



Document Detail

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Document No.: IBTS/PMF/SPEC/0209[5]
Title: **RED CELLS SUITABLE FOR NEONATAL USE**
Owner: QA DOC CON QA DOC CONTROL
Status: CURRENT
Effective Date: 13-May-2021
Expiration Date: 03-Aug-2025

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>
1	DOCUMENT CONTROLLER	REBECCA WALDEN	REBECCA WALDEN
2	QUALITY ASSURANCE WRITER IBTS	REBECCA WALDEN	REBECCA WALDEN
3	NATIONAL MEDICAL DIRECTOR	TOR HERVIG	TOR HERVIG
3	SSCD HEAD OF DEPT IBTS	AILEEN FARRELLY	AILEEN FARRELLY
3	LABS PHS DIR IBTS	BARRY DOYLE	BARRY DOYLE
3	COMPONENTS HEAD OF DEPT MRTC	AINE FITZPATRICK	AINE FITZPATRICK
4	DIRECTOR OF QUALITY	KAREN BYRNE	KAREN BYRNE
4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS

Review: IBTS UNEXPIRE

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off By</u>
1	DOCUMENT CONTROLLER	REBECCA WALDEN	REBECCA WALDEN
3	NATIONAL MEDICAL DIRECTOR	TOR HERVIG	REBECCA WALDEN
3	SSCD HEAD OF DEPT IBTS	AILEEN FARRELLY	REBECCA WALDEN
3	COMPONENTS HEAD OF DEPT MRTC	AINE FITZPATRICK	REBECCA WALDEN
3	LABS PHS DIR IBTS	BARRY DOYLE	REBECCA WALDEN
4	QUALITY ASSURANCE REVIEWER IBTS	REBECCA WALDEN	REBECCA WALDEN

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/0229/21

**IRISH BLOOD TRANSFUSION SERVICE
PRODUCT MASTER FILE**

TITLE: RED CELLS SUITABLE FOR NEONATAL USE

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

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 ⁶ /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 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.

Irradiation: 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. 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.

Transportation: 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

Indications for Use: 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.

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, Split 1/2/3/4/5 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, Split 1/2/3/4/5 are not recommended in:
 - large volume transfusion in neonates unless the red cells are less than 5 days old.
 - Intrauterine Transfusion
 - exchange transfusions in newborns.

Adverse Effects Include:

- Circulatory Overload.
- Haemolytic transfusion reaction;
- Non-haemolytic transfusion reaction (mainly chills, fever and urticaria).
The risk is reduced by leucodepletion and washing

- 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 13 May 2021

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)

95A0

IBTS ver 4.0

RED CELLS,
 Suitable for Neonatal Use, Split 1

Store at 4°C ± 2°C

021125

Drawn 05 May 2021

C7429VA0

200 ml

0211602359

Expiry 09 June 2021 23:59

93999999999917796

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

56830

Expiry 09/06/2021

O Neg

Rh D Negative
 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

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)

IBTS ver 4.0

95A0

RED CELLS,
Suitable for Neonatal Use, Split 2

Store at 4°C ± 2°C

021127
Drawn 07 May 2021

Rh D Negative
CMV Antibody Negative

350 ml
0211622359
Expiry 11 June 2021 23:59

C7429VB0

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.

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

56831 Expiry 11/06/2021 O Neg

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)

RED CELLS,
Suitable for Neonatal Use, Split 3

Store at 4°C ± 2°C

Rh D Negative
CMV Antibody Negative

200 ml

Expiry 09 June 2021 23:59

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

O Neg

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 13 May 2021

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)

95A0

IBTS ver 4.0

RED CELLS,
Suitable for Neonatal Use, Split 4

Store at 4°C ± 2°C

021125
Drawn 05 May 2021

Rh D Negative
CMV Antibody Negative

200 ml
0211602359
Expiry 09 June 2021 23:59

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.

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

56833

Expiry 09/06/2021

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)

95A0

IBTS ver 4.0

RED CELLS,
Suitable for Neonatal Use, Split 5

Store at 4°C ± 2°C

Rh D Negative
CMV Antibody Negative

021125
Drawn 05 May 2021

200 ml
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.

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

56834 Expiry 09/06/2021 O 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)

IBTS ver 4.0

95A0

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

Store at 4°C ± 2°C

Rh D Negative
IRRADIATED (Red Cell Splits)
CMV Antibody Negative

021125
Drawn 05 May 2021

C7442VA0

200 ml

0211602359
Expiry 09 June 2021 23:59

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

74422

Expiry 09/06/2021

O Neg

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.

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 4.0

95A0

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

Store at 4°C ± 2°C

Rh D Negative

IRRADIATED (Red Cell Splits)
CMV Antibody Negative

021125
Drawn 05 May 2021

200 ml

C7442VB0

0211602359
Expiry 09 June 2021 23:59

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

O Neg

74423

Expiry 09/06/2021

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 mg/ml: NaCl 150, Glucose 45, Adenine 1.25, Mannitol 29.

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

Drawn 05 May 2021

200 ml

C7442VC0

Rh D Negative
IRRADIATED (Red Cell Splits)
CMV Antibody Negative

Expiry 09 June 2021 23:59

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

74424

Expiry 09/06/2021

O Neg

IBTS ver 4.0

Effective 13 May 2021

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.

APPENDIX II

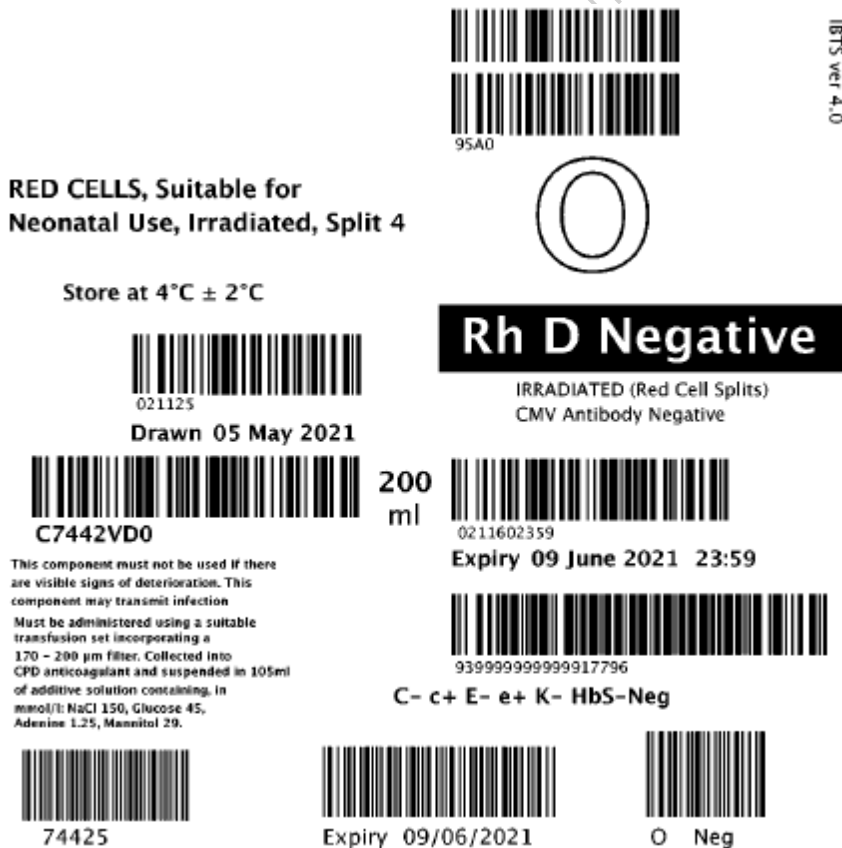
E Progesa Codabar Component Code: 74425

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)



IBTS ver 4.0

95A0

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

Store at 4°C ± 2°C

021125
Drawn 05 May 2021

Rh D Negative
IRRADIATED (Red Cell Splits)
CMV Antibody Negative

200 ml
0211602359
Expiry 09 June 2021 23:59

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.

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

74425

Expiry 09/06/2021

O 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



Drawn 05 May 2021



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 mg/ml: NaCl 150, Glucose 45, Adenine 1.25, Mannitol 29.



74426



Expiry 09/06/2021



O Neg



95A0

IBTS ver 4.0



Rh D Negative

IRRADIATED (Red Cell Splits)
CMV Antibody Negative



200 ml

Expiry 09 June 2021 23:59



93999999999917796

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