



**Canadian
Blood
Services**

BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

1800 Alta Vista Drive
Ottawa ON
K1G 4J5
Canada

ACTION REQUIRED

Introduction of ACD-A Apheresis Frozen Plasma

Customer Letter # 2021-26

2021-05-10

Dear Colleagues:

Executive Summary:

1. ACD-A Apheresis FFP (fresh frozen plasma) will be replaced with ACD-A Apheresis FP (frozen plasma).
2. FVIII QC acceptance criteria for ACD-A Apheresis FP is ≥ 0.52 IU/mL in $\geq 75\%$ of units tested.
3. New component code and product name.
4. Circular of Information will be revised to reflect the above changes.

In October 2021, pending Health Canada approval, Canadian Blood Services intends to make a change to all transfusable plasma collected on the Trima Accel collection system. The plasma will be placed in a freezer within 24 hours of collection (slow frozen), rather than frozen within 8 hours of collection (quick frozen). Confirmation of the implementation date will be sent to your facility via a Customer Letter.

Making this change will provide donor centres more flexibility with appointment times and the ability to collect more plasma.

The main changes will be:

- ACD-A Apheresis FFP (fresh frozen plasma) will be replaced with ACD-A Apheresis FP (frozen plasma). The Factor VIII activity in a typical unit of ACD-A Apheresis FP is well within the acceptance criteria ≥ 0.52 IU/mL in $\geq 75\%$ of units tested.
- Your hospital laboratory information system will require updating to add the new component codes. Please do not remove the current codes for ACD-A AAFP as this product may be distributed to your facility for up to 1 year after implementation. See Attachment 1 for a list of new codes and descriptions.
- New component name and component code – See Attachment 2 for sample labels.
- The Circular of Information, *Plasma Components (AAFP, FP CPD, Cryosupernatant CPD, Cryoprecipitate CPD)* will be updated to reflect changes.

Although studies indicate that the apheresis plasma slow frozen procedure provides lower FVIII results than the current apheresis plasma quick freeze procedure, the FVIII levels still well exceeded the minimum acceptance criteria ≥ 0.52 IU/mL in $\geq 75\%$ of units tested as shown in Table 1 below. It is also worth noting that the FVIII results passed the more stringent QC criteria for fresh frozen plasma (≥ 0.70 IU/mL in $\geq 75\%$ of units tested) as well.

Table 1 - FVIII & FV Results for ACD-A Apheresis Plasma Frozen Quick Frozen versus Slow Frozen

Quick Frozen FFP			Slow Frozen FP		
Typical unit content is based on the number of units (n) tested from July 2016 to December 2016, inclusive.		netCAD technical study (October 2018)	Validation Data (2019-03-15 to 2019-05-17)		netCAD technical study (October 2018)
Plasma Component	Factor VIII (IU/mL) Mean $\pm$ 1 SD	Factor V (IU/mL) Mean $\pm$ 1 SD	Plasma Component	Factor VIII (IU/mL) Mean $\pm$ 1 SD	Factor V (IU/mL) Mean $\pm$ 1 SD
ACD-A AFFP	1.29 $\pm$ 0.38 n = 389	1.01 $\pm$ 0.18 n = 30	ACD-A-AFP	1.05 $\pm$ 0.37 n = 30	0.926 $\pm$ 0.15 n = 30

Please share a copy of this customer letter with healthcare professionals at your hospital who might be interested in this information.

This customer letter can also be viewed at www.blood.ca in the "Hospitals Services" section. If you have questions about this letter, or if you require it in an accessible format, please contact your local hospital liaison specialist.

Sincerely,



David Howe
Director Supply Chain Process Management

ATTACHMENT 1/ PIÈCE JOINTE N° 1 – Component Codes/Codes-produit

LIS ACTION REQUIRED MESURE À PRENDRE	ISBT 128 COMPONENT CODE CODE ISBT 128	MNEMONIC TEXT (PACKING SLIP) AIDE-MÉMOIRE (BORDEREAU DE LIVRAISON)	DESCRIPTION DESCRIPTION	ADDITIONAL INFORMATION INFORMATION ADDITIONNELLE
ADD – NEW/ AJOUTER – NOUVEAU	E7637V00	ACD-A AFP – 1	APHERESIS/APHÉRÈSE FROZEN PLASMA PLASMA CONGELÉ CONTAINER/CONTENANT 1 Volume: nnn mL Store at/Conserver à < or/ou = - 18°C	Approximate Volume = 250 mL Post thaw storage time = 120 hours <i>Volume approximatif = 250 mL Temps d'entreposage après décongélation = 120 heures</i>
ADD – NEW/ AJOUTER – NOUVEAU	E7639V00	ACD-A AFP – 2	APHERESIS/APHÉRÈSE FROZEN PLASMA PLASMA CONGELÉ CONTAINER/CONTENANT 2 Volume: nnn mL Store at/Conserver à < or/ou = - 18°C	
ADD – NEW/ AJOUTER – NOUVEAU	E7641V00	ACD-A AFP – 3	APHERESIS/APHÉRÈSE FROZEN PLASMA PLASMA CONGELÉ CONTAINER/CONTENANT 3 Volume: nnn mL Store at/Conserver à < or/ou = - 18°C	



none – current/ <i>aucune – actuel</i>	E4689V00	ACD-A AAFP-1	APHERESIS/APHÉRÈSE FRESH FROZEN PLASMA PLASMA FRAIS CONGELÉ Volume: nnn mL Store at/Conserver à < or/ou = - 18°C	CBS will discontinue collecting components using these codes with implementation of the new process, however, components with this component code may be distributed up to 1 year after implementation, as current stock is exhausted. <i>La collecte des produits associés à ces codes cessera avec la mise en place du nouveau processus. Toutefois, en fonction de nos réserves, il est possible que vous continuiez à recevoir ces composants jusqu'à un an après l'arrêt de leur collecte.</i>
none – current/ <i>aucune – actuel</i>	E4693V00	ACD-A AAFP-2	APHERESIS/APHÉRÈSE FRESH FROZEN PLASMA PLASMA FRAIS CONGELÉ Volume: nnn mL Store at/Conserver à < or/ou = - 18°C	
none – current/ <i>aucune – actuel</i>	E4697V00	ACD-A AAFP-3	APHERESIS/APHÉRÈSE FRESH FROZEN PLASMA PLASMA FRAIS CONGELÉ Volume: nnn mL Store at/Conserver à < or/ou = - 18°C	

ATTACHMENT 2/ PIÈCE JOINTE N° 2 - ACD-A AFP Label Samples/Exemples d'étiquettes pour le plasma-aphérèse congelé ACD-A:

Figure 1 – Sample label of Apheresis Frozen Plasma for container 1



Canadian Blood Services / Société canadienne du sang
 Ottawa, ON K1G 4J5
 Establishment Licence/Licence d'établissement: 100390
 Volunteer donor. This product may transmit infectious agents. See Circular of Information for indications, contraindications, cautions and methods of infusion. Donneur bénévole. Ce produit peut transmettre des agents infectieux. Voir la Circulaire d'information pour les indications, les contre-indications, les mises en garde et les méthodes de perfusion.

Collected on / Prélevé le
 0210900845
 31 MAR 2021 08:45

Expires on / Périé le
 0220902359
 31 MAR 2022 23:59

E7637V00
 APHERESIS/APHÉRÈSE
 FROZEN PLASMA
 PLASMA CONGELÉ

CONTAINER/CONTENANT 1
 Volume: 243 mL
 Store at/Conserver à < or/ou = -18°C
 ACD-A 42 mL

Figure 2 – Sample label of Apheresis Frozen Plasma for container 2



Canadian Blood Services / Société canadienne du sang
 Ottawa, ON K1G 4J5
 Establishment Licence/Licence d'établissement: 100390
 Volunteer donor. This product may transmit infectious agents. See Circular of Information for indications, contraindications, cautions and methods of infusion. Donneur bénévole. Ce produit peut transmettre des agents infectieux. Voir la Circulaire d'information pour les indications, les contre-indications, les mises en garde et les méthodes de perfusion.

Collected on / Prélevé le
 0210900845
 31 MAR 2021 08:45

Expires on / Périé le
 0220902359
 31 MAR 2022 23:59

E7639V00
 APHERESIS/APHÉRÈSE
 FROZEN PLASMA
 PLASMA CONGELÉ

CONTAINER/CONTENANT 2
 Volume: 243 mL
 Store at/Conserver à < or/ou = -18°C
 ACD-A 42 mL

Figure 3 – Sample label of Apheresis Frozen Plasma for container 3



Canadian Blood Services / Société canadienne du sang
 Ottawa, ON K1G 4J5
 Establishment Licence/Licence d'établissement: 100390
 Volunteer donor. This product may transmit infectious agents. See Circular of Information for indications, contraindications, cautions and methods of infusion. Donneur bénévole. Ce produit peut transmettre des agents infectieux. Voir la Circulaire d'information pour les indications, les contre-indications, les mises en garde et les méthodes de perfusion.

Collected on / Prélevé le
 0210900845
 31 MAR 2021 08:45

Expires on / Périé le
 0220902359
 31 MAR 2022 23:59

E7641V00
 APHERESIS/APHÉRÈSE
 FROZEN PLASMA
 PLASMA CONGELÉ

CONTAINER/CONTENANT 3
 Volume: 243 mL
 Store at/Conserver à < or/ou = -18°C
 ACD-A 42 mL