Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

Document Detail

Type: PMF IBTS SPEC
Document No.: IBTS/PMF/SPEC/0203[4]
Title: **WHOLE BLOOD SUITABLE FOR NEONATAL USE**
Owner: QA DOC CON QA DOC CONTROL
Status CURRENT
Effective Date: 13-May-2021
Expiration Date: 03-Aug-2025

Review

Review: IBTS PMF REVIEW

Level	Owner Role	Actor	Sign-off By
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

Level	Owner Role	Actor	Sign-off By
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2	QUALITY ASSURANCE WRITER IBTS	REBECCA WALDEN	REBECCA WALDEN
3	NATIONAL MEDICAL DIRECTOR	TOR HERVIG	TOR HERVIG
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3	LABS PHS DIR IBTS	BARRY DOYLE	BARRY DOYLE
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4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS
4	DIRECTOR OF QUALITY	KAREN BYRNE	KAREN BYRNE

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

Valid on Day of Printing, Verify Current Version
Printed By: **Date:**

IRISH BLOOD TRANSFUSION SERVICE

PRODUCT MASTER FILE

TITLE: WHOLE BLOOD SUITABLE FOR NEONATAL USE

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

Verify when in Use. Status CURRENT Effective 13 May 2021

IRISH BLOOD TRANSFUSION SERVICE

PRODUCT MASTER FILE

Title: **Whole Blood Suitable for Neonatal Use**

Name of Products: **WHOLE BLOOD, Suitable for Neonatal Use for 5 days after Date Drawn / WHOLE BLOOD Suitable for Neonatal Use, Irradiated**

E Progesa Codabar Component Codes : **03151 / 39355**

E progesa ISBT – 128 Component Codes : **C6468V00 / C5584V00**

Verify when in Use. Status CURRENT Effective 13 May 202

General Description: The unit of blood is collected into CPD (Citrate, Phosphate Dextrose). The majority of leucocytes in the donation are removed by filtration. The selected donors meet the additional criteria for neonatal use.

General Specification:

Parameter	Quality Requirement	Frequency of Control
Volume	450-525 mL	100%
Haematocrit	≥0.35	≥1%
Haemoglobin	≥ 45 g/unit	≥1%
Leucocyte Content	< 1 x 10^6 / unit	1 per week
Haemolysis at end of shelf life	< 0.8% of red cell mass	4 per annum (including irradiated units)
ABO Agglutinins	No HighTitre Anti-A or Anti-B	100%
CMV	CMV ab negative	100%

Labelling: **S**ee Appendix I

Storage: Whole Blood, Suitable for Neonatal Use for 5 days after Date Drawn / WHOLE BLOOD Suitable for Neonatal Use, Irradiated should be stored at 4ºC ± 2ºC.

Irradiation: Whole Blood, Suitable for Neonatal Use for 5 days after Date Drawn should be irradiated before transfusion provided this does not unduly delay the transfusion. Post irradiation the component code changes to 39355/C5584V00. The irradiated product should be used within 24 hours. It **must** be irradiated prior to transfusion where the neonate has had a previous intrauterine transfusion.

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 should be maintained between 2^{o}C and 10^{o}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, is suitable for exchange transfusion and is used to augment the oxygen delivery capacity of the blood where this is critically impaired.

Verify when in Use. Status: CURRENT Issue 13 May 2021

Precautions in Use:

- Compatibility of this component with the intended recipient must be verified by suitable pre transfusion testing.
- 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.
- Not recommended in:
  - various types of plasma intolerance.
  - repeated leucocyte antigen/antibody mediated reaction unresponsive to medication

Adverse Effects Include:

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

- 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.

Verify when in Use. Status CURRENT Effective 15 May 2021

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

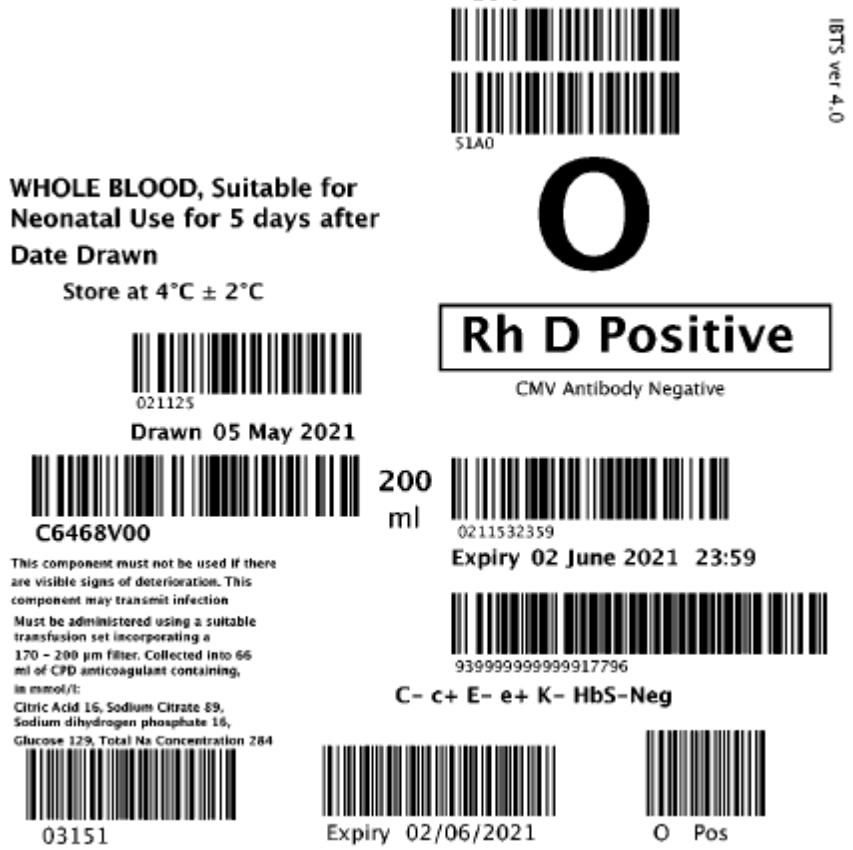
E Progesa Codabar Component Code: 03151

E Progesa ISBT – 128 Component Code : C6468V00

CURRENT Effective 13 May 2021

Product Name	**Shelf life**
WHOLE BLOOD**,** suitable for Neonatal Use for 5 Days after Date Drawn	28 days

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



APPENDIX I

E Progesa Codabar Component Code: 39355

E Progesa ISBT – 128 Component Code : C5584V00

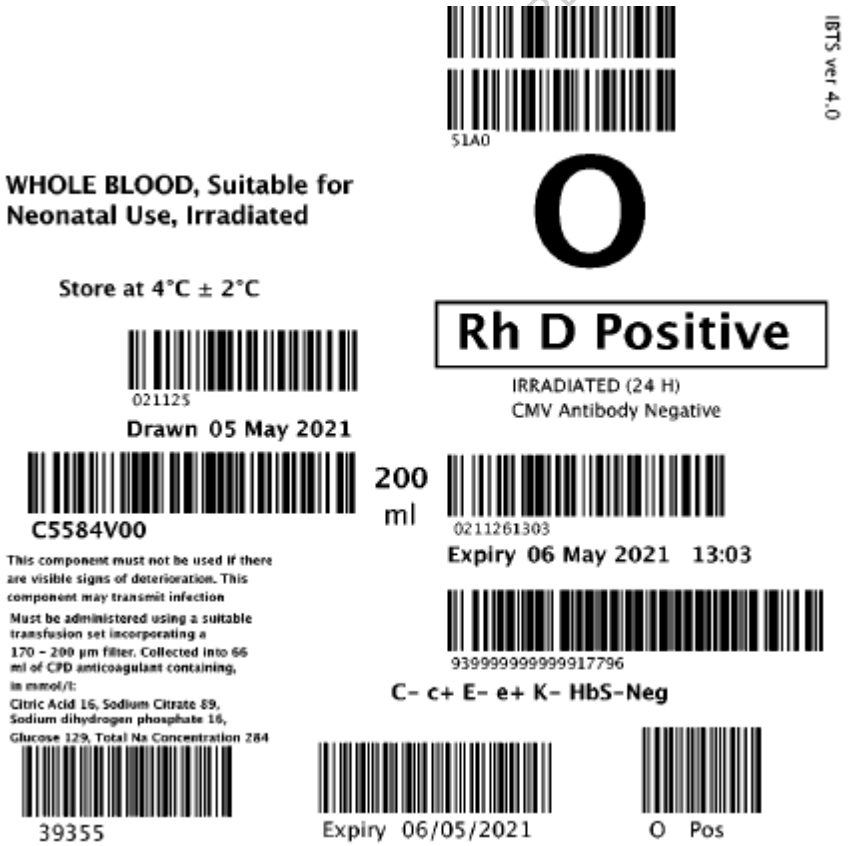
CURRENT Effective 13 May 2021

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

Shelf life
24 hours

Labelling and Barcode:

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



N.B. Stated volume for illustration purposes only.