



Document Detail

Type: PMF IBTS SPEC
Document No.: IBTS/PMF/SPEC/0213[4]
Title: **PLATELETS ADULT DOSE AND PAEDIATRIC DOSE**
Owner: QA DOC CON QA DOC CONTROL
Status: CURRENT
Effective Date: 18-Apr-2021
Expiration Date: 04-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	COMPONENTS HEAD OF DEPT MRTS	AINE FITZPATRICK	AINE FITZPATRICK
3	LABS PHS DIR IBTS	BARRY DOYLE	BARRY DOYLE
3	SSCD HEAD OF DEPT IBTS	AILEEN FARRELLY	AILEEN FARRELLY
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/0167/21

IRISH BLOOD TRANSFUSION SERVICE**PRODUCT MASTER FILE**

TITLE: PLATELETS ADULT DOSE AND PAEDIATRIC DOSE

Change Description:

Revise IBTS/PMF/SPEC/0203 – 0218, 0220, 0221, 0224, 0226, 0227, 0232, 0236 to update the product labels in the appendices for each product.

Reason for Change:

Fix to the labels as part of the semester patch reference CC 126/19/IBTS and reference IBTS/QA/IQ/0600 Deviation 008

Change order No.:

IBTS/CO/0167/21

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: Platelets Adult Dose and Paediatric Dose****Name of
Products:****PLATELETS, Adult Dose, Irradiated / PLATELETS, Adult Dose, Split 1/2/3,
Irradiated**

An aliquot can be taken from any component above to make

**PLATELETS, Paediatric Dose, Irradiated / PLATELETS, Paediatric Dose, Split 1/2/3,
Irradiated****E Progesa Codabar Component Codes: 39290 / 39291 / 39294 / 39297****39293 / 39296 / 39299****E Progesa ISBT-128 Component Codes: E3929V00 / E3929VA0 / E3929VB0 /
E3929VC0****E3929VAa / E3929VBa / E3929VCa****General Description:** A platelet apheresis preparation, with the majority of leucocytes removed, suspended in plasma obtained from a single donor using automated cell separation equipment.

Quality Control Requirements:

Parameter	Quality Requirement	Frequency of Control
Volume	40 mL per 60×10^9 platelets	100 %
Platelet Content	$\geq 200 \times 10^9$ / unit	100 %
Leucocyte Content	$< 1 \times 10^6$ / unit	100 %
pH measured (+22° C) at the end of the recommended shelf life	> 6.4	1%

Labelling: See Appendices I and II

Storage : Platelets should be stored at $22^\circ \text{C} \pm 2^\circ \text{C}$. The storage time is 7 days when stored with continuous gentle agitation. An aliquot may be removed for which the storage time is 6 hours. The storage time of the parent product is unchanged.

Irradiation: Platelets are irradiated routinely during preparation.

Transportation : Transport containers should be kept open at room temperature for 30 minutes before use. During transportation from the Irish Blood Transfusion Service to the place where they are intended for use, the temperature of platelets must be kept as close as possible to the recommended storage temperature for the validated time period. On receipt, unless intended for immediate therapeutic use, they should be transferred to storage with continuous gentle agitation on a device approved for the purpose, at $22^\circ \text{C} \pm 2^\circ \text{C}$.

Indications for Use: To provide platelet replacement where deficiency or functional abnormality is causing significant haemostatic problems.

Precautions in Use:

- Swirling phenomenon must be demonstrated before infusion.
- Platelets must be infused intravenously through a fresh infusion set containing an in line 170 – 200 μm filter.

- Rh D negative female recipients of child bearing potential should preferably not be transfused with platelets from Rh D positive donors.
- Because of the temperature of storage and preparation the risk of bacterial contamination is increased.
- No solution should be added to the bag or giving set.
- Components should be inspected visually for defects, leakage, abnormal colour or visible clots.
- Not recommended in cases of plasma intolerance.

Adverse Effects Include:

- Circulatory overload
- Haemolytic transfusion reaction due to transfusion of ABO-incompatible plasma in the component.
- 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
 - Citrate toxicity, especially in neonates and in patients with impaired hepatic function.
- Immunological effects
 - Alloimmunisation to HLA and HPA antigens
 - Post Transfusion purpura (PTP), especially in parous female recipients
 - The risk of Graft vs Host Disease (GvHD) in immuno

- compromised recipients is eliminated by irradiation
- Transfusion related Acute Lung injury (TRALI) by donor HLA/granulocyte antibodies

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: 39290

E Progesa ISBT-128 Component Code : E3929V00

Product Name :
 PLATELETS, Adult Dose,
 Irradiated

Shelf Life :
 7 days.

Product Label and Barcode:

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

IBTS ver 2.0

0600

**PLATELETS, Adult Dose,
 Irradiated**

Store at 22°C ± 2°C

021088
 Drawn 29 Mar 2021

A

Rh D Negative

300 ml

0210952359
 Expiry 05 Apr 2021 23:59

E3929V00

This component must not be used if there are visible signs of deterioration. This component may transmit infection
 AGITATE GENTLY THROUGHOUT STORAGE
 Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter.

39290

Expiry 05/04/2021

A Neg

APPENDIX I

E Progesa Codabar Component Code: 39291

E Progesa ISBT-128 Component Code : E3929VA0

Product Name :
 PLATELETS, Adult Dose,
 Split 1, Irradiated

Shelf Life :
 7 days.

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

IBTS ver 2.0

6200

**PLATELETS, Adult Dose,
 Split 1, Irradiated**

Store at 22°C ± 2°C

021088

Drawn 29 Mar 2021

300 ml

E3929VA0

0210952359

Expiry 05 Apr 2021 23:59

A

Rh D Positive

This component must not be used if there are visible signs of deterioration. This component may transmit infection
AGITATE GENTLY THROUGHOUT STORAGE
 Must be administered using a suitable transfusion set incorporating a 170 - 200 µm filter.

39291

Expiry 05/04/2021

A Pos

APPENDIX I

E Progesa Codabar Component Code: 39294

E Progesa ISBT-128 Code : E3929VB0

Product Name :
PLATELETS, Adult Dose,
Split 2, Irradiated,

Shelf Life :
7 days.

Product Label and Barcode:

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

Effective 18 April 2021

**PLATELETS, Adult Dose,
Split 2, Irradiated**

Store at 22°C ± 2°C

021088
Drawn 29 Mar 2021

B

Rh D Negative

300 ml
0210952359
Expiry 05 Apr 2021 23:59

E3929VB0

This component must not be used if there are visible signs of deterioration. This component may transmit infection

AGITATE GENTLY THROUGHOUT STORAGE
Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter.

39294 Expiry 05/04/2021 B Neg

APPENDIX I

E Progesa Codabar Component Code: 39297

E Progesa ISBT-128 Code : E3929VC0

Product Name :
PLTELETS, Adult Dose,
Split 3, Irradiated

Shelf Life :
7 days.

Product Label and Barcode:

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

IBTS ver 2.0

**PLATELETS, Adult Dose,
Split 3, Irradiated**

Store at 22°C ± 2°C

021088
Drawn 29 Mar 2021

B

Rh D Positive

300 ml
E3929VC0
0210952359
Expiry 05 Apr 2021 23:59

This component must not be used if there are visible signs of deterioration. This component may transmit infection.
AGITATE GENTLY THROUGHOUT STORAGE
Must be administered using a suitable transfusion set incorporating a 170 - 200 µm filter.

39297 Expiry 05/04/2021 B Pos

APPENDIX II

E Progesa Codabar Component Code : 39293

E Progesa ISBT-128 Component Code : E3929VAa

Product Name :
PLATELETS, Paediatric Dose,
Split 1, Irradiated

Shelf Life :
6 hours.

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

CURRENT Effective 18 April 2021


**PLATELETS, Paediatric Dose,
Split 1, Irradiated**

Store at 22°C ± 2°C



021088
Drawn 29 Mar 2021

300 ml
E3929VAa

This component must not be used if there are visible signs of deterioration. This component may transmit infection
AGITATE GENTLY THROUGHOUT STORAGE
Must be administered using a suitable transfusion set incorporating a 170 - 200 µm filter.




9500


Rh D Negative

IRRADIATED




0210881944
Expiry 29 Mar 2021 19:44


IBTS ver 2.0



39293



Expiry 29/03/2021



O Neg

APPENDIX II

E Progesa Codabar Component Code : 39296

E Progesa ISBT-128 Component Code : E3929VBa

Product Name :
 PLATELETS, Paediatric Dose,
 Split 2, Irradiated

Shelf Life :
 6 hours.

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

IBTS ver 2.0

9500

PLATELETS, Paediatric Dose,
 Split 2, Irradiated

Store at 22°C ± 2°C

021088

Drawn 29 Mar 2021

300 ml

E3929VBa

Rh D Negative
 IRRADIATED

0210881945
 Expiry 29 Mar 2021 19:45

This component must not be used if there are visible signs of deterioration. This component may transmit infection
 AGITATE GENTLY THROUGHOUT STORAGE
 Must be administered using a suitable transfusion set incorporating a 170 – 200 µm filter.

39296

Expiry 29/03/2021

O Neg

APPENDIX II

E Progesa Codabar Component Code : 39299

E Progesa ISBT-128 Component Code : E3929VCa

Product Name :
PLATELETS, Paediatric Dose,
Split 3, Irradiated

Shelf Life :
6 hours.

Product Label and Barcode:

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

IBTS ver 2.0

9500

**PLATELETS, Paediatric Dose,
Split 3, Irradiated**

Store at 22°C ± 2°C

021088

Drawn 29 Mar 2021

300 ml

E3929VCa

0210881945

Rh D Negative

IRRADIATED

Expiry 29 Mar 2021 19:45

This component must not be used if there are visible signs of deterioration. This component may transmit infection

AGITATE GENTLY THROUGHOUT STORAGE
Must be administered using a suitable transfusion set incorporating a 170 - 200 µm filter.

39299 Expiry 29/03/2021 O Neg