



Irish Blood Transfusion Service

Seirbhís Fuilaistriúcháin na hÉireann

Document Detail

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Review

Review: IBTS PMF REVIEW

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off By</u>
1	DOCUMENT CONTROLLER	REBECCA WALDEN	REBECCA WALDEN
2	QUALITY ASSURANCE WRITER IBTS	REBECCA WALDEN	REBECCA WALDEN
3	LABS HEAD OF MANUFACTURING & ISSUE IBTS	BARRY DOYLE	BARRY DOYLE
3	NATIONAL MEDICAL DIRECTOR	STEPHEN FIELD	STEPHEN FIELD
4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS

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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IRISH BLOOD TRANSFUSION SERVICE

PRODUCT MASTER FILE

TITLE: FRESH FROZEN PLASMA

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

SmartSolve Roles

N/A

Training Type

N/A

SmartSolve Document Category

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

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IRISH BLOOD TRANSFUSION SERVICE

PRODUCT MASTER FILE

Title: Fresh Frozen Plasma

Name of Product: Fresh Frozen PLASMA

E Progesa Codabar Component Code: 18270

E Progesa ISBT-128 Component Code : E4048V00

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. Prepared from male donors only. Suitable for adult use.

General Specification

PARAMETER	QUALITY REQUIREMENTS	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

Labelling: See Appendices 1 and 11

Storage: Fresh Frozen Plasma should be stored at a core temperature of ≤ -25°C for a maximum of 12 months. Once thawed, Fresh Frozen Plasma 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: Place in a 37°C controlled dedicated waterbath in the plastic overwrap or by removing the overwrap and placing in a dedicated, validated microwave until the Fresh Frozen Plasma is thawed.

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Transportation: The air temperature of the transport container for units of Fresh Frozen Plasma should be maintained $\leq -25^{\circ}\text{C}$ during transportation from the Irish Blood Transfusion Service to the place that they are intended for use. Unless Fresh Frozen Plasma 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 may be used in coagulation disorders, particularly in those clinical situations in which a multiple coagulation deficit exists.

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

Precautions for Use:

- Fresh Frozen Plasma should not be used where a suitable viral inactivated alternative product is available.
- Fresh Frozen Plasma should be infused intravenously through a set containing an in line 170-200 μm filter.
- Fresh Frozen Plasma 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.
- No solution should be added to the bag or giving set.

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.

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- 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
 - Alloimmunisation 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

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APPENDIX 1

E Progesa Codabar Component Code : 18270

E Progesa ISBT -128 Component Code: E4048V00

Product Name

Fresh Frozen PLASMA

Shelf Life

365 days

Labelling and Barcode:

(for illustration purposes only – barcodes not suitable for scanning – label not to scale)

IBTS ver 2.0

8400

Fresh Frozen PLASMA

Store Frozen at $\leq -25^{\circ}\text{C}$

021088

Drawn 29 Mar 2021

AB

Rh D Positive

0220882359

E4048V00

300 ml

Expiry 29 Mar 2022 23:59

This component must not be used if there are visible signs of deterioration. This component may transmit infection. USE WITHIN 6 HOURS OF THAWING

TIME THAWED: DATE:



APPENDIX 11

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**Irish Blood
Transfusion Service**

Seirbhís Fuilaidriúcháin 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