# Irish Blood Transfusion Service
## Seirbhís Fuilaistriúcháin na hÉireann

## *Document Detail*

**Type:** PMF IBTS SPEC
**Document No.:** IBTS/PMF/SPEC/0232[4]
**Title:** **RED CELLS, SUITABLE FOR NEONATAL USE FOR 5 DAYS AFTER DATE DRAWN**
**Owner:** QA DOC CON QA DOC CONTROL
**Status** CURRENT
**Effective Date:** 13-May-2021
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### *Review*

**Review:** IBTS PMF REVIEW

| Level | Owner Role | Actor | Sign-off By |
|---|---|---|---|
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### *Change Orders*

| Changes as described on Change Order: | Change Order No. |
|---|---|

### *Change Orders - Incorporated*

| Changes as described on Change Order: | Change Order No. |
|---|---|
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**Valid on Day of Printing, Verify Current Version**
**Printed By:** **Date:**

# IRISH BLOOD TRANSFUSION SERVICE

# PRODUCT MASTER FILE

## TITLE: RED CELLS, SUITABLE FOR NEONATAL USE FOR 5 DAYS AFTER DATE DRAWN

**Change Description:**
Revise IBTS/PMF/SPEC/0203 to IBTS/PMF/SPEC/0212 and IBTS/PMF/SPEC/0232 to amend the product labels.

**Reason for Change:**
Fix to the labels with reference to IR 361/21/IBTS, IBTS/QA/PQ/0600 Deviation 012 and CC 134/21/IBTS

**Change order No.:**
IBTS/CO/0229/21

**Referenced Documents**
N/A

**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: Red Cells, Suitable for Neonatal Use for 5 Days after Date Drawn**

**Name of Products: RED CELLS, Suitable for Neonatal Use for 5 Days after Date Drawn /**

**RED CELLS, Suitable for Neonatal Use for 5 Days after Date Drawn, Irradiated**



**E Progesa Codabar Component Codes: 54481 / 74421**

**E Progesa ISBT – 128 Component Codes : C7429V00 / C7442V00.**

**General Description:** A red cell suspension obtained from whole blood by centrifugation, removal of plasma with subsequent addition of a nutrient solution SAG-M. The removal of the majority of leucocytes is achieved by filtration. The selected donors meet the additional criteria for neonatal use.

**General Specification:**

| Parameter | Quality Requirements | Frequency of Control |
|---|---|---|
| Volume | 231 – 355 ml | 100% |
| Haematocrit | 0.50 - 0.70 L/L | 1% |
| Haemoglobin | ≥ 40 g/unit | 1% |
| Leucocyte Content | < 1 x $10^6$/unit | 1% |
| Haemolysis at end of shelf life | < 0.8% of red cell mass | 4 per month<br>(RED CELLS, 04333/E7429V00) |
| ABO Agglutinins | No HighTitre<br>Anti-A or Anti-B | 100% |
| CMV | CMV ab negative | 100% |

**Labelling:** See Appendix I

**Storage:** Red Cells, Suitable for Neonatal Use for 5 Days after Date Drawn (including Irradiated) should be stored at $4^{o}C \pm 2^{o}C$.

**Irradiation:** Red Cells, Suitable for Neonatal Use for 5 Days after Date Drawn may be irradiated up to 14 days from date of collection. Post irradiation the storage is 14 days.
If irradiated, product code will change into codabar:74421and ISBT-128 barcode: C7442V00.

**Transportation:** The air temperature of transport containers for units of Red Cells, Suitable for Neonatal Use for 5 Days after Date Drawn (including Irradiated) should be maintained between $2^{o}C$ and $10^{o}C$ during transport from the Irish Blood Transfusion Service to the place where they are intended for use. Transport time under these conditions normally should not exceed 8 hours.

**Indications for Use:** Red Cells, Suitable for Neonatal Use for 5 Days after Date Drawn (including Irradiated) are used for augmenting the oxygen carrying capacity of the blood where this is critically reduced in infants requiring large volume transfusion, particularly in the surgical setting, within 5 days from date drawn.

**Precautions in Use:**

- Compatibility of this component with the intended recipient must be verified by appropriate pre transfusion testing.
- Red Cells, Suitable for Neonatal Use for 5 Days after Date Drawn (including Irradiated) should be transfused through a standard 170 – 200 µm filter.
- No solution should be added to the bag or to the giving set.
- Components should be inspected visually for defects, leakage, abnormal colour or visible clots.
- Red Cells, Suitable for Neonatal Use for 5 Days after Date Drawn (including Irradiated) are not recommended in:
  - large volume transfusion in neonates **unless** the red cells are less than 5 days old.
  - exchange transfusions in newborns.
    Intrauterine Transfusions
- This component does not contain platelets or soluble coagulation factors.

**Adverse Effects Include:**

- Circulatory Overload.
- Haemolytic transfusion reaction;
- Non-haemolytic transfusion reaction (mainly chills, fever and urticaria)

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- 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)

- Immunological effects
  - Alloimunisation to HLA, HPA and red cell antigens
  - Post Transfusion purpura (PTP), especially in parous female recipients
  - Graft versus host disease due to transfusion of viable lymphocytes can occur, but is minimised by exposure of the suspension to ionising radiation before transfusion
  - Transfusion related Acute Lung injury (TRALI) by donor HLA/granulocyte antibodies

- Metabolic upset
  - Citrate toxicity, especially in neonates and in patients with impaired hepatic function.
  - ↑ $K^+$ in massive transfusions, especially where patient is hypothermic or acidotic or has impaired renal function.
  - Hypocalcaemia.
  - Hypoglycaemia.
  - Hypokalaemia.

- Iron overload
  - In patients on chronic red cell transfusion support programmes.

**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:** 54481

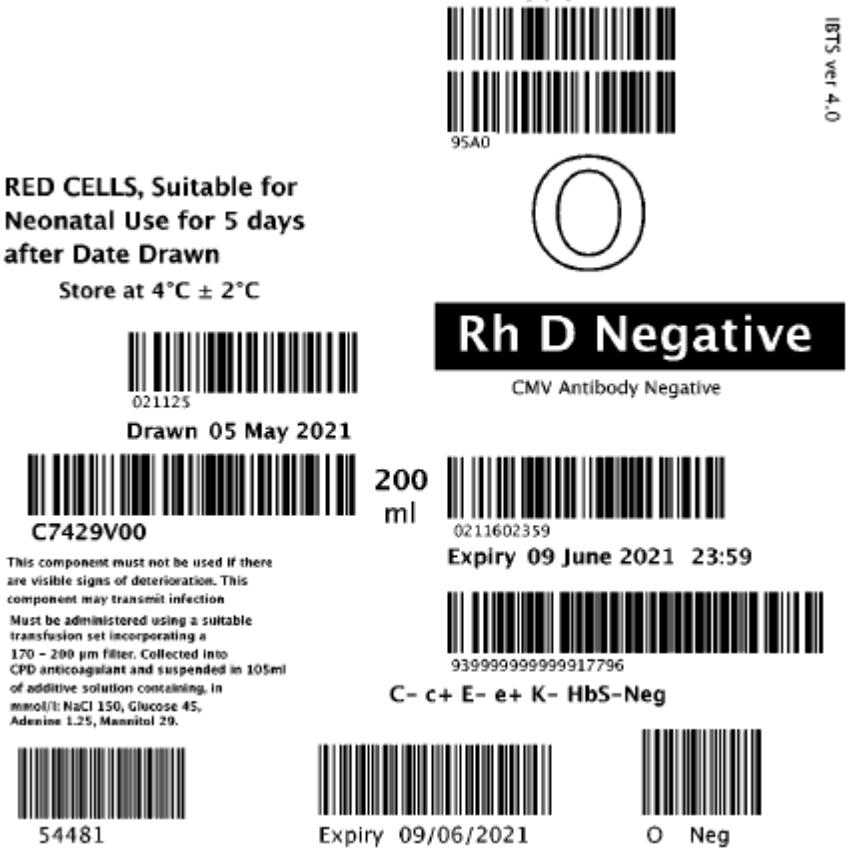
**E Progesa ISBT – 128 Component Code:** C7429V00



**Product Name**
RED CELLS, Suitable for Neonatal Use for 5 Days after Date Drawn

**Shelf life**
35 days

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



# APPENDIX II

**E Progesa Codabar Component Code:** 74421

**E Progesa ISBT – 128 Component Code :** C7442V00



**Product Name**
RED CELLS, Suitable for Neonatal Use for 5 Days after Date Drawn, Irradiated

**Shelf life**
14 days

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