



# Irish Blood Transfusion Service

## Seirbhís Fuilaidriúcháin na hÉireann

### Document Detail

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**Type:** PMF IBTS SPEC  
**Document No.:** IBTS/PMF/SPEC/0220[3]  
**Title:** **FRESH FROZEN PLASMA**  
**Owner:** QA DOC CON QA DOC CONTROL  
**Status:** CURRENT  
**Effective Date:** 18-Apr-2021  
**Expiration Date:** 04-Aug-2025

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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 PHS DIR IBTS               | BARRY DOYLE    | BARRY DOYLE        |
| 3            | NATIONAL MEDICAL DIRECTOR       | STEPHEN FIELD  | STEPHEN FIELD      |
| 4            | QUALITY ASSURANCE REVIEWER IBTS | COLIN JOHNS    | COLIN JOHNS        |

**Review:** IBTS DOC PERIODIC REVIEW

| <u>Level</u> | <u>Owner Role</u>               | <u>Actor</u>     | <u>Sign-off By</u> |
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| 4            | QUALITY ASSURANCE REVIEWER IBTS | COLIN JOHNS      | COLIN JOHNS        |
| 4            | DIRECTOR OF QUALITY             | KAREN BYRNE      | KAREN BYRNE        |

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### Change Orders

**Changes as described on Change Order:** **Change Order No.**  
IBTS/CO/0070/23

### Change Orders - Incorporated

**Changes as described on Change Order:** **Change Order No.**  
IBTS/CO/0167/21

**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  |

Verify when in Use. Status CURRENT Effective 12 April 2021

**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 <sup>9</sup> /l            | 4 per month          |
| Leucocyte Content | < 1 x 10 <sup>6</sup> /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.

**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  $\mu\text{m}$  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.

- 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

## 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)

effective 18 April 2021



IBTS ver 2.0

**Fresh Frozen PLASMA**

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



021088

Drawn 29 Mar 2021

AB  
Rh D Positive



E4048V00

300 ml



0220882359

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

BT - 0196

**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  $37^{\circ}\text{C}$  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