

July 21, 2010

10-28

**RECALLS AND FIELD CORRECTIONS: COSMETICS - CLASS III**

---

**PRODUCT**

Plus White 5 Minute Bleach Whitening, Gel, Net wt 3.0 oz/85g. Product code JBAA, JBBA, JBBA; Finished product items # 27616A, 26162 are sold as individual tubes and item # 7610W-3B and 7610-3B as individual tubes as parts of kits. Recall # F-2505-2010

**CODE**

Product code only.

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: CCA Industries, Inc., E Rutherford NJ., by e-mails on April 9, 2010. Manufacturer: Altaire Pharmaceuticals, Inc., Aquebogue, NY. Firm initiated recall is ongoing.

**REASON**

The firm has become aware of a stability problem with Plus White 5 Minute Teeth Whitening Gel, which has become liquefied.

**VOLUME OF PRODUCT IN COMMERCE**

142196 units

**DISTRIBUTION**

Nationwide and South Africa, Ukraine, Ireland and St. Marten.

---

**PRODUCT**

Aloe Vesta Cleansing Foam; Multi purpose – No Rinse, pH balanced; 8 fl oz. (236 mL). Product order number: 325208. Recall # F-2506-2010

**CODE**

Lot numbers: 0110MD, 0120MD, 0130MD, 0140MD, 0150MD, 0170MD, 00180MD, 0190MD

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Convar Tec, Skillman, NJ, by letters dated May 26, 2010. Manufacturer: Medicia Holding LLC, Dayton, NJ. Firm initiated recall is ongoing.

**REASON**

Aloe Vesta Cleansing Foam bottles were filled with Aloe Vesta Perineal Skin Cleanser.

**VOLUME OF PRODUCT IN COMMERCE**

35,600 cases

**DISTRIBUTION**

Nationwide

**RECALLS AND FIELD CORRECTIONS: FOODS - CLASS I**

---

**PRODUCT**

Gorton's Shrimp Scampi 12.0 oz Box. Recall # F-2500-2010

**CODE**

Date codes: 9348K1, 9350K1, 9351K1, 9357K1, 0005K1, 0006K1, 0007K1, 0011K1, 0015K1, 0019K1, 0026K1, 0041K1, 0047K1, 0048K1, 0055K1, 0061K1, 0067K1

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Gorton's Inc., Gloucester, MA, by letter dated April 9, 2010.  
Manufacturing: King & Prince Seafood, Brunswick, GA. FDA initiated recall is ongoing.

**REASON**

Product manufactured with black pepper recalled by Mincing Overseas Spice Company due to *salmonella* contamination

**VOLUME OF PRODUCT IN COMMERCE**

34,000 cases

**DISTRIBUTION**

Nationwide

---

**PRODUCT**

Scampi Seasoning for Shrimp X1, Item number G40088, Net Wt 45 lbs (1 bag per unit).  
Recall # F-2504-2010

**CODE**

Lots: 381289, 381290, 381291, 381292, 383003, 383004, 383005, 386750, 391547, 391548, 391549, and 391550

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Newly Weds Food, Inc., Chicago, IL, by letter dated on March 12, 2010.  
Manufacturing: Newly Weds Food, Inc., Horn Lake, MS. FDA initiated recall is complete.

**REASON**

Product contains a pepper ingredient that may have the potential to be contaminated with *Salmonella*.

**VOLUME OF PRODUCT IN COMMERCE**

748 units

**DISTRIBUTION**

GA

---

**PRODUCT**

H.D.W. Foods Whole Black Peppercorns in 2.0 oz bags, UPC 080869654293. Recall # F-2518-2010

**CODE**

None

**RECALLING FIRM/MANUFACTURER**

Perfect Candy & Packaging Co., Reading, PA, by telephone on March 25, 2010. FDA initiated recall is ongoing.

**REASON**

May be contaminated with *Salmonella* recalled by Mincing Overseas Spice.

**VOLUME OF PRODUCT IN COMMERCE**

1320 bags

**DISTRIBUTION**

PA

---

**PRODUCT**

Dried Apricots, Net Wt. 16 oz. UPC 7 61734 73018 1. Recall # F-2519-2010

**CODE**

None

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Ys Health Trading Inc., Ridgefield, NJ, by letters dated May 14, 2010 and press release on May 17, 2010.

Manufacturing: Palmas Palmiye Gida Sanayi Ve Ticaret A.S., Gaziemir, Turkey. New York initiated recall is complete.

**REASON**

New York State Department of Agriculture and Markets randomly sampled Dried Apricots and found them to contain a sulfite level of 2714 ppm. Sulfites were not declared on the ingredient listing.

**VOLUME OF PRODUCT IN COMMERCE**

4 cases of 27 x 16 oz bags

**DISTRIBUTION**

NY and NJ

---

**PRODUCT**

Heartland Foods brand Coarse Ground Black Pepper, sold in 1 lb, 4 lb, 8 lb and 16 lb containers. Recall # F-2520-2010

**CODE**

None

**RECALLING FIRM/MANUFACTURER**

Heartland Food Specialties, Inc., Indianapolis, IN, by a press release on February 26, 2010 and statement on March 1, 2010. FDA Initiated recall is ongoing.

**REASON**

Product is contaminated with *Salmonella*

**VOLUME OF PRODUCT IN COMMERCE**

79 lbs.

**DISTRIBUTION**

IN, OH, KY

---

**PRODUCT**

Allen brand Bavarian Crème Filling, Product Code 02881, Net Wt 31 lb (14 kg). Recall # F-2521-2010

**CODE**

Production codes 11870137F21, F-22, F-23, F-24, F-25; Use by Dec 13 2010

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Rich Products Corp., Buffalo, NY, by press release on June 18, 2010. Manufacturing: Rich Products Corp., Wheeling, IL. Firm initiated recall is ongoing.

**REASON**

The product may contain undeclared milk, pecans, and coconuts.

**VOLUME OF PRODUCT IN COMMERCE**

318 pails

**DISTRIBUTION**

NJ, MA, PA, MD, and OH

---

**PRODUCT**

Cheese packaged in clear vacuum package or in loose bread style bags and labeled in part: Del Bueno Queso Fresco, Net Wt. 16 oz (450g), Keep Refrigerated Ingredients: Pasteurized Milk, Salt, Rennet, and Starter Culture. Product has a code stamp on the back of package to signify the expiration date. Recall # F-2522-2010

**CODE**

The expiration dates are up to and including "May 30, 2010".

**RECALLING FIRM/MANUFACTURER**

Del Bueno, Grandview, WA, by telephone on March 29, 2010, by visit on April 2, 2010 and by press release on April 5, 2010 and April 6, 2010. Washington initiated recall is complete.

**REASON**

Product is contaminated with Listeria monocytogenes.

**VOLUME OF PRODUCT IN COMMERCE**

8,950 lbs

**DISTRIBUTION**

WA, OR

**RECALLS AND FIELD CORRECTIONS: FOODS - CLASS II**

---

**PRODUCT**

Part Skim Mozzarella cheese packaged as follows: 1) Crave Brothers Farmstead Classics, Fresh Mozzarella Cheese, Net Wt. 16 oz, UPC 356715 00105; 2) El Latino Quesillo Nica Nicaraguan Style String Cheese, Net Wt. 16 oz, UPC 33911 0020; 3) El Latino Oaxaca Authentic Mexican String cheese, Net. Wt. 12 oz., UPC 33911 00037; 4) Oaxaca Authentic Mexican Melting Cheese, Net Wt. 12 oz. Recall # F-2501-2010

**CODE**

1) Sell by date 07-03-10; 2) sell by 10-31-10; 3) sell by 10-31-10; 4) sell by 3/1/10

**RECALLING FIRM/MANUFACTURER**

Crave Brothers Farmstead Cheese, LLC, Waterloo, WI, by telephone beginning April 21, 2010 and by letter, dated May 21, 2010. FDA initiated recall is ongoing.

**REASON**

The product is manufactured under insanitary conditions, which can lead to micro-contamination.

**VOLUME OF PRODUCT IN COMMERCE**

4090.5 lbs

**DISTRIBUTION**

FL, GA, TX

---

**PRODUCT**

1) Dark Chocolate Covered Pecans. Recall # F-2502-2010;  
2) Creamy White Pecans. Recall # F-2503-2010

**CODE**

None

**RECALLING FIRM/MANUFACTURER**

Recalling Firm/Manufacturer: Bragg Pecan Farms, Inc., Hondo, TX, by letter on June 10, 2010. Firm recall initiated is ongoing.

**REASON**

Product contains undeclared soy lecithin.

**VOLUME OF PRODUCT IN COMMERCE**

6 1/2 cases of creamy white; 8 cases of dark chocolate

**DISTRIBUTION**

SC, TX, FL, WA

---

**PRODUCT**

- 1) Coke Zero, 2 liter plastic bottles. Recall #F-2507-2010;
- 2) Coca Cola Cherry, 2 liter plastic bottles. Recall #F-2508-2010;
- 3) Diet Dr. Pepper Cherry, 2 liter plastic bottles. Recall #F-2509-2010;
- 4) Dr. Pepper Cherry, 2 liter plastic bottles. Recall #F-2510-2010;
- 5) Caffeine Free Diet Coke, 2 liter plastic bottles. Recall # F-2511-2010;
- 6) Diet Coke, 2 liter plastic bottles. Recall # F-2512-2010;
- 7) Coca Cola Classic, 2 liter plastic bottles. Recall #F-2513-2010;
- 8) Sprite, 2 liter plastic bottles. Recall #F-2514-2010;
- 9) Minute Maid Fruit Punch, 2 liter plastic bottles. Recall #F-2515-2010;
- 10) Fresca, 2 liter plastic bottles. Recall #F-2516-2010;
- 11) Sprite Zero, 2 liter plastic bottles. Recall #F-2517-2010

**CODE**

- 1) AUG3010DTD
- 2) AUG3010DTD
- 3) AUG3010DTD
- 4) AUG3010DTD
- 5) AUG3010DTE
- 6) AUG3010DTE, AUG3010DTB, AUG3010DTC and AUG3010DTD
- 7) AUG3010DTE, AUG3010DTF, AUG3010DTB and AUG3010DTC
- 8) AUG3010DTF
- 9) NOV2910DTB
- 10) AUG3010DTB
- 11) AUG3010DTD

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Coca Cola Enterprises, Inc., Atlanta, GA, by visit and by letter starting June 12, 2010.

Manufacturing: Coca Cola Bottling Co. of Michigan, Detroit, MI. Firm initiated recall is ongoing.

**REASON**

The specified production lots may exhibit off-flavors due to a leak in the ammonia refrigeration system.

**VOLUME OF PRODUCT IN COMMERCE**

62,024 2 liter units

**DISTRIBUTION**

IN, MI, OH, and PA

---

**RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS II**

**PRODUCT**

Instant Hand Sanitizer (ethyl alcohol 62%) Topical Gel, Net contents one US Gallon (129 fl oz), OTC. Recall # D-688-2010

**CODE**

Lot number: 080809 Exp. date 08/2010; 080909 Exp. date 08 /2010; 081009 Exp. date 08/2010; 081109 Exp. date 08/2010; 081309 Exp. date 08/2010.

**RECALLING FIRM/MANUFACTURER**

Gasco Industrial, Gurabo, PR, by telephone on March 22, 2010. Firm initiated recall is ongoing.

**REASON**

cGMP Deviations: The product was manufactured while several cGMP measures were not met.

**VOLUME OF PRODUCT IN COMMERCE**

8,000 gallons

**DISTRIBUTION**

PR

---

**PRODUCT**

Liothyronine Sodium Tablets, USP 5 mcg, RX only, Net contents 100 tablets, NDC0574-0220-01, UPC code (01) 00305740220016. Recall # D-695-2010

**CODE**

Lot # 9C548

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Paddock Laboratories, Inc., Minneapolis, MN, by letter dated May 18, 2010.

Manufacturer: Metrics Inc., Greenville, NC. Firm initiated recall is ongoing.

**REASON**

The recall is being conducted due to a stability failure at the 12 month timepoint; the assay value of this lot was found to be sub-potent.

**VOLUME OF PRODUCT IN COMMERCE**

11,064 bottles

**DISTRIBUTION**

Nationwide including DC and PR

---

**PRODUCT**

Motrin IB (Ibuprofen) Caplets USP, 200mg, Pain Reliever/Fever Reducer (NSAID), 24 Coated Caplets. Recall # D-696-2010

**CODE**

Lot # SDA149 Exp Date 10/2010

**RECALLING FIRM/MANUFACTURER**

McNeil Healthcare, LLC, Las Piedras, PR, by e-mail beginning February 17, 2010. Firm initiated recall is ongoing.

**REASON**

Failed Dissolution Specification.

**VOLUME OF PRODUCT IN COMMERCE**

555,696

**DISTRIBUTION**

Nationwide, PR and Jamaica

---

**PRODUCT**

IBUDONE (hydrocodone bitartrate and ibuprofen tablets), 5 mg/200 mg, 100 count bottles, Rx only. Recall # D-697-2010

**CODE**

Lot # T036K09A, exp 11/11

**RECALLING FIRM/MANUFACTURER**

Vintage Pharmaceuticals LLC, Huntsville, AL, by letter dated April 28, 2010. Firm initiated recall is ongoing.

**REASON**

Subpotent (Multiple Ingredient Drug): Below specification for the assay at the room temperature 3-month stability time-point for Ibuprofen and Hydrocodone Bitartrate.

**VOLUME OF PRODUCT IN COMMERCE**

6,372 units

**DISTRIBUTION**

Nationwide

**RECALLS AND FIELD CORRECTIONS: DRUGS - CLASS III**

---

**PRODUCT**

1) Honey Lemon Soothing Cough Drops (Menthol) 9.1 mg, Individually twist wrapped drops; Packaged under the following labels and packaging: a) Smith Brothers Honey Lemon Soothing Cough Drops; i) 30 drop bag, 12 bags per case, item F8023, UPC 0 72560 08023 5; ii) 50 drop bag, 12 bags per case, item F8106, UPC 0 72560 08106 5; b) CVS Honey Lemon Cough Drops, individually twist wrapped drops, 10 drops per bag, 36 bags per case; item F7243, UPC 0 50428 12750 6. Recall # D-690-2010;

2) Menthol Eucalyptus Soothing Cough Drops (Menthol) 6.5 mg, packaged under the following labels and packaging: a) Smith Brothers Menthol Eucalyptus Soothing Cough Drops, Individually twist wrapped drops in 40 drop bags, item F8038, UPC 0 72560 08038 9; b) Smith Brothers Menthol Eucalyptus Cough Drops, individually twist wrapped drops in 2 lb. plastic jar, 6 jars per case, item F2972. Recall # D-691-2010;

3) Therastat Cough Lozenges (Menthol) 7 mg, Cherry Flavor, Individually twist wrapped lozenges in a 30 lb. bulk carton; item F5127. Recall # D-692-2010;

4) Thoracol Cough Lozenges, Honey Lemon (Menthol) 8 mg, individually twist wrapped lozenges in a 30 lb. bulk pack; item F5125. Recall # D-693-2010

**CODE**

1) Lot numbers: 0098, 0060;

2) Lot number: 0069;

3) Lot number: 0097;

4) Lot numbers: 0098

**RECALLING FIRM/MANUFACTURER**

F & F Foods, Inc., Chicago, IL, by letters dated June 14, 2010. Firm initiated recall is ongoing.

**REASON**

Subpotent (Single Ingredient Drug): Cough drops are out of specification for menthol.

**VOLUME OF PRODUCT IN COMMERCE**

1,621 cases

**DISTRIBUTION**

Nationwide, India

---

**PRODUCT**

UltraTag RBC, Kit for the Preparation of Technetium TC 99m-Labeled Red Blood Cells, Sterile, non-pyrogenic, For Intravenous use after drug preparation, Kits, Rx Only, NDC 0019-N068-B0. Recall # D-698-2010

**CODE**

Lot: 068-0003, Exp. 04/13/11

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Mallinckrodt Inc., Hazelwood, MO, by letters on May 5, 2010.

Manufacturer: Mallinckrodt Inc., Maryland Heights, MO. Firm initiated recall is complete.

**REASON**

CGMP Deviations: The reaction vial was not packaged in some of the clamshell containers.

**VOLUME OF PRODUCT IN COMMERCE**

7,145 kits

**DISTRIBUTION**

Nationwide

---

**PRODUCT**

Heparin Sodium, USP (API) #: NDC #: 046655 000009 and DMF #: 2712, powder, store at or below 30C. Recall # D-699-2010

**CODE**

Lot 80405A Exp. 10/25/08

**RECALLING FIRM/MANUFACTURER**

Pfizer Inc, Franklin, OH, by letters and telephone on March 6, 2008. Firm initiated recall is ongoing.

**REASON**

Impurities/Degradation Products: Heparin Sodium, USP lot 80405A is outside the endotoxin specification of not more than 0.03 EU/U.

**VOLUME OF PRODUCT IN COMMERCE**

83.403 kg

**DISTRIBUTION**

NY

**RECALLS AND FIELD CORRECTIONS: BIOLOGICS - CLASS II**

---

**PRODUCT**



Source Plasma, Recall # B-1069-10

**CODE**

Units: 09VMNM6140, 09VMNM4297, 09VMNL8158, 09VMNL6969, 09VMNL0562, 09VMNK8176, 09VMNK5683, 09VMNK4450, 09VMNK0982, 09VMNJ7794 and 09VMNJ4860

**RECALLING FIRM/MANUFACTURER**

BioLife Plasma Services L.P., Mounds View, MN, by facsimile on March 10, 2010. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor who had not had an annual physical performed, were distributed

**VOLUME OF PRODUCT IN COMMERCE**

11 units

**DISTRIBUTION**

CA

---

**PRODUCT**

Source Plasma, Recall # B-1284-10;

**CODE**

Units: 4920206775, 4920205016, 4920203888, 4920203241, 4920198342, 4920197920, 4920196898, 4920196384, 4920195250, 4920194746, 4920193637, 4920193115, 4920191644, 4920190213, 4920189291, 4920188842, 4920187437, 4920186141, 4920185273, 4920184886, 4920183704, 4920182733, 4920180857, 4920179969, 4920179518, 4920170811, 4920169878, 4920169439, 4920168495, 4920168123, 4920167239, 4920166812, 4920165914, 4920165466, 4920164582, 4920164150, 4920163324, 4920162938

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: CSL Plasma, Boca Raton, FL, by telephone on July 28, 2007.  
Manufacturer: CSL Plasma, Springfield, OH. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor, whose suitability to donate was not adequately determined, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

38 units

**DISTRIBUTION**

IL, Germany, Switzerland

---

**PRODUCT**

Red Blood Cells, Recall # B-1285-10

**CODE**

Unit: 6059180

**RECALLING FIRM/MANUFACTURER**

Community Blood Center, Dayton, OH, by letter on November 13, 2008. Firm initiated recall is complete.

**REASON**

Blood product, which was collected from a donor who traveled to a malarial endemic

area, was distributed

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

OH

---

**PRODUCT**

Source Plasma, Recall # B-1286-10

**CODE**

Units: 0530622293, 0530620404, 0530618722, 0530617861, 0530617047, 0530616124, 0530615083, 0530614455, 0530613150, 0530612740, 0530611053, 0530610490, 0530609346, 0530608732, 0530607573, 0530606970, 0530605820, 0530605309, 0530604211, 0530603610, 0530602636, 0530602065, 0530600978, 0530599819, 0530599356, 0530598411, 0530597977

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: CSL Plasma, Boca Raton, FL, by letter dated November 4, 2007.

Manufacturer: CSL Plasma, Lexington, KY. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor whose physical examination was expired, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

27 units

**DISTRIBUTION**

IL, Germany, Switzerland

---

**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1347-10

**CODE**

Unit: 72M913057

**RECALLING FIRM/MANUFACTURER**

LifeSouth Community Blood Centers, Inc., Huntsville, AL, by facsimile on March 20, 2010. Firm initiated recall is complete.

**REASON**

Blood product, with a low platelet count, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

AL

---

**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1467-10

**CODE**

Unit: 19LR15032

**RECALLING FIRM/MANUFACTURER**

American Red Cross Blood Services Tennessee Valley Region, Nashville, TN, by facsimile and letter on December 10, 2009. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for which donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

TN

---

**PRODUCT**

- 1) Red Blood Cells Leukocytes Reduced. Recall # B-1469-10;
- 2) Red Blood Cells Leukocytes Reduced Irradiated. Recall # B-1470-10

**CODE**

- 1) Unit: 22FM06806;
- 2) Unit: 22KC95930

**RECALLING FIRM/MANUFACTURER**

American National Red Cross, Penn Jersey Region, Philadelphia, PA, by facsimile on December 4, 2009. Firm initiated recall is complete.

**REASON**

Blood products, which were labeled as negative for the S antigen, but were collected from a donor who subsequently tested positive for S antigen, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

PA

---

**PRODUCT**

- 1) Red Blood Cells Leukocytes Reduced. Recall # B-1475-10;
- 2) Fresh Frozen Plasma. Recall # B-1476-10

**CODE**

- 1) and 2) Unit: 22LC33672

**RECALLING FIRM/MANUFACTURER**

American National Red Cross, Penn Jersey Region, Philadelphia, PA, by facsimile on November 18, 2009. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor for whom donor suitability was not adequately determined, were distributed

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

PA

---

**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1477-10

**CODE**

Unit: 72N116982

**RECALLING FIRM/MANUFACTURER**

LifeSouth Community Blood Centers, Inc., Huntsville, AL, by facsimile on March 9, 2010. Firm initiated recall is complete.

**REASON**

Blood product, with a low platelet count, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

AL

---

**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1478-10

**CODE**

Unit: 72M734461

**RECALLING FIRM/MANUFACTURER**

LifeSouth Community Blood Centers, Mobile, AL, by facsimile on March 9, 2010. Firm initiated recall is complete.

**REASON**

Blood product, with a low platelet count, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

AL

---

**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1479-10

**CODE**

Unit: 72M912884

**RECALLING FIRM/MANUFACTURER**

LifeSouth Community Blood Centers, Inc., Huntsville, AL, by facsimile on March 5, 2010. Firm initiated recall is complete.

**REASON**

Blood product, with a low platelet count, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

AL

---

**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1480-10

**CODE**

Unit: 72N337557

**RECALLING FIRM/MANUFACTURER**

LifeSouth Community Blood Centers, Montgomery Region, Montgomery, AL, by facsimile on March 4, 2010. Firm initiated recall is complete.

**REASON**

Blood product, with a low platelet count, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

AL

---

**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1481-10

**CODE**

Unit: 72N10496X

**RECALLING FIRM/MANUFACTURER**

LifeSouth Community Blood Centers, Inc., Huntsville, AL, by facsimile on March 1, 2010. Firm initiated recall is complete.

**REASON**

Blood product, with a low platelet count, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

AL

---

**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1482-10

**CODE**

Unit: 72M694354

**RECALLING FIRM/MANUFACTURER**

LifeSouth Community Blood Centers, Inc., Dunwoody, GA, by facsimile on March 10, 2010. Firm initiated recall is complete.

**REASON**

Blood product, with a low platelet count, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

GA

---

**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1505-10

**CODE**

Unit: 72N11739X

**RECALLING FIRM/MANUFACTURER**

LifeSouth Community Blood Centers, Inc., Huntsville, AL, by facsimile on March 9, 2010. Firm initiated recall is complete.

**REASON**

Blood product, with a platelet count below the specified minimum requirement, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

AL

---

**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1506-10

**CODE**

Unit: 03FM47035

**RECALLING FIRM/MANUFACTURER**

The American National Red Cross - Southern Region, Douglasville, GA, by facsimile on February 20, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whom donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

GA

---

**PRODUCT**

Source Plasma. Recall # B-1507-10

**CODE**

Unit: 09DIAL2608

**RECALLING FIRM/MANUFACTURER**

BioLife Plasma Services LP, Dubuque, IA, by facsimile on March 15, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whose scheduled physical exam was incomplete, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

CA

---

**PRODUCT**

1) Red Blood Cells Leukocytes Reduced. Recall # B-1508-10;

2) Platelets. Recall # B-1509-10

**CODE**

1) and 2) Unit: 01KX00785

**RECALLING FIRM/MANUFACTURER**

American Red Cross Blood Services, West Henrietta, NY, by facsimile on February 08, 2010 and February 11, 2010. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor for whom donor suitability was not adequately determined, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

PA, NY

---

**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1511-10

**CODE**

Unit: 53K56871

**RECALLING FIRM/MANUFACTURER**

American National Red Cross-Greater Chesapeake & Potomac Region, Baltimore, MD, by facsimile, letter and LOGIC on January 12, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for whom donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

MD

---

**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1512-10

**CODE**

Unit: 53J29500

**RECALLING FIRM/MANUFACTURER**

American National Red Cross-Greater Chesapeake & Potomac Region, Baltimore, MD, by facsimile on January 10, 2010 and letter on January 11, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for whom donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

MD

---

**PRODUCT**

- 1) Red Blood Cells Leukocytes Reduced. Recall B-1513-10;
- 2) Platelets Leukocytes Reduced. Recall # B-1514-10

**CODE**

1) Unit: W037709000423;

2) Unit: W0307709000423

**RECALLING FIRM/MANUFACTURER**

Hoxworth Blood Center UC Medical Center, Cincinnati, OH, by letter on October 16, 2009. Firm initiated recall is complete.

**REASON**

Blood products, collected from an unsuitable donor based on travel to an area considered endemic for malaria, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

OH

---

**PRODUCT**

- 1) Red Blood Cells Leukocytes Reduced. Recall B-1558-10;
- 2) Fresh Frozen Plasma. Recall # B-1559-10

**CODE**

- 1) and 2) Unit: Unit 38FV68983

**RECALLING FIRM/MANUFACTURER**

American National Red Cross, Indiana-Ohio Region, Fort Wayne, IN, by telephone on October 8, 2008 and follow-up letter dated October 11, 2008. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor whose suitability to donate was not adequately determined, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

IN, OH

---

**PRODUCT**

- 1) Red Blood Cells Leukocytes Reduced. Recall # Recall # B-1645-10;
- 2) Platelets Pooled Leukocytes Reduced. Recall # B-1646-10

**CODE**

- 1) Unit: 42H60009;

- 2) Units: 42FX67497POOL; 42FX67520POOL; 42H60009POOL; 42H60004POOL; 42H60006POOL; 42H59997POOL; 42H60018POOL

**RECALLING FIRM/MANUFACTURER**

American Red Cross Blood Services, Cleveland, OH, by telephone on January 28, 2008 and letter on February 1, 2008. Firm initiated recall is complete.

**REASON**

Blood products, possibly contaminated with air, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

8 units

**DISTRIBUTION**

OH

---

**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1700-10

**CODE**

Units: 22GZ39134 and 22GM60502

**RECALLING FIRM/MANUFACTURER**

American National Red Cross, Penn Jersey Region, Philadelphia, PA, by facsimile on December 11, 2009. Firm initiated recall is complete.



**REASON**

Blood products, collected from a donor for which donor suitability was not adequately determined, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

NJ, PA

---

**PRODUCT**

Source Plasma. Recall # B-1718-10

**CODE**

Units: 4240226541, 4240220002, 4240218712, 4240217265, 4240216761, 4240215513, 4240215160, 4240214045, 4240213506, 4240211631, 4240210895, 4240209695, 4240208742, 4240207633, 4240206837, 4240205362, 4240204790

**RECALLING FIRM/MANUFACTURER**

ZLB Bioplasma, Inc., Davenport, IA, by electronic notification on April 27, 2009. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor who did not receive a complete physical examination, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

17 units

**DISTRIBUTION**

Switzerland, IL

---

**PRODUCT**

Source Plasma. Recall # B-1722-10

**CODE**

Units: 4100364838, 4100361389, 4100356793, 4100347367, 4100342910

**RECALLING FIRM/MANUFACTURER**

ZLB Bioplasma, Inc., Kansas City, MO, by letter dated October 23, 2009. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor who received a tattoo within 12 months of donation, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

5 units

**DISTRIBUTION**

IL

---

**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1727-10

**CODE**

Unit: 8883824

**RECALLING FIRM/MANUFACTURER**

Florida's Blood Centers, Inc., Ocala, FL, by letters dated December 16, 2009 and December 21, 2009. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor who was previously deferred for testing repeat reactive for HTLV-I/II, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

FL

---

**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1742-10

**CODE**

Unit: 24FW31505

**RECALLING FIRM/MANUFACTURER**

The American Red Cross Blood Services, Louisville, KY, by letter and e-mail on December 10, 2007. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

KY

---

**PRODUCT**

- 1) Red Blood Cells Leukocytes Reduced. Recall # B-1745-10;
- 2) Plasma Frozen. Recall # B-1746-10

**CODE**

Unit: 42FP27508

**RECALLING FIRM/MANUFACTURER**

The American National Red Cross, Cleveland, OH, by telephone on September 5, 2007 and by letter on September 11, 2007. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor whose suitability to donate was not adequately determined, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

OH

---

**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1747-10

**CODE**

Unit: 24KE69016

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: The American National Red Cross, River Valley Region, Louisville, KY, by letter and email on September 21, 2007, September 26, 2007 and October 29, 2007. Manufacturer: American Red Cross Blood Services, River Valley Region, Louisville, KY. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

KY

---

**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1749-10

**CODE**

Unit: 24GY32502

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: The American National Red Cross, River Valley Region, Louisville, KY, by letter and email on August 2, 2007.

Manufacturer: American Red Cross Blood Services, River Valley Region, Louisville, KY. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

KY

---

**PRODUCT**

Source Plasma. Recall # B-1758-10

**CODE**

Units: 09GUTD6504, 09GUTD8499, 09GUTD5081, 09GUTD4387, 09GUTD2986, 09GUTD2235, 09GUTC6434, 09GUTC5653, 09GUTC4209, 09GUTC3441, 09GUTC0173, 09GUTB9405, 09GUTB8011, 09GUTB7278, 09GUTB5903, 09GUTB5174 and 09GUTB3900

**RECALLING FIRM/MANUFACTURER**

BioLife Plasma Services L.P., Saint George, UT, by facsimile on February 3, 2010. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor who had not had an annual physical performed, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

17 units

**DISTRIBUTION**

CA

---

**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1759-10

**CODE**

Unit: W091009328162

**RECALLING FIRM/MANUFACTURER**

Oklahoma Blood Institute - Sylvan N Goldman Center, Oklahoma City, OK, by telephone on December 28, 2009 and facsimile January 6, 2010. Firm initiated recall is complete.

**REASON**

Blood product, which was collected from a donor who had taken aspirin prior to the donation, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

OK

---

**PRODUCT**

1) Platelets Leukocytes Reduced. Recall # B-1760-10;

2) Red Blood Cells Leukocytes Reduced. Recall # B-1761-10

**CODE**

1) Unit: 2956896;

2) Units: 2956896, 2924787

**RECALLING FIRM/MANUFACTURER**

Hoxworth Blood Center UC Medical Center, Cincinnati, OH, by letter dated October 8, 2009. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor who reported travel to an area designated as endemic for malaria, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

3 units

**DISTRIBUTION**

OH, KY

---

**PRODUCT**

1) Recovered Plasma. Recall # B-1772-10;

2) Red Blood Cells Leukocytes Reduced. Recall # B-1773-10;

3) Fresh Frozen Plasma. Recall # B-1774-10

**CODE**

1) Unit: 6174086;

2) Units: 6205935, 6174086, 6142542;

3) Units: 6205935, 6142542

**RECALLING FIRM/MANUFACTURER**

South Texas Blood and Tissue Center, San Antonio, TX, by facsimile on September 29, 2009, October 6, 2009, November 3, 2009, and November 4, 2009. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor who was at risk for variant Creutzfeldt-Jakob Disease (vCJD), were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

6 units

**DISTRIBUTION**

Austria, TX

---

**PRODUCT**

Red Blood Cells (Apheresis) Leukocytes Reduced. Recall # B-1809-10

**CODE**

Unit: W037709086436

**RECALLING FIRM/MANUFACTURER**

Hoxworth Blood Center UC Medical Center, Cincinnati, OH, by letter and telephone on November 19, 2009 and November 30, 2009. Firm initiated recall is complete.

**REASON**

Blood product, which did not meet acceptable product specifications, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

OH

---

**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1823-10

**CODE**

Unit: 9648372

**RECALLING FIRM/MANUFACTURER**

Gulf Coast Regional Blood Center, Houston, TX, by facsimile on May 1, 2008. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor who was previously deferred for testing positive for the human immunodeficiency virus (HIV), was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

TX, NJ

---

**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1824-10

**CODE**

Units: 18FW73596

**RECALLING FIRM/MANUFACTURER**

American National Red Cross Great Lakes Region, Lansing, MI, by facsimile on February 10, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for which donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

MI

---

**PRODUCT**

Red Blood Cells. Recall # B-1825-10

**CODE**

Unit: W088409008173

**RECALLING FIRM/MANUFACTURER**

Blood Bank Of Hawaii, Honolulu, HI, by letter on January 26, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from an unsuitable donor based on travel to an area considered endemic for malaria, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

HI

---

**PRODUCT**

1) Red Blood Cells Leukocytes Reduced. Recall # B-1826-10;

2) Platelets. Recall # B-1827-10;

3) Plasma Frozen. Recall # B-1828-10

**CODE**

1), 2) and 3) Unit: P51128

**RECALLING FIRM/MANUFACTURER**

Blood Assurance Inc., Chattanooga, TN, by facsimile on January 27, 2010. Firm initiated recall is complete.

**REASON**

Blood products collected from a donor who may have warranted deferral for residency in an area at risk for Creutzfeldt-Jakob Disease (vCJD) were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

3 units

**DISTRIBUTION**

TN, GA

---

**PRODUCT**

Red Blood Cells Leukocytes. Recall # B-1830-10

**CODE**

Unit: W117009119797

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Blood Centers of the Pacific - Irwin Center, San Francisco, CA, by telephone on September 19, 2009 and letter January 26, 2009.

Manufacturer: Blood Centers Of The Pacific- Redwood City Center, Redwood City, CA.  
Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor who visited a malarial endemic area, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

CA

**RECALLS AND FIELD CORRECTIONS: BIOLOGICS - CLASS III**

---

**PRODUCT**

Recovered Plasma, Recall # B-1468-10

**CODE**

Unit: 19LR15032

**RECALLING FIRM/MANUFACTURER**

American Red Cross Blood Services Tennessee Valley Region, Nashville, TN, by facsimile and letter on December 10, 2009. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for which donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

CA

---

**PRODUCT**

Recovered Plasma. Recall # B-1510-10

**CODE**

Unit: 53K56871

**RECALLING FIRM/MANUFACTURER**

American National Red Cross-Greater Chesapeake & Potomac Reg., Baltimore, MD, by facsimile, letter and LOGIC on January 12, 2010. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor for whom donor suitability was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

MD

---

**PRODUCT**

- 1) Red Blood Cells Leukocytes Reduced. Recall # B-1642-10;
- 2) Platelets Pooled Leukocytes Reduced. Recall # B-1643-10;
- 3) Platelets Leukocytes Reduced. Recall # Recall # B-1644-10

**CODE**

1) Units: 42FG33587; 42FG33588; 42FG33598; 42FG33602; 42FG33603; 42FG33604;  
42FG33606; 42FG33610; 42FG33611; 42FG33613; 42FG33616; 42FG33617;  
42FG33618; 42FG33619

2) Units: 11509; 11510; 11526;

3) Units: 42FG33585; 42FG33615

**RECALLING FIRM/MANUFACTURER**

American Red Cross Blood Services, Cleveland, OH, by telephone on September 26, 2007 and letter on October 3, 2007. Firm initiated recall is complete.

**REASON**

Blood products, labeled as volunteer were collected from donors who received monetary payment, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

19 units

**DISTRIBUTION**

OH

---

**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1647-10

**CODE**

Units: 42FR48513; 42J86868; 42J86879; 42J86885

**RECALLING FIRM/MANUFACTURER**

American Red Cross Blood Services, Cleveland, OH, by telephone on May 3, 2008 and by letter on May 9, 2008. Firm initiated recall is complete.

**REASON**

Blood products, collected using a scales that had unacceptable quality control results, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

4 units

**DISTRIBUTION**

OH

---

**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1648-10

**CODE**

Units: 20M57203; 20KK55929; 20LS32166

**RECALLING FIRM/MANUFACTURER**

The American National Red Cross, Salt Lake City, UT, by fax on October 25, 2007 and letter on October 26, 2007. Firm initiated recall is complete.

**REASON**

Blood products, lacking assurance of having been maintained at an acceptable temperature during shipping, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

3 units

**DISTRIBUTION**

UT



---

**PRODUCT**

Recovered Plasma. Recall # B-1701-10

**CODE**

Units: 22GZ39134 and 22GM60502

**RECALLING FIRM/MANUFACTURER**

American National Red Cross, Penn Jersey Region, Philadelphia, PA, by facsimile on December 11, 2009. Firm initiated recall is complete.

**REASON**

Blood products, collected from a donor for which donor suitability was not adequately determined, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

CA

---

**PRODUCT**

Recovered Plasma. Recall # B-1743-10

**CODE**

Unit: 24FW31505

**RECALLING FIRM/MANUFACTURER**

The American Red Cross Blood Services, Louisville, KY, by letter and e-mail on December 10, 2007. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

CA

---

**PRODUCT**

Recovered Plasma. Recall # B-1748-10

**CODE**

Unit: 24KE69016

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: The American National Red Cross, River Valley Region, Louisville, KY, by letter and email on September 21, 2007, September 26, 2007 and October 29, 2007. Manufacturer: American Red Cross Blood Services, River Valley Region, Louisville, KY. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

CA

---

**PRODUCT**

Recovered Plasma. Recall # B-1750-10

**CODE**

Unit: 24GY32502

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: The American National Red Cross, River Valley Region, Louisville, KY, by letter and email on August 2, 2007.

Manufacturer: American Red Cross Blood Services, River Valley Region, Louisville, KY. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

CA

---

**PRODUCT**

Source Plasma. Recall # B-1752-10

**CODE**

Unit: AQ030483

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Plasma Biological Services, Inc., Memphis, TN, by fax on October 1, 2007.

Manufacturer: Plasma Biological Services, Asheville, NC. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor whose suitability to donate was not adequately determined, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

NC

---

**PRODUCT**

Recovered Plasma. Recall # B-1822-10

**CODE**

Unit: 9648372

**RECALLING FIRM/MANUFACTURER**

Gulf Coast Regional Blood Center, Houston, TX, by facsimile on May 1, 2008. Firm initiated recall is complete.

**REASON**

Blood product, collected from a donor who was previously deferred for testing positive for the human immunodeficiency virus (HIV), was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

TX, NJ

---

**PRODUCT**

Platelets Pheresis Leukocytes Reduced. Recall # B-1829-10

**CODE**

Unit: W045109960002 (split)

**RECALLING FIRM/MANUFACTURER**

Community Blood Center of the Ozarks, Springfield, MO, by letter on February 12, 2010. Firm initiated recall is complete.

**REASON**

Platelets, mislabeled as leukoreduced, were distributed.

**VOLUME OF PRODUCT IN COMMERCE**

2 units

**DISTRIBUTION**

MO

---

**PRODUCT**

Red Blood Cells Leukocytes Reduced. Recall # B-1832-10

**CODE**

Unit: W036209407248

**RECALLING FIRM/MANUFACTURER**

Belle Bonfils Memorial Blood Center, Denver, CO, by facsimile on December 29, 2009. Firm initiated recall is complete.

**REASON**

Blood product, manufactured without the entire quantity of additive solution added, was distributed.

**VOLUME OF PRODUCT IN COMMERCE**

1 unit

**DISTRIBUTION**

CO

---

**RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS II**

---

**PRODUCT**

1) Triage Total Controls 5, Level 1: Five 0.25 mL tubes. Storage Temp <-20C. Intended use: Assayed materials used with the Triage Profiler S.O.B. Panel, Triage CardioProfilER Panel, Triage BNP Test, Triage D-Dimer Test and Triage Meters to assist in monitoring test performance. Model 88753. Z-1788-2010;

2) Triage Total Controls 5, Level 2: Five 0.25 mL tubes. Storage Temp <-20C. Intended use: Assayed materials used with the Triage Profiler S.O.B. Panel, Triage CardioProfilER Panel, Triage BNP Test, Triage D-Dimer Test and Triage Meters to assist in monitoring test performance. Model 88754. Recall # Z-1789-2010;

3) Triage Total Controls Calibration Verification 5: Two - 0.25 mL tubes for each of five different levels (A,B,C,D,E). Storage Temp <-20C. Intended use: Materials used with the Triage Profiler S.O.B. Panel, Triage CardioProfilER Panel, Triage BNP Test, Triage D-Dimer Test and Triage Meters to verify the calibration of the Test Devices throughout the measurable range. Model 88755. Recall # Z-1790-2010

**CODE**

- 1) Lot numbers: C1916A, C1931A, C1932A & C1999A;
- 2) Lot numbers: C1919A, C1933A, C1934A & C2001A;
- 3) Lot numbers: 194444 & 194450

**RECALLING FIRM/MANUFACTURER**

Biosite Inc., San Diego, CA, by letter dated February 6, 2009. Firm initiated recall is complete.

**REASON**

Incidence of low recovery results has exceeded post market surveillance thresholds of customer complaints in the field.

**VOLUME OF PRODUCT IN COMMERCE**

1,738

**DISTRIBUTION**

Nationwide

---

**PRODUCT**

CaviBleach Wipes; a disinfectant medical device, active ingredient Sodium hypochlorite 0.525%; a single 9" x 9" towelette, pre-moistened with 0.525% - 0.656% sodium hypochlorite, packaged in a flexible poly foil pouch, 50 wipes per dispenser box, 8 boxes per case. General purpose disinfectant wipe for hard, non-porous surfaces, patient care equipment and point of care equipment. Reorder No. 10-1155. Recall # Z-1815-2010

**CODE**

Lot number: F29, Exp June 2010

**RECALLING FIRM/MANUFACTURER**

Medtrol, Inc., Niles, IL, by telephone on December 2, 2009 and by letters dated December 3, 2009. Firm initiated recall is complete.

**REASON**

The disinfectant wipes were found out of specifications for the disinfectant activity prior to the expiration date.

**VOLUME OF PRODUCT IN COMMERCE**

150 cases

**DISTRIBUTION**

Nationwide

---

**PRODUCT**

1) Ultraflex Tracheobronchial Stent System. Uncovered - 8/20 Catalog Number: M00568920. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1817-2010;

- 2) Ultraflex Tracheobronchial Stent System. Uncovered - 8/40 Catalog Number: M00568930. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1818-2010;
- 3) Ultraflex Tracheobronchial Stent System. Uncovered - 10/20 Catalog Number: M00568940. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1819-2010;
- 4) Ultraflex Tracheobronchial Stent System. Uncovered - 10/40 Catalog Number: M00568950. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1820-2010;
- 5) Ultraflex Tracheobronchial Stent System. Uncovered - 12/20 Catalog Number: M00568960. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1821-2010;
- 6) Ultraflex Tracheobronchial Stent System. Uncovered - 12/40 Catalog Number: M00568970. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1822-2010;
- 7) Ultraflex Tracheobronchial Stent System. Uncovered - 14/20 Catalog Number: M00568980. Single Use, Rx only. Boston Scientific, Natick, MA 01760. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Z-1823-2010;
- 8) Ultraflex Tracheobronchial Stent System. Uncovered - 14/80 Catalog Number: M00569000. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1824-2010;
- 9) Ultraflex Tracheobronchial Stent System. Covered - 14/30/15 Catalog Number: M00569040. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1825-2010;
- 10) Ultraflex Tracheobronchial Stent System. Covered - 10/30/15 Catalog Number: M00569050. Single Use, Rx only. Boston Scientific, Natick, MA 01760. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1826-2010;
- 11) Ultraflex Tracheobronchial Stent System. Covered - 12/30/15 Catalog Number: M00569060. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1827-2010;
- 12) Ultraflex Tracheobronchial Stent System. Uncovered - 10/30 Catalog Number: M00569070. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1828-2010;

13) Ultraflex Tracheobronchial Stent System. Uncovered - 12/30 Catalog Number: M00569080. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1829-2010;

14) Ultraflex Tracheobronchial Stent System. Uncovered - 14/30 Catalog Number: M00569090. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1830-2010;

15) Ultraflex Tracheobronchial Stent System. Uncovered - 16/40 Catalog Number: M00569230. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1831-2010;

16) Ultraflex Tracheobronchial Stent System. Uncovered - 16/60 Catalog Number: M00569240. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1832-2010;

17) Ultraflex Tracheobronchial Stent System. Uncovered - 16/80 Catalog Number: M00569250. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1833-2010;

18) Ultraflex Tracheobronchial Stent System. Uncovered - 18/40 Catalog Number: M00569260. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1834-2010;

19) Ultraflex Tracheobronchial Stent System. Uncovered - 18/60 Catalog Number: M00569270. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1835-2010;

20) Ultraflex Tracheobronchial Stent System. Uncovered - 18/80 Catalog Number: M00569280. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1836-2010;

21) Ultraflex Tracheobronchial Stent System. Uncovered - 20/40 Catalog Number: M00569290. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1837-2010;

22) Ultraflex Tracheobronchial Stent System. Uncovered - 20/60 Catalog Number: M00569300. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1838-2010;

23) Ultraflex Tracheobronchial Stent System. Uncovered - 20/80 Catalog Number: M00569310. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1839-201;

24) Ultraflex Tracheobronchial Stent System. Covered - 8/40/25 Catalog Number: M00569410. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1840-2010;

25) Ultraflex Tracheobronchial Stent System. Covered - 10/40/25 Catalog Number: M00569430. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1841-2010;

26) Ultraflex Tracheobronchial Stent System. Covered - 12/40/25 Catalog Number: M00569450. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1842-2010;

27) Ultraflex Tracheobronchial Stent System. Covered - 14/40/25 Catalog Number: M00569480. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1843-2010;

28) Ultraflex Tracheobronchial Stent System. Covered - 14/60/45 Catalog Number: M00569490. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1844-2010;

29) Ultraflex Tracheobronchial Stent System. Covered - 18/40/65 Catalog Number: M00569500. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1845-2010;

30) Ultraflex Tracheobronchial Stent System. Covered - 16/40/25 Catalog Number: M00569510. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1846-2010;

31) Ultraflex Tracheobronchial Stent System. Covered - 16/60/45 Catalog Number: M00569520. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1847-2010;

32) Ultraflex Tracheobronchial Stent System. Covered - 16/80/65 Catalog Number: M00569530. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1848-2010;

33) Ultraflex Tracheobronchial Stent System. Covered - 18/40/25 Catalog Number: M00569540. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1849-2010;

34) Ultraflex Tracheobronchial Stent System. Covered - 18/60/45 Catalog Number: M00569550. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1850-2010

35) Ultraflex Tracheobronchial Stent System. Covered - 18/80/65 Catalog Number: M00569560. Single Use, Rx only. Indicated for the use in the treatment of

tracheobronchial structures produced by malignant neoplasms. Recall # Z-1851-2010;

36) Ultraflex Tracheobronchial Stent System. Covered - 20/40/25 Catalog Number: M00569570. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1852-2010;

37) Ultraflex Tracheobronchial Stent System. Covered - 20/60/45 Catalog Number: M00569580. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1853-2010;

38) Ultraflex Tracheobronchial Stent System. Covered - 20/80/65 Catalog Number: M00569590. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1854-2010;

39) Ultraflex Tracheobronchial Stent System. Uncovered - 14/40 Catalog Number: M00569920. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1855-2010;

40) Ultraflex Tracheobronchial Stent System. Covered - 14/60. Catalog Number: M00569930. Single Use, Rx only. Indicated for the use in the treatment of tracheobronchial structures produced by malignant neoplasms. Recall # Z-1856-2010;

41) Ultraflex Esophageal Stent System. Uncovered – Distal Release – 18/23/7. Catalog Number: M00513700. Single Use, Rx only. Intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors only and occlusion of concurrent esophageal fistulas. Recall # Z-1858-2010;

42) Ultraflex Esophageal Stent System. Uncovered - Distal Release - 18/23/10. Catalog Number M00513710. Single Use, Rx only. Intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors only and occlusion of concurrent esophageal fistulas. Recall # Z-1859-2010;

43) Ultraflex Esophageal Stent System. Uncovered - Distal Release - 18/23/15. Catalog Number M00513720. Single Use, Rx only. Intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors only and occlusion of concurrent esophageal fistulas. Recall # Z-1860-2010;

44) Ultraflex Esophageal Stent System. Covered - Distal Release - 18/23/10/7. Catalog Number M00513730. Single Use, Rx only. Intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors only and occlusion of concurrent esophageal fistulas. Recall # Z-1861-2010;

45) Ultraflex Esophageal Stent System. Covered - Distal Release - 18/23/12/9. Catalog Number M00513740. Single Use, Rx only. Intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors only and occlusion of concurrent esophageal fistulas. Recall # Z-1862-2010;



46) Ultraflex Esophageal Stent System. Covered - Distal Release - 18/23/15/12. Catalog Number M00513750. Single Use, Rx only. Intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors only and occlusion of concurrent esophageal fistulas. Recall # Z-1863-2010;

47) Ultraflex Esophageal Stent System. Uncovered - Proximal Release - 18/23/7. Catalog Number M00513800. Single Use, Rx only. Intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors only and occlusion of concurrent esophageal fistulas. Recall # Z-1864-2010;

48) Ultraflex Esophageal Stent System. Uncovered - Proximal Release - 18/23/10. Catalog Number M00513810. Single Use, Rx only. Intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors only and occlusion of concurrent esophageal fistulas. Recall # Z-1865-2010;

49) Ultraflex Esophageal Stent System. Uncovered - Proximal Release - 18/23/15. Catalog Number M00513830. Single Use, Rx only. Intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors only and occlusion of concurrent esophageal fistulas. Recall # Z-1866-2010;

50) Ultraflex Esophageal Stent System. Covered - Proximal Release - 18/23/10/7. Catalog Number M00513840. Single Use, Rx only. Intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors only and occlusion of concurrent esophageal fistulas. Recall # Z-1867-2010

51) Ultraflex Esophageal Stent System. Covered - Proximal Release - 18/23/12/9. Catalog Number M00513850. Single Use, Rx only. Intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors only and occlusion of concurrent esophageal fistulas. Recall # Z-1868-2010;

52) Ultraflex Esophageal Stent System. Covered - Proximal Release - 18/23/15/12. Catalog Number M00513860. Single Use, Rx only. Intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors only and occlusion of concurrent esophageal fistulas. Recall # Z-1869-2010

53) Ultraflex Esophageal Stent System. Covered - Large - Distal Release - 23/28/10/7. Catalog Number M00514200. Single Use, Rx only. Intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors only and occlusion of concurrent esophageal fistulas. Recall # Z-1870-2010;

54) Ultraflex Esophageal Stent System. Covered - Large - Distal Release - 23/28/12/9. Catalog Number M00514210. Single Use, Rx only. Intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors only and occlusion of concurrent esophageal fistulas. Recall # Z-1871-2010;

55) Ultraflex Esophageal Stent System. Covered - Large - Proximal Release - 23/28/10/7. Catalog Number M00514240. Single Use, Rx only. Intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors only and occlusion of concurrent esophageal fistulas. Recall # Z-1872-2010;

56) Ultraflex Esophageal Stent System. Covered - Large - Proximal Release - 23/28/12/9. Catalog Number M00514250. Single Use, Rx only. Intended for maintaining esophageal luminal patency in esophageal structures caused by intrinsic and/or extrinsic malignant tumors only and occlusion of concurrent esophageal fistulas. Recall # Z-1873-2010

**CODE**

1) Lot Numbers: 9660870 9660872 9683259 9684033 9825237 9825239 11020615 11021161 11045326 11046908 11092500 11092870 11100790 11101034 11179772 11180064 11221518 11286599 11291273 11397900 11586714 11586715 11630143 11630145 11665462 11665465 11682848 11682993 11722727 11722780 11740953 11740954 11767032 11767102 11791247 11791249 11808612 11809670 11858089 11858099 11858579 11858749 11864991 11864994 11890538 11890539 11993334 11993685 12054532 12054538 12066671 12066674 12088721 12088722 12119772 12119773 12150166 12150167 12166898 12167101 12201772 12201774 12233042 12233045 12239685 12239686 12273120 12273121 12371428 12386419 12441414 12554477 12607521 12624788 12652041 12728696 12732815 12746858 12753767 12781521 12832159 12836470 12849336 12862447 12933275 13081073 13110153 13119400 13203258 13236093 13318985;

2) Lot Numbers: 9730258 9825738 9825746 11147367 11147373 11223562 11223563 11748615 11748616 11887697 11887698 12124979 12125049 12232145 12232151 12370304 12467916 12755428 12914233 12947902;

3) Lot Numbers: 9816662 9816664 9825225 9825231 11040448 11041182 11078192 11078420 11093973 11093975 11108899 11110944 11162018 11191140 11191143 11318358 11318707 11412065 11412066 11428368 11428370 11522460 11522461 11559400 11559402 11593826 11593832 11626022 11626025 11659418 11659419 11666874 11666875 11682980 11682981 11722921 11722925 11734945 11756575 11756620 11782914 11782919 11792137 11792360 11825611 11825614 11829608 11829612 11846116 11846118 11902527 11903035 11927690 11927691 11943670 11943683 11973645 11973646 12035398 12035641 12051921 12089897 12089898 12122981 12143396 12143721 12197267 12197268 12205131 12205132 12238955 12238956 12274500 12274503 12314919 12318374 12391990 12398060 12404315 12491821 12500427 12536945 12587048 12603447 12606861 12619342 12635155 12675579 12729536 12743685 12771606 12844953 12888561 12906495 12989820 13016857 13064646 13071656 13075798 13103652 13119112 13173450 13188899 13191108 13218308 13221250 13315928;

4) Lot Numbers: 9819553 9819558 11057820 11057934 11128481 11128701 11188630 11188633 11254268 11254269 11327810 11327811 11486465 11486466 11591307 11648322 11648324 11687601 11740562 11792533 11828568 11828569 11891601 11933261 11933262 12150199 12295530 12305996 12395349 12463767 12517752

12602517 12619264 12652845 12685511 12687464 12862108 12870991 13074818  
13103999 13129113 13138519 13203489;

5) Lot Numbers: 9720597 9755979 9756229 9813932 9814314 11034603 11035130  
11063713 11063717 11093465 11093640 11153776 11153778 11186490 11186672  
11218848 11218850 11297029 11374028 11374029 11392183 11392185 11533277  
11533278 11544884 11544888 11590117 11590118 11670373 11670374 11682020  
11682021 11738236 11738238 11751778 11751962 11783448 11783449 11820117  
11820400 11847074 11847076 11880513 11880514 11890238 11890239 11909647  
11909649 12011299 12011504 12035650 12035653 12103761 12126706 12145708  
12145716 12174398 12174442 12176836 12176838 12247707 12247719 12256107  
12256112 12274740 12274757 12404311 12425971 12469263 12511836 12554701  
12591792 12644752 12668989 12691285 12742109 12834559 12835799 12847349  
12863315 12872341 12982802 13115358 13120034 13136943 13148608 13313933;

6) Lot Numbers: 9664693 9666853 9695256 9698132 9739398 11000897 11000980  
11054466 11054467 11062673 11062675 11114765 11150891 11150896 11162419  
11162500 11184613 11184618 11202587 11202588 11224039 11224064 11440573  
11440575 11496518 11496519 11537476 11582518 11582519 11611462 11611463  
11648741 11648746 11677545 11677547 11686362 11735097 11756197 11756872  
11773064 11773065 11792820 11792827 11824406 11824407 11864997 11864998  
11870587 11870588 11876728 11926873 11926874 12010500 12010501 12012711  
12069086 12069087 12080433 12094484 12094485 12218376 12218379 12221872  
12222047 12277621 12277625 12403510 12413928 12514613 12562220 12608808  
12622580 12691428 12836476 12907151 12918367 12921603 13097256 13106258  
13136404 13138517 13229828 13233112 13233284;

7) Lot Numbers: 9790074 9790076 11003371 11003538 11059367 11118676 11118678  
11187506 11187507 11242343 11242356 11270352 11296916 11296917 11377103  
11377104 11433735 11434016 11470448 11487990 11488029 11514456 11514458  
11554796 11554991 11610744 11639021 11639030 11677818 11678048 11757152  
11757154 11793164 11793166 11837438 11837483 11876610 11876622 11979808  
11979811 12025013 12025143 12054670 12054671 12066948 12066951 12092005  
12147149 12147208 12163806 12163809 12184724 12184725 12185876 12185878  
12269162 12269163 12277634 12277635 12545679 12600436 12621164 12702786  
12723775 12740615 12830189 12935877 13165824 13187801 13207649 13230712;

8) Lot Numbers: 9797597 9797735 11770153 1177015;

9) Lot Numbers: 9719329 9719476 9729181 9747916 9747921 9785574 9785747  
11006481 11006663 11042916 11043090 11074295 11074881 11115970 11115971  
11160469 11180422 11217496 11217564 11235362 11251397 11251560 11258555  
11258557 11275758 11275941 11318345 11318350 11498129 11498131 11565628  
11588877 11613354 11613355 11645064 11645070 11729278 11729991 11730401  
11744479 11744701 11748621 11748625 11782235 11782320 11804654 11823976  
11823977 11828579 11828765 11846774 11846775 11865642 11865645 11901264

11957879 11957942 11958712 11959235 11968138 11968608 11992410 12017068  
12107569 12107576 12119779 12120061 12140337 12140501 12159709 12159711  
12234169 12234170 12244050 12244051 12250400 12250404 12310678 12320289  
12352241 12376738 12393799 12412806 12450877 12496948 12510971 12535301  
12598614 12601477 12615078 12651492 12676873 12696897 12755536 12779717  
12832673 12843633 12862111 12871361 12901537 12927773 12931867 12982299  
13005936 13052037 13065350 13071860 13121813 13131549 13183683 13190261  
13263228 13313935 13318995;

10) Lot Numbers: 9703315 9714662 9714664 9821713 9821714 11037142 11037488  
11065953 11067756 11085020 11107374 11107379 11119412 11120147 11187951  
11187955 11329333 11330281 11356485 11356486 11393422 11393424 11458543  
11459948 11506685 11506686 11541160 11541162 11578196 11578520 11597599  
11597682 11610973 11610975 11678541 11678549 11696764 11696767 11753789  
11753920 11787647 11787649 11821207 11883892 11883922 11888074 11888321  
11895796 11895845 11907389 11907390 11963638 11964061 12033762 12033763  
12101027 12101029 12113346 12113347 12140516 12140517 12150322 12150326  
12217034 12217323 12225070 12225213 12251730 12251733 12284357 12312841  
12329238 12334705 12377720 12409688 12414272 12426158 12552665 12571603  
12620323 12643126 12654667 12707139 12739832 12746937 12778328 12831272  
12831461 12851487 12868350 12897747 12933682 12975410 12989155 12992395  
12992922 13074849 13149043 13167175 13171927 13204146 13218651 13220534;

11) Lot Numbers: 9634841 9634845 9721675 9727354 9727372 9765848 9766323  
9817320 9817497 9823497 9824440 11005050 11005053 11041572 11041573 11060439  
11061476 11063331 11063374 11096068 11096073 11119006 11119173 11152523  
11153335 11169338 11169594 11197217 11249077 11250366 11255391 11255392  
11260093 11260352 11267520 11268170 11273309 11273315 11338177 11338360  
11357474 11357581 11404600 11404603 11429217 11429701 11465855 11465859  
11478134 11478135 11506003 11506008 11525146 11525151 11560635 11560741  
11563824 11565626 11581527 11581529 11592362 11592363 11601963 11601964  
11647778 11647839 11676517 11676740 11680039 11680220 11700034 11700221  
11703828 11703830 11750111 11750113 11771497 11771664 11774304 11774308  
11774845 11787063 11787064 11814052 11814054 11847077 11847078 11847079  
11847100 11847101 11847102 11875440 11875445 11877337 11877339 11888467  
11888470 11924826 11924839 11925156 11925324 11934143 11934144 12001530  
12001748 12002494 12002820 12008477 12013635 12013636 12014267 12014268  
12033293 12033298 12120841 12120848 12125328 12125523 12148793 12149185  
12199930 12200253 12219246 12219250 12225782 12225783 12238688 12238689  
12298022 12298031 12303604 12316035 12333642 12374153 12384435 12397962  
12403279 12421962 12445505 12479777 12514709 12529441 12565953 12571272  
12605210 12624519 12632783 12639187 12655072 12675646 12685515 12727552  
12739070 12742771 12776530 12829072 12833391 12836271 12860941 12880204  
12895590 12916220 12935597 12976131 12989433 12992137 12992930 13022704  
13047831 13051711 13058915 13072983 13141887 13148451 13149042 13149052  
13180609 13182177 13183332 13185668 13248151 13253753;

12) Lot Numbers: 9752358 11001400 11001402 11057106 11057486 11133494  
11134003 11206281 11206282 11261393 11261396 11337238 11337381 11444217  
11444219 11499381 11499399 11543942 11543945 11592688 11592689 11664729  
11664734 11688255 11688256 11724218 11724381 11794682 11794685 11845373  
11845374 11914027 11914032 11979190 11979425 12034909 12034910 12122990  
12173686 12173687 12185338 12185339 12314457 12396282 12535625 12586819  
12635961 12706496 12749115 12833386 12882124 12937032 13056438 13084405  
13198350;

13) Lot Numbers: 9663612 9693003 9693004 9708705 9709379 9763608 9763610  
9828124 9828280 11027105 11027229 11053709 11076452 11151542 11171283  
11171287 11199522 11203740 11203744 11261000 11261458 11281926 11282276  
11539261 11540270 11582708 11582709 11643976 11644160 11688258 11688640  
11698615 11698685 11724216 11724217 11772331 11772332 11821584 11821588  
11860799 12002002 12002178 12013093 12013094 12018679 12019188 12082197  
12082420 12129860 12129863 12169049 12169051 12181375 12181395 12229947  
12229950 12293029 12293033 12298605 12298607 12317788 12368065 12388264  
12430522 12490847 12495053 12568403 12606620 12624516 12644379 12732528  
12754940 12759600 12830237 12896795 12930767 13015806 3019421 13075118  
13110000 13125440 13232453 13237201;

14) Lot Numbers: 9657941 9658105 9696978 9737028 9822915 9822918 11084897  
11143496 11150354 11150355 11252315 11253322 11485085 11485088 11540266  
11540268 11603795 11605485 11640294 11640296 11716316 11723616 11775490  
11808563 11808564 11871267 11871268 12026243 12026244 12049248 12049249  
12107672 12150138 12150139 12206312 12206316 12239697 12239880 12271577  
12271579 12407609 12441821 12494755 12518886 12570571 12601507 12604799  
12621237 12645436 12697020 12889006 12957090 12986896 13116725;

15) Lot Numbers: 9693597 9707156 9707160 9747573 9814658 11004430 11084430  
11084929 11198518 11205517 11205646 11414976 11414978 11426316 11427030  
11525747 11582705 11582707 11625818 11742318 11754655 11783903 11783916  
11801818 11863663 11863665 11929648 11929649 11984064 11984067 12027354  
12027359 12028637 12072106 12072107 12124357 12124358 12126012 12165276  
12165660 12251056 12338598 12342299 12410559 12465391 12530170 12581224  
12603074 12614784 12639041 12720461 12721047 12829960 12836461 12881567  
12978472 12987063 12989502 13173448 13184243 13196679 13203253 13235388;

16) Lot Numbers: 9788267 9788271 11049037 11056582 11056585 11403326 11403328  
11431343 11717548 11755703 11830899 11831041 11951517 11951518 11959858  
12073643 12147846 12150333 12150334 12351322 12396570 12570576 12622864  
12659254 12833387 12898137 12946945 13199903;

17) Lot Number: 9806034 9806035 11502332 11502334 12333641;

18) Lot Numbers: 9775346 9820252 9821003 11073086 11125407 11162573 11162577  
11209018 11209603 11409760 11425714 11425716 11480359 11482285 11542522  
11542525 11592820 11631290 11753170 11771715 11801806 11801807 11871828  
11871829 11926337 11926338 12049734 12180770 12237417 12278108 12367211  
12374936 12410617 12423649 12536705 12564510 12592185 12701997 12722753  
12905184 12939325 13010286 13058269 13133434 13151193;

19) Lot Numbers: 9819301 11041579 11041980 11095566 11095723 11200891  
11258165 11258427 11441491 11482295 11482672 11526837 11527124 11580505  
11627827 11666837 11666980 11753928 11753933 11869280 11869284 11878524  
11878885 11968615 11968617 12065934 12065937 12084948 12084951 12185009  
12185011 12317446 12394535 12562141 12641804 12672047 12836122 12913900  
13105281 13183699;

20) Lot Numbers: 11021753 11021758 11480991 11480993 11721839 11722425  
11859270 118641921;

21) Lot Numbers: 9710497 9710747 9822080 9822106 11112045 11112046 11184460  
11184466 11201847 11201848 11431347 11477279 11477540 11576821 11624591  
11661903 11662027 11768846 11768848 11873424 12025943 12025945 12110520  
12110523 12163277 12235155 12235454 12270227 12375502 12407153 12470816  
12531186 12604039 12618533 12650205 13131724 13314095;

22) Lot Numbers: 9828690 9828691 11084898 11084899 11207573 11207575  
11503181 11503182 11631699 11631921 11710669 11710670 11750563 11750569  
11807425 11877662 11957664 11957676 11977820 11977826 12105341 12105346  
12297199 12297365 12305456 12305800 12411409 12482912 12485984 12591205  
12624300 12650674 12836583 13168173 13200037;

23) Lot Numbers: 9820027 9820415 11092859 11093048 11752551 11962126  
11962127;

24) Lot Numbers: 9719739 11024662 11026969 11141579 11142082 11234436  
11234516 11579871 11580155 11629573 11720857 11720859 11770928 11770932  
11805568 11805570 11963314 11963318 12160054 12160056 12316137 12371714  
12403737 12464577 12588801 12639049 12853698 12906234 13073202 13104729  
13200936;

25) Lot Numbers: 9712531 9762941 9786756 9786758 11001359 11001979 11043683  
11043800 11078393 11079920 11101039 11156231 11156290 11165772 11165862  
11385291 11416306 11416308 11466396 11486463 11486464 11536291 11536292  
11543527 11543747 11572672 11573001 11592360 11612611 11612614 11700873  
11700879 11736859 11749903 11749912 11785565 11819200 11819204 11827491  
11827975 11843616 11843618 11895264 11906873 11906878 11907383 11907795  
11992543 11992544 11997778 11999498 12032294 12032295 12111093 12111094  
12133077 12133261 12133498 12159529 12159531 12169410 12227755 12227940

12291519 12291601 12316960 12321582 12351310 12354222 12379103 12410878  
12458771 12459865 12493388 12519286 12568893 12605103 12617988 12635145  
12674723 12732191 12776336 12887585 12905643 13006251 13064436 13071724  
13098533 13121663 13177437 13187570 13188674 13221382;

26) Lot Numbers: 9607764 9710083 9755805 9755807 9768417 9780170 9781422  
9807265 9808558 9828820 11000667 1004425 11025299 11025360 11035316 11037596  
11044751 11045323 11059724 11059725 11077979 11089728 11089854 11090227  
11090550 11117598 11117617 11144052 11144056 11161115 11161176 11169321  
11169323 11172782 11172787 11181008 11181009 11223594 11225459 11225720  
11272056 11297064 11345267 11355632 11355901 11378895 11386405 11393437  
11393640 11407218 11422202 11422204 11452161 11452169 11467545 11469425  
11495261 11505745 11505746 11517843 11531097 11531581 11562738 11564170  
11564171 11578121 11578189 11588544 11610966 11610970 11614256 11614257  
11643232 11660971 11676049 11676053 11679449 11679451 11695932 11695933  
11712716 11712961 11731528 11732301 11732307 11732314 11732394 11752640  
11768968 11768970 11785578 11785719 11811929 11811934 11811937 11814041  
11814045 11824069 11824070 11847070 11847071 11847073 11874721 11878009  
11878014 11879531 11879532 11889175 11889176 11895277 11897357 11897881  
11897882 11898065 11898066 11933117 11933119 12002822 12002823 12009747  
12009749 12010111 12010112 12010113 12010114 12019195 12026993 12026994  
12030473 12030476 12063603 12063940 12082473 12082620 12121290 12122287  
12122291 12131566 12131570 12149801 12149802 12175989 12175992 12183041  
12183441 12183444 12189993 12189996 12208356 12208546 12217885 12218027  
12220981 12220982 12221573 12221574 12224645 12265914 12284768 12284863  
12305129 12313575 12326181 12367818 12379040 12386123 12391778 12395945  
12406564 12433678 12448651 12448652 12497202 12509682 12510968 12515884  
12528713 12550761 12554815 12583260 12599567 12601779 12615974 12632667  
12634089 12639184 12642784 12651488 12659759 12675648 12688236 12689565  
12723744 12752291 12773198 12827715 12843003 12850405 12859761 12877471  
12886396 12891104 12901510 12908947 12920883 12953537 13047823 13068377  
13082945 13084926 13085100 13145598 13171637 13174862 13175884 13177730  
13184625 13200422 13200511 13206064 13214653 13215008;

27) Lot Numbers: 9675787 9678955 9678956 9685713 9700042 9701214 9708694  
9718171 9718423 9787116 9806405 9806407 I 9825828 9825829 I 11002211 11002216  
11004224 11022907 11026502 11037598 11038840 11098334 11099064 11114947  
11115457 11125814 11125963 11129766 11154252 11154253 11165895 11186004  
11189618 11189619 11215293 11221076 11221079 11223129 11223130 11286037  
11286086 11324465 11365656 11373612 11379188 11390045 11413568 11413571  
11453152 11453280 11471884 11471885 11495621 11497130 11516427 11517654  
11521978 11526301 11556970 11556972 11605499 11605781 11609300 11613205  
11613748 11613750 11628939 11646227 11646228 11663541 11664190 11715754  
11715758 11718378 11719268 11719763 11733878 11733879 11748775 11755177  
11755284 11776079 11781706 11781714 11806870 11809391 11809666 11819616  
11819745 11823701 11826595 11836818 11839220 11839223 11841655 11841657

11847115 11847116 11860299 11860308 11863346 11863350 11875676 11875678  
11946538 11946539 11947854 11948339 11948989 11959404 11959407 11962428  
11962485 11974712 11986375 11994962 11995194 11995500 11997264 11997271  
12053445 12082841 12106198 12106261 12113045 12123470 12123477 12144389  
12144394 12155695 12155697 12165260 12165268 12195971 12196218 12216228  
12216230 12221236 12221239 12224849 12236070 12262002 12292383 12292388  
12312637 12347521 12348761 12349176 12350357 12357022 12359134 12364763  
12387116 12392378 12402544 12407469 12422732 12426997 12433392 12452638  
12452639 12480309 12512028 12516640 12548558 12566304 12583816 12587489  
12605365 12620519 12626453 12637034 12641949 12653601 12676728 12694132  
12708041 12754409 12761517 12783585 12847116 12851429 12866166 12869743  
12882135 12899102 12928223 12928696 12939851 12955133 13015589 13036331  
13068360 13088446 13112649 13122350 13122408 13125445 13213505 13213675  
13217443 13231039;

28) Lot Numbers: 9677978 9782770 9815916 9818226 11114442 11136721 11293746  
11363706 11363710 11446486 11446487 11469423 11469424 11505595 11533039  
11533260 11609089 11609091 11641656 11641657 11719767 11719779 11724859  
11775292 11810807 11810808 11826778 11827140 11844030 11902674 11976448  
11976450 11983554 11983581 12032282 12032283 12104904 12104909 12165663  
12202729 12240622 12240624 12268113 12268117 12347713 12358111 12389244  
12411182 12493383 12549443 12569914 12625606 12641424 12651730 12670352  
12745821 12836479 12861706 12928786 13020239 13023144 13025849 13103653  
13128160 13241825;

29) Lot Numbers: 11029594 11029595 11226325 11226327 11541170 11542416  
11751348 12028200 12107950 12107953 12186090 12186348 12242724 12242734  
12269818 13165598;

30) Lot Numbers: 9814671 9815162 9821720 9821721 11019719 11039445 11040234  
11061780 11061785 11065663 11065861 11126505 11164159 11164696 11172644  
11172645 11209605 11209607 11460095 11463663 11489095 11489097 11501816  
11550941 11564168 11595564 11614158 11659024 11668908 11668909 11713151  
11717250 11744122 11748292 11752496 11791002 11791007 11808017 11821349  
11828775 11828777 11887496 11908857 11966713 11966717 11986377 11987450  
12000306 12070034 12070035 12084800 12084942 12112346 12112577 12122997  
12122999 12144572 12144574 12158228 12158364 12201191 12202918 12235143  
12235147 12237385 12251546 12251548 12257182 12338350 12339366 12342124  
12350106 12376903 12419809 12460961 12462132 12511148 12545474 12548330  
12589195 12625202 12635828 12656070 12673087 12678279 12695756 12778940  
12884818 12912157 12971590 13003857 13022422 13064129 13074777 13114616  
13117346 13133435 13194248 13194249 13200250 13222371;

31) Lot Numbers: 9802438 9825051 9825183 11028463 11096877 11134525 11134526  
11155266 11183180 11183184 11190929 11190931 11196982 11222307 11222308  
11322699 11322808 11342536 11344628 11412495 11412744 11430286 11471040



11471041 11502877 11502879 11520626 11520627 11560886 11560890 11573251  
11573299 11623680 11643650 11643653 11721511 11721514 11741999 11742422  
11744401 11749506 11749507 11772333 11772334 11790411 11790658 11800001  
11800005 11809015 11809019 11841642 11841643 11847105 11847108 11847140  
11882025 11883117 11883118 11889174 11893116 11894017 11894018 11996479  
12018168 12052699 12052822 12071288 12071290 12082047 12082049 12177977  
12194992 12207113 12207118 12227747 12227750 12342973 12343830 12655844  
12670341 12981613 12993133 12249944 12249956 12254267 12254270 12302279  
12337166 12339597 12408719 12446794 12467731 12561009 12589371 12608594  
12626429 12714003 12747821 12777144 12853912 12884155 12902924 12932464  
13069362 13078443 13147743 13190260 13194410 13240287;

32) Lot Numbers: 9795348 9795351 11072288 11145414 11145416 11206284 11206295  
11502622 11627566 11715171 11775940 11794241 11794243 11967261 11967263  
12108333 12109170 12180191 12180721 12242449 12242450 12391764 12501651  
12624797 12827512 12917370 13022711 13097248 13220248;

33) Lot Numbers: 9681425 9702667 9702668 9717705 9805013 9805176 9826460  
9826461 11043810 11044745 11079254 11079255 11115641 11115646 11127080  
11127082 11148822 11148823 11172971 11173298 11201028 11201034 11262987  
11263514 11459616 11459617 11481585 11481640 11518709 11533436 11533880  
11584312 11584453 11603850 11603853 11633581 11633583 11669424 11669428  
11684387 11684393 11739270 11769537 11769538 11799112 11799114 11837690  
11847111 11847112 11875168 11875169 11912282 11912363 11949659 11949878  
11997274 11999499 12030707 12031033 12068405 12068412 12127111 12127202  
12155219 12155460 12161853 12161858 12168047 12170976 12171120 12189009  
12236551 12236553 12252017 12256858 12256859 12273744 12273745 12286484  
12286486 12375402 12408323 12433248 12444657 12515840 12550410 12581110  
12632664 12644160 12687082 12748618 12765279 12845905 12862780 12865729  
12915206 12950476 12964896 12969284 12972706 13075787 13106646 13173446  
13176567 13193882 13242715 13262862 13264738;

34) Lot Numbers: 9680008 9681085 9700231 9700374 9713320 9713438 9734409  
9802443 9803989 9817872 9818076 11028750 11028754 11058075 11089995 11105176  
11105906 11108385 11108395 11135858 11178064 11178948 11189414 11204847  
11326003 11326946 11346995 11346997 11408405 11408414 11411702 11411704  
11423540 11428371 11441873 11441874 11491180 11491197 11524858 11525005  
11535361 11535693 11555213 11555214 11582710 11582711 11633030 11641651  
11641652 11663056 11663143 11666007 11666008 11681509 11681821 11735629  
11757145 11758767 11789894 11790060 11803647 11803651 11807691 11807695  
11830050 11859112 11859115 11862564 11862566 11871607 11873110 11873111  
11911133 11929647 11931571 11950411 11994278 11994421 12017293 12032796  
12071583 12071584 12085237 12085239 12095745 12155466 12179770 12182204  
12182208 12200624 12236729 12248935 12252556 12252653 12303221 12303225  
12318367 12323565 12355391 12356517 12360258 12392955 12403141 12440786  
12504027 12521810 12565231 12591591 12620468 12634858 12657391 12658631

12678542 12723148 12746136 12756459 12834557 12844740 12852211 12868561  
12871162 12899113 12981367 13004199 13035639 13061429 13065825 13072177  
13077761 13108917 13118617 13177983 13180941 13188824 13190965 13196884  
13281686;

35) Lot Numbers: 9816069 9817313 11036675 11036678 11144629 11144633 11166987  
11166989 11216390 11216391 11323985 11396170 11445664 11482673 11482674  
11573664 11587624 11587625 11632696 11632698 11684142 11729256 11729291  
11758555 11758559 11800671 11857948 11857950 11864916 11864981 11924090  
11924160 11981528 12063950 12063951 12095744 12189616 12219705 12219708  
12222329 12300932 12300934 12323321 12372682 12422996 12493176 12533397  
12607272 12616628 12672122 12723732 12852679 12951197 12974865 13125446  
13191733 13197059;

36) Lot Numbers: 9756366 9756988 11020192 11056395 11099754 11132479 11133187  
11147078 11147156 11169806 11169807 11248614 11257090 11257098 11319126  
11319246 11498702 11499093 11577525 11582509 11582515 11639672 11639674  
11647173 11647422 11703446 11723976 11724210 11748608 11748610 11768753  
11768755 11791250 11791251 11840263 11840266 11862820 11902118 11902460  
11931828 11942286 11944801 12000422 12000425 12075443 12075444 12089895  
12089896 12156911 12156953 12223030 12294304 12294305 12295796 12295798  
12369548 12396685 12432385 12503377 12551946 12583949 12608681 12625461  
12710132 12731246 12748492 12830620 12848174 12869065 12903982 12946195  
12954565 12965789 12969280 12975407 13166713 13176564 13220243 13253488;

37) Lot Number: 9702666 9713744 9815286 9815735 9827448 11023940 11048031  
11048060 11090552 11091623 11100787 11100789 11130407 11130409 11169593  
11199527 11199535 11280856 11280880 11341089 11341176 11432241 11432242  
11449851 11450165 11478740 11478748 11508004 11508006 11544543 11544548  
11580979 11581280 11588652 11588654 11638613 11648449 11648451 11712580  
11712582 11713706 11714530 11749295 11749401 11768151 11768153 11788880  
11795319 11795584 11805726 11805727 11844354 11845372 11847118 11882868  
11882870 11940557 11965234 11965643 11975795 11976130 12031087 12068298  
12068464 12085102 12085111 12128423 12166213 12198180 12198183 12199117  
12199299 12238417 12253760 12272254 12321133 12376164 12394715 12445215  
12467922 12500371 12552399 12572753 12600206 12623799 12639192 12668979  
12715336 12744279 12752674 12833389 12846410 12860388 12877943 12917360  
12954186 12956938 12974683 12996101 13051719 13059606 13068104 13074855  
13076093 13115832 13142196 13181128 13186398 13191494 13281348 13282288;

38) Lot Numbers: 9649130 9649131 9818579 9818588 11107095 11170337 11170339  
11222550 11397903 11448934 11513546 11555992 11595776 11704469 11759267  
11759268 11794636 11794637 11809672 11809674 11847114 11877066 11877068  
12029553 12029554 12074329 12074333 12088528 12088533 12216682 12266301  
12266303 12412119 12551613 12572893 12616327 12639913 12744882 12745231

12834879 12862472 12881353 13016204 13055063 13086404 13176861 13282672  
13284402;

39) Lot Numbers: 9667182 9667456 9678329 976661r 9783326 9784576 11005496  
11005821 11055376 11109805 11110365 11111487 11111488 11124327 11124679  
11129759 11182502 11203182 11203183 11219588 11219589 11262131 11277906  
11279304 11320864 11320865 11327239 11327427 11379196 11379197 11389643  
11389684 11466799 11514285 11514449 11551574 11551706 11603424 11609889  
11609897 11621871 11621875 11723618 11741602 11741603 11790710 11790804  
11824403 11842316 11900249 11900251 11965095 11965222 12018497 12018498  
12072815 12072849 12124056 12124286 12126719 I 12182401 12182408 12203718  
12203719 12233126 12273963 12273964 12311839 12344667 12350349 12355457  
12414762 12503049 12573392 12634334 12673096 12730542 12741518 12749444  
12763036 12828633 12883686 12954041 13068696 13104060 13176719 13203739  
13204940 13209979;

40) Lot Numbers: 11002776, 11003099, 11126514, 11360728, 11360729, 11544244,  
11544247, 11737337, 11820892, 11882664, 11882665, 11984561, 11984652, 12128456,  
12294792, 12294796, 12883308, 13048349;

41) Lot Numbers: 11718271, 11744478, 11791957, 11824076, 11889563, 11889560,  
11909873, 11979879, 12000591, 12032284, 12067614, 12085722, 12147676, 12177136,  
12258645, 12273971, 12279726, 12279727, 12659132, 12668988, 12739530, 12865395;

42) Lot Number: 11724999 11750562 11772144 11789124 11804527 11805916  
11814267 11828772 11838215 11842853 11869860 11871017 11890226 11895585  
11910600 11938641 11946094 11960111 11991499 12010105 12106264 12112949  
12124527 12167829 12201387 12238992 12249808 12271795 12304585 12319567  
12354941 12439846 12464020 12480567 12510365 12547605 12581227 12604481  
12686690 12745544 12860643 12885056 12900596 12915092 12932252;

43) Lot Numbers: 11737197, 11773676, 11873568, 11930246, 11931993, 12106608,  
12123123, 12321371, 12353709, 1242701, 12440418, 12458739, 12601203, 12603432,  
12879476, 12898127, 12921104;

44) Lot Numbers: 11717046 11719760 11722823 11730797 11735875 11739720  
11741378 11749284 11755286 11758547 11766245 11766255 11770935 11772898  
11782339 11782638 11784123 11787640 11788215 11793317 11793678 11799428  
11801070 11808604 11809861 11813051 11823568 11825931 11826764 11828406  
11829617 11830543 11844880 11844881 11846140 11846187 11846250 11846323  
11846955 11846956 118592681 11860780 11862363 11875545 11876855 11878642  
11878895 11881993 11894585 11900366 11902662 11941163 11941475 11944370  
11945112 11958144 11962457 11964441 11964984 11975124 11976613 11978950  
11980458 11985020 11991404 11996203 12000595 12014137 12014819 12025006  
12026984 12029231 12030700 12031548 12071744 12074678 12080439 12089892  
12089893 12093959 12101193 12101344 12107261 12110119 12111716 12119440

12121281 12130410 12143028 12157296 12160343 12163708 12174550 12176831  
12178825 12183838 12186088 12190622 12194341 12194768 12198193 12200254  
12204410 12209757 12216188 12218964 12223445 12225246 12234329 12238454  
12241393 12246949 12249401 12252479 12253467 12262013 12266721 12268185  
12269177 12272831 12273974 12275979 12296685 12297508 12298033 12331011  
12331157 12348053 12351403 12356070 12359234 12359967 12365432 12368067  
12368865 12374844 12392365 12401348 12404546 12409395 12412810 12444650  
12448365 12452453 12459194 12462612 12498755 12502943 12513230 12530171  
12537525 12545037 12545470 12561706 12565956 12581805 12589539 12606199  
12616569 12620516 12672493 12702798 12704719 12739076 12772432 12827735  
12830234 112844257 12863664, 12871880 12917368 12918287 12920840 12844257  
12879017 12846812 12848138 12850863 12853691 12861342 12885055 12886776  
12895814 12912169 12917194 12930021;

45) Lot Numbers: 11717547 11724997 11730506 11733143 11735857 11744473  
11747850 11748115 11748703 11749504 11755828 11757441 11766371 11771487  
11773688 11782909 11784694 11788206 11791252 11793665 11800088 11810542  
11813053 11814272 11823572 11827356 11830766 11842301 11844882 11846141  
11846188 11846324 11846957 11846958 11860236 11863086 11872420 11874726  
11875667 11883102 11889562 11895930 11897032 11901171 11931570 11941341  
11942972 11945162 11946520 11951127 11969421 11982094 11985488 11991796  
11992174 11996653 12002493 12011513 12025015 12025155 12026256 12027554  
12031723 12034907 12072087 12073098 12087523 12104000 12114312 12120992  
12127636 12144382 12149504 12155217 12156134 12159842 12160987 12162782  
12163562 12164645 12176654 12177726 12179420 12180186 12186092 12194918  
12202044 12203137 12219719 12221575 12223039 12224998 12225622 12230470  
12242300 12246956 12254187 12256519 12260117 12266399 12267859 12269995  
12270505 12278319 12310298 12315601 12317781 12318554 12319015 12320698  
12322872 12333093 12334478 12339506 12348305 12351417 12354385 12356602  
12370142 12371627 12375358 12378613 12384525 12386325 12387668 12396150  
12440416 12444651 12448647 12450801 12457782 12492988 12498133 12501390  
12513016 12520688 12534067 12551273 12566989 12583267 12600950 12621171  
12645078 12645845 12657395 12669445 12673338 12703450 12740197 12741282  
12741506 12743202 12757005 12763032 12827702 12829801 12829966 12830765  
12830767 12832989 12844419 12849607 12850057 12859668 12864107 12865389  
12869468 12870028 12888380 12889011 12898412 12908635 12912946 12928517;

46) Lot Numbers: 11715911 11718855 11721501 11733380 11737041 11744475  
11748114 11749836 11753309 11757734 11773068 11776895 11781191 11783079  
11785780 11786669 11792650 11799423 11803891 11804901 11804903 11808603  
11811104 11813797 11825068 11832562 11837798 11839486 11844146 11845994  
11865279 11869709 11870018 11874733 11877079 11878207 11878534 11891873  
11896769 11897031 11900369 11908915 11914976 11931831 11940216 11942191  
11948332 11962704 11963527 11974203 11984656 11985798 11991407 12008476  
12016769 12017234 12017937 12027230 12028942 12034337 12036524 12107397  
12111087 12113254 12119300 12122048 12146152 12157571 12167096 12175984

12176236 12179549 12179914 12182371 12185246 12187448 12194153 12197235  
12199631 12203777 12207559 12221743 12225566 12226307 12232211 12239683  
12243609 12248852 12252040 12260390 12270659 12274852 12279258 12284188  
12293027 12294717 12295056 12296518 12304296 12313566 12320295 12324149  
12354951 12359299 12366728 12371092 12385419 12386549 12396077 12408703  
12438627 12450875 12462664 12468709 12479808 12480061 12483091 12483092  
12526619 12526856 12534769 12537534 12545479 12566190 12567336 12598395  
12601715 12607104 12617159 12623589 12672571 12722466 12742667 12752158  
12757235 12775303 12848177 12859537 12865592 12868161 12868573 12872625  
12881952 12895687 12905523 12913914 12917456 12921791 12950959;

47) Lot Numbers: 11723866, 11739730, 11789848, 11794249, 11832566, 11846146,  
11900857, 11973643, 11993058, 12007767, 12067869, 12083075, 12123937, 12157992,  
12160864, 12165825, 12232307, 12301515, 12310281, 12389357, 12448361, 12673255,  
12740409, 12878205, 12902239;

48) Lot Numbers: 11720486 11741834 11750686 11788787 11804318 11814051  
11824077 11846108 11870368 11870594 11909641 11931304 11974372 11982929  
12001740 12019957 12074676 12157485 12176238 12184464 12229977 12240225  
12297673 12305981 12406877 12464947 12536118 12571835 12882958 12914130  
12931878;

49) Lot Numbers: 11733714, 11795127, 11926208, 11940211, 11944364, 11978370,  
11992346, 12032789, 12113592, 12145289, 12276309, 12407234, 12449703, 12484002,  
12747379;

50) Lot Numbers: 11716102 11718857 11721518 11729141 11730796 11734326  
11737042 11740173 11742379 11747842 11748198 11748762 11751766 11752104  
11754592 11756879 11758874 11770296 11776238 11776423 11776898 11781199  
11783145 11784820 11786304 11786671 11788507 11793161 11800087 11800878  
11801310 11802512 11807680 11808607 11810811 11814431 11818783 11819837  
11820108 11820407 11822154 11822327 11827480 11829502 11838111 11839734  
11841828 11845996 11846102 11846184 11846247 11846252 11846949 11859975  
11861681 11861913 11863668 11877327 11877862 11880678 11883113 11891364  
11893105 11896488 11900240 11914977 11925892 11927140 11928700 11929618  
11929641 11931312 11943402 11944930 11947641 11958156 11958701 11959402  
11959844 11961829 11962134 11963885 11965640 11966958 11968136 11975349  
11977797 11984076 11984648 11987510 11995930 11999494 12007633 12009536  
12019753 12019850 12020700 12030082 12031029 12031379 12033697 12034966  
12067868 12072081 12075092 12080805 12086408 12088435 12089894 12094081  
12094082 12110533 12110939 12112728 12114314 12122375 12131926 12133884  
12140330 12143030 12145921 12148030 12149283 12160348 12168241 12185248  
12187446 12198194 12202732 12205869 12216690 12220041 12220652 12221564  
12223712 12224484 12224976 12225579 12235140 12235973 12253180 12253700  
12256606 12267248 12271794 12274288 12274743 12276749 12284195 12284440  
12293022 12295782 12297192 12304572 12310668 12314805 12320850 12323077

12329983 12330763 12336671 12336862 12340520 12341025 12342292 12347706  
12350476 12356258 12360029 12366256 12373534 12386335 12389512 12397531  
12406352 12419884 12432704 12438074 12438891 12439219 12447537 12448648  
12459331 12464438 12468706 12490240 12490247 12500831 12503264 12508815  
12508894 12512820 12512835 12516424 12520535 12530001 12534572 12547698  
12548555 12552381 12553585 12567326 12568885 12577395 12642875 12643419  
12645257 12654186 12678494 12686552 12690598 12722273 12723863 12780647  
12827835 12844407 12846151 12847549 12849601 12853101 12855377 12860946  
12862476 12864723 12866598 12868576 12880571 12884150 12884814 12887592  
12888765 12895363 12896895 12899207 12900009 12902141 12906760 12912761  
12918033 12920616 12921783 12929726 12932257 12932807;

51) Lot Numbers: 11716747 11719459 11721821 11729926 11729998 11731974  
11731983 11734667 117401681 11748529 11748768 11752059 11757914 11766370  
11767173 11770846 11776069 11777140 11781775 11784015 11787078 11793310  
11794248 11799820 11801118 11802514 11803110 11809195 11810170 11811464  
11820413 11821001 11822969 11826373 11831892 11838256 11838878 11839736  
11844020 11846185 11846248 11846253 11846951 11846953 11858576 11861902  
11863820 11871706 11875454 11876887 11880510 11883101 11891860 11892090  
11893164 11898231 11898232 11905969 11909657 11913442 11926201 11926876  
11930247 11930248 11940106 11942632 11945163 11947855 11947856 11958960  
11958965 11960293 11960789 11966833 11967086 11974373 11980938 11983599  
11985454 11991968 11994271 11994745 11995508 11997279 12000316 12002171  
12020711 12028205 12031085 12036202 12071753 12081195 12088720 12090373  
12103455 12104002 12113175 12120857 12125768 12126304 12130611 12132860  
12143419 12167827 12170973 12174452 12177448 12181376 12183455 12185865  
12199514 12202572 12204721 12205766 12206478 12215868 12217072 12221748  
12222787 12224170 12224983 12226310 12230469 12236287 12241937 12242446  
12247537 12256681 12260344 12261778 12270641 12277629 12277716 12284878  
12286552 12292490 12294566 12295525 12298435 12298619 12299291 12303231  
12317109 12322291 12322876 12336666 12339193 12350706 12356418 12358035  
12359808 12369556 12373110 12374928 12375936 12377238 12378467 12391988  
12402898 12411192 12448650 12458095 12464951 12468986 12469409 12493640  
12495520 12504814 12513458 12521091 12530616 12535032 12535250 12545690  
12551951 12553334 12562537 12566799 12577393 12579867 12589363 12590909  
12650905 12650919 12651073 12651493 12651739 12658453 12671016 12676815  
12690802 12696732 12722747 12723422 12752297 12754746 12758346 12759743  
12763271 12771600 12837116 12853231 12859758 12861354 12864736 12867422  
12869971 12872081 12878780 12880787 12891195 12895995 12899912 12914733  
12920992 129280381 129318721;

52) Lot Number: 11719602 11722423 11729258 11732395 11735494 11740570  
11748770 11752427 11769386 11773338 11777262 11781839 11782525 11787376  
11789954 11793314 11800869 11802155 11802156 11802392 11803116 11805913  
11809388 11811477 11819214 11820113 11821346 11825934 11829503 11837699  
11838728 11840630 11845911 11845999 11846186 11846954 11859652 11861339

11861519 11876752 11880158 11881724 11882311 11888837 11890230 11890763  
11893928 11896626 11900853 11914975 11943410 11944929 11945718 11947640  
11951128 11961828 11964989 11968323 11974818 11978689 11981527 11981530  
11985023 11987143 11992549 11995198 11997771 12000238 12001058 12017294  
12033555 12036413 12067309 12070913 12082058 12083306 12086237 12090369  
12105453 12108657 12110531 12125572 12131256 12132690 12141283 12141424  
12155213 12155470 12160040 12161209 12164029 12183457 12186933 12187088  
12190264 12196946 12201088 12217880 12220986 12224963 12228179 12229650  
12232155 12233566 12234040 12236724 12243605 12248412 12251722 12253571  
12262233 12266386 12274285 12299880 12310295 12311332 12315456 12332393  
12340662 12343184 12351555 12353153 12355764 12357518 12359391 12366246  
12367506 12371527 12384931 12392116 12393931 12395275 12401290 12422392  
12443899 12447623 12457607 12463314 12492570 12510368 12512594 12516809  
12518973 12530906 12546387 12548326 12552886 12562588 12566844 12568154  
12573314 12585649 12588803 12591982 12601924 12605701 12613136 12613556  
12615503 12617361 12642799 12675523 12686268 12693937 12723557 12870849  
12878017 12885918 12889226 12897317 12898258 12908632 12912758 12916654  
12917193 12927770 12931440 12932852 12953533 12953686;

53) Lot Numbers: 11724987 11724988 11734435 11737583 11748771 11748772  
11756570 11783350 11784125 11784126 11788500 11788503 11789459 11789742  
11791144 11812880 11838269 11839624 11839625 11846978 11862055 11862180  
11864139 11864324 11872977 11873066 11881271 11881274 11897035 11897036  
11897037 11899692 11899698 11931126 11933274 11933275 11946248 11946258  
11948987 11948996 11964769 11964770 11967548 11967553 11977090 11977095  
11978680 11978685 11992342 11992546 12000584 12009401 12015328 12015330  
12019592 12028945 12028946 12072518 12072702 12075379 12075447 12087138  
12088069 12088079 12088429 12095741 12095742 12120601 12120607 12133899  
12134066 12145573 12146922 12155699 12156122 12160344 12165839 12178975  
12179041 12182459 12182821 12197976 12206065 12208161 12217860 12225458  
12225459 12226308 12226309 12241286 12241291 12267605 12273755 12302865  
12302866 12323320 12373984 12378799 12401568 12404304 12408206 12425916  
12440785 12492053 12509060 12520229 12527380 12545466 12559352 12563316  
12588686 12779710 12868020 12873723 12913911 12946192;

54) Lot Numbers: 11717711 11724773 11724821 11740949 11740950 11758120  
11773829 11773830 11776233 11781153 11823969 11783845 11824410 11784685  
11785961 11825268 11841440 11787065 11845370 11789049 11845371 11789057  
11859979 11812345 11860149 11823964 11870001 11872198 11872240 11879539  
11879701 11909989 11909991 11926787 11928990 11939030 11940208 11942768  
11942770 11944927 11944928 11948620 11948621 11964244 11969470 11975135  
11975138 11976455 11976458 11978050 11980066 11981134 11981136 11987447  
11987449 11991648 11992547 11992548 11993075 11999174 11999301 12012794  
12012796 12015068 12015069 12018344 12018346 12020717 12020762 12028625  
12028626 12070326 12070331 12086417 12088066 12092750 12092932 12101606  
12104901 12108334 12108336 12114110 12141917 12144954 12144957 12148033

12148035 12161936 12167107 12167110 12175221 12175224 12200060 12200870  
12202393 12202394 12204539 12215871 12225291 12256259 12270642 12270651  
12310934 12312393 12317119 12320759 12336867 12353989 12358206 12378610  
12394716 12396146 12412092 12445307 12466351 12495403 12499619 12534929  
12549245 12550831 12579546 12583810 12607730 12757227 12759139 12851965  
12867689 12877475 12884421 12887318 12901429 12912301 12930193 12950469;

55) Lot Numbers: 11719777 11725283 11725285 11731295 11733159 11733871  
11736240 11736245 11748221 11748222 11769533 11769534 11770660 11773069  
11781831 11785979 11786181 11804308 11805464 11805927 11811114 11811115  
11818475 11837788 11846979 11847061 11847062 11863089 11863095 11863828  
11869296 11869297 11873760 11874291 11874294 11882312 11882313 11898225  
11898226 11909787 11930243 11932623 11945700 11951637 11952126 11958154  
11958155 11960385 11960393 11962429 11962483 11967085 11967545 11980803  
11980814 11982653 11991875 11994430 11996651 11998952 12009046 12010821  
12010822 12016310 12020766 12020767 12027558 12030201 12030205 12074060  
12074063 12091024 12091025 12092122 12104701 12114475 12140967 12157547  
12181371 12207523 12127208 12133084 12133089 12134191 12134193 12140325  
12140857 12157549 12158887 12159025 12174459 12174542 12179559 12179762  
12207527 12223707 12223708 12231513 12231515 12243095 12243096 12258817  
12259636 12259638 12260762 12260769 12266966 12271481 12291496 12297083  
12297086 12310288 12310290 12315146 12319215 12329858 12332564 12337624  
12368066 12376074 12384123 12389243 12391993 12403515 12407131 12414945  
12434427 12479810 12511711 12520902 12533381 12533534 12554981 12562315  
12568674 12584795 12589918 12643281 12848192 12859858 12863307 12895028  
12897936 12902732 12908445 12918858 12921793 12935498 12953825;

56) Lot Numbers: 11719045 11724984 11730519 11739735 11758860 11766259  
11774495 11777143 11795313 11795315 11795747 11795763 11796008 11801027  
11801490 11802516 11803656 11820724 11821974 11842687 11844355 11844358  
11846564 11846567 11859311 11870370 11870914 11879533 11881728 11881733  
11896058 11898224 11912084 11912087 11939279 11939387 11941468 11943227  
11943231 11944923 11946808 11950577 11950579 11957955 11957956 11959226  
11959229 11959854 11962714 11962715 11966089 11966095 11976134 11976136  
11980941 11980948 11984100 11985490 11986052 11993327 11994703 12000431  
12012604 12013638 12018783 12018793 12025261 12027612 12027618 12031725  
12031735 12069097 12069098 12070679 12070760 12080426 12091026 12092333  
12110014 12110472 12112183 12121139 12121211 12124535 12125531 12126010  
12129557 12129558 12130322 12130613 12130615 12130919 12167505 12167509  
12175379 12190056 12194142 12196631 12202053 12202058 12217038 12217074  
12224497 12224498 12224808 12225780 12229300 12232510 12232513 12239805  
12239811 12241299 12241500 12265999 12266244 12269166 12277042 12298771  
12299625 12299626 12304008 12321580 12331558 12341876 12360093 12368636  
12384937 12395288 12413526 12444004 12457796 12464955 12496904 12513232  
12515792 12517009 12517326 12526858 12530160 12609036 12744766 12774480



12783325 12844409 12849086 12854719 12865029 12879551 12885635 12887673  
12899623 12914805 12954056

**RECALLING FIRM/MANUFACTURER**

Boston Scientific Corp., Marlborough, MA, by letter dated May 17, 2010. Firm initiated recall is ongoing.

**REASON**

Suture related device failures during deployment and repositioning of the stent.

**VOLUME OF PRODUCT IN COMMERCE**

9,297 tracheobronchial; 4,834 Esophageal

**DISTRIBUTION**

Nationwide

---

**PRODUCT**

IMMULITE 2000/2500 Chemiluminescent Substrate Module For the use in the routine operation of the IMMULITE 2000 and IMMULITE 2500 Analyzer. Recall # Z-1891-2010

**CODE**

Substrate lot L2SUBX 253 packed into Module L2SUBM 282 (EXP: 2010-07-31);  
Substrate lot L2SUBX 254 packed into Module L2SUBM 283 (EXP:2010-07-31);  
Substrate lot L2SUBX 255 packed into Module L2SUBM 284 (EXP: 2010-07-31);  
Substrate lot L2SUBX 256A packed into Module L2SUBM 288 (EXP:2010-08-31);  
Substrate lot L2SUBX 257A packed into Module L2SUBM 286 (EXP:2010-08-31);  
Substrate lot L2SUBX 258 packed into Module L2SUBM 285 (EXP: 2010-08-31);  
Substrate lot L2SUBX 259A packed into Module L2SUBM 287 (EXP: 2010-08-31)

**RECALLING FIRM/MANUFACTURER**

Siemens Healthcare Diagnostics, Inc., Los Angeles, CA, by letter dated May 2009. Firm initiated recall is ongoing.

**REASON**

These substrate lots have shown a tendency to introduce a shift in both control and patient results with multiple methods.

**VOLUME OF PRODUCT IN COMMERCE**

41,573 units

**DISTRIBUTION**

Nationwide

---

**PRODUCT**

Syngo Imaging Version Lines VB20, VB30, VB35 in combination with a RIS.  
Material number 10014063. Recall # Z-1892-2010

**CODE**

Serial number: 1043, 1114, and 1198

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Siemens Medical Solutions USA, Inc., Malvern, by letter dated April 6, 2010.

Manufacturer: Siemens Medical Solutions Inc., Erlangen, Germany. Firm initiated recall is ongoing.

**REASON**

Siemens has become aware of a potential malfunction and hazard to patients when using Syngo Imaging version lines VB20, VB30, VB35A in combination with a RIS that is violating DICOM Standard by creating non-unique study instance UIDs.

**VOLUME OF PRODUCT IN COMMERCE**

3 units

**DISTRIBUTION**

CT, NM, WI

---

**PRODUCT**

Trilogy 100 Ventilator, Model/Catalog Number 1054260, U1054260 (Domestic). Provides continuous or intermittent ventilatory support for the care of individuals who require mechanical ventilation. Recall # Z-1896-2010

**CODE**

Serial Numbers: TV110051146, TV110051147, TV110051347, TV110051335, TV110050717, TV110052245, TV110051033, TV110051130, TV110050733, TV110051133, TV110051336, TV110051144, TV110051241, TV110051236, TV110051344, TV110051333, TV110051338, TV110051340, TV110051352, TV110051348

**RECALLING FIRM/MANUFACTURER**

Respironics, Inc., Murrysville, PA, by telephone beginning June 10, 2010. Firm initiated recall is ongoing.

**REASON**

It is possible that the battery could electrically short, resulting in a potential for fire or a thermal event.

**VOLUME OF PRODUCT IN COMMERCE**

23 units

**DISTRIBUTION**

MT, IL, NY, NC, TX, CA, FL, France, South Korea and Turkey

---

**PRODUCT**

Lenstar LS 900, Biomicroscope, Slit-Lamp, AC-powered. Used for obtaining ocular measurements and performing calculations to assist in determination of the appropriate power and type of Intraocular Lens for implantation after removal of the natural crystalline lens following cataract removal. Recall # Z-1897-2010

**CODE**

Serial Numbers: 223, 224, 225, 284, 285, 316, 317, 319, 320, 322, 323, 324, 325, 327, 330, 331, 332, 333, 364, 365, 366, 368, 369, 377, 378, 379, 381, 384, 385, 386, 405, 407, 408, 409, 411, 412, 413, 415, 416, 452, 454, 460, 461, 490 and 494

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Haag-Streit USA Inc., Mason, OH, by letters beginning May 19, 2010. Manufacturer: Haag Streit Ag, Koeniz, Switzerland. Firm initiated recall is ongoing.

**REASON**

During the creation of the Lenstar LS 900 software, the ability to perform a manual adjustment of the retinal thickness measurement was not disabled for products targeted for US distribution. The current software installed allows the user to manually alter the retinal thickness measurement, which could modify the automatic axial eye length

measurement resulting in the selection of an incorrect intra-ocular lens (IOL).

**VOLUME OF PRODUCT IN COMMERCE**

45 units

**DISTRIBUTION**

Nationwide

---

**PRODUCT**

Genesis II Tibial Drill Guide, REF 71440238, Size 5, Qty (1), Non-Sterile. Drill guide used as manual surgical instrument during knee replacement surgeries. Recall # Z-1900-2010

**CODE**

Batch # 08JM07761 and 08JM07761A

**RECALLING FIRM/MANUFACTURER**

Smith and Nephew, Inc., Memphis, TN, by letter dated April 16, 2010 and by e-mail on April 20, 2010. Firm initiated recall is ongoing.

**REASON**

Markings for the drill guides are on the incorrect side: left is printed on right side and right is printed on the left side.

**VOLUME OF PRODUCT IN COMMERCE**

12 units

**DISTRIBUTION**

Belgium, Spain, Germany, Australia, and Brazil

---

**PRODUCT**

1) VARIANT II Hemoglobin Testing System with CDM 3.5 Software Version 3.5; Model Number: 270-2000; Provides an integrated method for sample preparation, separation and determination of the relative percent of specific hemoglobin in whole blood. Recall # Z-1901-2010;

2) VARIANT II TURBO Hemoglobin Testing System with CDM 3.6T Software Version 3.5; Model Number: 270-2600; Provides an integrated method for sample preparation, separation and the percent determination of percent hemoglobin A1C in EDTA human whole blood. Recall # Z-1902-2010

**CODE**

All units of these models.

**RECALLING FIRM/MANUFACTURER**

Bio-Rad Laboratories, Inc., Hercules, CA, by letter dated January 22, 2009 followed by telephone calls. Firm initiated recall is ongoing.

**REASON**

Sample test results for the first run appears to be correct but all subsequent results during that run were assigned incorrect barcode and tube position.

**VOLUME OF PRODUCT IN COMMERCE**

397 units

**DISTRIBUTION**

Nationwide and Internationally

---

**PRODUCT**

Hydradjust IV DR Urological Table Sedecal Generator ( a) p/n 750732 - 64W generator & b) p/n 750733 80W generator). Facilitates digital radiologic and/or fluoroscopic procedures requiring a beam of diagnostic quality radiation and a flat imaging table. Recall # Z-1904-2010

**CODE**

a) Serial Numbers: G28619, G28622, G28623, G28625, G28627, G28630, G28633, G28668, G28669, G28679, G28680, G28924, G28926, G28928, G28930, G28939, G28997, G29001, G29002, G29006, G29028, G29029, G29063, G29064, G29065, G29068, G29069, G29070, G29071, G29138, G29141, G29143, G29151, G29155, G29157, G29162, G29234, G29236, G29238, G29242, G29243, G29248, G29257, G29258, G29261, G29265, G29268, G29277, G29814, G30632, G30635, G30852, G30856, G31123, G31128, G31134, G31344, G31347, G31355, G31359, G31435, G31437, G31439, G31440, G31503, G31505, G31609, G31610, G31612, G31614, G31616, G32275, G32279, G32284, G32288, G32290, G32456, G32461, G32463, G32464, G32468, G32470, G32476, G32511, G32516, G32518, G32520, G32523, G32524, G32537, G32541, G32565, G32566, G32568, G32571, G32578, G32644, G32647, G32649, G32650, G32774, G32776, G32778, G32779, G32786, G32912, G32914, G32915 and G32922; b) Serial Numbers: G29230, G29891, G30029, G30171, G30172, G30174, G30180, G30322, G30325, G30661, G30666, G30799, G30801, G31007, G31010, G31307, G31310, G315881, G32292, G32535, G32771, G32773, G32918, G-32924, G-32976, G329821, G33085, G33086, G33090, G33361, G33874, G33876, G34118, G34128 and G34232

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Mallinckrodt, Inc., Cincinnati, OH, by letter dated June 14, 2010. Manufacturers: Sedecal USA, Inc., Arlington Heights, IL; Sedecal S.A., Algete, Spain. Firm initiated recall is ongoing.

**REASON**

Covidien received complaints of the Sedecal Generator failing and producing smoke at customer sites. The failure modes are located in different parts of the generator and will lead to the generator becoming inoperative.

**VOLUME OF PRODUCT IN COMMERCE**

144 units

**DISTRIBUTION**

Nationwide, Canada and China

---

**PRODUCT**

GammaCoat Plasma Renin Activity 125 I RIA Kit, REF: CA-1533 (100 test kit), CA-1553 (500 test kit). Indicated for the quantitative determination of plasma renin activity (PRA) by the radioimmunoassay of generated angiotension I. Recall # Z-1914-2010

**CODE**

Lot numbers: 123574A, 123612A, 123612C, 123620, 123620A, 123574, 123612, and 123612B

**RECALLING FIRM/MANUFACTURER**

DiaSorin, Inc., Stillwater, MN, by letter dated October 21, 2009. Firm initiated recall is ongoing.

**REASON**

The kit control provided with the GammaCoat Plasma Renin Activity kit was labeled with the incorrect range.

**VOLUME OF PRODUCT IN COMMERCE**

289 kits

**DISTRIBUTION**

CA, CT, IN, LA, MI, NC, OH, TN, UT, WA, Canada, Belgium, Brazil, India, Norway, Portugal, Spain, and Sweden

---

**PRODUCT**

1) Automated External Defibrillator (AED) of brand name "Philips HeartStart FRx" (Model number 861304). Device is designed for use on a person in sudden cardiac arrest who is unresponsive when shaken and not breathing normally. Recall # Z-1915-2010;

2) Automated External Defibrillator (AED) of brand name "Philips HeartStart HS1 OnSite" (Model number M5066A). Device is designed for use on a person in sudden cardiac arrest who is unresponsive when shaken and not breathing normally. Recall # Z-1916-2010;

3) Automated External Defibrillator (AED) of brand name "Philips HeartStart HS1 Home" (Model Number M5068A). Device is designed for use on a person in sudden cardiac arrest who is unresponsive when shaken and not breathing normally. Recall # Z-1917-2010

**CODE**

1) Serial Numbers: B10C-02133, B10C-02135, B10C-02136, B10C-02172, B10C-02196, B10C-02475, B10C-02477, B10C-02478, B10C-02480, B10C-02481, B10C-02494, B10C-02495, B10C-02499, B10C-02610, B10C-02631, B10C-02634, B10C-02639, B10C-02640, B10C-02641, B10C-02644, B10C-02645, B10C-02646, B10C-02647, B10C-02648, B10C-02651, B10C-02652, B10C-02653, B10C-02654, B10C-02655, B10C-02660, B10C-02674, B10C-02685, B10C-02702, B10C-02704, B10C-02705, B10C-02706, B10C-02707, B10C-02708, B10C-02709, B10C-02712, B10C-02713, B10C-02715, B10C-02717, B10C-02718, B10C-02719, B10C-02720, B10C-02721, B10C-02722, B10C-02723, B10C-02724, B10C-02725, B10C-02729, B10C-02732, B10C-02733, B10C-02734, B10C-02735, B10C-02736, B10C-02740, B10C-02742, B10C-02743, B10C-02744, B10C-02745, B10C-02746, B10C-02747, B10C-02749, B10C-02771, B10C-02779, B10C-02780, B10C-02781, B10C-02782, B10C-02783, B10C-02784, B10C-02785, B10C-02801, B10C-02805, B10C-02806, B10C-02816, B10C-02818, B10C-02822, B10C-02823, B10C-02824, B10C-02826, B10C-02830, B10C-02831, B10C-02832, B10C-02835, B10C-02836, B10C-02837, B10C-02838, B10C-02839, B10C-02840, B10C-02841, B10C-02843, B10C-02844, B10C-02845, B10C-02846, B10C-02847, B10C-02848, B10C-02849, B10C-02850, B10C-02851, B10C-02852, B10C-02853, B10C-02854, B10C-02855, B10C-02856, B10C-02858, B10C-02879, B10C-02881, B10C-02884, B10C-02886, B10C-02895, B10C-02896, B10C-02897, B10C-02900, B10C-02904, B10C-02905, B10C-02906, B10C-02907, B10C-02908, B10C-02909, B10C-02910, B10C-02911, B10C-02912, B10C-02913, B10C-02914, B10C-02915, B10C-02917, B10C-02919, B10C-02928, B10C-02929,

B10C-02933, B10C-02937, B10C-02938, B10C-02943, B10C-02947, B10C-02948, B10C-02949, B10C-02950, B10C-02957, B10C-02965, B10C-03018, B10C-03019, B10C-03020, B10C-03021, B10C-03023, B10C-03024, B10C-03026, B10C-03040, B10C-03041, B10C-03042, B10C-03043, B10C-03045, B10C-03046, B10C-03047, B10C-03048, B10C-03049, B10C-03050, B10C-03119, B10C-03120, B10C-03121, B10C-03122, B10C-03123, B10C-03124, B10C-03125, B10C-03126, B10C-03127, B10C-03128, B10C-03156, B10C-03157, B10C-03158, B10C-03159, B10C-03160, B10C-03171, B10C-03175, B10C-03176, B10C-03178, B10C-03179, B10C-03180, B10C-03182, B10C-03194, B10C-03195, B10C-03196, B10C-03197, B10C-03198, B10C-03199, B10C-03200, B10C-03202, B10C-03203, B10C-03204, B10C-03205, B10C-03207, B10C-03208, B10C-03212, B10C-03213, B10C-03218, B10C-03247, B10C-03248, B10C-03251, B10C-03253, B10C-03255, B10C-03256, B10C-03257, B10C-03258, B10C-03259, B10C-03260, B10C-03262, B10C-03263, B10C-03265, B10C-03266, B10C-03267, B10C-03268, B10C-03269, B10C-03270, B10C-03271, B10C-03272, B10C-03273, B10C-03274, B10C-03275, B10C-03276, B10C-03286, B10C-03287, B10C-03288, B10C-03289, B10C-03290, B10C-03291, B10C-03292, B10C-03293, B10C-03295, B10C-03296, B10C-03297, B10C-03310, B10C-03329, B10C-03330, B10C-03332, B10C-03334, B10C-03335, B10C-03336, B10C-03338, B10C-03339, B10C-03340, B10C-03342, B10C-03349, B10C-03350, B10C-03355, B10C-03359, B10C-03360, B10C-03361, B10C-03362, B10C-03363, B10C-03364, B10C-03366, B10C-03367, B10C-03369, B10C-03384, B10C-03386, B10C-03437, B10C-03450, B10C-03451, B10C-03452, B10C-03453, B10C-03483, B10C-03484, B10C-03486, and B10C-03901;

2) Serial Numbers: A10C-04048, A10C-04050, A10C-04300, A10C-04301, A10C-04302, A10C-04315, A10C-04316, A10C-04317, A10C-04318, A10C-04319, A10C-04320, A10C-04321, A10C-04322, A10C-04324, A10C-04325, A10C-04326, A10C-04327, A10C-04328, A10C-04330, A10C-04332, A10C-04333, A10C-04334, A10C-04335, A10C-04337, A10C-04338, A10C-04339, A10C-04340, A10C-04351, A10C-04352, A10C-04353, A10C-04354, A10C-04356, A10C-04357, A10C-04358, A10C-04359, A10C-04360, A10C-04361, A10C-04363, A10C-04364, A10C-04365, A10C-04366, A10C-04367, A10C-04368, A10C-04369, A10C-04611, A10C-04763, A10C-04812, A10C-04824, A10C-04824, A10C-05077, A10C-05078, A10C-05079, A10C-05080, A10C-05081, A10C-05083, A10C-05086, A10C-05087, A10C-05088, A10C-05089, A10C-05098, A10C-05151, A10C-05185, A10C-05191, A10C-05206, A10C-05207, A10C-05211, A10C-05212, A10C-05215, A10C-05216, A10C-05219, A10C-05233, A10C-05314, A10C-05315, A10C-05324, A10C-05397, A10C-05398, A10C-05429, A10C-05554, A10C-05569, A10C-05570, A10C-05571, A10C-05575, A10C-05578, A10C-05579, A10C-05580, A10C-05581, A10C-05583, A10C-05584, A10C-05585, A10C-05586, A10C-05587, A10C-05588, A10C-05591, A10C-05592, A10C-05593, A10C-05594, A10C-05595, A10C-05597, A10C-05599, A10C-05600, A10C-05751, A10C-05752, A10C-05759, A10C-05763, A10C-05764, A10C-05765, A10C-05767, A10C-05768, A10C-05769, A10C-05770, A10C-05771, A10C-05772, A10C-05775, A10C-05776, A10C-05777, A10C-05778, A10C-05779, A10C-05780, A10C-05781, A10C-05784, A10C-05785, A10C-05786, A10C-05787, A10C-05788, A10C-05789, A10C-05791, A10C-05792, A10C-05800, A10C-05913, A10C-05941, A10C-

05968, A10C-05969, A10C-05970, A10C-05976, A10C-05977, A10C-05982, A10C-05983, A10C-06001, A10C-06002, A10C-06003, A10C-06006, A10C-06011, A10C-06013, A10C-06018, A10C-06020, A10C-06026, A10C-06027, A10C-06028, A10C-06354, A10C-06355, A10C-06356, A10C-06357, A10C-06358, A10C-06359, A10C-06360, A10C-06361, A10C-06364, A10C-06365, A10C-06366, A10C-06367, A10C-06368, A10C-06369, A10C-06370, A10C-06371, A10C-06372, A10C-06373, A10C-06374, A10C-06375, A10C-06376, A10C-06377, A10C-06378, A10C-06379, A10C-06381, A10C-06382, A10C-06383, A10C-06384, A10C-06385, A10C-06386, A10C-06387, A10C-06388, A10C-06390, A10C-06391, A10C-06392, A10C-06393, A10C-06394, A10C-06395, A10C-06396, A10C-06399, A10C-06400, A10C-06401, A10C-06402, A10C-06403, A10C-06404, A10C-06405, A10C-06406, A10C-06407, A10C-06408, A10C-06410, A10C-06411, A10C-06417, A10C-06418, A10C-06419, A10C-06420, A10C-06421, and A10C-06423;

3) Serial Numbers: A10C-05951

**RECALLING FIRM/MANUFACTURER**

Philips Medical Systems, Seattle, WA, by telephone, e-mail, and website posting on April 30, 2010 and by letter dated April 29, 2010. Firm initiated recall is ongoing.

**REASON**

Seventeen AEDs failed production line testing (Final Acceptance Test).

**VOLUME OF PRODUCT IN COMMERCE**

458 units

**DISTRIBUTION**

Nationwide, Canada, Japan, United Arab Emirates, Austria, Switzerland, Germany, Spain, France, Italy, and Norway

---

**PRODUCT**

1) MIRA CR4050 12mm Finger Probe 12mm surface x 27mm Length Intended for the destruction of tumors. Recall # Z-1918-2010;

2) MIRA CR4055 25mm Finger Probe 25mm surface x 30mm Length Intended for the destruction of tumors. Recall # Z-1919-2010;

3) MIRA CR4060 68 mm Finger Probe 68mm surface x 37mm Length Intended for the destruction of tumors. Recall # Z-1920-2010

**CODE**

1) SER# W04643-1 SER# 45-1109 SER# 44-1109 One Unit no Serial Number;

2) SER# W04672-1 SER# 47-0505 SER# 48-0508 SER# 03-0506 One Unit no Serial Number;

3) SER#W04712-1 SER# W04690-1 SER# 01-1205 SER# 02-0506 One Unit no Serial Number

**RECALLING FIRM/MANUFACTURER**

Mira, Inc., Uxbridge, MA, by e-mail between April 8, 2010 and May 21, 2010. Firm initiated recall is ongoing.

**REASON**

Devices distributed without an approved 510(k).

**VOLUME OF PRODUCT IN COMMERCE**

15 units

**DISTRIBUTION**

Nationwide, Israel and Italy

---

**PRODUCT**

1) Innova 2100IQ system with InnovaIQ Table Option Indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures, and optionally, rotational imaging procedures. Recall # Z-1921-2010;

2) Innova 3100/ 3100IQ system with InnovaIQ Table Option Indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures, and optionally, rotational imaging procedures. Recall # Z-1922-2010;

3) Innova 4100/4100IQ system with InnovaIQ Table Option Indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures, and optionally, rotational imaging procedures. Recall # Z-1923-2010

**CODE**

1) Units: 00000553797BU2, 00000000075WV2, 00000000112WV3, 00000000153WV7, 00000000146WV1, 00000000023WV2, 00000000162WV8, 00000000079WV4, 00000000149WV5, and 00000000033WV1;

2) Units: 00000008C20323, 00000519107BU7, 00000007C20116, 00000464098BU3, - 00000000057WV0, 00000000086WV9, 00000000130WV5, 00000000050WV5, 00000000083WV6, 00000000193WV3, 00000000203WV0, and 00000000076WV0;

3) Units: 00000008C20212 00000453925BU0 00000000200WV6 00000000154WV5  
00000000077WV8 00000000150WV3 00000000127WV1 00000000084WV4  
00000000040WV6 00000000046WV3 00000000148WV7 00000000051WV3  
00000000169WV3 00000000133WV9 00000000145WV3 00000000080WV2  
00000000034WV9 00000000088WV5 00000000147WV9 00000000037WV2  
00000000035WV6 00000000052WV1 00000000129WV7 00000000141WV2  
00000000113WV1 00000000055WV4 00000000189WV1 00000000131WV3  
00000000190WV9 00000000022WV4 00000000087WV7 00000000163WV6  
00000000230WV3 00000000134WV7 00000000058WV8 00000000044WV8  
00000000043WV0 00000000144WV6 00000000140WV4 00000000164WV4  
00000000152WV9 00000000039WV8 00000000136WV2 00000000025WV7  
00000000139WV6 00000000199WV0 00000000041WV4 00000000024WV09  
00000000054WV7 00000000165WV10 00000000198WV2 00000000191WV70  
00000000156WV0 00000000157WV8 00000000211WV3 00000000132WV1  
00000000026WV5 00000000158WV6 00000000205WV5 00000000143WV8



0000000049WV7 00000000168WV5 00000000078WV6 00000000240WV2  
00000000210WV5 00000000160WV2 00000000085WV1 00000000036WV4, and  
00000000038WV0

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: GE Healthcare, LLC, Waukesha, WI, by letter dated May 12, 2010.  
Manufacturer: GE Medical Systems, SCS, Buc Cedex, France. Firm initiated recall is ongoing.

**REASON**

GE Healthcare has become aware of a potential loss of gantry and table motions affecting Innova 2100IQ, 3100, 3100IQ, 4100 and 4100IQ systems with InnovaIQ Table that may impact patient safety.

**VOLUME OF PRODUCT IN COMMERCE**

92 units

**DISTRIBUTION**

Nationwide and Internationally

---

**PRODUCT**

Lumbar Matrix Scan, Diagnostic Electromyography System consisting of the CERSR Electromyography System and Electrode Array; the system consists of two devices. The first is a system of capital equipment referred to as CERSR Electromyography System, which includes a cart. The second device is disposable electrodes arrays, which are single use devices, used with the capital equipment that is adhered to the patient for monitoring the bioelectric signals produced by the muscles. Model Number(s): a) AM-0001-08-0 (CERSR) and b) 02003 (Electrode Array). The disposable is referred to as the Electrode Array. CERSR Electromyography System is packaged in a reusable crate maintained by SMI. The Electrode Array is packaged in a sealed foil pouch. Both devices are non-sterile and the packaging is for protection from damage during shipping. Recall # Z-1935-2010

**CODE**

a) CERSR serial numbers - 1, 3, 6, 8, 9, 11, 12, 12a, 13, 14, 17, 19, 20, 21, and 23. b) Electrode Array lot numbers: 112607-01, 112007-01, 112807-01, 112907-01, 120407-01, 120607-01, 120707-01, 121007-01, 121107-01, 121207-01, 121307-01, 030508-01, 031108-01, 031208-01, 031308-01, 031408-01, 031708-01, 031808-01, 032608-01, 032708-01, 032808-01, 040308-01, 040408-01, 040708-01, 041008-01, 041108-01, 041409-01, 041609-01, 111008-01, 111208-01, 111708-01, 071309-01, 111308-01, 111808-01, 041309-01, 041409-01, 091009-01, & 111309-01

**RECALLING FIRM/MANUFACTURER**

SpineMatrix, Inc., Akron, OH, by letter and telephone on January 29, 2010. Firm initiated recall is ongoing.

**REASON**

A full design review of the CERSR system was conducted in 7/2009. The audit revealed numerous design verification tests that either did not pass or did not meet the design input requirement. One requirement found that it was possible for the physician to think they were reviewing one patients scan, but were actually reviewing a scan from a different patient. This event did not happen; however, the possibility was there, which resulted in this recall.

**VOLUME OF PRODUCT IN COMMERCE**

14 units, Electrode Arrays - 1,152 units

**DISTRIBUTION**

CA, OH, OR & TX

---

**PRODUCT**

1) Dialysis On/Off Kit, DT11300, Sterile, Micropore Surgical Tape, Single Use Rolls, Port Access Dressing Change Tray. Recall # Z-1936-2010;

2) C.A.P.D. Tubing Exchange Tray, HT80, Sterile, Micropore Surgical Tape, Single Use Rolls. Recall # Z-1937-2010;

3) Dialysis Tray, SP560, Sterile, Micropore Surgical Tape, Single Use Rolls. Recall # Z-1938-2010

**CODE**

1) Lot numbers: 905058, 902188, 902118, 2008101390, 2008110390, 2008120190, 2009011990, 2009012690, 2009021690, 2009040690, 2009051190, 2009060190, 2009062990, 2009072790, 2009101290, 2009110290 and 2010011890;

2) Lot numbers: 801218, 802188, 2009080380 and 2009081080;

3) Lot numbers: 912317, 902048, 2008112490, 2009020290, 2009062290 and 2009070690

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Centurion Medical Products, Howell MI, by letter dated March 16, 2010. Manufacturer: Centurion Medical Products Corp., Yuma, AZ. Firm initiated recall is ongoing.

**REASON**

The 3M micropore tape is under recall due to the tape not performing and needles becoming loose and dislodged.

**VOLUME OF PRODUCT IN COMMERCE**

3, 312 kits

**DISTRIBUTION**

AR, OH

---

**PRODUCT**

1) Tabs Professional Monitor, includes one wall bracket, Model 25022. Recall # Z-1944-2010;

2) Tabs Professional Monitor without Wall Bracket, Model 25023. Recall # Z-1945-2010;

3) Tabs Professional Monitor without Pull Cord or wall bracket, Model 25025. Recall # Z-1946-2010;

4) Tabs Professional Monitor with Wire Bracket and Push Button Reset, Model 25223. Recall # Z-1947-2010

**CODE**

- 1) Serial numbers 235388 thru 237658;
- 2) Serial numbers 236662 thru 236697;
- 3) Serial numbers 236920 thru 236941;
- 4) Serial numbers 236348 thru 237499

**RECALLING FIRM/MANUFACTURER**

Stanley Security Solutions, Inc., Lincoln, NB, by letters dated March 25, 2010 and by telephone beginning March 26, 2010. Firm initiated recall is ongoing.

**REASON**

Product might not indicate low battery alarms or exit alarms when powered by a DC power supply.

**VOLUME OF PRODUCT IN COMMERCE**

187 units

**DISTRIBUTION**

Nationwide

---

**PRODUCT**

- 1) Stryker 7 MM AVS TL Trial Spacer; Catalog number: 48389407. Intended for use in the thoraco-lumbar spine. Recall # Z-1957-2010;
- 2) Stryker 8 MM AVS TL Trial Spacer; Catalog number: 48389408. Intended for use in the thoraco-lumbar spine. Recall # Z-1958-2010;
- 3) Stryker 9 MM AVS TL Trial Spacer; Catalog number: 48389409. Intended for use in the thoraco-lumbar spine. Recall # Z-1959-201;
- 4) Stryker 10 MM AVS TL Trial Spacer; Catalog number: 48389410. Intended for use in the thoraco-lumbar spine. Recall # Z-1960-2010;
- 5) Stryker 11 MM AVS TL Trial Spacer; Catalog number: 48389411. Intended for use in the thoraco-lumbar spine. Recall # Z-1961-2010;
- 6) Stryker 12 MM AVS TL Trial Spacer; Catalog number: 48389412. Intended for use in the thoraco-lumbar spine. Recall # Z-1962-2010;
- 7) Stryker 13 MM AVS TL Trial Spacer; Catalog number: 48389413. Intended for use in the thoraco-lumbar spine. Recall # Z-1963-2010;
- 8) Stryker 14 MM AVS TL Trial Spacer; Catalog number: 48389414. Intended for use in the thoraco-lumbar spine. Recall # Z-1964-2010;
- 9) Stryker 15 MM AVS TL Trial Spacer; Catalog number: 48389415. Intended for use in the thoraco-lumbar spine. Recall # Z-1965-2010;
- 10) Stryker 16 MM AVS TL Trial Spacer; Catalog number: 48389416. Intended for use in the thoraco-lumbar spine. Recall # Z-1966-2010;

11) Stryker 17 MM AVS TL Trial Spacer; Catalog number: 48389417. Intended for use in the thoraco-lumbar spine. Recall # Z-1967-2010;

12) Stryker 18 MM AVS TL Trial Spacer; Catalog number: 48389418. Intended for use in the thoraco-lumbar spine. Recall # Z-1968-2010

**CODE**

1) Lot numbers: 063931 - 066347 - 067528 - 06D467 - 071443 - 072671 - 074595 - 075338 - 076568 - 07C633 - 07D769 - 07H715 - 082963 – 084249;

2) Lot numbers: 063932 - 066348 - 067539 - 06D468 - 071444 - 072672 - 074596 - 074597 - 075339 - 076569 - 07C634 - 07H716 - 082964 – 084250;

3) Lot numbers: 063933 - 066349 - 067529 - 06D469 - 071445 - 072673 - 074598 - 075341 - 076570 - 07C635 - 07D770 - 07H717 - 082965 - 083245 - 083246 - 084251 - 08D836;

4) Lot numbers: 063934 - 066350 - 067530 - 06D470 - 071446 - 072674 - 074599 - 075342 - 076571 - 07C636 - 07D771 - 07H718 - 082966 – 084252;

5) Lot numbers: 063935 - 066351 - 067531 - 06D471 - 071447 - 072675 - 072735 - 074600 - 075343 - 076572 - 07C637 - 07H719 - 07H720 - 082967 – 084253;

6) Lot numbers: 063936 - 066352 - 067532 - 06D472 - 071448 - 072676 - 074601 - 075344 - 076573 - 07C638 - 07D772 - 07H721 - 082968 – 084254;

7) Lot numbers: 063937 - 066353 - 067533 - 067534 - 06D473 - 071449 - 073985 - 074602 - 075345 - 076574 - 07C639 - 07H722 - 082969 – 084255;

8) Lot numbers: 063938 - 066354 - 067535 - 06D474 - 071450 - 072677 - 074603 - 075346 - 076575 - 07C640 - 07D773 - 07H723 - 082970 – 084256;

9) Lot numbers: 064565 - 066355 - 067536 - 06D475 - 071452 - 072678 - 074604 - 075347 - 076576 - 07C641 - 07H724 – 082971;

10) Lot numbers: 064566 - 066356 - 067537 - 06D476 - 071453 - 072679 - 074605 - 075348 - 076577 - 07C642 - 07H725 – 082972;

11) Lot numbers: 066357 - 067540 - 06D477 - 071454 - 072680 - 074606 - 075349 - 076578 - 07C643 - 07H726 - 082973 – 084259;

12) Lot numbers: 064567 - 066358 - 067538 - 06D478 - 072681 - 074607 - 075350 - 076579 - 07C644 - 07H727 - 07H728 - 082974

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Stryker Spine, Allendale, NJ, by letters dated June 1, 2010.

Manufacturer: Stryker Spine, Cestas, Aquitaine, France. Firm initiated recall is ongoing.

**REASON**

Stryker Spine has received reports of breakage of the distal end of the AVS TL Spacer Trial during the trialing step of the AVS TL procedure.

**VOLUME OF PRODUCT IN COMMERCE**

2,110 units

**DISTRIBUTION**

Nationwide

**RECALLS AND FIELD CORRECTIONS: DEVICES - CLASS III**

---

**PRODUCT**

Bio-Rad's Monolisa (TM) Anti-HBs EIA test kit, Labeled as, "MONOLISA TM Anti-HBs EIA 25220; MONOLISA TM Anti-HBs Calibrator Kit 25219... For the qualitative detection of antibody to Hepatitis B Surface Antigen (anti-HBs) in Human Serum and EDTA or citrated plasma. Recall # Z-1620-2010

**CODE**

Lot #'s: 288BEE and 056CEE

**RECALLING FIRM/MANUFACTURER**

Bio-Rad Laboratories, Redmond, WA, by letter on August 11, 2008. Firm initiated recall is ongoing.

**REASON**

The package insert provided with this kit contains a typographical error, giving incorrect directions to prepare a Working Conjugate Solution. If these directions are followed, it would result in a 1:6 dilution and invalidate the assay.

**VOLUME OF PRODUCT IN COMMERCE**

795 kits

**DISTRIBUTION**

Nationwide and Canada

---

**PRODUCT**

Excyte Slider Barcode Tube Adapter used with Excyte Vacuum or Non-Vacuum ESR Tubes. Single Use. Product Number: EX-I0552. Slider allows a larger label to be applied to the ESR tube. Recall # Z-1816-2010

**CODE**

All Lot Numbers

**RECALLING FIRM/MANUFACTURER**

Recalling Firm: Vital Diagnostics, Inc., Lincoln, RI, by letter dated April 14, 2010. Manufacturer: Wilden Ag, Regensburg, Germany. Firm initiated recall is ongoing.

**REASON**

The tube may fall out or separate from the Slider adapter.

**VOLUME OF PRODUCT IN COMMERCE**

4723 units

**DISTRIBUTION**

Nationwide and Canada

**RECALLS AND FIELD CORRECTIONS: VETERINARY - CLASS I**

---

**PRODUCT**

1) Ketamine Hydrochloride Injection, USP, Equivalent to 100 mg per ml Ketamine, packaged in 10-ml. vials, CIII, RX, ANDA 200-042, manufactured under the following product names and labels: (1) AmTech Group, Inc. Ketamine Hydrochloride Injection; (2) Butler KetaThesia; (3) LLOYD Laboratories VetaKet; (4) Phoenix Ketaject; and (5) VEDCO KetaVed. Recall # V-183-2010;

2) Ketamine Hydrochloride Injection, USP, Equivalent to 100 mg per ml Ketamine, packaged in 10-ml. vials, CIII, RX, ANDA 200-042, manufactured under the following product names and labels: (1) AmTech Group, Inc. Ketamine Hydrochloride Injection; (2) Butler KetaThesia; (3) LLOYD Laboratories VetaKet; (4) Phoenix Ketaject; (5) RXV Keta-Sthetic; (6) VEDCO KetaVed; (7) Fort Dodge Ketaset; Recall # V-184-2010

**CODE**

1) 6111887, Exp. Nov-09; 2) 6101617, Exp. Oct-09; 3) 6091572, Exp. Sep-09, and 6111903, Exp. Nov-09; 4) 6101617, Exp. Oct-09 and 6111887, Exp. Nov-09; 5) 6101617, Exp. Oct-09, and 6111887, Exp. Nov-09;

2) 1) 6121994, Exp. Dec-09; 6122045, Exp. Dec-09; 7010148, Exp. Jan-10; and 7081091, Exp. Aug-10;

2) 6121994, Exp. Dec-09; 7010043, Exp. Jan-10; 7010101, Exp. Jan-10; 7010148, Exp. Jan-10; 7030369, Exp. Mar-10; 7060835, Exp. Jun-10; 7070963, Exp. Jul-10; and 7081091, Exp. Aug-10;

3) 7010001, Exp. Jan-10, and 540186J, Exp. Sep-11;

4) 6121972, Exp. Dec-09; 6121994, Exp. Dec-09; 6122045, Exp. Dec-09; 7010043, Exp. Jan-10; 7010101, Exp. Jan-10; 7010148, Exp. Jan-10; 7020267, Exp. Feb-10; 7030369, Exp. Mar-10; 7050706, Exp. May-10; 7060835, Exp. Jun-10; and 7081091, Exp. Aug-10;

5) 6121972, Exp. Dec-09; 6121994, Exp. Dec-09; and 7050706, Exp. May-10;

6) 6121972, Exp. Dec-09; 6122045, Exp. Dec-09; 7010043, Exp. Jan-10; 7010101, Exp. Jan-10; 7010148, Exp. Jan-10; 7020267, Exp. Feb-10; 7030369, Exp. Mar-10; 7050706, Exp. May-10; 7060835, Exp. Jun-10; 7070963, Exp. Jul-10; 540186J, Exp. Sep-11; 540186K, Exp. Sep-11; and 5401G4V, Exp. Feb-12;

7) 540186K, Exp. Sep-11; 540186L, Exp. Sep-11; 54018W7, Exp. Oct-11; 54018W8, Exp. Oct-11; 54018W9, Exp. Oct-11; 540197P, Exp. Nov-11; 54019NN, Exp. Jan-12; and 5401C9X, Exp. Feb-12

**RECALLING FIRM/MANUFACTURER**

TEVA Animal Health, Inc., Saint Joseph, MO, by letters dated September 4, 2009 and December 21, 2009 and by press release on December 21, 2009. Firm initiated recall is ongoing.

**REASON**

1) The products were not manufactured in conformance with GMP's;

2) Increased trend in serious adverse events associated with the product

**VOLUME OF PRODUCT IN COMMERCE**

Ketamine-965,587/10-ml vials;

**DISTRIBUTION**

Nationwide, Hong Kong, Canada, Taiwan, and China

## **RECALLS AND FIELD CORRECTIONS: VETERINARY - CLASS II**

---

### **PRODUCT**

Butorphanol Tartrate Injection, contains 10-mg butorphanol base per ml as butorphanol tartrate, packaged in 10- and 50-ml vials, CIV, RX, ANDA 200-322, manufactured under the following product names and labels: (1) AmTech Group, Inc. Butorphanol Tartrate Injection; (2) Butler Torphaject; (3) Phoenix ButorJect; and (4) VEDCO Equanol. Recall # V-185-2010

### **CODE**

- 1) 540175T, Exp. Jul-10 (10 & 50 ml); and 540175V, Ex. Jul-10 (50 ml);
- 2) 540175T, Exp. Jul-10 (10 & 50 ml); 540175V, Ex. Jul-10 (10 & 50 ml); and 540175W, Exp Aug-10 (50 ml);
- 3) 540175T, Exp. Jul-10 (10 & 50 ml); 540175V, Ex. Jul-10 (10 & 50 ml); 540175W, Exp Aug-10 (50 ml);
- 4) 540175T, Exp. Jul-10 (10 & 50 ml); 540175V, Ex. Jul-10 (10 & 50 ml); and 540175W, Exp Aug-10 (50 ml)

### **RECALLING FIRM/MANUFACTURER**

TEVA Animal Health, Inc., Saint Joseph, MO, by letters dated September 4, 2009 and December 21, 2009 and by press release on December 21, 2009. Firm initiated recall is ongoing.

### **REASON**

The products were not manufactured in conformance with GMP's.

### **VOLUME OF PRODUCT IN COMMERCE**

Butorphanol-11,544/10-ml and 19,812/50-ml vials

### **DISTRIBUTION**

Nationwide, Hong Kong, Canada, Taiwan, and China

### **END OF ENFORCEMENT REPORT FOR JULY 21, 2010**

#