



Irish Blood Transfusion Service

Seirbhís Fuilaeistriúcháin na hÉireann

Document Detail

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Review

Review: IBTS PMF REVIEW

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off By</u>
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3	LABS HEAD OF MANUFACTURING & ISSUE IBTS	BARRY DOYLE	BARRY DOYLE
4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	

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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.
IBTS/CO/0348/21

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 $4^{\circ}\text{C} \pm 2^{\circ}\text{C}$ and used within 24 hours.

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- 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

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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)

RED CELLS, Washed

Store at 4°C ± 2°C



Drawn 05 May 2021



E4999V00

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



0600

A

Rh D Negative



0211261252

Expiry 06 May 2021 12:52



9999999999999999

IBTS ver 4.0

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

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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)

CURRENT Effective 15 June 2022

**RED CELLS, Washed,
Irradiated**


Store at 4°C ± 2°C

Drawn 05 May 2021

E5000V00

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



0600

A

Rh D Negative




IRRADIATED
IRRADIATED (24 H)

200 ml

Expiry 06 May 2021 12:53

A Neg

IBTS ver 4.0

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