



Document Detail

Type: PMF IBTS SPEC
Document No.: IBTS/PMF/SPEC/0205[4]
Title: **RED CELLS**
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>
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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>
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2	QUALITY ASSURANCE WRITER IBTS	REBECCA WALDEN	REBECCA WALDEN
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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

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

Name of Products: RED CELLS / RED CELLS, Irradiated

E Progesa Codabar Component Codes: 04333 / 74420

E Progesa ISBT-128 Component Codes: E7429V00 / E7442V00

General Description: A red cell suspension obtained from whole blood by centrifugation and removal of plasma with subsequent addition of a nutrient solution Sag-M. The removal of the majority of leucocytes is achieved by filtration.

Quality Control Requirements:

Parameter	Quality Requirement	Frequency of Control
Volume	231ml -355ml	100%
Haematocrit	0.50 - 0.70 L/L	1%
Haemoglobin	≥ 40 g/unit	1%
Leucocyte Content	< 1.0 x 10 ⁶ /unit	1%
Haemolysis at end of shelf life	< 0.8% of red cell mass	4 per month

Labelling: See Appendix 1

Storage: Red Cells / Red Cells, Irradiated, should be stored at 4°C ± 2°C. The storage time is up to 35 days.

Irradiation: Red Cells may be irradiated up to 14 days after collection. The component code then changes to 74420/E7442V00. Post irradiation the storage time is 14 days.

Transportation: The air temperature of the validated transport containers for units of Red Cells / Red Cells, Irradiated, should be maintained between 2°C and 10°C during transport from the Irish Blood Transfusion Service to the place that they are intended for use. Transport time under these conditions normally should not exceed 8 hours.

Indications for Use: Red Cells / Red Cells, Irradiated, are used to augment the oxygen delivery capacity of the blood where this is critically impaired.

Precautions in Use:

- Compatibility of this component with the intended recipient must be verified by suitable pre transfusion testing.
- Red Cells / Red Cells, Irradiated, should be infused intravenously through a set containing an inline 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 / Red Cells, Irradiated, are **not** recommended in:
 - various types of plasma intolerance (may not apply to units with a low plasma content);

Adverse Effects Include:

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

APPENDIX 1



E Progesa Codabar Component Code : 04333

E Progesa ISBT -128 Component Code: E7429V00

Product Name
RED CELLS

Shelf Life
35 days



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




 51F0

IBTS ver 4.0

RED CELLS



Store at 4°C ± 2°C


 021125
Drawn 05 May 2021

E7429V00




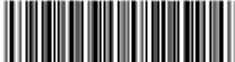
Rh D Positive


200 ml


 0211602359
Expiry 09 June 2021 23:59

 939999993999918399
C- c+ E+ e- K- Fya-

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.


 04333


 Expiry 09/06/2021


 O Pos

APPENDIX 1



E Progesa Codabar Component Code : 74420

E Progesa ISBT -128 Component Code: E7442V00

Product Name
RED CELLS, Irradiated

Shelf Life
14 days

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




 51A0

IBTS ver 4.0

RED CELLS, Irradiated


O

Store at 4°C ± 2°C



 021125
Drawn 05 May 2021

Rh D Positive


IRRADIATED
CMV Antibody Negative



E7442V00


200 ml



 0211602359
Expiry 09 June 2021 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/l: NaCl 150, Glucose 45, Adenine 1.25, Mannitol 29.


 74420


 Expiry 09/06/2021


 O Pos


 93939999999917796
C- c+ E- e+ K- M- HbS-Neg