

Enforcement Report - Week of October 23, 2024

Class III Biologics Event

Event ID:

95385

Product Type:

Biologics

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

06/25/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/11/2024

Initial Firm Notification of Consignee or Public:

N/A

Recalling Firm:

Immucor, Inc.

3130 Gateway Dr

Peachtree Corners, GA 30071-1106

United States

Distribution Pattern:

AL, AR, AZ, CA, FL, GA, HI, IA, IL, IN, KS, KY, LA, MA, MD, MI, MN, MO, MS, NC, NH, NJ, NV, NY, OH, OK, PA, RI, SC, TN, TX, UT, VA, VT, WA, WI, WV

Associated Products

Product Description:

Reagent Red Blood Cells

Product Quantity:

218 kits

Reason for Recall:

Immucor has detected that some kits of Panocell-10, Ficin treated exhibit an unexpected dark color (hemolysis) and darkening of the red blood cells. Immucor has confirmed fungal growth in the vials where the hemolysis and darkening of the red blood cells has been observed. Fungal contamination may lead to erroneous test results.

Recall Number:

B-0510-2024

Code Information:

Lot 19919E

Class III Biologics Event

Event ID:

95386

Product Type:

Biologics

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

06/25/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/15/2024

Initial Firm Notification of Consignee or Public:

N/A

Recalling Firm:

Immucor, Inc.

3130 Gateway Dr

Peachtree Corners, GA 30071-1106

United States

Distribution Pattern:

AZ, CA, CO, CT, FL, GA, HI, IA, IL, IN, KY, MA, MD, MI, MN, MO, ND, NH, NJ, NM, NY, OH, OK, OR, PA, SC, TN, TX, VA, and WA

Associated Products**Product Description:**

Reagent Red Blood Cells

Product Quantity:

149

Reason for Recall:

Immucor has detected that some kits of Panocell-10 exhibit an unexpected dark color (hemolysis) and darkening of the red blood cells. Immucor has confirmed fungal growth in the vials where the hemolysis and darkening of the red blood cells has been observed. Fungal contamination may lead to erroneous test results.

Recall Number:

B-0511-2024

Code Information:

lot number 21934

Class III Biologics Event**Event ID:**

95387

Product Type:

Biologics

Status:

Ongoing

Date Terminated:

N/A

Recall Initiation Date:

06/04/2024

Voluntary / Mandated:

Voluntary: Firm initiated

Center Classification Date:

10/16/2024

Initial Firm Notification of Consignee or Public:

N/A

Recalling Firm:

Immucor, Inc.
3130 Gateway Dr
Peachtree Corners, GA 30071-1106
United States

Distribution Pattern:

AK, AL, AR, AZ, CA, CO, FL, GA, HI, IA, IL, KS, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NJ, NM, NV, NY, OH, OK, OR, PA, SC, TN, TX, VA, WA, WI, and WV

Associated Products**Product Description:**

Reagent Red Blood Cells

Product Quantity:

591

Reason for Recall:

Immucor has detected that some kits of Panoscreen I, II & III exhibit an unexpected dark color (hemolysis) and darkening of the red blood cells. Immucor has confirmed fungal growth in the vials where the hemolysis and darkening of the red blood cells has been observed. Fungal contamination may lead to erroneous test results.

Recall Number:

B-0512-2024

Code Information:

Lot number 17845