

To: Transfusion Services Managers
From: Hospital Relations
Date: April 19, 2021
Re: UPDATE: Apheresis Platelets - Large Volume Delayed Sampling (LVDS) – Example Labels

Background:

The guidance issued by the FDA around bacterial risk strategies for platelets must be implemented before October 1, 2021. Carter BloodCare intends to implement the large volume delayed sampling single-step strategy using the FDA approved, bioMerieux® BACT/ALERT system on June 22, 2021. The associated pass-through cost will also be effective on June 22, 2021.

Impact to Clients:

- Apheresis platelets will be labeled with a seven day expiration.
- The guidelines stipulate that we must hold these platelets for 48 hours prior to sampling and then incubate for an additional 12 hours before distribution to hospitals.
- New ISBT product codes are required and are listed below for your reference (example labels are also included.)
- A pass-through cost of \$45 will be added to the apheresis platelet fee effective June 22, 2021.
- Acrodose® platelet expiration, cost and bacterial detection strategy remains unchanged.
- Rapid bacterial testing will be discontinued following full implementation of LVDS.

Client Action Required:

- Build and validate 7-day apheresis platelet ISBT product codes.
- Notify administration of the fee increase.
- In cases where platelet availability is limited, we might have to import pathogen reduced platelets. There will be a \$150 pass through fee for these products.



W0352 21 600012 2

Carter BloodCare
Bedford TX 76021
FDA Registration Number 1650777

Properly identify intended recipient.
See circular of information for indications,
contraindications, cautions, and methods of infusion.
This product may transmit infectious agents.
Rx only

VOLUNTEER DONOR



E5030V00

APHERESIS
PLATELETS
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D
248 mL containing approx 32 mL ACD - A
Store at 20 to 24 C



8400
AB

Rh POSITIVE



0211102359

20 APR 2021

Expiration
Date



W0352 21 600013 0

Carter BloodCare
Bedford TX 76021
FDA Registration Number 1650777

Properly identify intended recipient.
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Rx only

VOLUNTEER DONOR



E5031V00

APHERESIS
PLATELETS
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D
218 mL containing approx 30 mL ACD - A
Store at 20 to 24 C
1st Container



0600
A

Rh NEGATIVE



0211102359

20 APR 2021

Expiration
Date



W0352 21 600013 0

Carter BloodCare
Bedford TX 76021
FDA Registration Number 1650777

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Rx only

VOLUNTEER DONOR



E5032V00

APHERESIS
PLATELETS
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D
219 mL containing approx 30 mL ACD - A
Store at 20 to 24 C
2nd Container



0600
A

Rh NEGATIVE



0211102359

20 APR 2021

Expiration
Date



W0352 21 600013 0

Carter BloodCare
Bedford TX 76021
FDA Registration Number 1650777

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Rx only

VOLUNTEER DONOR



E5033V00

APHERESIS
PLATELETS
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D
219 mL containing approx 30 mL ACD - A
Store at 20 to 24 C
3rd Container



0600
A

Rh NEGATIVE



0211102359

20 APR 2021

Expiration
Date



W0352 21 600015

Carter BloodCare
Bedford TX 76021
FDA Registration Number 1650777

Properly identify intended recipient.
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contraindications, cautions, and methods of infusion.
This product may transmit infectious agents.
Rx only

VOLUNTEER DONOR



E5034V00

**APHERESIS
PLATELETS
IRRADIATED
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D**

247 mL containing approx 32 mL ACD - A
Store at 20 to 24 C



5100
O

Rh POSITIVE



0211102359

20 APR 2021

Expiration
Date



W0352 21 600016

Carter BloodCare
Bedford TX 76021
FDA Registration Number 1650777

Properly identify intended recipient.
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contraindications, cautions, and methods of infusion.
This product may transmit infectious agents.
Rx only

VOLUNTEER DONOR



E5035V00

**APHERESIS
PLATELETS
IRRADIATED
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D**

220 mL containing approx 30 mL ACD - A
Store at 20 to 24 C

1st Container



2800
AB

Rh NEGATIVE



0211102359

20 APR 2021

Expiration
Date



W0352 21 600016

Carter BloodCare
Bedford TX 76021
FDA Registration Number 1650777

Properly identify intended recipient.
See circular of information for indications,
contraindications, cautions, and methods of infusion.
This product may transmit infectious agents.
Rx only

VOLUNTEER DONOR



E5036V00

**APHERESIS
PLATELETS
IRRADIATED
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D**

220 mL containing approx 30 mL ACD - A
Store at 20 to 24 C

2nd Container



2800
AB

Rh NEGATIVE



0211102359

20 APR 2021

Expiration
Date



W0352 21 600016

Carter BloodCare
Bedford TX 76021
FDA Registration Number 1650777

Properly identify intended recipient.
See circular of information for indications,
contraindications, cautions, and methods of infusion.
This product may transmit infectious agents.
Rx only

VOLUNTEER DONOR



E5037V00

**APHERESIS
PLATELETS
IRRADIATED
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D**

220 mL containing approx 30 mL ACD - A
Store at 20 to 24 C

3rd Container



2800
AB

Rh NEGATIVE



0211102359

20 APR 2021

Expiration
Date



W0352 21 600014 Z

Carter BloodCare
Bedford TX 76021
FDA Registration Number 1650777



1700

B

Rh NEGATIVE

Properly identify intended recipient.
See circular of information for indications,
contraindications, cautions, and methods of infusion.
This product may transmit infectious agents.
Rx only

VOLUNTEER DONOR



E5073V00



Expiration
Date

0211102359
20 APR 2021

**APHERESIS
PLATELETS**
IRRADIATED
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D

235 mL containing approx 31 mL ACD - A

CONTAINS < 3.0E11 PLATELETS

Store at 20 to 24 C



W0352 21 600011 4

Carter BloodCare
Bedford TX 76021
FDA Registration Number 1650777



6200

A

Rh POSITIVE

Properly identify intended recipient.
See circular of information for indications,
contraindications, cautions and methods of infusion.
This product may transmit infectious agents.
Rx only

VOLUNTEER DONOR



E5075V00



Expiration
Date

0211102359
20 APR 2021

**APHERESIS
PLATELETS**
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D

235 mL containing approx 31 mL ACD - A

CONTAINS < 3.0E11 PLATELETS

Store at 20 to 24 C

Questions and Additional Information:

Please contact hospitalrelations@carterbloodcare.org with any concerns.