



Irish Blood Transfusion Service

Seirbhís Fuilaidriúcháin na hÉireann

Document Detail

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Title: **APHERESIS CONVALESCENT PLASMA COVID-19**
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Status: CURRENT
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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 HEAD OF MANUFACTURING & ISSUE IBTS	BARRY DOYLE	BARRY DOYLE
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4	QUALITY ASSURANCE REVIEWER IBTS	COLIN JOHNS	COLIN JOHNS

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: APHERESIS CONVALESCENT PLASMA COVID-19

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 FILE

Name of Product: Apheresis CONVALESCENT PLASMA COVID-19
Apheresis CONVALESCENT PLASMA COVID-19, SPLIT 1
Apheresis CONVALESCENT PLASMA COVID-19, SPLIT 2

General Description: Plasma obtained by plasmapheresis from donors who have recovered from COVID-19 infection, rapidly frozen to a temperature that adequately maintains the proteins in a functional state. The majority of leucocytes are removed during the collection process. Prepared from male donors or from female donors negative for HLA/HNA antibodies if required. Suitable for adult use where the intended recipient has laboratory confirmed COVID-19 infection and has been hospitalised due to the illness.

Codabar Component Code: 97480 / 97481 / 97482

ISBT-128 Component Code : E9748V00 / E9748VA0 / E9748VB0

General Specification:

Parameter	Quality Requirement	Frequency of Control
Volume	300 ml \pm 30ml	100%*
Factor VIIIc	> 0.7 iu/ml	10 per 3 months
Platelet Content	< 30 x 10 ⁹ /l	4 per month
Leucocyte Content	< 1 x 10 ⁶ /unit	4 per month
Red Cell presence	Absent when examined macroscopically	100 %
Total Protein	\geq 50g/L	10 per 3 months

*Visual inspection at time of labelling

Labelling: See Appendices I, II and III

Storage: The shelf life of Apheresis Convalescent Plasma COVID-19 is dependent on the core storage temperature as follows:

36 months if stored at \leq -25°C

3 months if stored at -18°C to -25°C

Once thawed, Apheresis Convalescent Plasma COVID-19 must not be refrozen and should be used immediately. If delay is unavoidable, the thawed product should be used as follows:

Within 24 hours if stored at $+4^{\circ}\text{C} \pm 2^{\circ}\text{C}$

Within 4 hours if stored at $+22^{\circ}\text{C} \pm 2^{\circ}\text{C}$

Thawing: Place in a 37°C controlled dedicated waterbath in the plastic overwrap or by removing the overwrap and placing in a dedicated, validated thawing device until the Apheresis Convalescent Plasma COVID-19 is thawed.

Transportation: The air temperature of the transport container for units of Convalescent Plasma COVID-19 must be maintained during transportation from the Irish Blood Transfusion Service to the place that they are intended for use. Unless the Convalescent Plasma COVID-19 is to be thawed for immediate therapeutic use, it must be transferred immediately to storage at the recommended temperature (refer to Storage above).

Indications for Use: Apheresis Convalescent Plasma COVID-19 may be used in the treatment of hospitalised COVID-19 patients with acute respiratory symptoms between 3 and 7 days after the onset of symptoms.

Apheresis Convalescent Plasma COVID-19 **must not** be used simply to correct a volume deficit in the absence of acute respiratory symptoms in COVID-19 patients.

Precautions for Use:

- Apheresis Convalescent Plasma COVID-19 must be infused intravenously through a set containing an in line $170\text{-}200\ \mu\text{m}$ filter.
- Apheresis Convalescent Plasma COVID-19 must not be used in a patient with intolerance to plasma proteins.
- ABO blood group compatible Apheresis Convalescent Plasma COVID-19 should be used and where possible, women of child bearing age and younger should receive Rh D compatible plasma.
- Before use the component must be thawed as described above and the integrity of the pack must be verified to exclude any defects or leakages. No insoluble particulate matter should be visible on completion of the thawing procedure.

- No solution should be added to the bag or giving set.

Adverse Effects Include:

- Transfusion Associated Circulatory Overload (TACO)
- Haemolytic transfusion reaction due to transfusion of ABO-incompatible plasma in the component.
- Non Haemolytic transfusion reactions - chills, fever, hypersensitivity.
- Anaphylaxis
- Metabolic upset
 - Citrate toxicity in patients with impaired hepatic function or where large volumes are rapidly transfused.
- Immunological effects
 - Alloimmunisation to HLA and HPA antigens
 - Transfusion related Acute Lung injury (TRALI) by donor HLA/granulocyte antibodies
- Pathogen Transmission
 - Despite careful donor selection and laboratory screening procedures, viral transmission may, in rare instances, occur.
 - vCJD transmission
 - Transmission of other pathogens that are not tested for or recognised.
 - Sepsis due to bacterial contamination (reduced but not eliminated by bacterial screening)

Serious Adverse Reaction

Serious adverse reactions should be reported to:

National Haemovigilance Office
Irish Blood Transfusion Service
National Blood Centre
James's Street
Dublin 8
D08 NH5R

AND

National Quality Assurance Manager
Irish Blood Transfusion Service
National Blood Centre
James's Street
Dublin 8
D08 NH5R

OR

Medical Department
Munster Regional Transfusion Centre
St Finbarr's Hospital
Douglas Road
Cork.
T12 Y312

Verify when in Use. Status CURRENT Effective 18 April 2021

APPENDIX I

Product Name **Apheresis CONVALESCENT PLASMA COVID-19**

E Progesa Codabar Component Code : 97480

E Progesa ISBT -128 Component Code: E9748V00

Shelf Life (Frozen) 36 months if stored at $\leq -25^{\circ}\text{C}$
 3 months if stored at -18°C to -25°C

Shelf Life (Thawed) 24 hours if stored at $+4^{\circ}\text{C} \pm 2^{\circ}\text{C}$
 4 hours if stored at $+22^{\circ}\text{C} \pm 2^{\circ}\text{C}$

Labelling and Barcode:

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

**Apheresis CONVALESCENT
 PLASMA COVID-19**

Store Frozen at $\leq - 25^{\circ}\text{C}$

021088
 Drawn 29 Mar 2021

B

Rh D Negative

300 ml
 E9748V00

0240882359
 Expiry 28 Mar 2024 23:59

IBTS ver 2.0

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

TIME THAWED: DATE:
 Store for 36 months at \leq minus 25°C
 Store for 3 months at minus 18°C to minus 25°C
 Use within 24 hours if stored at $4 \pm 2^{\circ}\text{C}$
 Use within 4 hours if stored at $22 \pm 2^{\circ}\text{C}$

97480 Expiry 28/03/2024 B Neg

APPENDIX II

Product Name **Apheresis CONVALESCENT PLASMA COVID-19, SPLIT 1**

E Progesa Codabar Component Code : 97481

E Progesa ISBT -128 Component Code: E9748VA0

Shelf Life (Frozen) 36 months if stored at $\leq -25^{\circ}\text{C}$
 3 months if stored at -18°C to -25°C

Shelf Life (Thawed) 24 hours if stored at $+4^{\circ}\text{C} \pm 2^{\circ}\text{C}$
 4 hours if stored at $+22^{\circ}\text{C} \pm 2^{\circ}\text{C}$

Labelling and Barcode:

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

**Apheresis CONVALESCENT
 PLASMA COVID-19, Split 1**

Store Frozen at $\leq - 25^{\circ}\text{C}$



021088

Drawn 29 Mar 2021



E9748VA0

**300
ml**



0240882359

Expiry 28 Mar 2024 23:59

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

TIME THAWED: DATE:
 Store for 36 months at \leq minus 25°C
 Store for 3 months at minus 18°C to minus 25°C
 Use within 24 hours if stored at $4 \pm 2^{\circ}\text{C}$
 Use within 4 hours if stored at $22 \pm 2^{\circ}\text{C}$



97481



Expiry 28/03/2024



A Neg



0600

IBTS ver 2.0

A

Rh D Negative

APPENDIX III

Product Name **Apheresis CONVALESCENT PLASMA COVID-19, SPLIT 2**

E Progesa Codabar Component Code : 97482

E Progesa ISBT -128 Component Code: E9748VB0

Shelf Life (Frozen) 36 months if stored at $\leq -25^{\circ}\text{C}$
 3 months if stored at -18°C to -25°C

Shelf Life (Thawed) 24 hours if stored at $+4^{\circ}\text{C} \pm 2^{\circ}\text{C}$
 4 hours if stored at $+22^{\circ}\text{C} \pm 2^{\circ}\text{C}$

Labelling and Barcode:

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

6200

IBTS ver 2.0

**Apheresis CONVALESCENT
 PLASMA COVID-19, Split 2**

Store Frozen at $\leq - 25^{\circ}\text{C}$

A

Rh D Positive

021088
 Drawn 29 Mar 2021

E9748VB0 300 ml 0240882359

Expiry 28 Mar 2024 23:59

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

TIME THAWED: DATE:
 Store for 36 months at \leq minus 25°C
 Store for 3 months at minus 18°C to minus 25°C
 Use within 24 hours if stored at $4 \pm 2^{\circ}\text{C}$
 Use within 4 hours if stored at $22 \pm 2^{\circ}\text{C}$

97482 Expiry 28/03/2024 A Pos