



**IRISH BLOOD TRANSFUSION SERVICE**  
**PRODUCT MASTER FILE**

**TITLE: RED CELLS, WASHED**

**Change Description:**

Update the product General Description to specify that the routine procedure is **TWO** washes using cold (4°C) SAGM as per standard procedure, and **NO** extra washes can be performed.

**Reason for Change:**

IBTS validation studies have shown that the optimal number of washes in SAG-M to remove sufficient residual plasma proteins was **two**. Additional washes also resulted in an increased frequency of burst packs, which would lead to wastage of blood products. Therefore it was agreed that the routine procedure is **TWO** washes using cold (4°C) SAGM, with no deviations from the validated product.

**Change order No.:**

IBTS/CO/0348/21

**Referenced Documents**

Ref. CC 218/21/IBTS Validation Ref. IBTS/QA/PQ2/0614

**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, Washed

**Name of Products:** RED CELLS, Washed  
RED CELLS, Washed, Irradiated

**E Progesa Codabar Component Codes:** 04403 / 50000

**E Progesa ISBT – 128 Component Codes:** E4999V00 / E5000V00

**General Description:** A red cell suspension obtained from one unit of Red Cells, less than 5 days old, washed **TWICE** in an SAGM solution to remove most of the remaining plasma.

**General Specification:**

Parameter	Quality Requirement	Frequency of Control
Volume	≥ 226 ml	100 %
Haematocrit	0.50 - 0.70 L/L	100 %
Haemoglobin	≥ 40 g/unit	100 %
Protein Content	< 0.5 g/unit	100%
Haemolysis at the end of the preparation	<0.8% of Red Cell Mass	100%

**Labelling:** See Appendix 1

**Storage:** Red Cells, Washed/Red Cells, Washed, Irradiated should be used immediately. If delay is unavoidable, the component should be stored between 4°C ± 2°C and used within 24 hours.

- Irradiation:** Red Cells, Washed may be irradiated. The component code then changes to 50000/E5000V00.
- Transportation:** The air temperature of transport containers for units of Red Cells, Washed / Red Cells, Washed, Irradiated should be maintained between 2°C and 10°C during transportation from 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, Washed / Red Cells, Washed, Irradiated are used to augment the oxygen delivery capacity of the blood where this is critically impaired in patients with significant reaction to plasma.
- Red Cells, Washed / Red Cells, Washed, Irradiated (protein content < 0.5 g/unit) are not designated for the transfusion of patients with IgA deficiency.
- Precautions in Use:**
- Compatibility of red cells with the intended recipient must be verified by suitable pretransfusion testing.
  - Red Cells, Washed / Red Cells, Washed, Irradiated should be infused intravenously through a set containing an inline 170-200 µm filter.
  - No other solutions should be added to the bag or 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 and washing
- 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 I

E Progesa Codabar Component Code: 04403

E Progesa ISBT -128 Component Code: E4999V00

**Product Name**  
RED CELLS, Washed

**Shelf Life:** 24 hours

**Labelling and Barcodes:**

(for illustration purposes only – barcodes not suitable for scanning – label not to scale)

IBTS ver 4.0

0600

RED CELLS, Washed

Store at 4°C ± 2°C

021123

Drawn 05 May 2021

200 ml

E4999V00

0211261252

Expiry 06 May 2021 12:52

999999999999999999

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. Washed in additive solution and suspended in 50 – 100 ml of SAGM containing, in mmol/l: NaCl 150, Glucose 45, Adenine 1.25, Mannitol 29

04403

Expiry 06/05/2021

A Neg

N.B. Stated label volume is for illustration purposes only

## APPENDIX I

E Progesa Codabar Component Code : 50000

E Progesa ISBT -128 Component Code: E5000V00

**Product Name**  
RED CELLS, Washed,  
Irradiated

**Shelf Life**  
24 hours

**Labelling and Barcodes:**

(for illustration purposes only – barcodes not suitable for scanning – label not to scale)

IBTS ver 4.0

0600

**RED CELLS, Washed,  
Irradiated**

Store at 4°C ± 2°C

021125

**Drawn 05 May 2021**

**E5000V00**

**200 ml**

**Rh D Negative**

IRRADIATED  
IRRADIATED (24 H)

0211261253

**Expiry 06 May 2021 12:53**

9999999999999999

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. Washed in additive solution and suspended in 50 – 100 ml of SAGM containing, in mmol/l: NaCl 150, Glucose 45, Adenine 1.25, Mannitol 29

50000

Expiry 06/05/2021

A Neg

N.B. Stated label volume is for illustration purposes only