



Irish Blood Transfusion Service

Seirbhís Fuilaeistriúcháin na hÉireann

Document Detail

Type: PMF IBTS SPEC
Document No.: IBTS/PMF/SPEC/0208[5]
Title: **WHOLE BLOOD, SUITABLE FOR NEONATAL USE FOR 5 DAYS AFTER DATE DRAWN**
Owner: QA DOC CON QA DOC CONTROL
Status: CURRENT
Effective Date: 13-May-2021
Expiration Date: 13-May-2023

Review

Review: IBTS PMF REVIEW

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off By</u>
1	DOCUMENT CONTROLLER	REBECCA WALDEN	REBECCA WALDEN
2	QUALITY ASSURANCE WRITER IBTS	REBECCA WALDEN	REBECCA WALDEN
3	LABS HEAD OF MANUFACTURING & ISSUE IBTS	BARRY DOYLE	BARRY DOYLE
3	NATIONAL MEDICAL DIRECTOR	STEPHEN FIELD	STEPHEN FIELD
4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS

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

IBTS/PMF/SPEC/0208	Ver 5	Page 2 of 10
--------------------	-------	--------------

IRISH BLOOD TRANSFUSION SERVICE

PRODUCT MASTER FILE

TITLE: **WHOLE BLOOD, SUITABLE FOR NEONATAL USE
FOR 5 DAYS AFTER DATE DRAWN**

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: Whole Blood, Suitable for Neonatal Use for 5 Days after Date Drawn

Name of Products:

- WHOLE BLOOD, Suitable for Neonatal Use for 5 days after Date Drawn. HCT Range: 0.50 -0.60
- WHOLE BLOOD, Suitable for Neonatal Use, Irradiated HCT Range: 0.50 - 0.60

And

- WHOLE BLOOD, Suitable for Neonatal Use for 5 days after Date Drawn. HCT Range: 0.50 -0.55
- WHOLE BLOOD, Suitable for Neonatal Use, Irradiated HCT Range: 0.50 - 0.55

E Progesa Codabar Component Codes:

54350 / 39360 and 39361 / 39362

E Progesa ISBT -128 Component Codes:

E8215V00 / E8212V00 and E8217V00 / E8216V00

General Description: Plasma reduced whole blood obtained from:
WHOLE BLOOD, Suitable for Neonatal Use for 5 days after Date Drawn
or

WHOLE BLOOD, Reconstituted, Suitable for Neonatal Use obtained
by centrifugation and removal of part of the plasma or additive solution,
respectively.

General Specification:

Parameter	Quality Requirement	Frequency of Control
Volume	volume monitored by SPC	100%
Haematocrit	0.50 - 0.60 L/L 0.50 – 0.55 L/L	100 %
Haemoglobin	≥ 40 g/unit	≥1%
Leucocyte Content	< 1 x 10 ⁶ /unit	≥1%
Haemolysis at end of shelf life	< 0.8% of red cell mass	4 per annum (including irradiated)
ABO Agglutinins	No HighTitre Anti-A or Anti-B	100%
CMV	CMV ab negative	100%

IBTS/PMF/SPEC/0208	Ver 5	Page 4 of 10
--------------------	-------	--------------

Labelling: See Appendix I and II

Storage: Whole Blood, Suitable for Neonatal Use for 5 days after date drawn / Whole Blood, Suitable for Neonatal Use, Irradiated (with Hct. ranges of 0.50-0.60 L/L or 0.50-0.55 L/L,) should be stored at $4^{\circ}\text{C} \pm 2^{\circ}\text{C}$.
For exchange or massive transfusion of neonates it should be used within 5 days after date drawn and up to 24 hrs after irradiation. For adult use it can be stored up to 28 days.

Irradiation: Whole Blood, Suitable for Neonatal Use for 5 days after date drawn for exchange should be irradiated before transfusion provided this does not unduly delay the transfusion. Post irradiation the product should be used within 24 hours. It **must** be irradiated prior to transfusion where the neonate has had a previous intrauterine transfusion. If irradiated, the component codes will change to 39360/E8212V00 and 39362/E8216V00.

Transportation: The air temperature of transport containers for units of Whole Blood, Suitable for Neonatal Use for 5 days after date drawn / Whole Blood, Suitable for Neonatal Use, Irradiated (with Hct. ranges of 0.50-0.60 L/L or 0.50-0.55 L/L,) should be maintained between 2°C and 10°C during transport from the 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: Whole Blood, Suitable for Neonatal Use for 5 days after date drawn / Whole Blood, Suitable for Neonatal Use, Irradiated (with Hct. ranges of 0.50-0.60 L/L or 0.50-0.55 L/L,) are used to augment the oxygen delivery capacity of the blood where this is critically impaired. Typically indicated for:

- Exchange transfusion of neonates.
- Massive transfusion in neonates and small infants.
- adult transfusion.

Precautions in Use:

- Compatibility of this component with the intended recipient must be verified by suitable pre transfusion testing.
- Whole Blood, Suitable for Neonatal Use for 5 days after date drawn / Whole Blood, Suitable for Neonatal Use, Irradiated (with Hct. ranges of 0.50-0.60 L/L or 0.50-0.55 L/L,) should be transfused through a standard 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.
- Whole Blood, Suitable for Neonatal Use for 5 days after date drawn / Whole Blood, Suitable for Neonatal Use, Irradiated (with Hct. ranges of 0.50-0.60 L/L or 0.50-0.55 L/L,) are not recommended in:
 - various types of plasma intolerance.
 - repeated leucocyte antigen/antibody mediated reaction unresponsive to medication

IBTS/PMF/SPEC/0208	Ver 5	Page 5 of 10
--------------------	-------	--------------

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.

IBTS/PMF/SPEC/0208	Ver 5	Page 6 of 10
---------------------------	--------------	---------------------

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

Verify when in Use. Status CURRENT Effective 13 May 2021

APPENDIX I

E Progesa Codabar Component Code: 54350

E Progesa ISBT – 128 Component Code : E8215V00

Product Name

WHOLE BLOOD, Suitable for
Neonatal Use for 5 Days after Date
Drawn. HCT Range: 0.50 – 0.60

Shelf life

28 days

Labelling and Barcode:

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

Effective 13 May 2021

**WHOLE BLOOD, Suitable for
Neonatal Use for 5 days after Date
Drawn. HCT Range: 0.50–0.60**

Store at 4°C ± 2°C

021125
Drawn 05 May 2021


E8215V00

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 66ml of CPD anticoagulant containing, in mmol/l:

Citric Acid 16, Sodium Citrate 89, Sodium Dihydrogen Phosphate 16, Glucose 129, Total Na Concentration 284.

54350



95A0



Rh D Negative

CMV Antibody Negative

200 ml

0211532359
Expiry 02 June 2021 23:59

93999999999917796

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

Expiry 02/06/2021

O Neg

APPENDIX 1

E Progesa Codabar Component Code:

39360

E Progesa ISBT – 128 Component Code :

E8212V00

Product Name

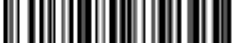







WHOLE BLOOD, Suitable for Neonatal Use, Irradiated.
HCT Range: 0.50 – 0.60

Shelf life

24 hours

Labelling and Barcode:

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

 51G0	
WHOLE BLOOD, Suitable for Neonatal Use, Irradiated. HCT Range: 0.50-0.60	
Store at 4°C ± 2°C	
 021125	O
Drawn 05 May 2021	Rh D Positive
	IRRADIATED (24 H) CMV Antibody Negative
 E8212V00	200 ml
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 66ml of CPD anticoagulant containing, in mmol/l: Citric Acid 16, Sodium Citrate 89, Sodium Dihydrogen Phosphate 16, Glucose 129, Total Na Concentration 284.	 0211261307 Expiry 06 May 2021 13:07
 39360	 93999999999924796 C+ c- E- e+ K- HbS-Neg
 Expiry 06/05/2021	 O Pos

APPENDIX II

E Progesa Codabar Component Code: 39361

E Progesa ISBT – 128 Component Code : E8217V00

Product Name

WHOLE BLOOD, Suitable for
Neonatal Use for 5 Days after Date
Drawn. HCT Range: 0.50 – 0.55

Shelf life

28 days

Labelling and Barcode:

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

WHOLE BLOOD, Suitable for
Neonatal Use for 5 days after Date
Drawn. HCT Range: 0.50-0.55

Store at 4°C ± 2°C

021125
Drawn 05 May 2021

200 ml

E8217V00

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 66ml of CPD anticoagulant containing, in mmol/l:
Citric Acid 16, Sodium Citrate 89, Sodium Dihydrogen Phosphate 16, Glucose 129, Total Na Concentration 284.

39361

Expiry 02/06/2021

O

Rh D Positive

CMV Antibody Negative

Expiry 02 June 2021 23:59

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

O Pos

Effective 13 May 2021

APPENDIX II

E Progesa Codabar Component Code: 39362

E Progesa ISBT – 128 Component Code : E8216V00

Product Name

WHOLE BLOOD, Suitable for Neonatal Use,
Irradiated.

HCT Range: 0.50 – 0.55

Shelf life

24 hours

Labelling and Barcode:

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

95A0

IBTS ver 3.0

**WHOLE BLOOD, Suitable for Neonatal Use,
Irradiated**

HCT Range: 0.50 – 0.55

Store at 4°C ± 2°C

021125

Drawn 05 May 2021

200 ml

E8216V00

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 65ml of CPD anticoagulant containing, in mmol/l: Citric Acid 16, Sodium Citrate 89, Sodium Dihydrogen Phosphate 16, Glucose 129, Total Na Concentration 284.

Rh D Negative

IRRADIATED (24 H)
CMV Antibody Negative

0211261308

Expiry 06 May 2021 13:08

93999999999917796

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

39362

Expiry 06/05/2021

O Neg