

**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.



Carter BloodCare Bedford TX 76021 FDA Registration Number 1650777

Properly ideality intended recipient. See circular of talormation for indications, contratadicaticas, easilions, and methods of intesion. This product may transmit orderious agents. By only

#### **VOLUNTEER DONOR**



APHERESIS PLATELETS
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D

248 mL containing approx 32 mL ACD - A

Store at 20 to 24 G

# Rh POSITIVE



20 APR 2021

Carter BloodCare Bedford TX 76021 FDA Registration Number 1658777

Properly identify intended recipient. See careful of information for radications, contraticleshoes, cautions, and methods of inter This product may transmit informers agents. Rx only

Rh NEGATIVE





APHERESIS PLATELETS LEUKOCYTES REDUCED BACTERIAL MONITORING 7D

218 mL containing approx 30 mL ACD - A

Store at 20 to 24 G

1st Container



Date







Carter BloodCare Bedford TX 76021 FDA Registration Number 1650777

Properly ideality intended resipient.
See contain of information for indications, contraindications, castions, and castleds of infusion this product may feature infectious agents.
Rx only

#### **VOLUNTEER DONOR**



APHERESIS PLATELETS
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D

219 mL containing approx 30 mL ACD - A

Store at 20 to 24 C

2nd Container





# Rh NEGATIVE



20 APR 2021



W0352 21 600013 B 0

Carter BloodCare Bedford TX 76021 FDA Registration Number 1650777



Property identify introduct recipient.
See sincular of information for indications, charled additions, castiness, and methods of infusion. This product may transmit infortious agents.
See only

#### **VOLUNTEER DONOR**



APHERESIS
PLATELETS
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D

219 mt, containing approx 30 mt ACD - A

Store at 20 to 24 C

3rd Container



# Rh NEGATIVE



20 APR 2021



W0352 21 600015 8 X Carter BloodCare Bedford TX 76021

Rh POSITIVE

20 APR 2021

Date

FDA Registration Number 1650777

Properly identify intended recipient.
See circular of information for indications, strainfications, cautions, and methods of infu. This product may treasent infectious apents.

Rx only

**VOLUNTEER DONOR** 



APHERESIS
PLATELETS
IRRADIATED
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D

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

FDA Registration Number 1650777

Properly identity intended resipiest. See circular of information for indications, contrandications, cautions, and methods of unity fits product may transmit allectious agents. Rx only

**VOLUNTEER DONOR** 



APHERESIS PLATELETS
IRRADIATED
LEUKOGYTES REDUCED
BACTERIAL MONITORING 7D

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

1st Container

Rh NEGATIVE



Date

20 APR 2021

W0352 21 600016

Carter BloodCare Bedford TX 76021 FDA Registration Number 1650777

Properly identify intended recipient. See circular of information for indications, contraindications, subtice, and methods of informa-tion product may transmit infectious agents. Rx only

**VOLUNTEER DONOR** 



APHERESIS
PLATELETS
IRRADIATED
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D

220 mL containing approx 30 mL ACD - A

Store at 20 to 24 C

2nd Container

Rh NEGATIVE



20 APR 2021

W0352 21 600016

Carter BloodCare Bedford TX 76021 FDA Registration Number 1650777

Properly ideatily relended recipient. See streatly of information for indications, contraindications, castions, and mathods of info Tass product may transmit infectious agents for only

VOLUNTEER DONOR



APHERESIS PLATELETS
IRRADIATED
LEUKOCYTES REDUCED
BACTERIAL MONITORING 7D

220 mL containing approx 30 mL ACD - A

Store at 20 to 24 C

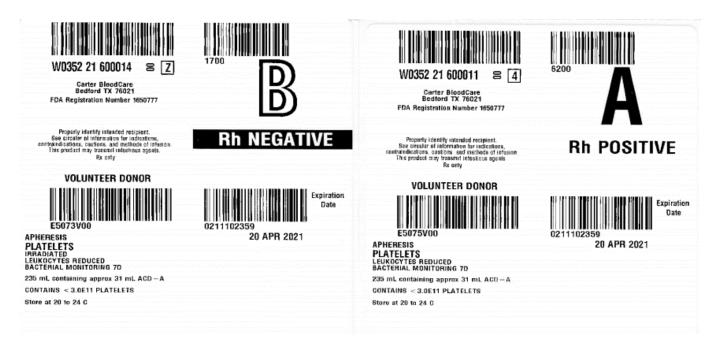
3rd Container

Rh NEGATIVE



Date

20 APR 2021



### **Questions and Additional Information:**

Please contact <a href="mailto:hospitalrelations@carterbloodcare.org">hospitalrelations@carterbloodcare.org</a> with any concerns.