Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

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Review

Review: IBTS PMF REVIEW

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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.**
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IRISH BLOOD TRANSFUSION SERVICE

PRODUCT MASTER FILE

TITLE: RED CELLS

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

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	< 1.0×10^6 /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
  - Alloimunisation 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

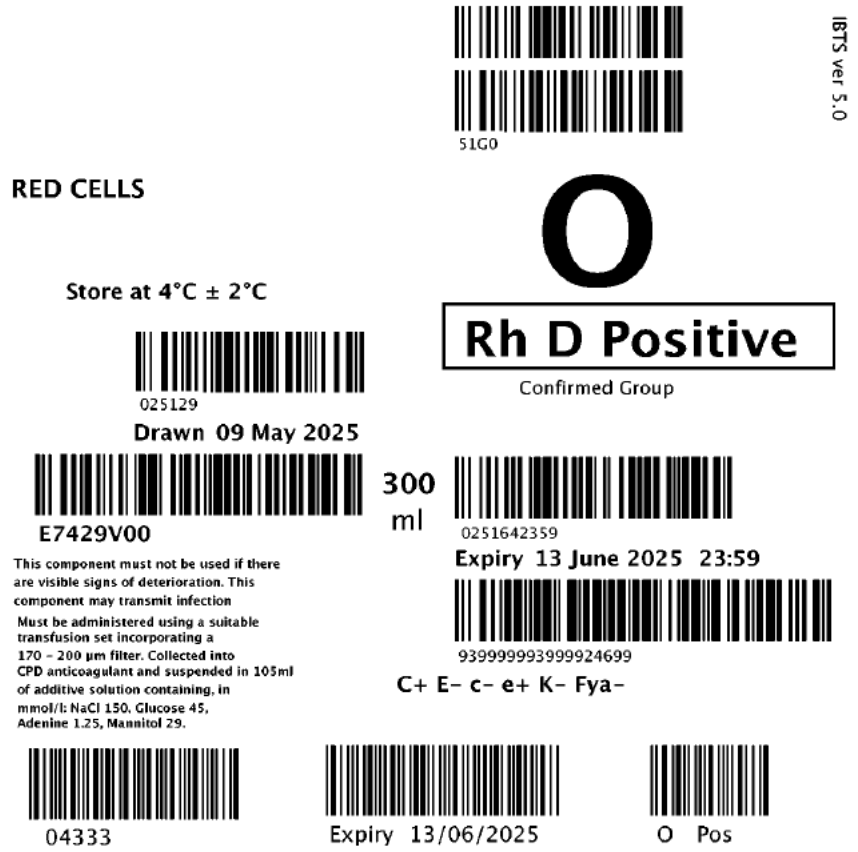
E Progesa Codabar Component Code : 04333

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)



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)