

To: Transfusion Services Managers

From: Hospital Relations

Date: July 13, 2020

Re: UPDATE – Cold Stored Platelets

Carter BloodCare continues to prepare submission for an FDA variance to implement the use of cold stored platelets. The previous target FDA submission period was Q2 of 2020. The new target FDA submission period is August 2020. Once the variance has been received by the FDA, the FDA has twelve months to review and approve. We will continue to keep you apprised of the timeline as we receive updates.

In the meantime, please take the following actions:

- Update laboratory and/or blood bank information systems to accept the ISBT product codes associated with cold-stored apheresis platelets. Example labels are contained for your reference including irradiated product codes.
- Review and update policies associated with platelet storage and indications for use.
- Inform laboratory medical directors and clinicians of the anticipated new component and its indications for use.



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Garter BloodCare Bedford TX 76021 FDA Registration Number 1650777

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VOLUNTEER DONOR



APHERESIS PLATELETS LEUKOCYTES REDUCED

230 mL containing approx 28 mL AGD – A

Store at 1 to 6 C



Rh POSITIVE



Expiration

04 MAY 2020

Rh POSITIVE

04 MAY 2020

Expiration Date

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Carter BloodCare Bedford TX 76021

FDA Registration Number 1650777

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245 mL containing approx 30 mL ACD - A Stere at 1 to 6 C

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3rd Centainer

Carter BloodCare Bedford TX 76021 FDA Registration Number 1650777

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APHERESIS PLATELETS LEUKOCYTES REDUCED

230 mL containing approx 28 mL ACD -- A

Store at 1 to 5 C

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Rx only

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APHERESIS PLATELETS
IRRADIATED
LEUKOCYTES REDUCED

235 mL containing approx 30 mL ACD - A

Store at 1 to 6 C

3rd Container



Rh POSITIVE



10 JUL 2020

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APHERESIS PLATELETS
IRRADIATED
LEUKOCYTES REDUCED

235 mL containing approx 30 mL ACD – A Store at 1 to 6 C

Date

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Carter BloodCare Bedford TX 76021 FDA Registration Number 1650777

Properly identity intended recipient.
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Rx only

VOLUNTEER DONOR



APHERESIS PLATELETS
IRRADIATED
LEUKOCYTES REDUCED

235 mL containing approx 30 mL ACD - A

Store at 1 to 6 C

1st Container





Rh POSITIVE



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Carter BloodCare Bedford TX 76021 FDA Registration Number 1650777

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Rx only

VOLUNTEER DONOR



APHERESIS PLATELETS
IRRADIATED
LEUKOCYTES REDUCED

255 mL containing approx 32 mL ACD - A Store at 1 to 6 C

10 JUL 2020

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