



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
Expiration Date: 04-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	COMPONENTS HEAD OF DEPT MRTC	AINE FITZPATRICK	AINE FITZPATRICK
3	LABS PHS DIR IBTS	BARRY DOYLE	BARRY DOYLE
3	SSCD HEAD OF DEPT IBTS	AILEEN FARRELLY	AILEEN FARRELLY
4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS
4	DIRECTOR OF QUALITY	KAREN BYRNE	KAREN BYRNE

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 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 (RED CELLS, 04333/E7429V00)
ABO Agglutinins	No HighTitre 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 $4^{\circ}\text{C} \pm 2^{\circ}\text{C}$.
- 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:74421 and 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°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 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)
- 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
 - Alloimmunisation 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

Verify when in Use. Status CURRENT Effective 13 May 2021

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)

95A0

IBTS ver 4.0

RED CELLS, Suitable for
 Neonatal Use for 5 days
 after Date Drawn

Store at 4°C ± 2°C

Rh D Negative
 CMV Antibody Negative

021125
 Drawn 05 May 2021

200 ml
 0211602359
 Expiry 09 June 2021 23:59

C7429V00

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

54481

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

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)

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

Store at 4°C ± 2°C



Drawn 05 May 2021



C7442V00

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.



74421



Expiry 09/06/2021



O Neg



95A0



Rh D Negative

IRRADIATED
CMV Antibody Negative

200 ml



0211602359

Expiry 09 June 2021 23:59



93999999999917796

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

IBTS ver 4.0

IRRENT Effective 13 May 2021