Irish Blood Transfusion Service
Seirbhís Fuilaistriúcháin na hÉireann

Document Detail

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Title: **WHOLE BLOOD SUITABLE FOR NEONATAL USE**
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Review

Review: IBTS PMF REVIEW

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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.
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IRISH BLOOD TRANSFUSION SERVICE

PRODUCT MASTER FILE

TITLE: WHOLE BLOOD SUITABLE FOR NEONATAL USE

Change Description:
Revise the Labelling and Barcode Illustrations.

Reason for Change:
To update the PMFs with new Label Versions (Ref CC 208/23 & 002/24)

Change order No.:
IBTS/CO/0219/25

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**

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**

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 $4^oC \pm 2^oC$.

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°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, is suitable for exchange transfusion and is used to augment the oxygen delivery capacity of the blood where this is critically impaired.

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.

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

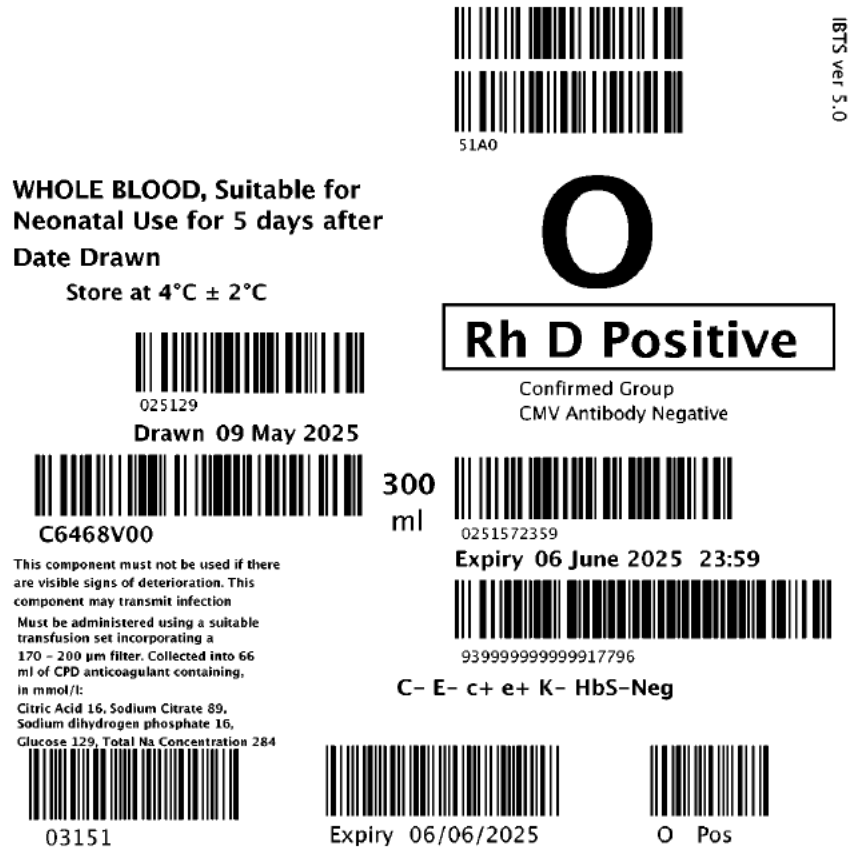
APPENDIX I

E Progesa Codabar Component Code: 03151

E Progesa ISBT – 128 Component Code : C6468V00

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)



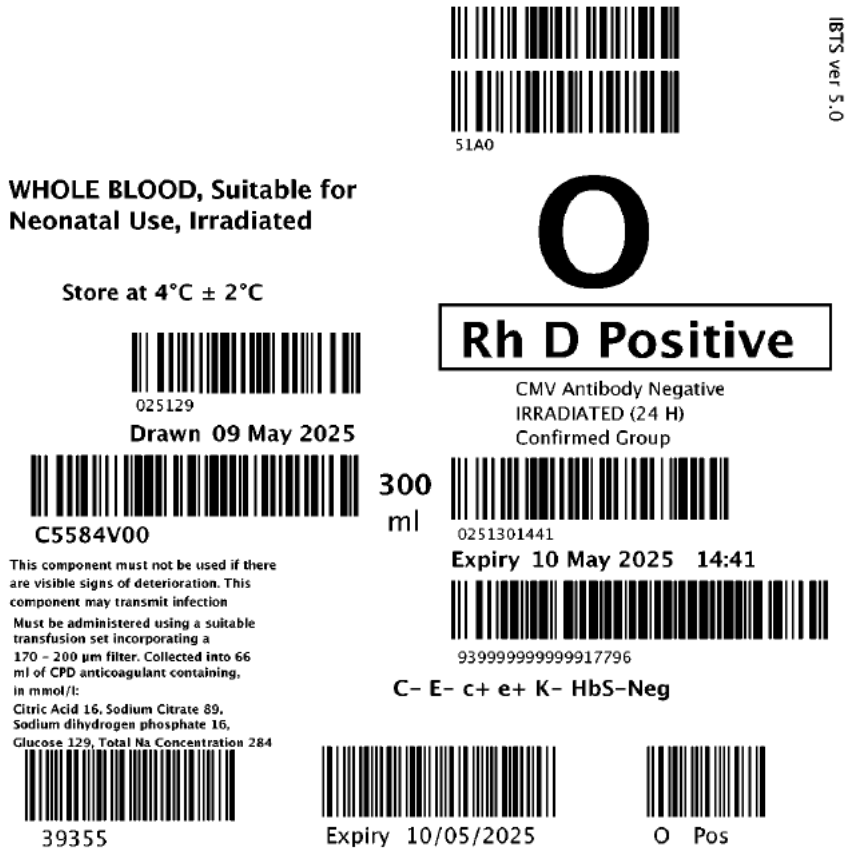
APPENDIX I

E Progesa Codabar Component Code: 39355

E Progesa ISBT – 128 Component Code : C5584V00

Product Name	**Shelf life**
WHOLE BLOOD, Suitable for Neonatal Use, Irradiated	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.