

Document Detail

Type:	PMF IBTS SPEC
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:	13-May-2023

Review

Review: IBTS PMF REVIEW

Level	Owner Role	Actor	Sign-off By
1	DOCUMENT CONTROLLER	REBECCA WALDEN	REBECCA WALDEN
2	QUALITY ASSURANCE WRITER IBTS	REBECCA WALDEN	REBECCA WALDEN
3	LABS HEAD OF MANUFACTURING & ISSUE IBTS	BARRY DOYLE	BARRY DOYLE
3	NATIONAL MEDICAL DIRECTOR	STEPHEN FIELD	STEPHEN FIELD
4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS

Change Orders

Changes as described on Change Order: <u>Change Order No.</u>

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 status current theetive 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.

71.		
Parameter	Quality Requirements	Frequency of Control
Volume	45 – 71 ml x 5 split units	100%
Haematocrit	0.50 - 0.70 L/L	1%
Haemoglobin	\geq 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%

General Specification:

Labelling:

See Appendix 1

Storage:

Red Cells Suitable for Neonatal Use, Split 1/2/3/4/5 should be stored at $4^{\circ}C \pm 2^{\circ}C$. The storage time is up to 35 days.

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Irradiation:	to 14 If irrac codaba	Cells Suitable for Neonatal Use, Split days from date of collection. Post irr diated, product codes for the split un ar:74422 / 74423 / 74424 / 74425 / 7 2VA0 / C7442VB0 / C7442VC0 / C7	adiation the storage is 14 days its will change into 4426 and ISBT-128 barcodes:
Transportation:	Suitab during where	ir temperature of transport containers ole for Neonatal Use should be maint g transport from the Irish Blood Tran they are intended for use. Transport ally should not exceed 8 hours	ained between 2°C and 10°C sfusion Service to the place
Indications for Use:	augme critica within unit sl split u shelf l	Cells Suitable for Neonatal Use, Split enting the oxygen carrying capacity of ally reduced in infants requiring repea- na four to five week period. It is reco- nould be transfused within 5 days fro- units from the same donation may be life. The first split may be transfused led if fresher product is not available sary.	of the blood where this is ated small volume transfusions ommended that the first split om date bled and subsequent transfused up to the end of greater than 5 days from the
Precautions in Use:	•	Compatibility of this component wi be verified by appropriate pre transfo	-
<i></i>	-	Red Cells Suitable for Neonatal Use, transfused through a standard 170 –	-
when	•	No solution should be added to the b	ag or to the giving set.
Jerity when it	•	Components should be inspected vis abnormal colour or visible clots.	ually for defects, leakage,
		 Red Cells Suitable for Neonatal Use, recommended in: large volume transfusion in neona than 5 days old. Intrauterine Transfusion exchange transfusions in newborr 	ates unless the red cells are les
Adverse Effects Inclu	ude:		
	• (Circulatory Overload.	
	• H	Iaemolytic transfusion reaction;	

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

- <u>Pathogen transmission</u>
 - 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)
- <u>Metabolic upset</u>
 - 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.
- <u>Immunological effects</u>
 - Alloimunisation to HLA and red cell antigens.
 - - Transfusion related Acute Lung injury (TRALI) by donor HLA/granulocyte antibodies.
 - Post transfusion purpura (PTP).
 - Iron overload

Verify when in

- In patients on chronic red cell transfusion support programmes.

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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 +31/2021 James's Street Dublin 8

AND

Quality Assurance Manager Irish Blood Transfusion Service

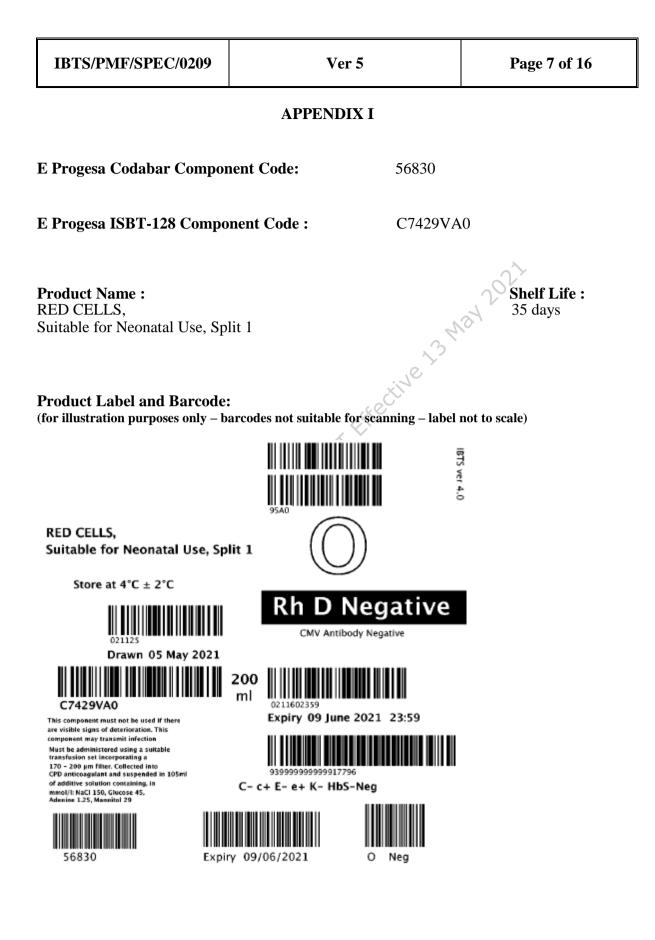
AT EITHER

National Blood Centre James's Street Dublin 8

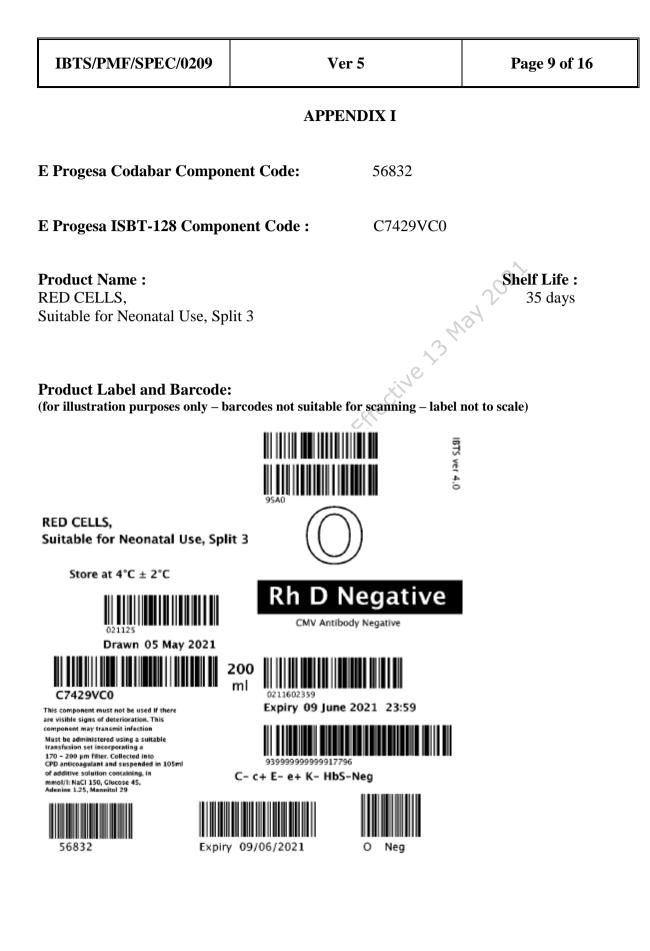
<u>OR</u>

Munster Regional Transfusion Centre St Finbarr's Hospital .sh Status Verity when in USE. Status Douglas Road, Cork

rective



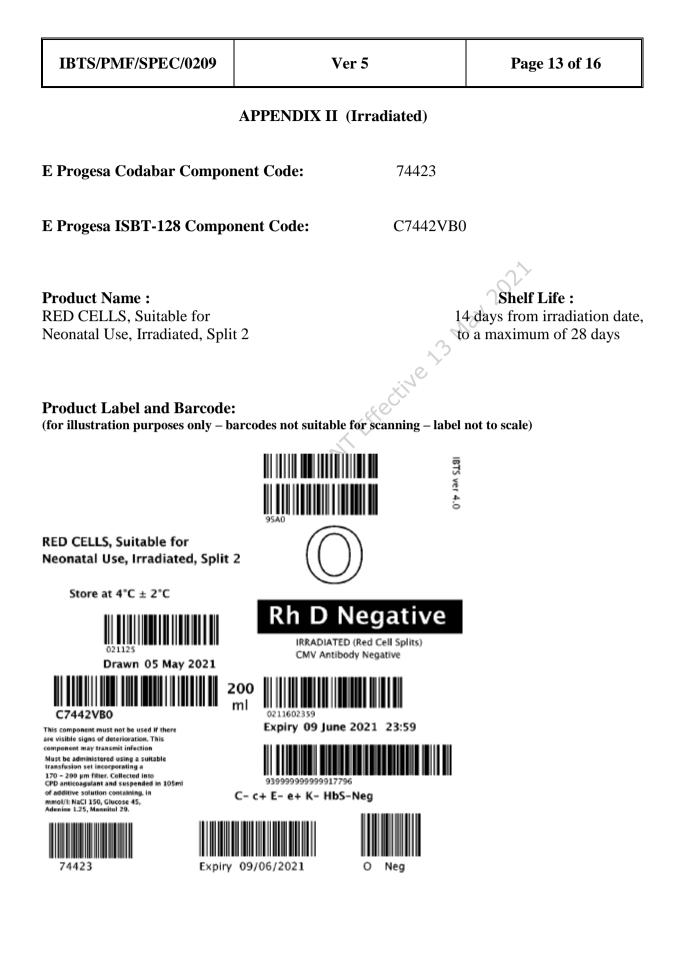
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	APPENDIX	I	
Progesa Codabar Compo	nent Code:	56831	
Progesa ISBT-128 Compo	onent Code :	C7429VB	0
roduct Name : ED CELLS, uitable for Neonatal Use, Sp	olit 2	tive 13 M	Shelf Life : 35 days
roduct Label and Barcode or illustration purposes only – h	•		
		IBTS ver 4.0	
ED CELLS, uitable for Neonatal Use, Sp	lit 2		
Store at 4°C ± 2°C	Rh D Neg	ative	
Drawn 07 May 2021	350 ml 0211622359 Expiry 11 June 2021		
re visible signs of deterioration. This emponent may transmit infection flust be administered using a suitable ransfusion set incorporating a 70 - 200 µm filter. Collected into PD anticoagulant and suspended in 105ml f additive solution containing, in men0/IL NaCI 150, Glucose 45, usemise 1.25, Mammitol 29.	9399999999999917796 C- c+ E- e+ K- HbS-Neg		
56831 Expi	ry 11/06/2021 O	Neg	



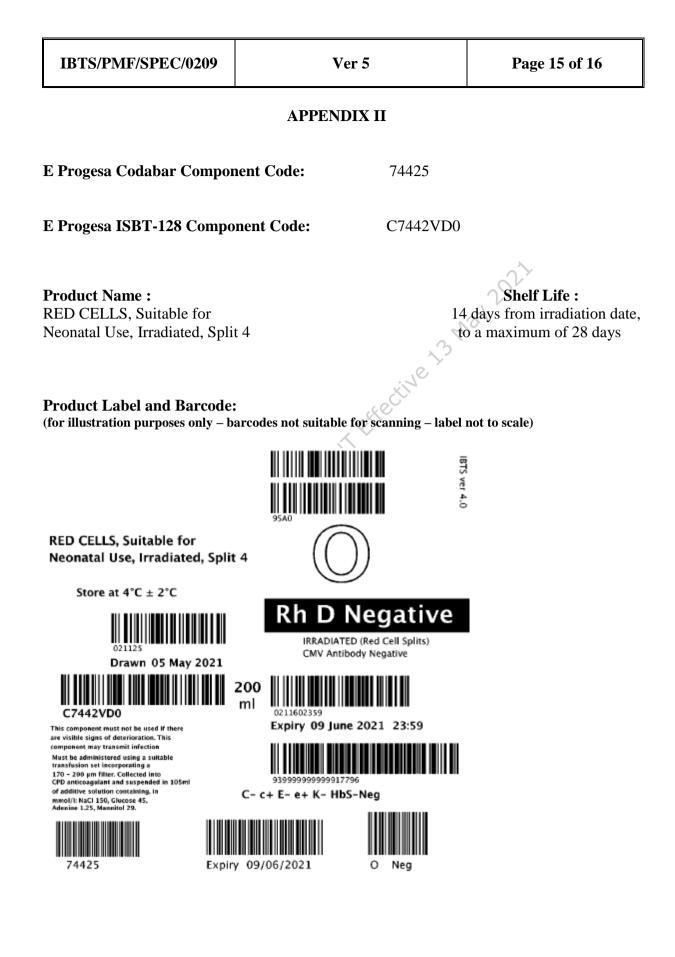
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	APPENDIX I	[
E Progesa Codabar Compor	nent Code:	56833		
E Progesa ISBT-128 Compo	nent Code :	C7429VD0		
Product Name : RED CELLS, Suitable for Neonatal Use, Split 4 Product Label and Barcode:				
Product Label and Barcode: (for illustration purposes only – b				
		IBTS ver 4.0		
RED CELLS, Suitable for Neonatal Use, Spli	it 4			
Store at 4°C ± 2°C	Rh D Nega			
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 smoot/it: NoI 130, Glucose 45, Adenine 1.25, Mannitol 29.	200 ml 0211602359 Expiry 09 June 2021 23 93999999999999917796 C- c+ E- e+ K- HbS-Neg			

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	APPENDIX I		
E Progesa Codabar Compon	ent Code:	56834	
E Progesa ISBT-128 Compo	nent Code :	C7429V	Έ0
Product Name : RED CELLS, Suitable for Neonatal Use, Spl	lit 5	Net 3 M	Shelf Life : 35 days
Product Label and Barcode: (for illustration purposes only – ba			
		IBTS ver 4.0	
RED CELLS, Suitable for Neonatal Use, Spl	it 5		
Store at 4°C ± 2°C	Rh D Nega CMV Antibody Negative		
Drawn 05 May 2021	200 ml 0211602359		
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 1700 – 200 µm filter. Collected into CPD anticoagulant and suspended in 105ml of additive solution containing, in mmoU(1: NaCI 150, Glucose 45, Admine 1.25, Mannitol 29.	Expiry 09 June 2021 23		
56834 Expin			

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	APPENDIX	I	
E Progesa Codabar Compor	ent Code:	74422	
E Progesa ISBT-128 Compo	nent Code:	C7442VA0	
Product Name : RED CELLS, Suitable for Neonatal Use, Irradiated, Split		14 days	Shelf Life : from irradiation date ximum of 28 days
Product Label and Barcode: (for illustration purposes only – ba		ning – label not to	scale)
		IBTS ver 4.0	
RED CELLS, Suitable for Neonatal Use, Irradiated, Split	1		
Store at 4°C ± 2°C	Rh D Neg IRRADIATED (Red Cel CMV Antibody Negat		
	200 ml 0211602359		
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 - 280 pm filter. Collected into CPD anticoagulant and suspended in 105ml of additive solution containing. In mmol/if: NaCI 150, Glucose 45,	Expiry 09 June 2021 2 939999999999999999999999 C- c+ E- e+ K- HbS-Neg	3:59	
Adenine 1.25, Mannitol 29.	09/06/2021 O N	leg	
Loging		- 2	



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	APPEND	IX II	
E Progesa Codabar Compo	nent Code:	74424	
E Progesa ISBT-128 Compo	onent Code:	C7442VC0	
Product Name : RED CELLS, Suitable for Neonatal Use, Irradiated, Spli	t 3		Shelf Life : 4 days from irradiation dat to a maximum of 28 days
Product Label and Barcode for illustration purposes only – b		scanning – labe	l not to scale)
			IBTS ver 4.0
RED CELLS, Suitable for Neonatal Use, Irradiated, Split	13		
Store at 4°C ± 2°C	Rh D Ne	d Cell Splits)	
C7442VC0	200 ml 0211602359 Expiry 09 June 202	21 23:59	
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/I: NaCl 150, Glucose 45, Adenine 1.25, Mannitol 29.	939999999999999917796 C- c+ E- e+ K- HbS-Ne		
	γ 09/06/2021		



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	APPENDIX II					
E Progesa Codabar Compor	nent Code: 74426					
E Progesa ISBT-128 Compo	nent Code: C7442VE	0				
Product Name : RED CELLS, Suitable for Neonatal Use, Irradiated, Split	t 5 +3 t	Shelf Life : 4 days from irradiation date, o a maximum of 28 days				
Product Label and Barcode: (for illustration purposes only – ba	arcodes not suitable for scanning – label	not to scale)				
RED CELLS, Suitable for Neonatal Use, Irradiated, Split	5 ()					
Store at 4°C ± 2°C	Rh D Negative					
C7442VEO 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	200 ml Expiry 09 June 2021 23:59					
Adenine 1.25, Mannitol 29.	C- c+ E- e+ K- HbS-Neg					