



Document Detail

Type: PMF IBTS SPEC
Document No.: IBTS/PMF/SPEC/0204[4]
Title: **WHOLE BLOOD AUTOLOGOUS**
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>
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3	COMPONENTS HEAD OF DEPT MRTS	AINE FITZPATRICK	AINE FITZPATRICK
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

**IRISH BLOOD TRANSFUSION SERVICE
PRODUCT MASTER FILE**

TITLE: WHOLE BLOOD AUTOLOGOUS

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 Autologous

Name of Product: WHOLE BLOOD for Autologous Transfusion (CPDA1)

E Progesa Codabar Component Code : 30002

E Progesa ISBT-128 Component Code : E4396100

General Description: Unit of whole blood collected for the **sole purpose** of re-infusion into the donor, if required. The removal of the majority of leucocytes is achieved by filtration.

General Specification: Autologous donations shall be identified, collected, processed and verified as to quality according to Standard Operating Procedures for homologous blood donations.

Storage: Whole Blood, Leucodepleted for Autologous Transfusion should be stored at $4^{\circ}\text{C} \pm 2^{\circ}\text{C}$. Autologous blood and blood components must be stored separately. The storage time is 35 days.

Labelling: See Appendix 1

Transportation: The air temperature of the validated transport containers for units of Whole Blood for autologous transfusion should be maintained between 2°C and 10°C during transport from the Irish Blood Transfusion Service to the place that they are intended for use. Transport time under these conditions normally should not exceed 8 hours.

Indications for Use:

- Whole blood for autologous transfusion can be used in selected elective surgical patients.
- Whole blood for autologous transfusion can also be considered for individuals with rare blood groups or with rare or multiple red cell antibodies.

Precautions in Use:

- Careful selection of appropriate patients is an important part of a safe and successful autologous pre-deposit programme.
- One or more venesections over a period of weeks may result in morbidity which needs to be balanced against the potential risks of receiving blood from volunteers.

- Careful attention to documentation is essential to reduce the risk of a clerical error which may lead to a haemolytic transfusion reaction.
- Pre-deposited blood should be transfused using similar clinical indications to those for allogeneic transfusion; it should not be transfused simply because it is available.
- Whole blood should be infused intravenously through a set containing an inline 170-200 µm filter.

Adverse Effects:

- Acute sepsis due to bacterial contamination.
- Autologous transfusions are also susceptible to adverse events such as acute haemolytic transfusion reactions that arise from errors in patient/recipient identification, and from failure to store the product within specified parameters.

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 1

E Progesa Codabar Component Code: 30002

E Progesa ISBT -128 Component Code: E4396100


Product Name:
 WHOLE BLOOD for Autologous
 Transfusion (CPDA1)

Shelf Life:
 35 days

Additional Tag containing the following data:

Side 1	Side 2
Donor's name	Unit Number
Address	Name of admitting hospital
Date of Birth	Donor's Signature
	Medical Officer's Signature


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



IBTS ver 4.0


WHOLE BLOOD for Autologous Transfusion (CPDA1)

Store at 4°C ± 2°C




021125

Drawn 05 May 2021




E4396100




Rh D Positive

200 ml



0211602359


Expiry 09 June 2021 23:59



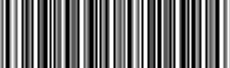
9999999999999999

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 66 ml of CPDA1 anticoagulant containing, in mmol/l:


Citric Acid 16, Sodium Citrate 89, Sodium dihydrogen phosphate 16, Glucose 161, Adenine 2



30002



Expiry 09/06/2021



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