# Irish Blood Transfusion Service
## Seirbhís Fuilaistriúcháin na hÉireann

## *Document Detail*

**Type:** PMF IBTS SPEC
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**Title:** **RED CELLS, SUITABLE FOR INTRAUTERINE TRANSFUSION, IRRADIATED**
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**Review:** IBTS PMF REVIEW

| Level | Owner Role | Actor | Sign-off By |
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### *Change Orders*

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## IRISH BLOOD TRANSFUSION SERVICE

## PRODUCT MASTER FILE

**TITLE:** **RED CELLS, SUITABLE FOR INTRAUTERINE TRANSFUSION, IRRADIATED**

**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, Suitable for Intrauterine Transfusion, Irradiated**

**Name of Product:** **RED CELLS, Suitable for Intrauterine Transfusion, Irradiated HCT Range: 0.70 – 0.85**

**E Progesa Codabar Component Code:** **30017**

**E Progesa ISBT – 128 Component Code :** **E8210V00**



**General Description:** Red cells obtained from whole blood within 5 days of donation by centrifugation, and removal of most of the plasma. 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 Requirement | Frequent of Control |
|---|---|---|
| Volume | 190-310 mL | 100 % |
| Haematocrit | 0.7 – 0.85 | 100 % |
| Haemoglobin | ≥ 40 g / unit | 100 % |
| Leucocyte Content | <1 x $10^6$ / unit | Parent Component tested |
| 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 Intrauterine Transfusion, Irradiated should be used immediately. If delay is unavoidable, the component should be stored at 4°C ± 2°C and used within 24 hours from the time of preparation.

**Irradiation:** Red Cells, Suitable for Intrauterine Transfusion, Irradiated **must be irradiated** before transfusion. Post irradiation the storage is unchanged.

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

**Indications for Use:** Red Cells, Suitable for Intrauterine Transfusion, Irradiated are prepared, on request, for use in intra-uterine transfusion. Haematocrit may be adjusted to the required value prior to issue.

**Precautions In Use:**

- Compatibility of red cells with the intended recipient must be verified by suitable pre-transfusion testing.
- Red Cells, Suitable for Intrauterine Transfusion, 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.

**Adverse Effects Include**:

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

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- 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 :** 30017

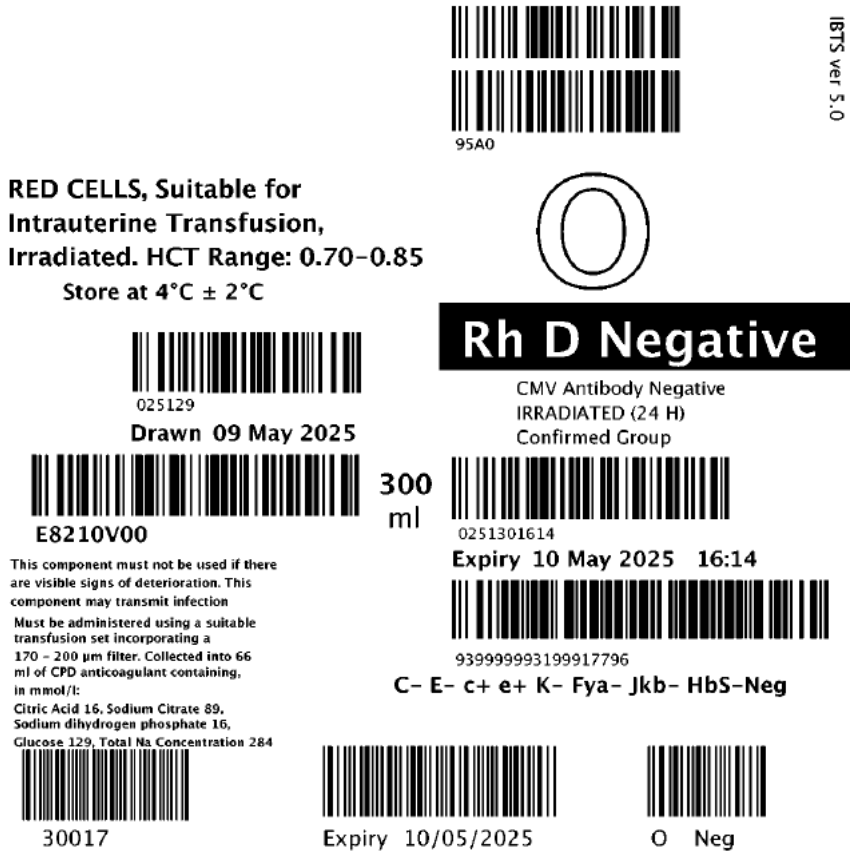
**E Progesa ISBT -128 Code**: E8210V00

**Product Name**
RED CELLS, Suitable for
Intrauterine Transfusion
Irradiated, HCT Range: 0.70 – 0.85

**Shelf Life**
24 hours



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




**N.B. Stated volume for illustration purposes only.**