

# Enforcement Report - Week of August 14, 2024

## Class II Biologics Event

<b>Event ID:</b> 94350	<b>Product Type:</b> Biologics
<b>Status:</b> Completed	<b>Date Terminated:</b> N/A
<b>Recall Initiation Date:</b> 02/02/2024	<b>Voluntary / Mandated:</b> Voluntary: Firm initiated
<b>Center Classification Date:</b> 08/07/2024	<b>Initial Firm Notification of Consignee or Public:</b> Telephone
<b>Recalling Firm:</b> Dendreon Pharmaceuticals LLC 6715 Oakley Industrial Blvd Union City, GA 30291-5124 United States	
<b>Distribution Pattern:</b> Maryland	

## Associated Products

<b>Product Description:</b> sipuleucel-T
<b>Product Quantity:</b> 1 unit
<b>Reason for Recall:</b> While manufacturing Provenge infusion therapy, Dendreon noted that a single infusion drug product was manufactured using components from another donor resulting in a product mix-up. The subsequent product was distributed to the clinic and administered to the patient.
<b>Recall Number:</b> B-0312-2024
<b>Code Information:</b> Lot 432794-1

## Class II Biologics Event

<b>Event ID:</b> 94490	<b>Product Type:</b> Biologics
<b>Status:</b> Ongoing	<b>Date Terminated:</b> N/A
<b>Recall Initiation Date:</b> 08/25/2023	<b>Voluntary / Mandated:</b> Voluntary: Firm initiated
<b>Center Classification Date:</b> 08/07/2024	<b>Initial Firm Notification of Consignee or Public:</b> N/A
<b>Recalling Firm:</b> ALBA Bioscience Limited 5 James Hamilton Way Penicuik United Kingdom	
<b>Distribution Pattern:</b> AL, AR, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, NE, NJ, NM, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VT, WI, and WY	

Associated Products

**Product Description:**  
Reagent Red Blood Cells

**Product Quantity:**  
1276

**Reason for Recall:**  
Alba Bioscience is issuing a field safety correction action because during routine testing of various anti-human globulin (AHG) products it was discovered that the lots listed below of ALBAcyte<sup>®</sup> A1 Cells were manufactured using a pool of donation composed of two A1 Red cells donations and one A2 Red cells donation.

**Recall Number:**  
B-0394-2024

**Code Information:**  
Lots: V263526 and V263527; product code Z401U

Class II Biologics Event

**Event ID:**  
95000

**Product Type:**  
Biologics

**Status:**  
Terminated

**Date Terminated:**  
08/02/2024

**Recall Initiation Date:**  
06/10/2024

**Voluntary / Mandated:**  
Voluntary: Firm initiated

**Center Classification Date:**  
08/02/2024

**Initial Firm Notification of Consignee or Public:**  
Telephone

**Recalling Firm:**  
Medic Inc  
1601 Ailor Ave  
Knoxville, TN 37921-6702  
United States

**Distribution Pattern:**  
Tennessee

Associated Products

**Product Description:**  
Platelets Extended Dating

**Product Quantity:**  
1

**Reason for Recall:**  
Platelet product, for which the pH did not meet specifications, was distributed.

**Recall Number:**  
B-0410-2024

**Code Information:**  
W071224024036

Class II Biologics Event

**Event ID:**  
95001

**Product Type:**  
Biologics

**Status:**  
Terminated

**Date Terminated:**  
08/02/2024

**Recall Initiation Date:**  
05/06/2024

**Voluntary / Mandated:**  
Voluntary: Firm initiated

**Center Classification Date:**  
08/02/2024

**Initial Firm Notification of Consignee or Public:**  
N/A

**Recalling Firm:**  
Component Processing Laboratory, UCLA Health, Blood & Platelet Center  
10833 Le Conte Ave Rm A4-239  
Los Angeles, CA 90095-3075  
United States

**Distribution Pattern:**  
California

**Associated Products**

<p><b>Product Description:</b> Apheresis Platelets, Leukocytes Reduced, Pathogen Reduced</p> <p><b>Product Quantity:</b> 2 units</p> <p><b>Reason for Recall:</b> Blood products, collected from a donor who had recently traveled to a malarial endemic area, were distributed.</p> <p><b>Recall Number:</b> B-0411-2024</p> <p><b>Code Information:</b> W121523603050 (double collection)</p>
<p><b>Product Description:</b> Red Blood Cells, Leukocytes Reduced, Irradiated</p> <p><b>Product Quantity:</b> 1</p> <p><b>Reason for Recall:</b> Blood products, collected from a donor who had recently traveled to a malarial endemic area, were distributed.</p> <p><b>Recall Number:</b> B-0412-2024</p> <p><b>Code Information:</b> W121523304947</p>
<p><b>Product Description:</b> Red Blood Cells, Leukocytes Reduced</p> <p><b>Product Quantity:</b> 4</p> <p><b>Reason for Recall:</b> Blood products, collected from a donor who had recently traveled to a malarial endemic area, were distributed.</p> <p><b>Recall Number:</b> B-0413-2024</p> <p><b>Code Information:</b> W121523306710; W121523305319; W121523304459; W121524301568</p>

**Class II Biologics Event**

**Event ID:**  
95002

**Product Type:**  
Biologics

**Status:**  
Terminated

**Date Terminated:**  
08/02/2024

**Recall Initiation Date:**  
04/01/2024

**Voluntary / Mandated:**  
Voluntary: Firm initiated

**Center Classification Date:**  
08/02/2024

**Initial Firm Notification of Consignee or Public:**  
N/A

**Recalling Firm:**  
New York Blood Center Inc  
737 Pelham Blvd  
Saint Paul, MN 55114-1739  
United States

**Distribution Pattern:**  
Minnesota

**Associated Products**

<b>Product Description:</b> Apheresis Platelets, Leukocytes Reduced
<b>Product Quantity:</b> 1
<b>Reason for Recall:</b> Apheresis Platelets, Leukocytes Reduced, labeled as a normal platelet yield component but should have been labeled as a low yield component, were distributed.
<b>Recall Number:</b> B-0414-2024
<b>Code Information:</b> W051524001925

**Class II Biologics Event**

**Event ID:**  
95003

**Product Type:**  
Biologics

**Status:**  
Terminated

**Date Terminated:**  
08/02/2024

**Recall Initiation Date:**  
06/11/2024

**Voluntary / Mandated:**  
Voluntary: Firm initiated

**Center Classification Date:**  
08/02/2024

**Initial Firm Notification of Consignee or Public:**  
Telephone

**Recalling Firm:**  
OneBlood, Inc.  
8669 Commodity Cir  
Orlando, FL 32819-9003  
United States

**Distribution Pattern:**  
Florida

**Associated Products**

<b>Product Description:</b> Apheresis Red Blood Cells, Leukocytes Reduced
<b>Product Quantity:</b> 2
<b>Reason for Recall:</b> Leukoreduced Apheresis Red Blood Cells, which were labeled as leukocytes reduced but were not tested to verify white blood cell count, were distributed.

<b>Recall Number:</b> B-0415-2024
<b>Code Information:</b> W036824578751 (Double Collection)

Class II Biologics Event

<b>Event ID:</b> 95004	<b>Product Type:</b> Biologics
<b>Status:</b> Terminated	<b>Date Terminated:</b> 08/02/2024
<b>Recall Initiation Date:</b> 05/29/2024	<b>Voluntary / Mandated:</b> Voluntary: Firm initiated
<b>Center Classification Date:</b> 08/02/2024	<b>Initial Firm Notification of Consignee or Public:</b> Telephone
<b>Recalling Firm:</b> ImpactLife 5500 Lakeview Pkwy Davenport, IA 52807-3481 United States	
<b>Distribution Pattern:</b> Missouri	

Associated Products

<b>Product Description:</b> Pooled Platelets, Leukocytes Reduced
<b>Product Quantity:</b> 3
<b>Reason for Recall:</b> Leukoreduced Pooled Platelet product, for which platelet yield did not meet specifications, was distributed.
<b>Recall Number:</b> B-0416-2024
<b>Code Information:</b> W038324029815; W038324029801; W038324029799

Class II Biologics Event

<b>Event ID:</b> 95013	<b>Product Type:</b> Biologics
<b>Status:</b> Terminated	<b>Date Terminated:</b> 08/05/2024
<b>Recall Initiation Date:</b> 06/20/2024	<b>Voluntary / Mandated:</b> Voluntary: Firm initiated
<b>Center Classification Date:</b> 08/05/2024	<b>Initial Firm Notification of Consignee or Public:</b> E-Mail
<b>Recalling Firm:</b> New York Blood Center Inc 737 Pelham Blvd Saint Paul, MN 55114-1739 United States	
<b>Distribution Pattern:</b> Nebraska	

Associated Products

**Product Description:**  
Apheresis Platelets, Leukocytes Reduced

**Product Quantity:**  
N/A

**Reason for Recall:**  
Leukoreduced Apheresis Platelets, for which platelet yield did not meet specifications, were distributed.

**Recall Number:**  
B-0419-2024

**Code Information:**  
W051524014065

Class II Biologics Event

**Event ID:**  
95014

**Product Type:**  
Biologics

**Status:**  
Terminated

**Date Terminated:**  
08/05/2024

**Recall Initiation Date:**  
05/17/2024

**Voluntary / Mandated:**  
Voluntary: Firm initiated

**Center Classification Date:**  
08/05/2024

**Initial Firm Notification of Consignee or Public:**  
FAX

**Recalling Firm:**  
LifeSouth Community Blood Centers, Inc  
4039 Newberry Rd  
Gainesville, FL 32607-2342  
United States

**Distribution Pattern:**  
Florida

Associated Products

**Product Description:**  
Red Blood Cells, Leukocytes Reduced

**Product Quantity:**  
1 unit

**Reason for Recall:**  
Red Blood Cell products, for which routine testing/testing performed, interpreted, documented, or labeled incorrectly, were distributed.

**Recall Number:**  
B-0409-2024

**Code Information:**  
W115124097242C

Class II Biologics Event

**Event ID:**  
95015

**Product Type:**  
Biologics

**Status:**  
Terminated

**Date Terminated:**  
08/05/2024

**Recall Initiation Date:**  
05/29/2024

**Voluntary / Mandated:**  
Voluntary: Firm initiated

**Center Classification Date:**  
08/05/2024

**Initial Firm Notification of Consignee or Public:**  
FAX

**Recalling Firm:**  
LifeSouth Community Blood Centers, Inc.  
4891 Ashford Dunwoody Rd  
Dunwoody, GA 30338-4894  
United States

**Distribution Pattern:**  
Georgia

## Associated Products

**Product Description:**  
Red Blood Cells, Leukocytes Reduced

**Product Quantity:**  
N/A

**Reason for Recall:**  
Red Blood Cell products, for which routine testing/testing performed, interpreted, documented, or labeled incorrectly, were distributed.

**Recall Number:**  
B-0421-2024

**Code Information:**  
W115124101683N

## Class II Biologics Event

**Event ID:**  
95049

**Product Type:**  
Biologics

**Status:**  
Terminated

**Date Terminated:**  
08/02/2024

**Recall Initiation Date:**  
07/02/2024

**Voluntary / Mandated:**  
Voluntary: Firm initiated

**Center Classification Date:**  
08/02/2024

**Initial Firm Notification of Consignee or Public:**  
Telephone

**Recalling Firm:**  
Versiti Indiana Inc  
3450 N Meridian St  
Indianapolis, IN 46208-4437  
United States

**Distribution Pattern:**  
Indiana

## Associated Products

**Product Description:**  
Liquid Plasma, Irradiated

**Product Quantity:**  
6 units

**Reason for Recall:**  
Liquid Plasma, Irradiated, which were inadequately irradiated due to malfunction of the irradiation device, were distributed.

**Recall Number:**  
B-0402-2024

**Code Information:**  
W040723200055; W040723203035; W040723300565; W040723200233; W040723200063; W040723300518

Class II Biologics Event

<b>Event ID:</b> 95050	<b>Product Type:</b> Biologics
<b>Status:</b> Terminated	<b>Date Terminated:</b> 08/02/2024
<b>Recall Initiation Date:</b> 07/02/2024	<b>Voluntary / Mandated:</b> Voluntary: Firm initiated
<b>Center Classification Date:</b> 08/02/2024	<b>Initial Firm Notification of Consignee or Public:</b> Telephone
<b>Recalling Firm:</b> Versiti Indiana Inc 3450 N Meridian St Indianapolis, IN 46208-4437 United States	
<b>Distribution Pattern:</b> Indiana; Ohio	

Associated Products

<b>Product Description:</b> Liquid Plasma, Irradiated
<b>Product Quantity:</b> 1 unit
<b>Reason for Recall:</b> Blood Products, for which documentation of irradiation was incomplete, were distributed.
<b>Recall Number:</b> B-0403-2024
<b>Code Information:</b> W040723223002

<b>Product Description:</b> Apheresis Platelets, Leukocytes Reduced, Irradiated
<b>Product Quantity:</b> N/A
<b>Reason for Recall:</b> Blood Products, for which documentation of irradiation was incomplete, were distributed.
<b>Recall Number:</b> B-0404-2024
<b>Code Information:</b> W040722117738 (Double Collection)

Class II Biologics Event

<b>Event ID:</b> 95052	<b>Product Type:</b> Biologics
<b>Status:</b> Terminated	<b>Date Terminated:</b> 08/02/2024
<b>Recall Initiation Date:</b> 05/30/2024	<b>Voluntary / Mandated:</b> Voluntary: Firm initiated
<b>Center Classification Date:</b> 08/02/2024	<b>Initial Firm Notification of Consignee or Public:</b> Telephone



**Recalling Firm:**  
Vitalant  
10536 Peter A Mccuen Blvd  
Mather, CA 95655-4128  
United States

**Distribution Pattern:**  
Nevada; California

**Associated Products**

<b>Product Description:</b> Apheresis Red Blood Cells, Leukocytes Reduced
<b>Product Quantity:</b> 4 units
<b>Reason for Recall:</b> Blood products, exposed to unacceptable shipping temperatures, were distributed
<b>Recall Number:</b> B-0406-2024
<b>Code Information:</b> W04192401299800P (Double Collection); W04192401038900X (Double Collection)

<b>Product Description:</b> Red Blood Cells, Leukocytes Reduced
<b>Product Quantity:</b> 4 units
<b>Reason for Recall:</b> Blood products, exposed to unacceptable shipping temperatures, were distributed
<b>Recall Number:</b> B-0407-2024
<b>Code Information:</b> W04192401039700X; W041924010392006; W041924012973006; W04192401039900T

**Class II Biologics Event**

<b>Event ID:</b> 95053	<b>Product Type:</b> Biologics
<b>Status:</b> Terminated	<b>Date Terminated:</b> 08/02/2024
<b>Recall Initiation Date:</b> 05/24/2024	<b>Voluntary / Mandated:</b> Voluntary: Firm initiated
<b>Center Classification Date:</b> 08/02/2024	<b>Initial Firm Notification of Consignee or Public:</b> N/A
<b>Recalling Firm:</b> Vitalant 875 Greentree Rd Ste 2 Pittsburgh, PA 15220-3508 United States	
<b>Distribution Pattern:</b> Pennsylvania	

**Associated Products**

<b>Product Description:</b> Apheresis Platelets, Leukocytes Reduced
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<b>Product Quantity:</b> 1 unit
<b>Reason for Recall:</b> Leukoreduced Apheresis Platelets, contaminated with coagulase-negative Staphylococcus, were distributed.
<b>Recall Number:</b> B-0408-2024
<b>Code Information:</b> W068524023526001

Class III Biologics Event

<b>Event ID:</b> 94373	<b>Product Type:</b> Biologics
<b>Status:</b> Ongoing	<b>Date Terminated:</b> N/A
<b>Recall Initiation Date:</b> 05/19/2023	<b>Voluntary / Mandated:</b> Voluntary: Firm initiated
<b>Center Classification Date:</b> 08/07/2024	<b>Initial Firm Notification of Consignee or Public:</b> N/A
<b>Recalling Firm:</b> Immucor, Inc. 3130 Gateway Dr Norcross, GA 30071-1106 United States	
<b>Distribution Pattern:</b> AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, TN, TX, UT, VA, WA, WI, WV, Mexico, Chile, Costa Rica, Israel, India, Peru, Hong Kong, Japan, Italy and Kuwait.	

Associated Products

<b>Product Description:</b> Blood Grouping Reagent, Anti-E (Monoclonal)
<b>Product Quantity:</b> 1115 vials
<b>Reason for Recall:</b> Immucor, Inc. has discovered that Gamma-clone Anti-E (Monoclonal) lot number 954255A (expiry September 14, 2024) reagent was received with the package insert for another reagent (Anti-C). This could result in the misinterpretation of test results associated with the testing.
<b>Recall Number:</b> B-0395-2024
<b>Code Information:</b> Lot 954255A

Class III Biologics Event

<b>Event ID:</b> 94374	<b>Product Type:</b> Biologics
<b>Status:</b> Terminated	<b>Date Terminated:</b> 08/06/2024
<b>Recall Initiation Date:</b> 03/14/2024	<b>Voluntary / Mandated:</b> Voluntary: Firm initiated
<b>Center Classification Date:</b> 08/06/2024	<b>Initial Firm Notification of Consignee or Public:</b> N/A

**Recalling Firm:**  
Alk-abello, Inc.  
35 Channel Dr  
Port Washington, NY 11050-2216  
United States

**Distribution Pattern:**  
Michigan; Louisiana; Kentucky; Arizona; Colorado; Virginia; New York; Alabama; Minnesota; New Jersey

**Associated Products**

<p><b>Product Description:</b> Candida albicans</p> <p><b>Product Quantity:</b> 3 units</p> <p><b>Reason for Recall:</b> Misbranded allergenic extracts were distributed.</p> <p><b>Recall Number:</b> B-0422-2024</p> <p><b>Code Information:</b> 0004356491; 0004356492;</p>
<p><b>Product Description:</b> Cladosporium cladosporoides</p> <p><b>Product Quantity:</b> 7 units</p> <p><b>Reason for Recall:</b> Misbranded allergenic extracts were distributed.</p> <p><b>Recall Number:</b> B-0423-2024</p> <p><b>Code Information:</b> 0004521366;</p>
<p><b>Product Description:</b> Botrytis cinerea</p> <p><b>Product Quantity:</b> 2 units</p> <p><b>Reason for Recall:</b> Misbranded allergenic extracts were distributed.</p> <p><b>Recall Number:</b> B-0424-2024</p> <p><b>Code Information:</b> 0004521367;</p>
<p><b>Product Description:</b> Dog Hair and Dander</p> <p><b>Product Quantity:</b> 5 units</p> <p><b>Reason for Recall:</b> Misbranded allergenic extracts were distributed.</p> <p><b>Recall Number:</b> B-0425-2024</p> <p><b>Code Information:</b> 0004389556; 0004526615;</p>

**Product Description:**

Allergenics - Other

**Product Quantity:**

20 units

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0426-2024

**Code Information:**

0004326241; 0004326242; 0004386585; 0004520405; 0004528973;

**Product Description:**

Sheep Sorrel

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0427-2024

**Code Information:**

0004530627;

**Product Description:**

Careless Weed

**Product Quantity:**

2 units

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0428-2024

**Code Information:**

0004554604;

**Product Description:**

Lamb's Quarters

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0429-2024

**Code Information:**

0004526310;

**Product Description:**

Cocklebur

**Product Quantity:**

3 units

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0430-2024

**Code Information:**

0004541012;

**Product Description:**

Walnut, Black

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0431-2024

**Code Information:**

0004453891;

**Product Description:**

Poplar, White

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0432-2024

**Code Information:**

0004504405;

**Product Description:**

Oak, Virginia Live

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0433-2024

**Code Information:**

0004480711;

**Product Description:**

Johnson Grass

**Product Quantity:**

2 units

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0434-2024

**Code Information:**

0004482357;

**Product Description:**

Maple, Hard

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0435-2024

**Code Information:**

0004514808;

**Product Description:**

Gum, Sweet

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0436-2024

**Code Information:**

0004535381;

**Product Description:**

Juniper, Western

**Product Quantity:**

2 units

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0437-2024

**Code Information:**

0004567265;

**Product Description:**

Mesquite

**Product Quantity:**

2 units

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0438-2024

**Code Information:**

0004568631;

**Product Description:**

Quack Grass

**Product Quantity:**

2 units

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0439-2024

**Code Information:**

0004569996;

**Product Description:**

Hickory, Shagbark

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0440-2024

**Code Information:**

0004569998;

**Product Description:**

Mugwort, Common

**Product Quantity:**

3 units

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0441-2024

**Code Information:**

0004448342; 0004448343; 0004576121;

**Product Description:**

Epicoccum nigrum

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0442-2024

**Code Information:**

0004576951;

**Product Description:**

Mucor plumbeus

**Product Quantity:**

6 units

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0443-2024

**Code Information:**

0004493833; 0004584385;

**Product Description:**

Pecan

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0444-2024

**Code Information:**

0004589271;

**Product Description:**

Penicillium notatum

**Product Quantity:**

1

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0445-2024

**Code Information:**

0004591082;

**Product Description:**

Aspergillus fumigatus

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0446-2024

**Code Information:**

0004599410;

**Product Description:**

Alternaria tenuis (alternata)

**Product Quantity:**

3 units

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0447-2024

**Code Information:**

0004557248; 0004599420;

**Product Description:**

Willow, Black

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0448-2024

**Code Information:**

0004601313;

**Product Description:**

Mulberry, Red

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0449-2024

**Code Information:**

0004612945;



<b>Product Description:</b> Oak, White
<b>Product Quantity:</b> 5 units
<b>Reason for Recall:</b> Misbranded allergenic extracts were distributed.
<b>Recall Number:</b> B-0450-2024
<b>Code Information:</b> 0004504402; 0004633237;

<b>Product Description:</b> Bassia
<b>Product Quantity:</b> 2 units
<b>Reason for Recall:</b> Misbranded allergenic extracts were distributed.
<b>Recall Number:</b> B-0451-2024
<b>Code Information:</b> 0004650522;

<b>Product Description:</b> Plantain, English
<b>Product Quantity:</b> 3 units
<b>Reason for Recall:</b> Misbranded allergenic extracts were distributed.
<b>Recall Number:</b> B-0452-2024
<b>Code Information:</b> 0004619034;

<b>Product Description:</b> Birch, Black/Sweet
<b>Product Quantity:</b> 1 unit
<b>Reason for Recall:</b> Misbranded allergenic extracts were distributed.
<b>Recall Number:</b> B-0453-2024
<b>Code Information:</b> 0004557601;

<b>Product Description:</b> Alder, White
<b>Product Quantity:</b> 1 unit
<b>Reason for Recall:</b> Misbranded allergenic extracts were distributed.
<b>Recall Number:</b> B-0454-2024

**Code Information:**

0004616506;

**Product Description:**

Ash, White

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0455-2024

**Code Information:**

0004637149;

**Product Description:**

Birch, White

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0456-2024

**Code Information:**

0004558463;

**Product Description:**

Cottonwood, Western

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0457-2024

**Code Information:**

0004565668;

**Product Description:**

Trichophyton mentagrophytes

**Product Quantity:**

1 unit

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

**Recall Number:**

B-0458-2024

**Code Information:**

0004578399;

**Product Description:**

Pullularia pullulans

**Product Quantity:**

2 units

**Reason for Recall:**

Misbranded allergenic extracts were distributed.

<b>Recall Number:</b> B-0459-2024
<b>Code Information:</b> 0004632297;

<b>Product Description:</b> Sagebrush, Common
<b>Product Quantity:</b> 4 units
<b>Reason for Recall:</b> Misbranded allergenic extracts were distributed.
<b>Recall Number:</b> B-0460-2024
<b>Code Information:</b> 0004594007;

Class III Biologics Event

<b>Event ID:</b> 94865	<b>Product Type:</b> Biologics
<b>Status:</b> Terminated	<b>Date Terminated:</b> 08/05/2024
<b>Recall Initiation Date:</b> 04/12/2024	<b>Voluntary / Mandated:</b> Voluntary: Firm initiated
<b>Center Classification Date:</b> 08/05/2024	<b>Initial Firm Notification of Consignee or Public:</b> FAX
<b>Recalling Firm:</b> We Are Blood 4300 N Lamar Blvd Austin, TX 78756-3421 United States	
<b>Distribution Pattern:</b> Texas	

Associated Products

<b>Product Description:</b> Pooled Cryoprecipitated AHF
<b>Product Quantity:</b> 1 unit
<b>Reason for Recall:</b> Blood products, collected from a previously deferred donor, were distributed.
<b>Recall Number:</b> B-0379-2024
<b>Code Information:</b> W221620751256

<b>Product Description:</b> Red Blood Cells, Leukocytes Reduced
<b>Product Quantity:</b> 4 units
<b>Reason for Recall:</b> Blood products, collected from a previously deferred donor, were distributed.

<b>Recall Number:</b> B-0378-2024
<b>Code Information:</b> W221623454679; W221621608818; W221620152951; W221620609218

Class III Biologics Event

<b>Event ID:</b> 95011	<b>Product Type:</b> Biologics
<b>Status:</b> Terminated	<b>Date Terminated:</b> 08/05/2024
<b>Recall Initiation Date:</b> 02/23/2024	<b>Voluntary / Mandated:</b> Voluntary: Firm initiated
<b>Center Classification Date:</b> 08/05/2024	<b>Initial Firm Notification of Consignee or Public:</b> Telephone
<b>Recalling Firm:</b> New York Blood Center Enterprises 1200 Prospect Ave Westbury, NY 11590-2723 United States	
<b>Distribution Pattern:</b> Rhode Island	

Associated Products

<b>Product Description:</b> Apheresis Platelets, Leukocytes Reduced
<b>Product Quantity:</b> 1 unit
<b>Reason for Recall:</b> Leukoreduced Apheresis Platelets, labeled with an incorrect volume, were distributed.
<b>Recall Number:</b> B-0417-2024
<b>Code Information:</b> W047024075575

Class III Biologics Event

<b>Event ID:</b> 95051	<b>Product Type:</b> Biologics
<b>Status:</b> Terminated	<b>Date Terminated:</b> 08/02/2024
<b>Recall Initiation Date:</b> 06/15/2024	<b>Voluntary / Mandated:</b> Voluntary: Firm initiated
<b>Center Classification Date:</b> 08/02/2024	<b>Initial Firm Notification of Consignee or Public:</b> Telephone
<b>Recalling Firm:</b> Central Pennsylvania Blood Bank Headquarters 8167 Adams Dr Hummelstown, PA 17036-8625 United States	
<b>Distribution Pattern:</b> Pennsylvania	

Associated Products

<b>Product Description:</b> Fresh Frozen Plasma
<b>Product Quantity:</b> 1 unit
<b>Reason for Recall:</b> Fresh Frozen Plasma, which was shipped at the incorrect temperature, was distributed.
<b>Recall Number:</b> B-0405-2024
<b>Code Information:</b> W270124514150