## AMERICAN RED CROSS CLASS II RECALLS FOR THE PERIOD 4/15/03 THROUGH 4/15/04

The following regions have no recall information included in this report:

Alabama Region Birmingham, AL (Registration #1073001)

Gulf Coast Region Mobile, AL (Registration #1073005)

Greater Ozarks-Arkansas Region Little Rock, AR (Registration #2372998)

Midwest Region Omaha, NE (Registration #1973037)

North Central Region St. Paul, MN (Registration #2173038)

Northeastern Pennsylvania Region Ashley, PA (Registration #2573018)

Northern California Oakland, CA (Registration #2971430)

Puerto Rico Region Rio Piedras, PR (Registration #2675945)

South Carolina Region Columbia, SC (Registration #1073009)

Southern Region Atlanta, GA (Registration #1073000)

Tennessee Valley Region Nashville, TN (Registration #1073006)

Region/CFN	<u>Recall</u> <u>Number</u>	Number of Recalled Products/Product <u>Type</u>	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Appalachian 1173010	B-0225-5 B-0226-5	43 – Platelets Pheresis 9 – Platelets Pheresis Irradiated	Failure to control suspect component(s) (inappropriate release-low platelet yield)	\$3,000	\$156,000
Arizona 2072997	B-0493-4	1 — Fresh Frozen Plasma	Failure to control suspect component(s) (inappropriate release after discovery of clots in red blood cells)	\$3,000	\$3,000
Badger- Hawkeye 2173028	B-1681-4	1 –Platelets Pheresis Leukocytes Reduced	Failure to control suspect component(s) (inappropriate release-quality control not completed)	\$3,000	\$3,000
Carolinas Region 1073007	B-0948-5	1 – Red Blood Cells	Failure to control suspect component(s) (failure to quarantine after receiving post donation information)	\$3,000	\$3,000
	B-0832-5	2 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$6,000
	B-0938-5	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (failure to defer donor for lymphoma)	\$3,000	\$3,000
	B-0933-5	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-0928-5	2 - Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$6,000
	B-0934-5	1 – Cryoprecipitated AHF	Donor suitability (failure to defer donor for CJD risk)	\$3,000	\$3,000
Central Ohio 1573013	B-1017-4 B-1018-4	1 – Red Blood Cells Leukocytes Reduced 1 – Recovered Plasma	Donor suitability (failure to follow SOPs—BDR high risk behavior answers changed by Health Historian)	\$3,000	\$6,000
	B-0256-4	1 –Red Blood Cells Leukocytes Reduced	Testing (recordkeeping error)	\$2,000	\$2,000
	B-0513-4	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Collection (sterility compromised)	\$2,000	\$2,000
	B-0655-4 B-0656-4	1 – Platelets Leukocytes Reduced 1 – Fresh Frozen Plasma	Failure to control suspect component(s) (inappropriate release after discovery of clots in red blood cells)	\$3,000	\$6,000
	B-1066-4	4 - Red Blood Cells Pheresis Leukocytes Reduced	Component preparation (low volume)	No fine	No fine
	B-1013-4 B-1014-4 B-1015-4	1 – Red Blood Cells Leukocytes Reduced     1 - Platelets Leukocytes Reduced     1 - Recovered Plasma	Donor suitability (failure to defer donor for CJD risk)	\$3,000	\$9,000

Region/CFN	<u>Recall</u> <u>Number</u>	Number of Recalled Products/Product <u>Type</u>	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
	B-1379-4	1 - Platelets Pheresis Leukocytes Reduced Irradiated	Component preparation (low volume)	\$2,000	\$2,000
Central Plains 1973042	B-1132-4	1 - Platelets Pheresis Leukocytes Reduced	Re-release of unsuitable blood component	\$10,000	\$10,000
Connecticut 1273014	B-0072-4 B-0073-4	1 – Red Blood Cells Leukocytes Reduced 1 – Platelets Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$6,000
	B-0358-4 B-0359-4	1 – Red Blood Cells Leukocytes Reduced 1 – Fresh Frozen Plasma	Donor suitability (BDR questions unanswered)	No fine	No fine
	B-0546-4 B-0547-4	1 – Red Blood Cells Leukocytes Reduced 1 – Platelets Leukocytes Reduced	Donor suitability (BDR questions unanswered)	\$3,000	\$6,000
	B-0549-4 B-0550-4 B-0551-4	1 – Red Blood Cells Leukocytes Reduced 1 – Platelets Leukocytes Reduced 1 – Recovered Plasma	Donor suitability (BDR questions unanswered)	\$3,000	\$9,000
	B-0534-4 B-0535-4 B-0536-4	1 – Red Blood Cells Leukocytes Reduced 1 – Platelets Leukocytes Reduced 1 – Fresh Frozen Plasma	Donor suitability (BDR questions unanswered)	\$3,000	\$9,000
	B-0920-4 B-0921-4	1 – Red Blood Cells Leukocytes Reduced 1 – Platelets Leukocytes Reduced	Donor suitability (BDR questions unanswered)	\$3,000	\$6,000
	B-0923-4 B-0924-4	1 – Red Blood Cells Leukocytes Reduced 1 – Platelets Leukocytes Reduced	Donor suitability (BDR questions unanswered)	\$3,000	\$6,000
	B-0827-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (BDR questions unanswered)	\$3,000	\$3,000
	B-1251-4	1 – Platelets Leukocytes Reduced	Donor suitability (BDR questions unanswered)	\$3,000	\$3,000
	B-1889-4 B-1890-4 B-1891-4	1 – Red Blood Cells Leukocytes Reduced 1 – Platelets Leukocytes Reduced 1 – Recovered Plasma	Donor suitability (failure to defer donor for CJD risk)	\$3,000	\$9,000
	B-1655-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-1801-4 B-1802-4	Red Blood Cells Leukocytes Reduced     Platelets Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$6,000

Region/CFN	Recall Number	Number of Recalled Products/Product <u>Type</u>	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
	B-0556-5	1 — Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
Greater Lakes 1873033	B-0743-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (BDR questions unanswered)	\$3,000	\$3,000
	B-0793-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (BDR documentation missing for SARS)	\$3,000	\$3,000
	B-0966-4 B-0967-4 B-0968-4	2 – Fresh Frozen Plasma 2 – Cryoprecipitated AHF 1 - Cryoprecipitated AHF Pooled	Failure to control suspect product (inappropriate release after discovery of clots in red blood cells)	\$3,000	\$15,000
	B-0406-4 B-0407-4	1 – Red Blood Cells Leukocytes Reduced 1 – Fresh Frozen Plasma	Donor suitability (BDR questions unanswered)	\$3,000	\$6,000
	B-1940-4 B-1941-4 B-1942-4 B-1943-4 B-1946-4 B-1944-4	32 – Red Blood Cells Leukocytes Reduced 1 – Cryoprecipitated AHF 1 – Cryoprecipitated AHF Pooled 5 – Platelets 8 – Fresh Frozen Plasma 1 – Plasma Cryoprecipitate Reduced	Collection (inadequate arm scrub)	\$2,000	\$96,000
	B-0477-4 B-0478-4	1 – Red Blood Cells Leukocytes Reduced 1 – Recovered Plasma	Donor suitability (BDR questions unanswered)	\$3,000	\$6,000
	B-0739-4	1 – Red Blood Cells Leukocytes Reduced	Component preparation (error in red cell recovery calculation)	No fine	No fine
	B-1342-4	2 – Red Blood Cells Pheresis	Component preparation (record keeping error)	\$2,000	\$4,000
	B-1519-4	1 – Plasma Cryoprecipitate Reduced	Failure to control suspect component(s) (inappropriate release after discovery of clots in red blood cells)	\$3,000	\$3,000
	B-1578-4 B-1579-4	<ul> <li>1 – Platelets Pheresis Leukocytes Reduced</li> <li>1 – Platelets Pheresis Leukocytes Reduced</li> <li>Irradiated</li> </ul>	Collection (failure to follow SOPs)	\$2,000	\$4,000
	B-1118-4	1 – Platelets	Failure to control suspect component(s) (after supply defect discovered)	\$3,000	\$3,000
	B-1198-4	1 – Platelets Pheresis Leukocytes Reduced	Failure to control suspect component(s) (inappropriate release after discovery of low platelet yield)	\$2,000	\$2,000
	B-1352-4	1 – Platelets Pheresis	Component preparation (platelet yield and volume out-of-specifications)	\$1,000	\$1,000

Region/CFN	<u>Recall</u> <u>Number</u>	Number of Recalled Products/Product  Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
Greater Alleghenies 2573016	B-0595-4	1 – Red Blood Cells Leukocytes Reduced	Testing (unresolved test results)	No fine	No fine
	B-1055-4	6 – Platelets	Failure to control suspect component(s) (inappropriate release after discovery of low platelet yield)	\$3,000	\$18,000
	B-2018-4	2 –Red Blood Cells Leukocytes Reduced Irradiated	Component preparation (recordkeeping errors for irradiated components)	\$2,000	\$4,000
	B-2019-4	1 –Red Blood Cells Leukocytes Reduced	Donor suitability (an answer on BDR was "yes" with no supporting documentation)	\$3,000	\$3,000
	B-0219-5	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-1280-4	1 – Red Blood Cells	Component preparation (volume)	\$2,000	\$2,000
	B-0881-5 B-0882-5 B-0883-5 B-0884-5 B-0885-5 B-0886-5 B-0887-5 B-0888-5	A total of 3,279 blood components were involved with this recall; approximately 382 of these blood components were collected between the date the Decree was entered on 4/15/2003.and the date the recall occurred on 7/22/2003.  Red Blood Cells Red Blood Cells Leukocytes Reduced Red Blood Cells Leukocytes Reduced Irradiated Platelets Platelets Irradiated Fresh Frozen Plasma Plasma Red Blood Cells for Further Manufacture of Non-Injectables	Collection (inadequate arm scrub)	\$2,000 for each of 100 components	\$200,000
Greater Chesapeake and Potomac 1173011	B-1603-4	8 – Platelets Pheresis Leukocytes Reduced	Component preparation (failure to determine white blood cell count)	\$2,000	\$16,000
	B-1585-4	3 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$9,000
	B-1584-4	3 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$9,000

Region/CFN	<u>Recall</u> <u>Number</u>	Number of Recalled Products/Product  Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
	B-1596-4	6 – Platelets Pheresis Leukocytes Reduced	Collection (failure to follow manufacturer's instructions)	\$2,000	\$12,000
	B-1383-4	125 – Platelets Pheresis	Failure to control suspect component(s) (failure to perform QC testing)	\$3,000 for each of 100 blood components	\$300,000
	B-1586-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel/residency in malarial risk area)	\$3,000	\$3,000
	B-0799-5	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-0851-5 B-0852-5 B-0853-5	1 — Red Blood Cells Leukocytes Reduced 1 — Platelets 1 — Fresh Frozen Plasma	Donor suitability (failure to defer donor for taking Amiodarone)	\$3,000	\$9,000
Heart of America 1473043	B-0300-4	3 – Red Blood Cells Leukocytes Reduced	Collection (sterility compromised)	\$2,000	\$6,000
	B-1574-4 B-1575-4 B-1576-4	166 – Platelets Pheresis Leukocytes Reduced 34 – Platelets Pheresis Leukocytes Reduced Irradiated 47 – Fresh Frozen Plasma	Collection (failure to follow manufacturer's instructions)	\$2,000 for each of 100 blood components	\$200,000
	B-1421-4	3 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$9,000
	B-1630-4 B-1632-4 B-1634-4 B-1635-4 B-1637-4	43 – Red Blood Cells Leukocytes Reduced 4 – Platelets Pheresis Leukocytes Reduced 5 – Fresh Frozen Plasma 4 – Frozen Plasma 23 – Recovered Plasma	Donor suitability (use of obsolete SOP for CJD risk)	\$3,000	\$237,000
	B-1622-4	2 – Platelets Pheresis	Labeling (wrong product code)	\$2,000	\$4,000
	B-1707-4 B-1708-4	1 – Red Blood Cells Leukocytes Reduced 1 – Fresh Frozen Plasma	Donor suitability (failure to perform a complete search of donor information in the database)	\$3,000	\$6,000
	B-1722-4	2 – Platelets Pheresis Leukocytes Reduced	Component preparation (failure to perform QC testing)	No fine	No fine
	B-1839-4	2 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$6,000

Region/CFN	<u>Recall</u> <u>Number</u>	Number of Recalled Products/Product  Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
	B-1920-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (failure to defer donor for cancer)	\$3,000	\$3,000
Indiana-Ohio 1873031	B-0053-5	2 – Red Blood Cells Leukocytes Reduced (Split unit)	Failure to control suspect component(s) (failure to quarantine components after receiving post donation information)	\$3,000	\$6,000
	B-0096-5	1 - Red Blood Cells Leukocytes Reduced	Component preparation (failure to collect QC sample)	\$2,000	\$2,000
	B-0854-4	3 – Red Blood Cells Leukocytes Reduced	Failure to control suspect component(s) (inappropriate release of components that were to be discarded)	\$3,000	\$9,000
	B-0142-5	2 – Platelets Pheresis	Component preparation (volume too great for one collection bag)	\$1,000	\$2,000
	B-1811-4 B-1812-4 B-1813-4 B-1814-4	155 – Red Blood Cells Leukocytes Reduced 1 – Red Blood Cells Leukocytes Reduced Irradiated 25 – Platelets Leukocytes Reduced 31 – Fresh Frozen Plasma	Collection (inadequate arm scrub)	\$2,000 for each of 100 blood components	\$200,000
	B-1518-4	1 – Red Blood Cells Leukocytes Reduced	Failure to control suspect component(s) (quarantine error with overweight unit)	\$3,000	\$3,000
Lewis and Clark 3072990	B-1843-4 B-1844-4 B-1845-4	6 – Cryoprecipitated AHF 4 – Fresh Frozen Plasma 1 – Plasma Cryporecititate Reduced	Failure to control suspect component(s) (inappropriate release after discovery of clots in Red Blood Cells)	\$3,000	\$33,000
Mid-Atlantic 1173024	B-1011-4	13 – Red Blood Cells Leukocytes Reduced 11 – Recovered Plasma	Collections (sterility compromised)	\$2,000	\$48,000
	B-1720-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (failure to defer donor with melanoma)	\$3,000	\$3,000
Missouri- Illinois 1973035	B-1512-4 B-1513-4	1 – Red Blood Cells Leukocytes Reduced 1 – Recovered Plasma	Donor deferral (duplicate donor records)	\$2,000	\$4,000
	B-1524-4	1 – Platelets Pheresis Leukocytes Reduced	Failure to control suspect component(s) (inappropriate release due to low platelet yield)	\$3,000	\$3,000
New England 1270026	B-0091-5	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000

Region/CFN	<u>Recall</u> <u>Number</u>	Number of Recalled Products/Product <u>Type</u>	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
	B-0810-4 B-0811-4 B-0812-4	15 – Red Blood Cells Leukocytes Reduced 1 – Red Blood Cells Leukocytes Reduced Irradiated 1 – Fresh Frozen Plasma	Donor suitability (failure to ask and document BDR questions for SARS)	\$3,000	\$51,000
	B-0755-4	1 – Platelets Pheresis Leukocytes Reduced	Failure to control suspect component(s) (inappropriate release due to low platelet yield)	\$3,000	\$3,000
	B-0723-4	1 — Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-0865-5 B-0866-5 B-0868-5 B-0870-5 B-0871-5 B-0872-5 B-0873-5 B-0875-5 B-0876-5	A total of 16,393 blood components were involved in this recall; approximately 7,330 of those blood components were collected between the date of the entry of the Decree on 4/15/2003 and the date of the recall on 3/8/2004.  Red Blood Cells Red Blood Cells Pheresis Red Blood Cells Leukocytes Reduced Red Blood Cells Leukocytes Reduced Irradiated Red Blood Cells Washed Red Blood Cells Leukocytes Reduced Washed Red Blood Cells Deglycerolized Leukocytes Reduced Red Blood Cells Frozen Platelets Pheresis Leukocytes Reduced Irradiated Platelets Pheresis Irradiated	Donor suitability (obsolete CJD information sheet used)	\$3,000 for each of 100 blood components	\$300,000
	B-1238-4 B-1239-4	1 – Fresh Frozen Plasma 3 – Plasma Frozen Within 24 hours	Failure to control suspect component(s) (inappropriate release after discovery of clots in red blood cells)	\$3,000	\$12,000
	B-1926-4	2 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$6,000
	B-1486-4 B-1487-4	2 – Red Blood Cells Leukocytes Reduced Irradiated 1 – Recovered Plasma	Donor suitability (failure to defer donor for hepatitis risk)	\$3,000	\$9,000

Region/CFN	<u>Recall</u> <u>Number</u>	Number of Recalled Products/Product  Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
	B-1723-4 B-1724-4	26 – Platelets Pheresis Leukocytes Reduced 14 – Fresh Frozen Plasma	Collection (failure to follow manufacturer's instructions)	\$2,000	\$80,000
	B-1475-4	1 – Platelets Pheresis Leukocytes Reduced	Component preparation (inappropriate volume)	\$2,000	\$2,000
	B-1473-4 B-1474-4	2 – Red Blood Cells 1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$9,000
	B-1479-4 B-1480-4	1 – Red Blood Cells Leukocytes Reduced 1 – Recovered Plasma	Donor suitability (failure to defer donor for hepatitis risk)	\$3,000	\$6,000
	B-1803-4 B-1804-4	5 – Red Blood Cells Leukocytes Reduced 3 – Recovered Plasma	Donor suitability (BDR questions unanswered for CJD)	\$3,000	\$24,000
	B-1904-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (failure to determine hepatitis risk)	\$3,000	\$3,000
	B-0616-4	1 – Recovered Plasma	Donor suitability (failure to defer donor for CJD risk)	\$3,000	\$3,000
	B-1832-4 B-1833-4	2 – Red Blood Cells Leukocytes Reduced 1 – Fresh Frozen Plasma	Donor suitability (use of obsolete SOP for CJD risk)	\$3,000	\$9,000
	B-1645-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area).	\$3,000	\$3,000
	B-1816-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (residence in malarial risk area)	\$3,000	\$3,000
New York- Penn 2438445	B-0328-5	1 –Red Blood Cells Leukocytes Reduced	Donor suitability (BDR questions unanswered)	\$3,000	\$3,000
	B-0565-5 B-0566-5	7 – Platelets Pheresis Leukocytes Reduced 9 – Platelets Pheresis Leukocytes Reduced Irradiated	Collection (failure to follow manufacturer's instructions)	\$2,000	\$32,000
	B-0625-5	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-1295-4 B-1296-4	1 – Platelets Pheresis Leukocytes Reduced 1 – Platelets Pheresis Leukocytes Reduced Irradiated	Component preparation (platelet yield and plasma volume not adequate)	\$1,000	\$2,000
	B-1762-4 B-1763-4	2 – Platelets Pheresis Leukocytes Reduced 3 – Platelets Pheresis Leukocytes Reduced Irradiated	Donor suitability (travel in malarial risk area)	\$3,000	\$15,000

Region/CFN	<u>Recall</u> <u>Number</u>	Number of Recalled Products/Product  Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
	B-0428-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-1838-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
Northern Ohio 1573019	B-0541-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel/residence in malarial risk area)	\$3,000	\$3,000
	B-0271-4	1 – Platelets Pheresis Leukocytes Reduced	Component preparation (no documentation of white blood cell count for leukocytes reduced component)	\$2,000	\$2,000
	B-0295-5 B-0298-5 B-0299-5	1 – Red Blood Cells Leukocytes Reduced 1 – Platelets Leukocytes Reduced 1 – Recovered Plasma	Donor suitability (failure to defer donor for hepatitis risk)	\$3,000	\$9,000
	B-0439-5 B-0440-5	1 – Red Blood Cells Leukocytes Reduced 1 – Recovered Plasma	Donor suitability (failure to defer donor for CJD risk)	\$3,000	\$6,000
	B-0545-4	1 – Red Blood Cells Pheresis	Failure to control suspect component(s) (inappropriate release without required testing)	\$3,000	\$3,000
	B-0809-4	1 – Platelets Pheresis Leukocytes Reduced	Collection (sterility compromised)	\$2,000	\$2,000
	B-1476-4	349 – Platelets Pheresis Leukocytes Reduced; distributed between 3/19/2003 to 5/2/2003;120 of these blood components were distributed between the entry of the Decree on 4/15/2003 and the date of the recall on 5/2/2003.	Failure to control suspect component(s) (inappropriate release without required testing)	\$2,000 for each of 100 blood components	\$200,000
	B-1381-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-1382-4	1 – Platelets Pheresis Leukocytes Reduced	Collection (sterility compromised)	\$2,000	\$2,000
	B-1443-4	1 – Platelets Pheresis Leukocytes Reduced	Failure to control suspect component(s) (failure to quarantine components after receiving post donation information)	\$3,000	\$3,000
	B-1610-4	1 – Platelets Pheresis Leukocytes Reduced	Failure to control suspect component(s) (failure to quarantine after receiving post donation information)	\$2,000	\$2,000
Pacific Northwest 3072996	B-0040-5	1 – Plasma Cryoprecitate Reduced	Component preparation (recordkeeping errors related to freezing times)	No fine	No fine

Region/CFN	<u>Recall</u> <u>Number</u>	Number of Recalled Products/Product  Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
	B-0182-5	2 – Red Blood Cells	Donor suitability (travel in a malarial risk area)	\$3,000	\$6,000
	B-0581-5	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-0768-5	255 – Cryoprecipitated AHF Pooled	Component preparation (failure to perform QC testing)	\$2,000 for each of 100 blood components	\$200,000
	B-1864-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (failure to follow donor screening SOPs for hematocrit determination)	\$2,000	\$2,000
Penn-Jersey 2573021	B-1154-4	5 – Red Blood Cells Pheresis Leukocytes Reduced	Failure to control suspect component(s) (inappropriate release of low volume component)	\$2,000	\$10,000
River Valley 1573003	B-1450-4	1 – Cryoprecipitated AHF	Failure to control suspect component(s) (inappropriate release after discovering clots in red blood cells)	\$3,000	\$3,000
	B-1531-4 B-1532-4 B-1533-4 B-1534-4 B-1536-4 B-1537-4 B-1538-4	12 – Whole Blood 26 – Red Blood Cells 333 – Red Blood Cells Leukocytes Reduced 25 – Red Blood Cells Leukocytes Reduced Irradiated 70 – Platelets 9 – Platelets Irradiated 108 – Fresh Frozen Plasma 6 – Cryoprecipitated AHF	Collection (inadequate arm scrub)	\$2,000 for each of 100 blood components	\$200,000
	B-1593-4 B-1594-4 B-1595-4	39 – Platelets Pheresis 5 – Platelets Pheresis Leukocytes Reduced 1- Fresh Frozen Plasma	Collection (collection kits not used within acceptable time period)	\$2,000	\$90,000
Southeastern Michigan 1873044	B-0311-5 B-0312-5	85 – Red Blood Cells Leukocytes Reduced 45 – Platelets Leukocytes Reduced	Collection (failure to follow manufacturer's instructions)	\$2,000 for each of 100 blood components	\$200,000
	B-0320-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-0380-4	1 – Red Blood Cells Leukocytes Reduced	Component preparation (failure to follow SOPs-red blood cells prepared >8 hours after collection)	\$2,000	\$2,000
	B-0563-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000

Region/CFN	<u>Recall</u> <u>Number</u>	Number of Recalled Products/Product  Type	Reason for Recall	Penalty Amount Per Blood Component	Total Penalty Amount
	B-0776-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
	B-0819-4 B-0820-4	1 – Red Blood Cells Leukocytes Reduced 1 – Platelets Leukocytes Reduced	Component preparation (overweight unit)	\$2,000	\$4,000
	B-1484-4	2 – Red Blood Cells Pheresis	Failure to control suspect component(s) (inappropriate release of low volume components)	\$2,000	\$4,000
	B-0774-4 B-0775-4	1 – Red Blood Cells Leukocytes Reduced 1 – Platelets	Donor suitability (residence in malarial risk area)	\$3,000	\$6,000
	B-0821-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
Southern California 2072994	B-0756-4	4 – Fresh Frozen Plasma	Failure to control suspect component(s) (inappropriate release due to clots)	\$3,000	\$12,000
Southwest 1673040	B-1912-4 B-1913-4 B-1914-4	1 – Red Blood Cells Leukocytes Reduced 1 – Red Blood Cells Leukocytes Reduced Irradiated 2 – Platelets Leukocytes Reduced	Donor suitability (residence in malarial risk area)	\$3,000	\$12,000
	B-1910-4	1 – Red Blood Cells Leukocytes Reduced	Donor suitability (travel in malarial risk area)	\$3,000	\$3,000
Western Lake Erie 1573020	B-1704-3	1 – Platelets Pheresis Leukocytes Reduced	Component preparation (low platelet yield)	No fine	No fine