



# Irish Blood Transfusion Service

## Seirbhís Fuilaeistriúcháin na hÉireann

### Document Detail

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**Type:** PMF IBTS SPEC  
**Document No.:** IBTS/PMF/SPEC/0209[6]  
**Title:** **RED CELLS SUITABLE FOR NEONATAL USE**  
**Owner:** QA DOC CON QA DOC CONTROL  
**Status:** CURRENT  
**Effective Date:** 19-May-2025  
**Expiration Date:** 19-May-2027

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### Review

**Review:** IBTS PMF REVIEW

| <u>Level</u> | <u>Owner Role</u>               | <u>Actor</u>     | <u>Sign-off By</u> |
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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.**  
IBTS/CO/0219/25

|                    |        |              |
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**IRISH BLOOD TRANSFUSION SERVICE**  
**PRODUCT MASTER FILE**

**TITLE:** **RED CELLS SUITABLE FOR NEONATAL USE**

**Change Description:**

Revise the Labelling and Barcode Illustrations.

**Reason for Change:**

To update the PMFs with new Label Versions (Ref CC 208/23 & 002/24)

**Change order No.:**

IBTS/CO/0219/25

**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

**Name of Products:** RED CELLS Suitable for Neonatal Use, Split 1 / 2 / 3 / 4 / 5 and  
RED CELLS Suitable for Neonatal Use, Irradiated, Split 1 / 2 / 3 / 4 / 5

**E Progesa Codabar Component Codes :** 56830 / 56831 / 56832 / 56833 / 56834  
74422 / 74423 / 74424 / 74425 / 74426

**E Progesa ISBT – 128 Component Codes :**

C7429VA0 / C7429VB0 / C7429VC0 / C7429VD0 / C7429VE0  
C7442VA0 / C7442VB0 / C7442VC0 / C7442VD0 / C7442VE0

**General Description:** A red cell suspension obtained from whole blood by centrifugation, removal of plasma with subsequent addition of a nutrient solution SAG-M and using a closed system divided into 5 approximately equal volumes. 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                          | 45 – 71 ml x 5 split units        | 100%   |
| Haematocrit                     | 0.50 - 0.70 L/L                   | 1%   |
| Haemoglobin                     | ≥ 8 g / split unit                | 1%   |
| Leucocyte Content               | < 1 x 10 <sup>6</sup> /unit       | Counted in units of red cells (04333/E7429V00) ≥1% |
| Haemolysis at end of shelf life | < 0.8% of red cell mass           | 1 per month  |
| ABO Agglutinins                 | No High Titre<br>Anti-A or Anti-B | 100%   |
| CMV                             | CMV ab negative                   | 100%   |

**Labelling:** See Appendix 1

**Storage:** Red Cells Suitable for Neonatal Use, Split 1/2/3/4/5 should be stored at 4°C ± 2°C. The storage time is up to 35 days.

|                                 |   |
|---------------------------------|---|
| <b>Irradiation:</b>             | <p>Red Cells Suitable for Neonatal Use, Split 1/2/3/4/5 may be irradiated up to 14 days from date of collection. Post irradiation the storage is 14 days.</p> <p>If irradiated, product codes for the split units will change into codabar:74422 / 74423 / 74424 / 74425 / 74426 and ISBT-128 barcodes: C7442VA0 / C7442VB0 / C7442VC0 / C7442VD0 / C7442VE0.</p>   |
| <b>Transportation:</b>          | <p>The air temperature of transport containers for split units of Red Cells Suitable for Neonatal Use should be maintained between 2°C and 10°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</p>  |
| <b>Indications for Use:</b>     | <p>Red Cells Suitable for Neonatal Use, Split 1/2/3/4/5 are used for augmenting the oxygen carrying capacity of the blood where this is critically reduced in infants requiring repeated small volume transfusions within a four to five week period. It is recommended that the first split unit should be transfused within 5 days from date bled and subsequent split units from the same donation may be transfused up to the end of shelf life. The first split may be transfused greater than 5 days from the date bled if fresher product is not available. Seek medical advice where necessary.</p>   |
| <b>Precautions in Use:</b>      | <ul style="list-style-type: none"> <li>• Compatibility of this component with the intended recipient must be verified by appropriate pre transfusion testing.</li> <li>• Red Cells Suitable for Neonatal Use, Split 1/2/3/4/5 should be transfused through a standard 170 – 200 µm filter.</li> <li>• No solution should be added to the bag or to the giving set.</li> <li>• Components should be inspected visually for defects, leakage, abnormal colour or visible clots.</li> <li>• Red Cells Suitable for Neonatal Use, Split 1/2/3/4/5 are not recommended in: <ul style="list-style-type: none"> <li>- large volume transfusion in neonates unless the red cells are less than 5 days old.</li> <li>- Intrauterine Transfusion</li> <li>- exchange transfusions in newborns.</li> </ul> </li> </ul> |
| <b>Adverse Effects Include:</b> | <ul style="list-style-type: none"> <li>• Circulatory Overload.</li> <li>• Haemolytic transfusion reaction;</li> <li>• Non-haemolytic transfusion reaction (mainly chills, fever and urticaria).</li> </ul> <p>The risk is reduced by leucodepletion and washing</p>   |

- 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
  - Possible elevated potassium level in massive transfusions, especially where patient is hypothermic or acidotic or has impaired renal function.
  - Citrate toxicity, especially in neonates and in patients with impaired hepatic function.
  - Hypocalcaemia.
  - Hypoglycaemia.
  - Hypokalaemia.
- Immunological effects
  - Alloimmunisation to HLA and red cell antigens.
  - Graft vs Host Disease (GvHD) in immuno compromised recipients . The risk of GvHD is eliminated by irradiation
  - Transfusion related Acute Lung injury (TRALI) by donor HLA/granulocyte antibodies.
  - Post transfusion purpura (PTP).
- 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

Verify when in Use. Status CURRENT Effective 19 May 2025

## APPENDIX I

E Progesa Codabar Component Code: 56830

E Progesa ISBT-128 Component Code : C7429VA0

**Product Name :**  
RED CELLS,  
Suitable for Neonatal Use, Split 1

**Shelf Life :**  
35 days

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

RED CELLS,  
Suitable for Neonatal Use, Split 1

Store at 4°C ± 2°C



025129

Drawn 09 May 2025



C7429VA0

This component must not be used if there are visible signs of deterioration. This component may transmit infection. Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter. Collected into CPD anticoagulant and suspended in 105ml of additive solution containing, in mmol/l: NaCl 150, Glucose 45, Adenine 1.25, Mannitol 29



56830



Expiry 13/06/2025



O Neg



95A0



**Rh D Negative**

Confirmed Group  
CMV Antibody Negative



0251642359

Expiry 13 June 2025 23:59



93999999999917796

C- E- c+ e+ K- HbS-Neg

IBTS ver 5.0

## APPENDIX I

E Progesa Codabar Component Code: 56831

E Progesa ISBT-128 Component Code : C7429VB0

**Product Name :**

RED CELLS,  
Suitable for Neonatal Use, Split 2

**Shelf Life :**

35 days

**Product Label and Barcode:**

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

95A0

IBTS ver 5.0

RED CELLS,  
Suitable for Neonatal Use, Split 2

Store at 4°C ± 2°C

025129  
Drawn 09 May 2025

C7429VB0

300 ml

0251642359  
Expiry 13 June 2025 23:59

93999999999917796  
C- E- c+ e+ K- HbS-Neg

O Neg

56831

Expiry 13/06/2025

**Rh D Negative**  
Confirmed Group  
CMV Antibody Negative

This component must not be used if there are visible signs of deterioration. This component may transmit infection  
Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter. Collected into CPD anticoagulant and suspended in 105ml of additive solution containing, in mmol/l: NaCl 150, Glucose 45, Adenine 1.25, Mannitol 29.

Effective 19 May 2025



## APPENDIX I

E Progesa Codabar Component Code: 56832

E Progesa ISBT-128 Component Code : C7429VC0

**Product Name :**  
RED CELLS,  
Suitable for Neonatal Use, Split 3

**Shelf Life :**  
35 days

**Product Label and Barcode:**

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

95A0

IBTS ver 5.0

RED CELLS,  
Suitable for Neonatal Use, Split 3

Store at 4°C ± 2°C

025129  
Drawn 09 May 2025

C7429VC0

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

Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter. Collected into CPD anticoagulant and suspended in 105ml of additive solution containing, in mmol/l: NaCl 150, Glucose 45, Adenine 1.25, Mannitol 29

300 ml

**Rh D Negative**

Confirmed Group  
CMV Antibody Negative

0251642359  
Expiry 13 June 2025 23:59

93999999999917796  
C- E- c+ e+ K- HbS-Neg

56832

Expiry 13/06/2025

O Neg

## APPENDIX I

E Progesa Codabar Component Code: 56833

E Progesa ISBT-128 Component Code : C7429VD0

**Product Name :**

RED CELLS,  
Suitable for Neonatal Use, Split 4

**Shelf Life :**

35 days

**Product Label and Barcode:**

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



IBTS ver 5.0

RED CELLS,  
Suitable for Neonatal Use, Split 4

Store at 4°C ± 2°C



025129

Drawn 09 May 2025



C7429VD0

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

Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter. Collected into CPD anticoagulant and suspended in 105ml of additive solution containing, in mmol/l: NaCl 150, Glucose 45, Adenine 1.25, Mannitol 29.



56833



**Rh D Negative**

Confirmed Group  
CMV Antibody Negative

300  
ml



0251642359

Expiry 13 June 2025 23:59



93999999999917796

C- E- c+ e+ K- HbS-Neg



Expiry 13/06/2025



O Neg

## APPENDIX I

E Progesa Codabar Component Code: 56834

E Progesa ISBT-128 Component Code : C7429VE0

**Product Name :**

RED CELLS,  
Suitable for Neonatal Use, Split 5

**Shelf Life :**

35 days

**Product Label and Barcode:**

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

RED CELLS,  
Suitable for Neonatal Use, Split 5

Store at 4°C ± 2°C



025129

Drawn 09 May 2025



C7429VE0

This component must not be used if there are visible signs of deterioration. This component may transmit infection. Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter. Collected into CPD anticoagulant and suspended in 105ml of additive solution containing, in mmol/l: NaCl 150, Glucose 45, Adenine 1.25, Mannitol 29.



56834



Expiry 13/06/2025



O Neg



95A0

IBTS ver 5.0



**Rh D Negative**

Confirmed Group  
CMV Antibody Negative



0251642359

Expiry 13 June 2025 23:59



93999999999917796

C- E- c+ e+ K- HbS-Neg

## APPENDIX II

E Progesa Codabar Component Code: 74422

E Progesa ISBT-128 Component Code: C7442VA0

**Product Name :**

RED CELLS, Suitable for  
Neonatal Use, Irradiated, Split 1

**Shelf Life :**

14 days from irradiation date,  
to a maximum of 28 days

**Product Label and Barcode:**

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

RED CELLS, Suitable for  
Neonatal Use, Irradiated, Split 1

Store at 4°C ± 2°C



025129

Drawn 09 May 2025



C7442VA0

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

Must be administered using a suitable  
transfusion set incorporating a  
170 – 200 µm filter. Collected into  
CPD anticoagulant and suspended in 105ml  
of additive solution containing, in  
mmol/l: NaCl 150, Glucose 45,  
Adenine 1.25, Mannitol 29.



74422



Expiry 13/06/2025



O Pos



51E0

IBTS ver 5.0

O

**Rh D Positive**

CMV Antibody Negative  
IRRADIATED (Red Cell Splits)  
Confirmed Group



0251642359

Expiry 13 June 2025 23:59



93999999999918796

C- E+ c+ e+ K- HbS-Neg

## APPENDIX II (Irradiated)

E Progesa Codabar Component Code: 74423

E Progesa ISBT-128 Component Code: C7442VB0

## Product Name :

RED CELLS, Suitable for  
Neonatal Use, Irradiated, Split 2

## Shelf Life :

14 days from irradiation date,  
to a maximum of 28 days

## Product Label and Barcode:

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

IBTS ver 5.0

RED CELLS, Suitable for  
Neonatal Use, Irradiated, Split 2

Store at 4°C ± 2°C

025129  
Drawn 09 May 2025

C7442VB0

This component must not be used if there are visible signs of deterioration. This component may transmit infection. Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter. Collected into CPD anticoagulant and suspended in 105ml of additive solution containing, in mmol/l: NaCl 150, Glucose 45, Adenine 1.25, Mannitol 29.

300 ml

**Rh D Positive**

CMV Antibody Negative  
IRRADIATED (Red Cell Splits)  
Confirmed Group

0251642359  
Expiry 13 June 2025 23:59

93999999999918796  
C- E+ c+ e+ K- HbS-Neg

74423

Expiry 13/06/2025

O Pos

## APPENDIX II

E Progesa Codabar Component Code: 74424

E Progesa ISBT-128 Component Code: C7442VC0

**Product Name :**RED CELLS, Suitable for  
Neonatal Use, Irradiated, Split 3**Shelf Life :**14 days from irradiation date,  
to a maximum of 28 days**Product Label and Barcode:**

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

RED CELLS, Suitable for  
Neonatal Use, Irradiated, Split 3

Store at 4°C ± 2°C



025129

Drawn 09 May 2025



C7442VC0

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

Must be administered using a suitable  
transfusion set incorporating a  
170 – 200 µm filter. Collected into  
CPD anticoagulant and suspended in 105ml  
of additive solution containing, in  
mmol/l: NaCl 150, Glucose 45,  
Adenine 1.25, Mannitol 29.



74424



Expiry 13/06/2025



O Pos



51E0

IBTS ver 5.0

**O****Rh D Positive**CMV Antibody Negative  
IRRADIATED (Red Cell Splits)  
Confirmed Group300  
ml

0251642359

Expiry 13 June 2025 23:59



93999999999918796

C- E+ c+ e+ K- HbS-Neg

## APPENDIX II

E Progesa Codabar Component Code: 74425

E Progesa ISBT-128 Component Code: C7442VD0

**Product Name :**

RED CELLS, Suitable for  
Neonatal Use, Irradiated, Split 4

**Shelf Life :**

14 days from irradiation date,  
to a maximum of 28 days

**Product Label and Barcode:**

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

RED CELLS, Suitable for  
Neonatal Use, Irradiated, Split 4

Store at 4°C ± 2°C



025129

Drawn 09 May 2025



C7442VD0

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

Must be administered using a suitable  
transfusion set incorporating a  
170 – 200 µm filter. Collected into  
CPD anticoagulant and suspended in 105ml  
of additive solution containing, in  
mmol/l: NaCl 150, Glucose 45,  
Adenine 1.25, Mannitol 29.



74425



Expiry 13/06/2025



O Pos



51E0

IBTS ver 5.0

O

**Rh D Positive**

CMV Antibody Negative  
IRRADIATED (Red Cell Splits)  
Confirmed Group

300  
ml



0251642359

Expiry 13 June 2025 23:59



93999999999918796

C- E+ c+ e+ K- HbS-Neg

## APPENDIX II

E Progesa Codabar Component Code: 74426

E Progesa ISBT-128 Component Code: C7442VE0

**Product Name :**

RED CELLS, Suitable for  
Neonatal Use, Irradiated, Split 5

**Shelf Life :**

14 days from irradiation date,  
to a maximum of 28 days

**Product Label and Barcode:**

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

RED CELLS, Suitable for  
Neonatal Use, Irradiated, Split 5

Store at 4°C ± 2°C



025129

Drawn 09 May 2025



C7442VE0

This component must not be used if there are visible signs of deterioration. This component may transmit infection. Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter. Collected into CPD anticoagulant and suspended in 105ml of additive solution containing, in mmol/l: NaCl 150, Glucose 45, Adenine 1.25, Mannitol 29.



74426



Expiry 13/06/2025



O Pos



51E0

IBTS ver 5.0

O

**Rh D Positive**

CMV Antibody Negative  
IRRADIATED (Red Cell Splits)  
Confirmed Group



0251642359

Expiry 13 June 2025 23:59



93999999999918796

C- E+ c+ e+ K- HbS-Neg