



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: 03-Aug-2025

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 PHS DIR IBTS	BARRY DOYLE	BARRY DOYLE
3	NATIONAL MEDICAL DIRECTOR	STEPHEN FIELD	STEPHEN FIELD
4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS

Review: IBTS DOC PERIODIC 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	NATIONAL MEDICAL DIRECTOR	TOR HERVIG	TOR HERVIG
3	SSCD HEAD OF DEPT IBTS	AILEEN FARRELLY	AILEEN FARRELLY
3	LABS PHS DIR IBTS	BARRY DOYLE	BARRY DOYLE
3	COMPONENTS HEAD OF DEPT MRTC	AINE FITZPATRICK	AINE FITZPATRICK
4	DIRECTOR OF QUALITY	KAREN BYRNE	KAREN BYRNE
4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS

Review: IBTS UNEXPIRE

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off By</u>
1	DOCUMENT CONTROLLER	REBECCA WALDEN	REBECCA WALDEN
3	NATIONAL MEDICAL DIRECTOR	TOR HERVIG	REBECCA WALDEN
3	SSCD HEAD OF DEPT IBTS	AILEEN FARRELLY	REBECCA WALDEN
3	COMPONENTS HEAD OF DEPT MRTC	AINE FITZPATRICK	REBECCA WALDEN
3	LABS PHS DIR IBTS	BARRY DOYLE	REBECCA WALDEN
4	QUALITY ASSURANCE REVIEWER IBTS	REBECCA WALDEN	REBECCA WALDEN

Document Detail

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

**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%

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

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

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)




95A0




**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




Rh D Negative
CMV Antibody Negative




E8215V00

200 ml




0211532359
Expiry 02 June 2021 23:59


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



Expiry 02/06/2021



O Neg



93999999999917796
C- c+ E- e+ K- HbS-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

IBTS ver 3.0


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

Store at 4°C ± 2°C




021125

Drawn 05 May 2021




E8212V00



Rh D Positive


IRRADIATED (24 H)
CMV Antibody Negative

200 ml



0211261307

Expiry 06 May 2021 13:07




9399999999924796

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


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.



39360



Expiry 06/05/2021



O Pos


APPENDIX II

E Progesa Codabar Component Code: 39361

E Progesa ISBT – 128 Component Code : E8217V00

Product Name	Shelf life
WHOLE BLOOD, Suitable for Neonatal Use for 5 Days after Date Drawn. HCT Range: 0.50 – 0.55	28 days

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




51G0

IBTS ver 3.0


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




E8217V00

O

Rh D Positive


CMV Antibody Negative

200 ml



0211532359


Expiry 02 June 2021 23:59




9399999999924796

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 Pos


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
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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



Rh D Negative


IRRADIATED (24 H)
CMV Antibody Negative



021125


Drawn 05 May 2021

200 ml




0211261308

Expiry 06 May 2021 13:08




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




93999999999917796


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



39362



Expiry 06/05/2021



O Neg