



Irish Blood Transfusion Service

Seirbhís Fuilaistriúcháin na hÉireann

Document Detail

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Title: **PLATELETS ADULT DOSE AND PAEDIATRIC DOSE**
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Review

Review: IBTS PMF REVIEW

<u>Level</u>	<u>Owner Role</u>	<u>Actor</u>	<u>Sign-off By</u>
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2	QUALITY ASSURANCE WRITER IBTS	REBECCA WALDEN	REBECCA WALDEN
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3	MEDICAL & SCIENTIFIC 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 MRTC	AINE FITZPATRICK	AINE FITZPATRICK
4	DIRECTOR OF QUALITY	KAREN BYRNE	KAREN BYRNE
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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4	DIRECTOR OF QUALITY	KAREN BYRNE	KAREN BYRNE
4	QUALITY ASSURANCE REVIEWER IBTS	KAREN BYRNE	KAREN BYRNE

Document Detail

Change Orders

Changes as described on Change Order:	Change Order No.
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Change Orders - Incorporated

Changes as described on Change Order: **Change Order No.**
IBTS/CO/0167/21

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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

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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.

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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

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- 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

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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)

Effective 18 April 2021

IBTS ver 2.0

0600

PLATELETS, Adult Dose,
Irradiated

Store at 22°C ± 2°C

021088

Drawn 29 Mar 2021

300 ml

E3929V00

0210952359

Expiry 05 Apr 2021 23:59

A

Rh D Negative

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

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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

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

Store at 22°C ± 2°C

021088

Drawn 29 Mar 2021

E3929VA0

300 ml

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.

39291

Expiry 05/04/2021

A Pos

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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



1700

IBTS ver 2.0

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

Store at 22°C ± 2°C


021088
Drawn 29 Mar 2021

Rh D Negative


E3929VB0

300
ml


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.


39294


Expiry 05/04/2021


B Neg

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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

7300

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

Store at 22°C ± 2°C

021088

Drawn 29 Mar 2021

E3929VC0

300 ml

0210952359

Expiry 05 Apr 2021 23:59

B

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.

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)

PLATELETS, Paediatric Dose,
Split 1, Irradiated

Store at 22°C ± 2°C

021088

Drawn 29 Mar 2021

E3929VAa

300 ml

0210881944

Expiry 29 Mar 2021 19:44

Rh D Negative

IRRADIATED

O Neg

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.

IBTS ver 2.0

9500

39293

Expiry 29/03/2021

O Neg

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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

CURRENT Effective 18 April 2021



9500



Rh D Negative

IRRADIATED

**PLATELETS, Paediatric Dose,
Split 2, Irradiated**

Store at 22°C ± 2°C


021088
Drawn 29 Mar 2021

E3929VBa

300
ml

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

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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

CURRENT Effective 18 April 2021



9500



Rh D Negative

IRRADIATED

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

Store at 22°C ± 2°C


021088
Drawn 29 Mar 2021


E3929VCa

300 ml


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.


39299


Expiry 29/03/2021


O Neg