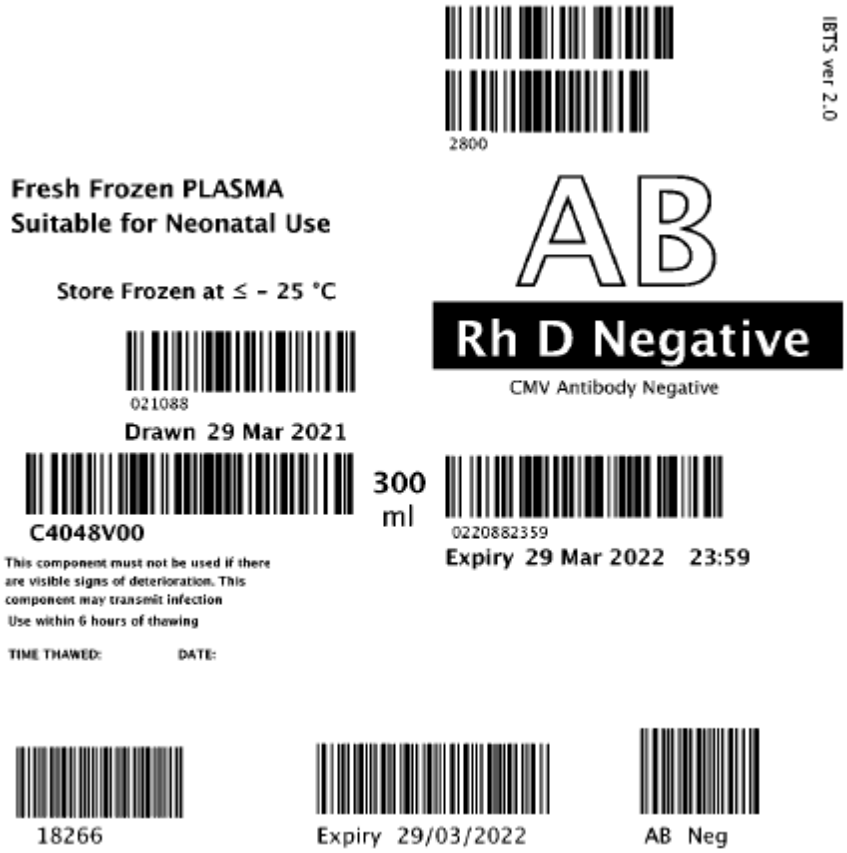
APPENDIX I

E Progesa Codabar Component Code : 18266

E Progesa ISBT -128 Component Code: C4048V00

Product Name	**Shelf Life**
Fresh Frozen PLASMA Suitable for Neonatal Use	365 days

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



APPENDIX II

BT - 0196

Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin 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 ≤ -25°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 III

BT – 0605

Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

FRESH FROZEN PLASMA SUITABLE FOR NEONATAL USE

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 ≤ -25ºC.

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.

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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