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Division of Inspections and Surveillance (HFM-650)

SUBJECT: ERROR AND ACCIDENT REPORTS - ANNUAL SUMMARY FOR FY-99

TO : Director, Division of Inspections and Surveillance (HFM-650)

Between October 1, 1998 and September 30, 1999, the Division of Inspections and Surveillance received 6,616 error and accident reports from the American Red Cross (ARC), 6,664 error and accident reports from non-ARC licensed blood establishments, 127 error and accident reports from unlicensed registered blood establishments, 30 error and accident reports from transfusion services, 1997 error and accident reports from plasma centers, 40 error and accident reports from blood derivative manufacturers, 17 error and accident report from in-vitro diagnostic manufacturers, 16 error and accident reports from vaccine manufacturers, 12 error and accident reports from allergenic manufacturers, and 13 error and accident reports from therapeutic manufacturers. A total of 15,532 error and accident reports were received. There were 1,745 (11.2%) reports forwarded to the District Offices for follow-up and evaluation as potential recall situations. Based on the information submitted in the error and accident reports, 706 (4.5%) reports did not appear to meet the threshold for reporting, i.e., products were not made available for distribution or the safety, purity, or potency of a product was not affected.

The categories of errors and accidents were grouped by manufacturing systems, and the distribution of reports is as follows:

<u>REPORTABLE ERRORS/ACCIDENTS</u>		<u>NON-REPORTABLE ERRORS/ACCIDENTS</u>	
Donor Suitability – 78.2%		Miscellaneous	42.9%
Post Donation Information	72.2%	Labeling	21.5%
Donor Screening	5.0%	Donor Suitability – 17.9%	
Donor Deferral	1.0%	Post Donation Information	8.7%
Storage and Distribution	9.0%	Donor Screening	8.1%
Labeling	6.2%	Donor Deferral	1.1%
Product Testing – 4.5%		Storage and Distribution	9.4%
Routine Testing	1.9%	Collection	5.3%
Viral Testing	2.6%	Product Testing – 2.4%	
Component Preparation	1.2%	Viral Testing	1.4%
Collection	0.9%	Routine Testing	1.0%
Miscellaneous	0.1%	Component Preparation	0.4%

Additional tables are attached which identify in more detail the types of errors and accidents included under the categories that represent the greatest percentage of reports received, i.e., for Reportables: Post Donation Information (72.2%), Storage and Distribution (9.0%), Labeling (6.2%), and Donor Screening (5.0%) and for Non-Reportables: Miscellaneous (42.9%), Labeling (21.5%), Storage and Distribution (9.4%), and Post Donation Information (8.7%). A table and graphs are also provided that illustrate the distribution of the reporting time, i.e., time from the date that the error or accident was discovered to the date CBER received the report.

More specific summary charts are provided related to post donation information reports. Using the information provided in the error and accident reports, the post donation information reports were categorized based on how the information was obtained. The reports were also categorized based on whether the information was known (or could have been known), or not known at the time of donation. The most frequently reported type of post donation information involved donors who, at a previous donation, neglected to provide information of receiving a tattoo, ear or body piercing, accidental needlestick, or a transfusion within 12 months of donation.

Of the 10,639 post donation information reports received, 8514 (80.0%) reports involved the donor providing the information at a subsequent donation, 1379 (13.0%) reports involved the donor calling back to the center within a few days of donating, and 746 (7.0%) reports involved a third party providing the information.

INFORMATION RECEIVED BY:	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	PLASMA CENTERS	TOTAL	
SUBSEQUENT DONATION	4045	3138	14	1317	8514	80.0%
TELEPHONE CALL	661	699	2	17	1379	13.0%
THIRD PARTY	210	150	0	386	746	7.0%
TOTAL	4916	3987	16	1720	10639	100.0%

Of the 10,639 post donation information reports received, 8656 (81.4%) reports involved information in which the donor should have known at the time of donation, such as travel outside the United States, having a tattoo or body piercing, history of cancer, etc. 1983 (18.6%) reports involved information in which the donor was not aware, such as post donation illness, sex partner participated in high risk behavior or tested positive, or cancer diagnosed post donation, etc.

INFORMATION	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	PLASMA CENTERS	TOTAL	
AVAILABLE, NOT PROVIDED	4009	3011	15	1621	8656	81.4%
NOT KNOWN AT TIME OF DONATION	907	976	1	99	1983	18.6%
Total	4916	3987	16	1720	10639	100.0%

ATTACHMENTS

## Attachments

- 1 - Tables - Number of Error/Accident Reports
  - Total Reports and Potential Recalls
  - Total Reports and Reportable Errors/Accidents
  - Total Reports and Non-Reportable Errors/Accidents
- 2 - Tables - Types of Errors/Accidents for Blood and Plasma Manufacturers
  - Total Errors/Accidents
  - Potential Recalls
- 3 - Pie chart - All Blood and Plasma Establishments
  - Total Reports
  - Potential Recalls
- 4 - Tables - Types of Errors/Accidents for Blood and Plasma Manufacturers
  - Reportable Errors/Accidents
  - Non-Reportable Errors/Accidents
- 5 - Pie charts - Reportable versus Non-Reportable Errors/Accidents
- 6 - Table - Types of Errors/Accidents for Non-Blood Manufacturers
- 7 (3 pages) - Tables - Detailed Listing of Errors/Accidents for Non-Blood Manufacturers
- 8- Tables - Types of Errors/Accidents - American Red Cross
  - Reportable Errors/Accidents
  - Non-Reportable Errors/Accidents
  - Total Errors/Accidents
- 9 - Tables - Types of Errors/Accidents - Non-ARC Licensed Blood Banks
  - Reportable Errors/Accidents
  - Non-Reportable Errors/Accidents
  - Total Errors/Accidents
- 10 - Tables - Types of Errors/Accidents - Unlicensed Blood Banks
  - Reportable Errors/Accidents
  - Non-Reportable Errors/Accidents
  - Total Errors/Accidents
- 11 - Tables - Types of Errors/Accidents - Plasma Centers
  - Reportable Errors/Accidents
  - Non-Reportable Errors/Accidents
  - Total Errors/Accidents
- 12 - Pie charts - Types of Total Errors/Accidents by Establishment
- 13 - Pie charts - Blood Banks versus Plasma Centers
- 14 - Pie charts - Blood Banks versus Plasma Centers
  - Licensed Blood Banks, Unlicensed Blood Banks, Plasma Centers
- 15 - Pie charts - Types of Reportable Errors/Accidents by Establishment
- 16 (5 pages) - Tables - Post Donation Information Reports
- 17 (3 pages) - Tables - Storage/Distribution Errors/Accidents
- 18 - Tables - Labeling Errors/Accidents
- 19 (3 pages) - Tables - Donor Screening Errors/Accidents
- 20 - Pie charts - Non-Reportable Errors/Accident by Establishment
- 21 - Tables - Miscellaneous Errors/Accidents
- 22 - Table - Labeling Errors/Accidents
- 23 - Tables - Storage and Distribution Errors/Accidents
- 24 - Tables - Post Donation Information Reports
- 25 - Pie charts - Types of Errors/Accident by Fiscal Year
- 26 - Pie charts - All Reporting Blood Establishments
- 27 - Bar graph - All Reporting Non-blood Establishments

Attachments (continued)

- 28 - Table - Reporting Time
- 29 - Line graph - Reporting Time - All Blood Establishments
- 30 - Line graph - Reporting Time - American Red Cross
- 31 - Line graph - Reporting Time - Non-ARC Licensed Blood Banks
- 32 - Line graph - Reporting Time - Unlicensed Blood Banks
- 33 - Line graph - Reporting Time - Plasma Centers
- 34 - Line graph - Reporting Time - All Licensed Blood Banks
- 35 (16 pages) - List of Reportable Error/Accident Codes
- 36 (2 pages) - List of Non-Reportable Error/Accident Codes
- 37 - List of Non-Blood Error/Accident Codes
- 38 (5 pages) - Table - Number of Reportable Errors/Accidents by Establishment
- 39 - Table - Number of Non-Reportable Errors/Accident by Establishments

**ERROR AND ACCIDENT REPORTS  
RECEIVED 10/1/98 - 9/30/99**

	TOTAL REPORTS	POTENTIAL RECALLS	%RECALLS
AMERICAN RED CROSS	6616	480	7.3%
NON-ARC LICENSED BLOOD BANKS	6664	1081	16.2%
UNLICENSED BLOOD BANKS	127	17	13.4%
TRANSFUSION SERVICES	30	1	3.3%
PLASMA CENTERS	1997	145	7.3%
BLOOD DERIVATIVE MANUFACTURER	40	7	17.5%
IN-VITRO DIAGNOSTIC MANUFACTURER	17	5	29.4%
VACCINE MANUFACTURER	16	1	6.3%
ALLERGENICS MANUFACTURER	12	4	33.3%
THERAPEUTIC MANUFACTURER	13	4	30.8%
<i>TOTAL</i>	15532	1745	11.2%

	TOTAL REPORTS	REPORTABLE	%REPORTABLE
AMERICAN RED CROSS	6616	6249	94.5%
NON-ARC LICENSED BLOOD BANKS	6664	6397	96.0%
UNLICENSED BLOOD BANKS	127	94	74.0%
TRANSFUSION SERVICES	30	28	93.3%
PLASMA CENTERS	1997	1965	98.4%
BLOOD DERIVATIVE MANUFACTURER	40	37	92.5%
IN-VITRO DIAGNOSTIC MANUFACTURER	17	16	94.1%
VACCINE MANUFACTURER	16	15	93.8%
ALLERGENICS MANUFACTURER	12	12	100.0%
THERAPEUTIC MANUFACTURER	13	13	100.0%
<i>TOTAL</i>	15532	14826	95.5%

	TOTAL REPORTS	NON- REPORTABLE	%NON- REPORTABLE
AMERICAN RED CROSS	6616	367	5.5%
NON-ARC LICENSED BLOOD BANKS	6664	267	4.0%
UNLICENSED BLOOD BANKS	127	33	26.0%
TRANSFUSION SERVICES	30	2	6.7%
PLASMA CENTERS	1997	32	1.6%
BLOOD DERIVATIVE MANUFACTURER	40	3	7.5%
IN-VITRO DIAGNOSTIC MANUFACTURER	17	1	5.9%
VACCINE MANUFACTURER	16	1	6.3%
ALLERGENICS MANUFACTURER	12	0	0.0%
THERAPEUTIC MANUFACTURER	13	0	0.0%
<i>TOTAL</i>	15532	706	4.5%

The following tables and pie charts show the type of errors and accidents reported:

BLOOD AND PLASMA MANUFACTURERS  
TOTAL ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	ARC	NON-ARC LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
ROUTINE TESTING	100	174	6	5	2	287	1.9%
VIRAL TESTING	28	345	10	0	9	392	2.5%
COLLECTION	104	58	0	0	1	163	1.1%
COMPONENT PREPARATION	68	100	4	0	1	173	1.1%
LABELING	473	551	29	7	3	1063	6.9%
DONOR SCREENING	240	422	5	0	123	790	5.1%
DONOR DEFERRAL	20	132	0	0	9	161	1.0%
POST DONATION INFO	4946	4018	16	0	1720	10700	69.3%
STORAGE/DISTRIBUTION	494	741	30	16	104	1385	9.0%
MISCELLANEOUS	143	123	27	2	25	320	2.1%
TOTAL	6616	6664	127	30	1997	15434	100.0%

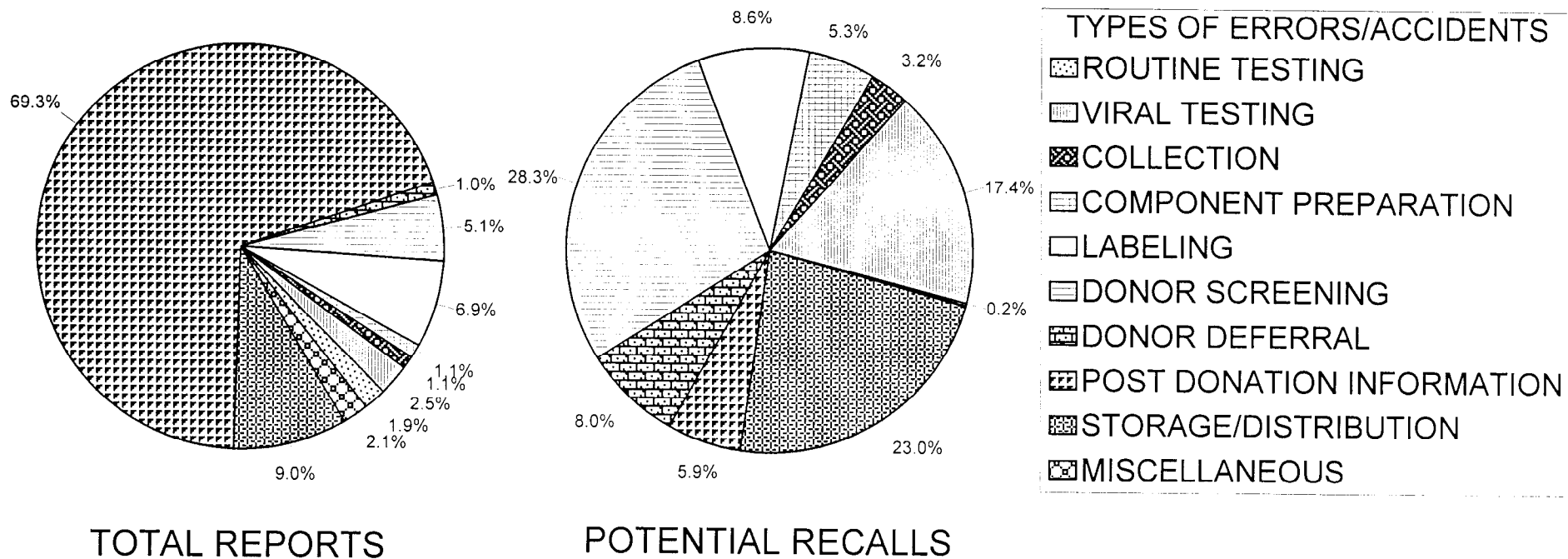
BLOOD AND PLASMA MANUFACTURERS  
POTENTIAL RECALLS

TYPE OF ERROR/ACCIDENT	ARC	NON-ARC LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
ROUTINE TESTING	1	3	0	0	0	4	0.2%
VIRAL TESTING	7	282	8	0	3	300	17.4%
COLLECTION	31	24	0	0	1	56	3.2%
COMPONENT PREPARATION	38	54	0	0	0	92	5.3%
LABELING	59	86	2	1	0	148	8.6%
DONOR SCREENING	162	268	3	0	55	488	28.3%
DONOR DEFERRAL	11	121	0	0	6	138	8.0%
POST DONATION INFO	74	16	0	0	11	101	5.9%
STORAGE/DISTRIBUTION	97	227	4	0	69	397	23.0%
MISCELLANEOUS	0	0	0	0	0	0	0.0%
TOTAL	480	1081	17	1	145	1724	100.0%

# ERROR AND ACCIDENT REPORTS

## ALL BLOOD AND PLASMA ESTABLISHMENTS

### FY99



TOTAL REPORTS RECEIVED (10/1/98 - 9/30/99) = 15,434  
 POTENTIAL RECALLS = 1724

BLOOD AND PLASMA MANUFACTURERS  
REPORTABLE ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	ARC	NON-ARC LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
ROUTINE TESTING	96	172	5	5	2	280	1.9%
VIRAL TESTING	28	336	9	0	9	382	2.6%
COLLECTION	69	56	0	0	1	126	0.9%
COMPONENT PREPARATION	66	99	4	0	1	170	1.2%
LABELING	385	491	27	7	2	912	6.2%
DONOR SCREENING	214	402	5	0	112	733	5.0%
DONOR DEFERRAL	15	129	0	0	9	153	1.0%
POST DONATION INFO	4916	3987	16	0	1720	10639	72.2%
STORAGE/DISTRIBUTION	458	717	28	16	100	1319	9.0%
MISCELLANEOUS	2	8	0	0	9	19	0.1%
TOTAL	6249	6397	94	28	1965	14733	100.0%

BLOOD AND PLASMA MANUFACTURERS  
NON-REPORTABLE ERRORS AND ACCIDENTS

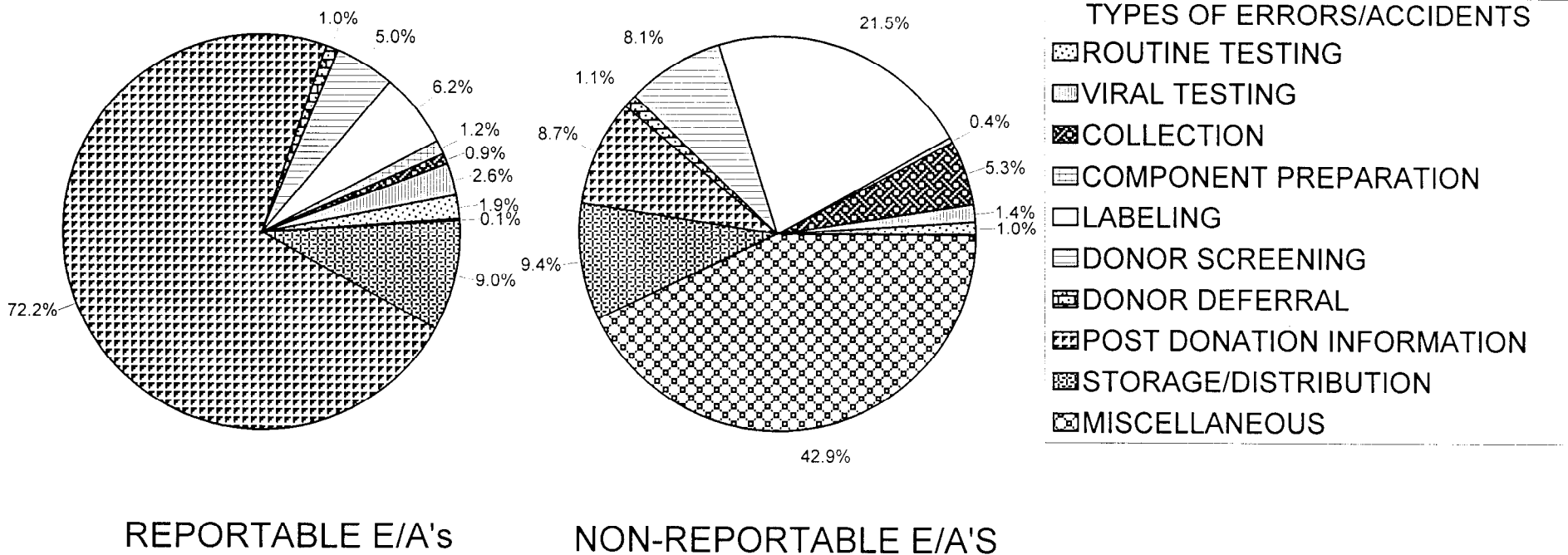
TYPE OF ERROR/ACCIDENT	ARC	NON-ARC LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
ROUTINE TESTING	4	2	1	0	0	7	1.0%
VIRAL TESTING	0	9	1	0	0	10	1.4%
COLLECTION	35	2	0	0	0	37	5.3%
COMPONENT PREPARATION	2	1	0	0	0	3	0.4%
LABELING	88	60	2	0	1	151	21.5%
DONOR SCREENING	26	20	0	0	11	57	8.1%
DONOR DEFERRAL	5	3	0	0	0	8	1.1%
POST DONATION INFO	30	31	0	0	0	61	8.7%
STORAGE/DISTRIBUTION	36	24	2	0	4	66	9.4%
MISCELLANEOUS	141	115	27	2	16	301	42.9%
TOTAL	367	267	33	2	32	701	100.0%



# ERROR AND ACCIDENT REPORTS

## ALL BLOOD AND PLASMA ESTABLISHMENTS

### FY99



REPORTS RECEIVED (10/1/98 - 9/30/99)  
 REPORTABLE ERRORS/ACCIDENTS = 14,733  
 NON-REPORTABLE ERRORS/ACCIDENTS = 701

NON-BLOOD MANUFACTURERS

TYPE OF ERROR/ACCIDENT	DERIVATIVE		IN-VITRO DIAGNOSTIC		ALLERGENIC		THERAPUETIC		VACCINE		TOTAL REPORTS		POTENTIAL RECALL	
	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL				
REAGENT PERFORMANCE	0	0	1	1	0	0	0	0	0	0	1	1.0%	1	4.8%
STERILITY COMPROMISED	4	0	3	2	1	0	3	3	1	0	12	12.2%	5	23.8%
LABELING	2	1	9	2	6	4	1	0	0	0	18	18.4%	7	33.3%
STORAGE/DISTRIBUTION	6	0	1	0	1	0	1	0	1	0	10	10.2%	0	0.0%
MISCELLANEOUS	25	6	2	0	4	0	8	1	13	1	52	53.1%	8	38.1%
NOT REPORTABLE	3	0	1	0	0	0	0	0	1	0	5	5.1%	0	0.0%
<b>TOTAL</b>	<b>40</b>	<b>7</b>	<b>17</b>	<b>5</b>	<b>12</b>	<b>4</b>	<b>13</b>	<b>4</b>	<b>16</b>	<b>1</b>	<b>98</b>	<b>100.0%</b>	<b>21</b>	<b>100.0%</b>

## NON-BLOOD MANUFACTURERS

**DERIVATIVES**

ERROR/ACCIDENT	#REPORTS
<i>STERILITY COMPROMISED</i>	4
Visible clotted material observed in product	2
Green label tape introduced into the process stream	1
Bacterial contamination – contamination due to defective stopper	1
<i>LABELING</i>	2
Expiration date extended	2
<i>STORAGE/DISTRIBUTION</i>	6
Source material not frozen within 15 hours	1
Product shipped or stored at incorrect temperature	5
<i>MISCELLANEOUS</i>	25
Source material manufactured into final product after subsequent unit tested positive for anti-HIV 1/2	3
Source material manufactured into final product after subsequent unit tested positive for HBsAg	1
Source material unacceptable due to HIV-1 antigen and ALT testing error	1
Source material withdrawn due to HIV-1 antigen testing error	1
Source material withdrawn due to an error in syphilis testing	1
Source material withdrawn due to donor subsequently testing HIV positive	2
Source material unacceptable due to improper transfer of source plasma	1
Source material unacceptable due to testing positive for HCV by PCR	1
Incorrect sequence used in manufacturing process	1
Product reached unacceptable temperature during manufacture of fraction II paste	1
Moisture content exceeded specification	1
Unacceptable temperature increases during diafiltration	1
Handling of out-of-specification results was inappropriate	1
Resin #9 failed column release assays	1
Incorrect filter used	1
Run sheet for 1N HAC preparation missing	1
Stability testing failed	6
<i>NON-REPORTABLE</i>	3
Source material was identified incorrectly by supplier; shipping document discrepant - product quality not affected	2
Product not made available for distribution	1
<b>TOTAL</b>	<b>40</b>

## NON-BLOOD MANUFACTURERS

**IN-VITRO DIAGNOSTICS**

ERROR/ACCIDENT	#REPORTS
<b>REAGENT PERFORMANCE</b>	<b>1</b>
Loss of potency	1
<b>STERILITY COMPROMISED</b>	<b>3</b>
Endodontium album mold	1
Bacterial contamination	2
<b>LABELING</b>	<b>9</b>
Package insert incorrect	4
Product label incorrect	2
Lot number missing or incorrect	2
Storage temperature missing or incorrect	1
<b>STORAGE/DISTRIBUTION</b>	<b>1</b>
Product shipped or stored at incorrect temperature	1
<b>MISCELLANEOUS</b>	<b>2</b>
Fill volume too low	1
False positive reactivity	1
<b>NON-REPORTABLE</b>	<b>1</b>
Labeling – shortened expiration date; product quality not affected	1
<b>TOTAL</b>	<b>17</b>

**ALLERGENICS**

ERROR/ACCIDENT	#REPORTS
<b>STERILITY COMPROMISED</b>	<b>1</b>
Vial contained a hypodermic needle	1
<b>LABELING</b>	<b>6</b>
Incorrect concentration	3
Expiration date extended	3
<b>STORAGE/DISTRIBUTION</b>	<b>1</b>
Product released prior to Lot Release approval	1
<b>MISCELLANEOUS</b>	<b>4</b>
Patch below specifications	3
The specified linearity for the assay failed when using the extended incubation time and plastic microplate	1
<b>TOTAL</b>	<b>12</b>

## NON-BLOOD MANUFACTURERS

**VACCINES**

ERROR/ACCIDENT	#REPORTS
<i>STERILITY COMPROMISED</i>	<i>1</i>
Sterile diluent contained fine particulate matter-silicon dioxide	1
<i>STORAGE AND DISTRIBUTION</i>	<i>1</i>
Product shipped/stored at incorrect temperature	1
<i>MISCELLANEOUS</i>	<i>13</i>
Stability residual moisture out of specification	1
Distributed prior to expiration of CBE submission	1
Stability testing failed	11
<i>Non-reportable</i>	<i>1</i>
Fire in sterilization room – products not made available for distribution	1
<b>TOTAL</b>	<b>16</b>

**THERAPEUTICS**

ERROR/ACCIDENT	#REPORTS
<i>STERILITY COMPROMISED</i>	<i>3</i>
Bacterial contamination	3
<i>LABELING</i>	<i>1</i>
Labeling of carton incorrect – incorrect concentration	1
<i>STORAGE AND DISTRIBUTION</i>	<i>1</i>
Product shipped/stored at incorrect temperature	1
<i>MISCELLANEOUS</i>	<i>8</i>
Incorrect vial stopper used	1
Air pressure was shut off during addition of active drug substance	1
Out-of-specification values included in the potency determination	1
Failed media fill-receival tank with filter assembly connected held for 5 days, 18 hours prior to commencing fill	1
Specification for Total DNA Analysis had been set at lower level than limit of quantitation	1
Out-of-specification membranes used in production	1
Stability testing failed	2
<b>TOTAL</b>	<b>13</b>

## AMERICAN RED CROSS

### REPORTABLE ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	31	22	25	18	96	1.5%
VIRAL TESTING	5	4	7	12	28	0.4%
COLLECTION	27	17	11	14	69	1.1%
COMPONENT PREPARATION	18	18	17	13	66	1.1%
LABELING	90	81	98	116	385	6.2%
DONOR SCREENING	58	48	44	64	214	3.4%
DONOR DEFERRAL	0	3	8	4	15	0.2%
POST DONATION INFO	1183	1255	1165	1313	4916	78.7%
STORAGE/DISTRIBUTION	129	114	100	115	458	7.3%
MISCELLANEOUS	0	0	2	0	2	0.0%
<b>TOTAL</b>	<b>1541</b>	<b>1562</b>	<b>1477</b>	<b>1669</b>	<b>6249</b>	<b>100.0%</b>

### NON-REPORTABLE ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	0	0	0	4	4	1.1%
VIRAL TESTING	0	0	0	0	0	0.0%
COLLECTION	13	7	8	7	35	10.1%
COMPONENT PREPARATION	1	1	0	0	2	0.6%
LABELING	19	22	29	18	88	25.3%
DONOR SCREENING	11	5	9	1	26	7.5%
DONOR DEFERRAL	1	1	2	1	5	1.4%
POST DONATION INFO	6	8	14	2	30	8.6%
STORAGE/DISTRIBUTION	9	9	10	8	36	10.3%
MISCELLANEOUS	34	48	21	38	141	40.5%
<b>TOTAL</b>	<b>94</b>	<b>101</b>	<b>93</b>	<b>79</b>	<b>367</b>	<b>100.0%</b>

### TOTAL ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	31	22	25	22	100	1.5%
VIRAL TESTING	5	4	7	12	28	0.4%
COLLECTION	40	24	19	21	104	1.6%
COMPONENT PREPARATION	19	19	17	13	68	1.0%
LABELING	109	103	127	134	473	7.1%
DONOR SCREENING	69	53	53	65	240	3.6%
DONOR DEFERRAL	1	4	10	5	20	0.3%
POST DONATION INFO	1189	1263	1179	1315	4946	74.8%
STORAGE/DISTRIBUTION	138	123	110	123	494	7.5%
MISCELLANEOUS	34	48	23	38	143	2.2%
<b>TOTAL</b>	<b>1635</b>	<b>1663</b>	<b>1570</b>	<b>1748</b>	<b>6616</b>	<b>100.0%</b>

## NON-ARC LICENSED BLOOD BANKS

### REPORTABLE ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	50	38	48	36	172	2.7%
VIRAL TESTING	125	185	11	15	336	5.3%
COLLECTION	19	16	10	11	56	0.9%
COMPONENT PREPARATION	21	24	27	27	99	1.5%
LABELING	130	119	119	123	491	7.7%
DONOR SCREENING	95	109	110	88	402	6.3%
DONOR DEFERRAL	37	75	8	9	129	2.0%
POST DONATION INFO	875	989	1077	1046	3987	62.3%
STORAGE/DISTRIBUTION	225	178	170	144	717	11.2%
MISCELLANEOUS	5	1	1	1	8	0.1%
<b>TOTAL</b>	<b>1582</b>	<b>1734</b>	<b>1581</b>	<b>1500</b>	<b>6397</b>	<b>100.0%</b>

### NON-REPORTABLE ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	1	1	0	0	2	0.7%
VIRAL TESTING	0	9	0	0	9	3.4%
COLLECTION	0	0	1	1	2	0.7%
COMPONENT PREPARATION	0	0	0	1	1	0.4%
LABELING	23	13	13	11	60	22.5%
DONOR SCREENING	3	8	3	6	20	7.5%
DONOR DEFERRAL	1	0	0	2	3	1.1%
POST DONATION INFO	2	10	13	6	31	11.6%
STORAGE/DISTRIBUTION	3	9	5	7	24	9.0%
MISCELLANEOUS	37	27	25	26	115	43.1%
<b>TOTAL</b>	<b>70</b>	<b>77</b>	<b>60</b>	<b>60</b>	<b>267</b>	<b>100.0%</b>

### TOTAL ERRORS AND ACCIDENTS

TOTAL	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	51	39	48	36	174	2.6%
VIRAL TESTING	125	194	11	15	345	5.2%
COLLECTION	19	16	11	12	58	0.9%
COMPONENT PREPARATION	21	24	27	28	100	1.5%
LABELING	153	132	132	134	551	8.3%
DONOR SCREENING	98	117	113	94	422	6.3%
DONOR DEFERRAL	38	75	8	11	132	2.0%
POST DONATION INFO	877	999	1090	1052	4018	60.3%
STORAGE/DISTRIBUTION	228	187	175	151	741	11.1%
MISCELLANEOUS	42	28	26	27	123	1.8%
<b>TOTAL</b>	<b>1652</b>	<b>1811</b>	<b>1641</b>	<b>1560</b>	<b>6664</b>	<b>100.0%</b>

## UNLICENSED BLOOD BANKS

### REPORTABLE ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	2	1 <sup>1</sup>	4 <sup>1</sup>	3 <sup>3</sup>	10	8.2%
VIRAL TESTING	1	8	0	0	9	7.4%
COLLECTION	0	0	0	0	0	0.0%
COMPONENT PREPARATION	0	1	2	1	4	3.3%
LABELING	7	10 <sup>1</sup>	6 <sup>3</sup>	11 <sup>3</sup>	34	27.9%
DONOR SCREENING	0	3	0	2	5	4.1%
DONOR DEFERRAL	0	0	0	0	0	0.0%
POST DONATION INFO	8	4	4	0	16	13.1%
STORAGE/DISTRIBUTION	10 <sup>3</sup>	11 <sup>5</sup>	17 <sup>7</sup>	6 <sup>1</sup>	44	36.1%
MISCELLANEOUS	0	0	0	0	0	0.0%
<b>TOTAL</b>	<b>28</b>	<b>38</b>	<b>33</b>	<b>23</b>	<b>122</b>	<b>100.0%</b>

<sup>1,3,5,7</sup> Number of reports included from transfusion services

### NON-REPORTABLE ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	0	0	0	1	1	2.9%
VIRAL TESTING	0	1	0	0	1	2.9%
COLLECTION	0	0	0	0	0	0.0%
COMPONENT PREPARATION	0	0	0	0	0	0.0%
LABELING	1	1	0	0	2	5.7%
DONOR SCREENING	0	0	0	0	0	0.0%
DONOR DEFERRAL	0	0	0	0	0	0.0%
POST DONATION INFO	0	0	0	0	0	0.0%
STORAGE/DISTRIBUTION	0	1	0	1	2	5.7%
MISCELLANEOUS	15 <sup>1</sup>	11 <sup>1</sup>	3	0	29	82.9%
<b>TOTAL</b>	<b>16</b>	<b>14</b>	<b>3</b>	<b>2</b>	<b>35</b>	<b>100.0%</b>

<sup>1</sup> Number of reports included from transfusion services

### TOTAL ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	2	1 <sup>1</sup>	4 <sup>1</sup>	4 <sup>3</sup>	11	7.0%
VIRAL TESTING	1	9	0	0	10	6.4%
COLLECTION	0	0	0	0	0	0.0%
COMPONENT PREPARATION	0	1	2	1	4	2.5%
LABELING	8	11 <sup>1</sup>	6 <sup>3</sup>	11 <sup>3</sup>	36	22.9%
DONOR SCREENING	0	3	0	2	5	3.2%
DONOR DEFERRAL	0	0	0	0	0	0.0%
POST DONATION INFO	8	4	4	0	16	10.2%
STORAGE/DISTRIBUTION	10 <sup>3</sup>	12 <sup>5</sup>	17 <sup>7</sup>	7 <sup>1</sup>	46	29.3%
MISCELLANEOUS	15 <sup>1</sup>	11 <sup>1</sup>	3	0	29	18.5%
<b>TOTAL</b>	<b>44</b>	<b>52</b>	<b>36</b>	<b>25</b>	<b>157</b>	<b>100.0%</b>

<sup>1,3,5,7</sup> Number of reports included from transfusion services



## PLASMA CENTERS

### REPORTABLE ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	0	2	0	0	2	0.1%
VIRAL TESTING	3	3	1	2	9	0.5%
COLLECTION	0	0	1	0	1	0.1%
COMPONENT PREPARATION	0	1	0	0	1	0.1%
LABELING	1	0	1	0	2	0.1%
DONOR SCREENING	21	21	35	35	112	5.7%
DONOR DEFERRAL	2	4	2	1	9	0.5%
POST DONATION INFO	214	446	522	538	1720	87.5%
STORAGE/DISTRIBUTION	11	54	23	12	100	5.1%
MISCELLANEOUS	0	5	1	3	9	0.5%
<b>TOTAL</b>	<b>252</b>	<b>536</b>	<b>586</b>	<b>591</b>	<b>1965</b>	<b>100.0%</b>

### NON-REPORTABLE ERRORS AND ACCIDENTS

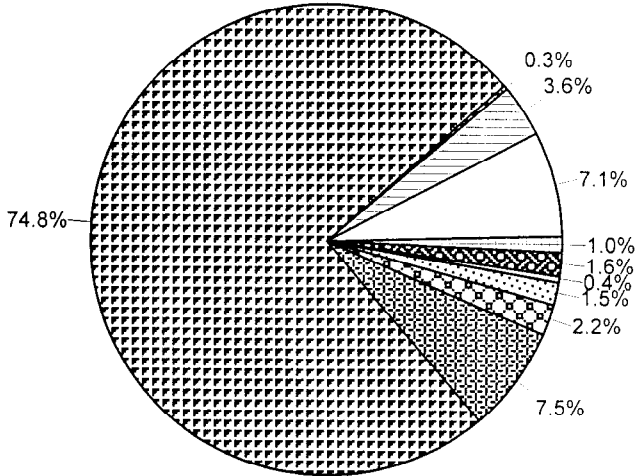
TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	0	0	0	0	0	0.0%
VIRAL TESTING	0	0	0	0	0	0.0%
COLLECTION	0	0	0	0	0	0.0%
COMPONENT PREPARATION	0	0	0	0	0	0.0%
LABELING	0	0	0	1	1	3.1%
DONOR SCREENING	1	0	9	1	11	34.4%
DONOR DEFERRAL	0	0	0	0	0	0.0%
POST DONATION INFO	0	0	0	0	0	0.0%
STORAGE/DISTRIBUTION	2	2	0	0	4	12.5%
MISCELLANEOUS	11	0	2	3	16	50.0%
<b>TOTAL</b>	<b>14</b>	<b>2</b>	<b>11</b>	<b>5</b>	<b>32</b>	<b>100.0%</b>

### TOTAL ERROR AND ACCIDENT REPORTS

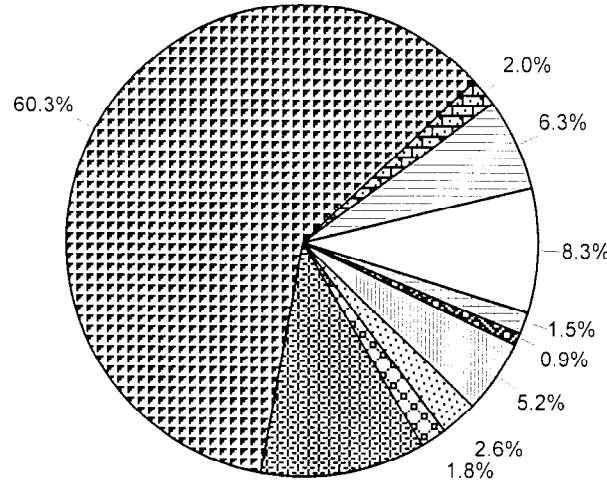
TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	0	2	0	0	2	0.1%
VIRAL TESTING	3	3	1	2	9	0.5%
COLLECTION	0	0	1	0	1	0.1%
COMPONENT PREPARATION	0	1	0	0	1	0.1%
LABELING	1	0	1	1	3	0.2%
DONOR SCREENING	22	21	44	36	123	6.2%
DONOR DEFERRAL	2	4	2	1	9	0.5%
POST DONATION INFO	214	446	522	538	1720	86.1%
STORAGE/DISTRIBUTION	13	56	23	12	104	5.2%
MISCELLANEOUS	11	5	3	6	25	1.3%
<b>TOTAL</b>	<b>266</b>	<b>538</b>	<b>597</b>	<b>596</b>	<b>1997</b>	<b>100.0%</b>

# ERROR AND ACCIDENT REPORTS FY99

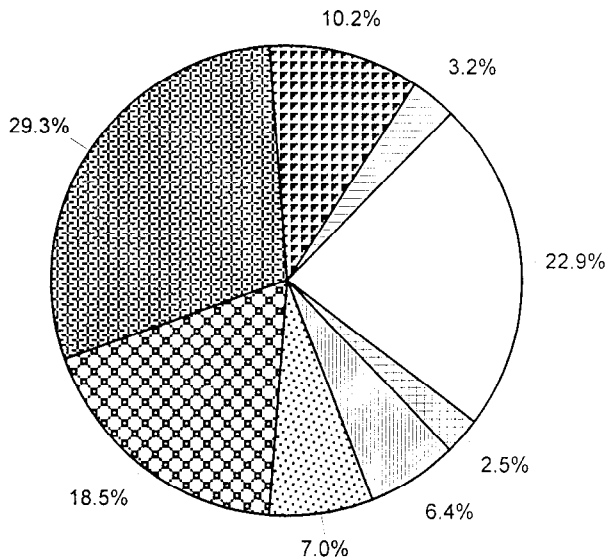
AMERICAN RED CROSS



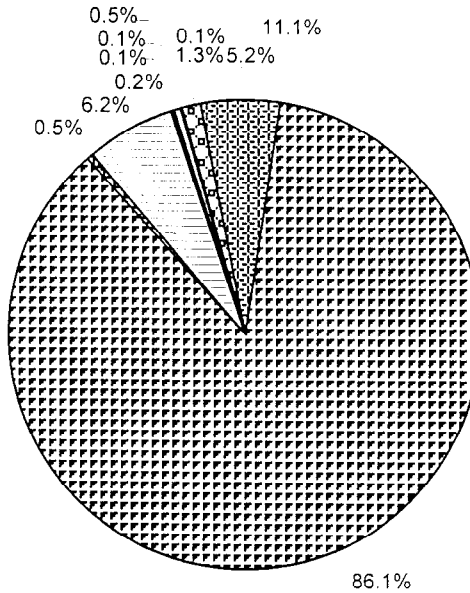
NON-ARC LICENSED BLOOD BANKS



- TYPES OF ERRORS/ACCIDENTS**
- ROUTINE TESTING
  - VIRAL TESTING
  - COLLECTION
  - COMPONENT PREPARATION
  - LABELING
  - DONOR SCREENING
  - DONOR DEFERRAL
  - POST DONATION INFORMATION
  - STORAGE/DISTRIBUTION
  - MISCELLANEOUS



PLASMA CENTERS



UNLICENSED BLOOD BANKS

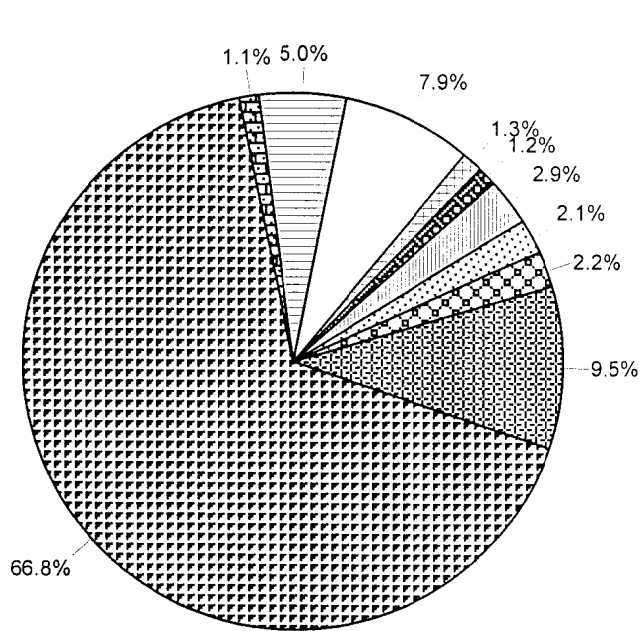
REPORTS RECEIVED (10/1/98 - 9/30/99) = 15,434

ARC = 6,616; NON-ARC LICENSED BLOOD BANKS = 6,664; UNLICENSED BLOOD BANKS = 157; PLASMA CENTERS = 1997

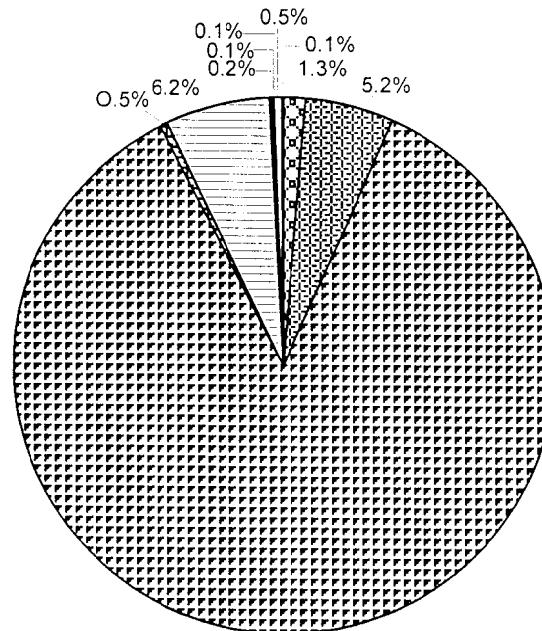
# ERROR AND ACCIDENT REPORTS

## BLOOD BANKS VERSUS PLASMA CENTERS

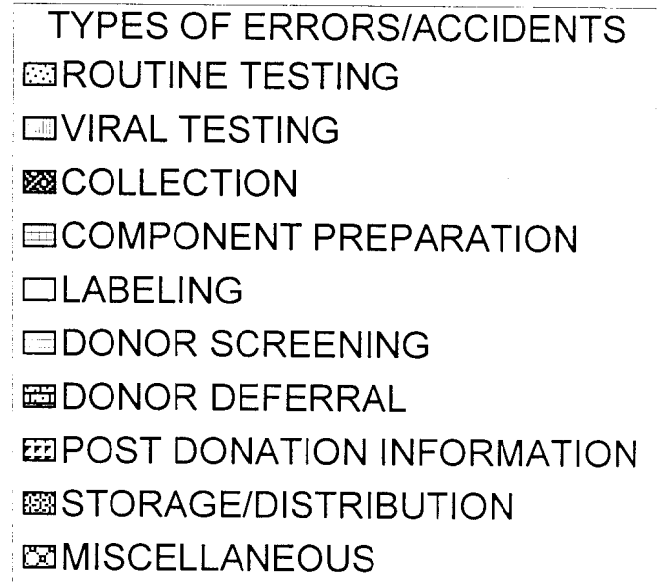
### FY99



BLOOD BANKS



PLASMA CENTERS

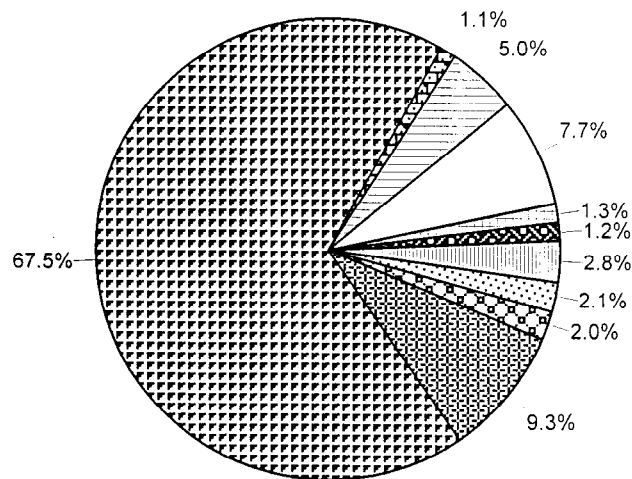


REPORTS RECEIVED 10/1/98 - 9/30/99  
 BLOOD BANKS = 13,437  
 PLASMA CENTERS = 1997

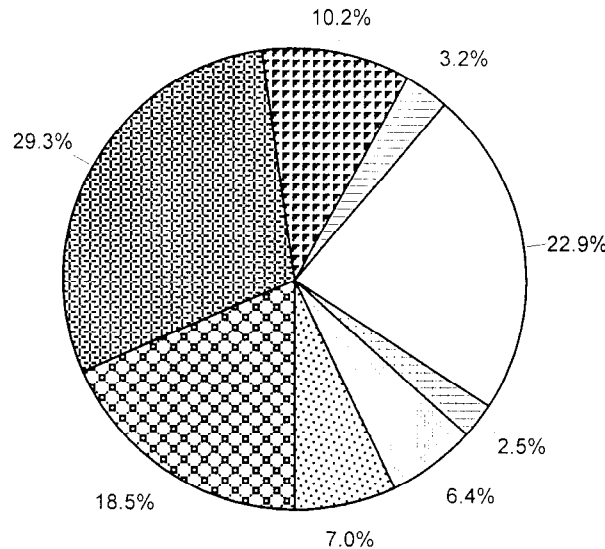
# ERROR AND ACCIDENT REPORTS

## BLOOD BANKS VERSUS PLASMA CENTERS

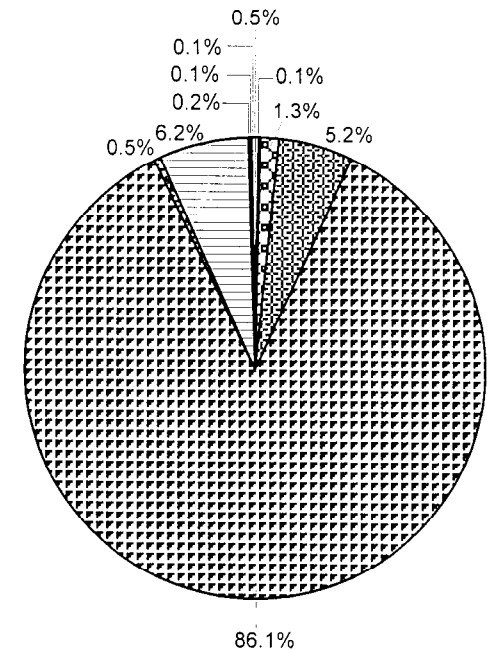
### FY99



LICENSED  
BLOOD BANKS



UNLICENSED  
BLOOD BANKS



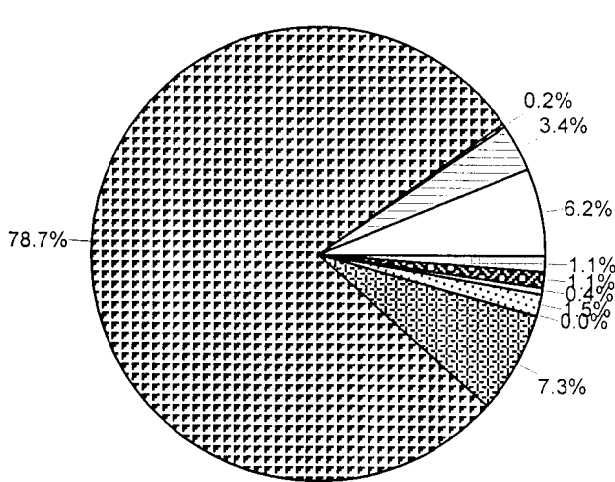
PLASMA  
CENTERS

TYPES OF ERRORS/ACCIDENTS		
ROUTINE TESTING	VIRAL TESTING	COLLECTION
COMPONENT PREPARATION	LABELING	DONOR SCREENING
DONOR DEFERRAL	POST DONATION INFORMATION	STORAGE/DISTRIBUTION
MISCELLANEOUS		

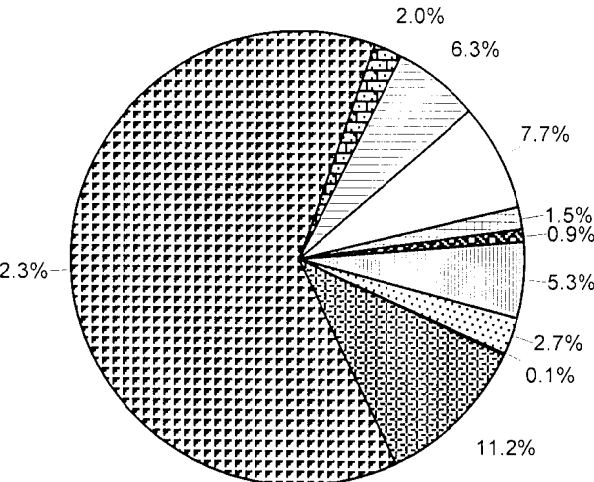
REPORTS RECEIVED 10/1/98 - 9/30/99  
 LICENSED BLOOD BANKS = 13,280  
 UNLICENSED BLOOD BANKS = 157  
 PLASMA CENTERS = 1997

# ERROR AND ACCIDENT REPORTS

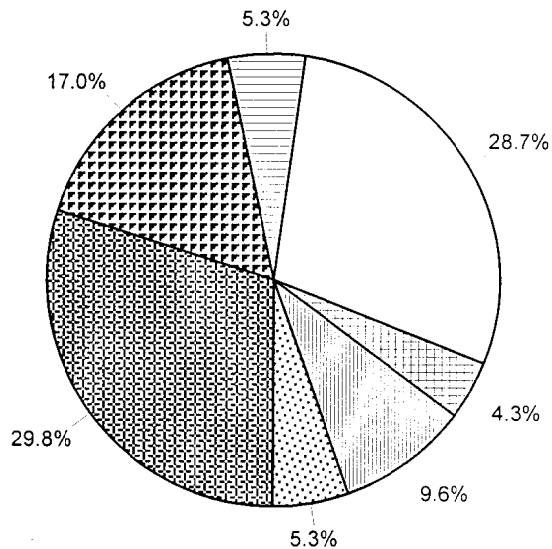
## REPORTABLE ERRORS/ACCIDENTS-FY99



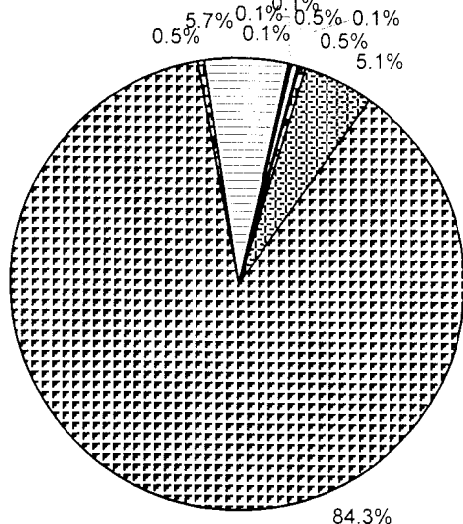
**AMERICAN RED CROSS**



**NON-ARC LICENSED BLOOD BANKS**



**UNLICENSED BLOOD BANKS**



**PLASMA CENTERS**

- TYPES OF ERRORS/ACCIDENTS**
- ROUTINE TESTING
  - VIRAL TESTING
  - COLLECTION
  - COMPONENT PREPARATION
  - LABELING
  - DONOR SCREENING
  - DONOR DEFERRAL
  - POST DONATION INFORMATION
  - STORAGE/DISTRIBUTION
  - MISCELLANEOUS

REPORTS RECEIVED (10/1/98 - 9/30/99) = 14,733

ARC = 6269; NON-ARC LICENSED BLOOD BANKS = 6397; UNLICENSED BLOOD BANKS = 122; PLASMA CENTERS = 1965

Of the 14,733 reportable error and accident reports received from blood and plasma establishments, 10,639 (72.2%) reports involved post donation information. 8919 (83.8%) reports were submitted by blood establishments and 1720 (16.2%) were submitted from plasma centers. The following 3 tables represent the type of post donation information reported in order of prevalence.

POST DONATION INFORMATION REPORTS - TABLE 1

POST DONATION INFORMATION RECEIVED	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
Tattoo, earpiercing, accidental needlestick, or transfusion	1143	12.8%	773	44.9%	1916	18.0%
Travel to malaria endemic area/history of malaria	1479	16.6%	1	0.1%	1480	13.9%
History of cancer	1297	14.5%	11	0.6%	1308	12.3%
Illness (not AIDS or Hepatitis related)	1007	11.3%	5	0.3%	1012	9.5%
History of disease or surgery	604	6.8%	17	1.0%	621	5.8%
Sexual partner testing positive for Hepatitis marker	549	6.2%	33	1.9%	582	5.5%
IV drug use	304	3.4%	103	6.0%	407	3.8%
High risk behavior*	123	1.4%	249	14.5%	372	3.5%
Incarcerated	32	0.4%	311	18.1%	343	3.2%
Non-sexual exposure to Hepatitis B or C	280	3.1%	15	0.9%	295	2.8%
Male to male sex	241	2.7%	47	2.7%	288	2.7%
History of Hepatitis B/C or jaundice	249	2.8%	12	0.7%	261	2.5%
Sex with IV drug user	243	2.7%	17	1.0%	260	2.4%
Received medication or antibiotics	234	2.6%	9	0.5%	243	2.3%
Travel to or immigration from high risk area (Hepatitis or AIDS)	160	1.8%	3	0.2%	163	1.5%
Post donation HBV or HCV related illness or positive hepatitis marker	117	1.3%	17	1.0%	134	1.3%
Risk factors associated with Creutzfeldt-Jakob Disease	123	1.4%	2	0.1%	125	1.2%
Received Proscar, Tegison or Accutane	107	1.2%	2	0.1%	109	1.0%
Exchanged sex for drugs/money	79	0.9%	14	0.8%	93	0.9%
History of Hepatitis A	80	0.9%	4	0.2%	84	0.8%
Sexual partner testing positive for HIV	56	0.6%	22	1.3%	78	0.7%
Received vaccine or immune globulin	53	0.6%	24	1.4%	77	0.7%
Information not related to Hepatitis or AIDS	59	0.7%	4	0.2%	63	0.6%
Female had sex with a man who has had sex with another man	56	0.6%	2	0.1%	58	0.5%
Exposure to Hepatitis A	39	0.4%	2	0.1%	41	0.4%
Sexually transmitted disease, or positive STS	33	0.4%	5	0.3%	38	0.4%
Do not use my blood	36	0.4%	1	0.1%	37	0.3%
Post donation AIDS or related illness or positive test for HIV, or anti-HTLV-I	32	0.4%	3	0.2%	35	0.3%
Received growth hormone	32	0.4%	0	0.0%	32	0.3%
Received Methotrexate	32	0.4%	0	0.0%	32	0.3%
Exposure to a disease	25	0.3%	1	0.1%	26	0.2%
Resided in a rehabilitation center or psychiatric hospital	3	0.0%	10	0.6%	13	0.1%
History of Creutzfeldt-Jakob Disease	7	0.1%	1	0.1%	8	0.1%
Sexual partner having sexually transmitted disease	3	0.0%	0	0.0%	3	0.0%
Non-sexual exposure to HIV	2	0.0%	0	0.0%	2	0.0%
<b>TOTAL</b>	<b>8919</b>	<b>100.0%</b>	<b>1720</b>	<b>100.0%</b>	<b>10639</b>	<b>100.0%</b>

\*includes – non-IV drug use, rape, unprotected sex, donor rejected at another center (reason not specified), sex partner engaged in high risk behavior

## POST DONATION INFORMATION REPORTS - TABLE 2

POST DONATION INFORMATION RECEIVED	BLOOD ESTABLISHMENTS		TOTAL	
Travel to malaria endemic area/history of malaria	1479	16.6%	1480	13.9%
History of cancer	1297	14.5%	1308	12.3%
Tattoo, earpiercing, accidental needlestick, or transfusion	1143	12.8%	1916	18.0%
Illness (not AIDS or Hepatitis related)	1007	11.3%	1012	9.5%
History of disease or surgery	604	6.8%	621	5.8%
Sexual partner testing positive for Hepatitis marker	549	6.2%	582	5.5%
IV drug use	304	3.4%	407	3.8%
Non-sexual exposure to Hepatitis B or C	280	3.1%	295	2.8%
History of Hepatitis B/C or jaundice	249	2.8%	261	2.5%
Sex with IV drug user	243	2.7%	260	2.4%
Male to male sex	241	2.7%	288	2.7%
Received medication or antibiotics	234	2.6%	243	2.3%
Travel to or immigration from high risk area (Hepatitis or AIDS)	160	1.8%	163	1.5%
High risk behavior*	123	1.4%	372	3.5%
Risk factors associated with Creutzfeldt-Jakob Disease	123	1.4%	125	1.2%
Post donation HBV or HCV related illness or positive hepatitis marker	117	1.3%	134	1.3%
Received Proscar, Tegison or Accutane	107	1.2%	109	1.0%
History of Hepatitis A	80	0.9%	84	0.8%
Exchanged sex for drugs/money	79	0.9%	93	0.9%
Information not related to Hepatitis or AIDS	59	0.7%	63	0.6%
Sexual partner testing positive for HIV	56	0.6%	78	0.7%
Female had sex with a man who has had sex with another man	56	0.6%	58	0.5%
Received vaccine or immune globulin	53	0.6%	77	0.7%
Exposure to Hepatitis A	39	0.4%	41	0.4%
Do not use my blood	36	0.4%	37	0.3%
Sexually transmitted disease, or positive STS	33	0.4%	38	0.4%
Incarcerated	32	0.4%	343	3.2%
Post donation AIDS or related illness or positive test for HIV, or anti-HTLV-I	32	0.4%	35	0.3%
Received growth hormone	32	0.4%	32	0.3%
Received Methotrexate	32	0.4%	32	0.3%
Exposure to a disease	25	0.3%	26	0.2%
History of Creutzfeldt-Jakob Disease	7	0.1%	8	0.1%
Resided in a rehabilitation center or psychiatric hospital	3	0.0%	13	0.1%
Sexual partner having sexually transmitted disease	3	0.0%	3	0.0%
Non-sexual exposure to HIV	2	0.0%	2	0.0%
<b>TOTAL</b>	<b>8919</b>	<b>100.0%</b>	<b>10639</b>	<b>100%</b>

\*includes – non-IV drug use, rape, unprotected sex, donor rejected at another center (reason not specified), sex partner engaged in high risk behavior

POST DONATION INFORMATION REPORTS - TABLE 3

POST DONATION INFORMATION RECEIVED	PLASMA CENTERS		TOTAL	
Tattoo, earpiercing, accidental needlestick, or transfusion	773	44.9%	1916	18.0%
Incarcerated	311	18.1%	343	3.2%
High risk behavior*	249	14.5%	372	3.5%
IV drug use	103	6.0%	407	3.8%
Male to male sex	47	2.7%	288	2.7%
Sexual partner testing positive for Hepatitis marker	33	1.9%	582	5.5%
Received vaccine or immune globulin	24	1.4%	77	0.7%
Sexual partner testing positive for HIV	22	1.3%	78	0.7%
Post donation HBV or HCV related illness or positive hepatitis marker	17	1.0%	134	1.3%
Sex with IV drug user	17	1.0%	260	2.4%
History of disease or surgery	17	1.0%	621	5.8%
Non-sexual exposure to Hepatitis B or C	15	0.9%	295	2.8%
Exchanged sex for drugs/money	14	0.8%	93	0.9%
History of Hepatitis B/C or jaundice	12	0.7%	261	2.5%
History of cancer	11	0.6%	1308	12.3%
Resided in a rehabilitation center or psychiatric hospital	10	0.6%	13	0.1%
Received medication or antibiotics	9	0.5%	243	2.3%
Illness (not AIDS or Hepatitis related)	5	0.3%	1012	9.5%
Sexually transmitted disease, or positive STS	5	0.3%	38	0.4%
Information not related to Hepatitis or AIDS	4	0.2%	63	0.6%
History of Hepatitis A	4	0.2%	84	0.8%
Post donation AIDS or related illness or positive test for HIV, or anti-HTLV-I	3	0.2%	35	0.3%
Travel to or immigration from high risk area (Hepatitis or AIDS)	3	0.2%	163	1.5%
Female had sex with a man who has had sex with another man	2	0.1%	58	0.5%
Risk factors associated with Creutzfeldt-Jakob Disease	2	0.1%	125	1.2%
Received Proscar, Tegison or Accutane	2	0.1%	109	1.0%
Exposure to Hepatitis A	2	0.1%	41	0.4%
Do not use my blood	1	0.1%	37	0.3%
Travel to malaria endemic area/history of malaria	1	0.1%	1480	13.9%
History of Creutzfeldt-Jakob Disease	1	0.1%	8	0.1%
Exposure to a disease	1	0.1%	26	0.2%
Sexual partner having sexually transmitted disease	0	0.0%	3	0.0%
Non-sexual exposure to HIV	0	0.0%	2	0.0%
Received growth hormone	0	0.0%	32	0.3%
Received Methotrexate	0	0.0%	32	0.3%
<b>TOTAL</b>	<b>1720</b>	<b>100.0%</b>	<b>10639</b>	<b>100.0%</b>

\*includes – non-IV drug use, rape, unprotected sex, donor rejected at another center (reason not specified), sex partner engaged in high risk behavior



The following 3 tables represent the distribution of post donation information reports in which the information was known, or should have been known at the time of donation, but was not provided until after the donation.

Table 1

POST DONATION INFORMATION	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
Tattoo, earpiercing, accidental needlestick, or transfusion	1140	16.2%	773	47.7%	1913	22.1%
Travel to malarial endemic area	1477	21.0%	1	0.1%	1478	17.1%
History of cancer	842	12.0%	9	0.6%	851	9.8%
History of disease or surgery	582	8.3%	17	1.0%	599	6.9%
Sexual partner testing positive for hepatitis marker	449	6.4%	25	1.5%	474	5.5%
IV drug use	303	4.3%	103	6.4%	406	4.7%
History of incarceration	32	0.5%	309	19.1%	341	3.9%
High risk behavior*	117	1.7%	203	12.5%	320	3.7%
Male to male sex	241	3.4%	47	2.9%	288	3.3%
Non-sexual exposure to Hepatitis B or C	249	3.5%	12	0.7%	261	3.0%
<b>TOTAL</b>	<b>5432</b>	<b>77.2%</b>	<b>1499</b>	<b>92.5%</b>	<b>6931</b>	<b>80.1%</b>

\*includes – non-IV drug use, rape, unprotected sex, donor rejected at another center (reason not specified), sex partner engaged in high risk behavior

Table 2

POST DONATION INFORMATION	BLOOD ESTABLISHMENTS		TOTAL	
Travel to malarial endemic area	1477	21.0%	1478	17.1%
Tattoo, earpiercing, accidental needlestick, or transfusion	1140	16.2%	1913	22.1%
History of cancer	842	12.0%	851	9.8%
History of disease or surgery	582	8.3%	599	6.9%
Sexual partner testing positive for hepatitis marker	449	6.4%	474	5.5%
IV drug use	303	4.3%	406	4.7%
Non-sexual exposure to Hepatitis B or C	249	3.5%	261	3.0%
History of Hepatitis B/C, or jaundice	248	3.5%	260	3.0%
Male to male sex	241	3.4%	288	3.3%
Received medication or antibiotics	233	3.3%	242	2.8%
<b>TOTAL</b>	<b>5764</b>	<b>81.9%</b>	<b>6772</b>	<b>78.2%</b>

Table 3

POST DONATION INFORMATION	PLASMA CENTERS		TOTAL	
Tattoo, earpiercing, accidental needlestick, or transfusion	773	47.7%	1913	22.1%
History of incarceration	309	19.1%	341	3.9%
High risk behavior*	203	12.5%	320	3.7%
IV drug use	103	6.4%	406	4.7%
<b>TOTAL</b>	<b>1388</b>	<b>85.6%</b>	<b>2980</b>	<b>34.4%</b>

\*includes – non-IV drug use, rape, unprotected sex, donor rejected at another center (reason not specified), sex partner engaged in high risk behavior

The following 3 tables represent the distribution of post donation information reports in which the information was not known at the time of donation.

Table 1

POST DONATION INFORMATION	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
Illness (not AIDS or hepatitis related)	1004	53.3%	5	5.1%	1009	50.9%
Diagnosis of cancer, post donation	455	24.2%	2	2.0%	457	23.0%
Sex partner tests positive for hepatitis	100	5.3%	8	8.1%	108	5.4%
Post donation HBV or HCV illness or positive hepatitis marker	58	3.1%	11	11.1%	69	3.5%
<b>TOTAL</b>	<b>1617</b>	<b>85.8%</b>	<b>26</b>	<b>26.3%</b>	<b>1643</b>	<b>82.9%</b>

Table 2

POST DONATION INFORMATION	BLOOD ESTABLISHMENTS		TOTAL	
Illness (not AIDS or hepatitis related)	1004	53.3%	1009	50.9%
Diagnosis of cancer, post donation	455	24.2%	457	23.0%
Sex partner tests positive for hepatitis	100	5.3%	108	5.4%
<b>TOTAL</b>	<b>1559</b>	<b>82.7%</b>	<b>1574</b>	<b>79.4%</b>

Table 3

POST DONATION INFORMATION	PLASMA CENTERS		TOTAL	
High risk behavior*	46	46.5%	52	2.6%
Sex partner tests positive for HIV/HTLV	12	12.1%	43	2.2%
Post donation HBV or HCV illness or positive hepatitis marker	11	11.1%	69	3.5%
Sex partner tests positive for hepatitis	8	8.1%	108	5.4%
Illness (not AIDS or hepatitis related)	5	5.1%	1009	50.9%
<b>TOTAL</b>	<b>82</b>	<b>82.8%</b>	<b>1281</b>	<b>64.6%</b>

\*includes – non-IV drug use, rape, unprotected sex, donor rejected at another center (reason not specified), sex partner engaged in high risk behavior

Of the 14,733 reportable error and accident reports received from blood and plasma establishments, 1319 (9.0%) reports were storage and distribution errors or accidents. 1219 (92.4%) reports were submitted by blood establishments and 100 (7.6%) were submitted from plasma centers. The following 3 tables represent the type of storage and distribution errors or accidents reported in order of prevalence. The 2 tables identified as Table 2A and Table 3A represent a detailed summary of at least 80% of the errors and accidents in the category of storage and distribution.

STORAGE/DISTRIBUTION - TABLE 1

STORAGE AND DISTRIBUTION ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
Unsuitable product	473	38.8%		0.0%	473	35.9%
Shipped/stored at incorrect temperature	209	17.1%	2	2.0%	211	16.0%
Failure to quarantine unit due to incorrect, incomplete, or positive testing	117	9.6%	61	61.0%	178	13.5%
Inappropriate release	143	11.7%	5	5.0%	148	11.2%
Failure to quarantine unit due to testing not performed or documented	121	9.9%	21	21.0%	142	10.8%
Failure to quarantine unit due to medical history	61	5.0%	11	11.0%	72	5.5%
Improper transfusion service practice	55	4.5%	0	0.0%	55	4.2%
Interstate shipment of unlicensed product	40	3.3%	0	0.0%	40	3.0%
<b>TOTAL</b>	<b>1219</b>	<b>100.0%</b>	<b>100</b>	<b>100.0%</b>	<b>1319</b>	<b>100.0%</b>

STORAGE/DISTRIBUTION - TABLE 2

STORAGE AND DISTRIBUTION ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		TOTAL	
Unsuitable product	473	38.8%	473	35.9%
Shipped/stored at incorrect temperature	209	17.1%	211	16.0%
Failure to quarantine unit due to testing not performed or documented	121	9.9%	142	10.8%
Failure to quarantine unit due to incorrect, incomplete, or positive testing	117	9.6%	178	13.5%
Inappropriate release	143	11.7%	148	11.2%
Failure to quarantine unit due to medical history	61	5.0%	72	5.5%
Improper transfusion service practice	55	4.5%	55	4.2%
Interstate shipment of unlicensed product	40	3.3%	40	3.0%
<b>TOTAL</b>	<b>1217</b>	<b>100.0%</b>	<b>1317</b>	<b>100.0%</b>

STORAGE/DISTRIBUTION - TABLE 3

STORAGE AND DISTRIBUTION ERRORS/ACCIDENTS	PLASMA CENTERS		TOTAL	
Failure to quarantine unit due to incorrect, incomplete, or positive testing	61	61.0%	178	13.5%
Failure to quarantine unit due to testing not performed or documented	21	21.0%	142	10.8%
Failure to quarantine unit due to medical history	11	11.0%	72	5.5%
Inappropriate release	5	5.0%	148	11.2%
Shipped/stored at incorrect temperature	2	2.0%	211	16.0%
Unsuitable product	0	0.0%	473	35.9%
Improper transfusion service practice	0	0.0%	55	4.2%
Interstate shipment of unlicensed product	0	0.0%	40	3.0%
<b>TOTAL</b>	<b>100</b>	<b>100.0%</b>	<b>1317</b>	<b>100.0%</b>

## STORAGE/DISTRIBUTION - TABLE 2A

STORAGE AND DISTRIBUTION ERRORS/ACCIDENTS (DETAILED)	BLOOD		TOTAL	
	ESTABLISHMENTS			
<i>Unsuitable product</i>				
Unit contained clots	271	22.2%	271	20.5%
Other <sup>1</sup>	100	8.2%	100	7.6%
Broken/damaged unit	52	4.3%	52	3.9%
Unit/segment hemolyzed	50	4.1%	50	3.8%
<i>Shipped or stored at incorrect temperature</i>				
	209	17.1%	211	16.0%
<i>Failure to quarantine unit due to testing not performed or documented for:</i>				
HBsAg	55	4.5%	55	4.2%
Other reasons <sup>2</sup>	34	2.8%	47	3.6%
Antigen screen	12	1.0%	12	0.9%
Antibody screen	10	0.8%	12	0.9%
<i>Failure to quarantine unit due to incorrect, incomplete, or positive testing for:</i>				
Anti-HBc	25	2.1%	25	1.9%
Antibody screen	23	1.9%	23	1.7%
Anti-HCV	16	1.3%	20	1.5%
Other reasons <sup>3</sup>	12	1.0%	59	4.5%
<i>Inappropriate release</i>				
Other <sup>4</sup>	104	8.5%	109	8.3%
Outdated product	39	3.2%	39	3.0%
<i>Failure to quarantine unit due to medical history</i>				
Other reasons <sup>5</sup>	31	2.5%	32	2.4%
<i>Improper transfusion service practice</i>				
Improper ABO/Rh type selected for patient	19	1.6%	19	1.4%
Unit issued to wrong patient	15	1.2%	15	1.1%
<i>Interstate shipment of unlicensed product</i>				
	40	3.3%	40	3.0%
<b>TOTAL</b>	<b>1117</b>	<b>91.6%</b>	<b>1191</b>	<b>90.3%</b>

<sup>1</sup> - Includes unit underweight or overweight; particulate matter in product; unacceptable platelet count, pH, WBC count, or RBC recovery

<sup>2</sup> - Includes all viral markers; DAT; anti-CMV; compatibility testing

<sup>3</sup> - Includes all viral markers; DAT; platelet count; HLA

<sup>4</sup> - Includes failure to quarantine during investigation of discrepancies; collection time discrepancy

<sup>5</sup> - Includes donor self deferred; information regarding post donation illness received prior to release of product

## STORAGE/DISTRIBUTION - TABLE 3A

STORAGE AND DISTRIBUTION ERRORS/ACCIDENTS (DETAILED)	PLASMA CENTERS		TOTAL	
<i>Failure to quarantine unit due to incorrect, incomplete, or positive testing for:</i>				
Other reasons <sup>1</sup>	47	47.0%	59	4.5%
Anti-HIV/HIV antigen	5	5.0%	14	1.1%
Anti-HCV	4	4.0%	20	1.5%
<i>Failure to quarantine unit due to testing not performed or documented for:</i>				
Other reasons <sup>2</sup>	13	13.0%	47	3.6%
Syphilis	3	3.0%	3	0.2%
<i>Failure to quarantine unit due to medical history</i>				
Received vaccine or immune globulin	3	3.0%	6	0.5%
High risk behavior, but does not specify what type	2	2.0%	5	0.4%
<b>TOTAL</b>	<b>77</b>	<b>77.0%</b>	<b>154</b>	<b>11.7%</b>

<sup>1</sup> - Includes all viral markers

<sup>2</sup> - Includes more than one test - anti-HIV-1/2 and HBsAg

Of the 14,733 reportable error and accident reports received from blood and plasma establishments, 912 (6.2%) reports were labeling errors or accidents. 910 (99.8%) reports were submitted by blood establishments and 2 (0.2%) were submitted from plasma centers. The following 3 tables represent the type of labeling errors or accidents reported in order of prevalence.

LABELING - TABLE 1

LABELING ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
Missing/incorrect label or tag-autologous labeling	195	21.4%	0	0.0%	195	21.4%
Extended expiration date	179	19.7%	0	0.0%	179	19.6%
Missing/incorrect donor number	92	10.1%	1	50.0%	93	10.2%
Incorrect ABO and/or Rh label or tag	85	9.3%	0	0.0%	85	9.3%
Incorrect product label or tag	56	6.2%	0	0.0%	56	6.1%
Missing/incorrect label or tag						
Other <sup>1</sup>	60	6.6%	0	0.0%	60	6.6%
CMV	54	5.9%	0	0.0%	54	5.9%
Antigen/antibody	45	4.9%	0	0.0%	45	4.9%
Recipient number	31	3.4%	0	0.0%	31	3.4%
Irradiation	24	2.6%	0	0.0%	24	2.6%
Platelet count	22	2.4%	0	0.0%	22	2.4%
Biohazard/test status	15	1.6%	0	0.0%	15	1.6%
Crossmatch	9	1.0%	0	0.0%	9	1.0%
Anticoagulant	6	0.7%	1	50.0%	7	0.8%
Unlicensed product labeled with license number	37	4.1%	0	0.0%	37	4.1%
<b>TOTAL</b>	<b>910</b>	<b>100.0%</b>	<b>2</b>	<b>100.0%</b>	<b>912</b>	<b>100.0%</b>

<sup>1</sup> - Includes leukoreduced, HLA

LABELING - TABLE 2

LABELING ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		TOTAL	
Missing incorrect label or tag-autologous labeling	195	21.4%	195	21.4%
Extended expiration date	179	19.7%	179	19.6%
Missing/incorrect donor number	92	10.1%	93	10.2%
Incorrect ABO and/or Rh label or tag	85	9.3%	85	9.3%
Incorrect product label or tag	56	6.2%	56	6.1%
Missing/incorrect label or tag				
Other <sup>1</sup>	60	6.6%	60	6.6%
CMV	54	5.9%	54	5.9%
Antigen/antibody	45	4.9%	45	4.9%
Recipient number	31	3.4%	31	3.4%
Irradiation	24	2.6%	24	2.6%
Platelet count	22	2.4%	22	2.4%
Biohazard/test status	15	1.6%	15	1.6%
Crossmatch	9	1.0%	9	1.0%
Anticoagulant	6	0.7%	7	0.8%
Unlicensed product labeled with license number	37	4.1%	37	4.1%
<b>TOTAL</b>	<b>910</b>	<b>100.0%</b>	<b>912</b>	<b>100.0%</b>

<sup>1</sup> - Includes leukoreduced, HLA

LABELING - TABLE 3

LABELING ERRORS/ACCIDENTS	PLASMA CENTERS		TOTAL	
Missing/incorrect donor number	1	50.0%	93	10.2%
Missing/incorrect anticoagulant	1	50.0%	7	0.8%
<b>TOTAL</b>	<b>2</b>	<b>100.0%</b>	<b>100</b>	<b>11.0%</b>

Of the 14,733 reportable error and accident reports received from blood and plasma establishments, 733 (5.0%) reports were donor screening errors or accidents. 621 (84.7%) reports were submitted by blood establishments and 112 (15.3%) were submitted from plasma centers. The following 3 tables represent the type of donor screening errors or accidents reported in order of prevalence. The 2 tables identified as Table 2A and Table 3A represent a detailed summary of at least 80% of the errors and accidents in the category of donor screening.

DONOR SCREENING - TABLE 1

DONOR SCREENING ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
	Donor gave history which warranted deferral and was not deferred	411	66.2%	27	24.1%	438
Donor record incomplete/incorrect/not reviewed	125	20.1%	31	27.7%	156	21.3%
Deferral screening not done, donor previously deferred	23	3.7%	30	26.8%	53	7.2%
Donor did not meet acceptance criteria	35	5.6%	15	13.4%	50	6.8%
Incorrect ID used during deferral search, donor previously deferred	27	4.3%	9	8.0%	36	4.9%
<b>TOTAL</b>	<b>621</b>	<b>100.0%</b>	<b>112</b>	<b>100.0%</b>	<b>733</b>	<b>100.0%</b>

DONOR SCREENING - TABLE 2

DONOR SCREENING ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		TOTAL	
	Donor gave history which warranted deferral and was not deferred	411	66.2%	438
Donor record incomplete/incorrect/not reviewed	125	20.1%	156	21.3%
Donor did not meet acceptance criteria	35	5.6%	50	6.8%
Incorrect ID used during deferral search, donor previously deferred	27	4.3%	36	4.9%
Deferral screening not done, donor previously deferred	23	3.7%	53	7.2%
<b>TOTAL</b>	<b>621</b>	<b>100.0%</b>	<b>733</b>	<b>100.0%</b>

DONOR SCREENING - TABLE 3

DONOR SCREENING ERRORS/ACCIDENTS	PLASMA CENTERS		TOTAL	
	Donor record incomplete/incorrect/not reviewed	31	27.7%	156
Deferral screening not done, donor previously deferred	30	26.8%	53	7.2%
Donor gave history which warranted deferral and was not deferred	27	24.1%	438	59.8%
Donor did not meet acceptance criteria	15	13.4%	50	6.8%
Incorrect ID used during deferral search, donor previously deferred	9	8.0%	36	4.9%
<b>TOTAL</b>	<b>112</b>	<b>100.0%</b>	<b>733</b>	<b>100.0%</b>

DONOR SCREENING - TABLE 2A

DONOR SCREENING ERRORS/ACCIDENTS (DETAILED)	BLOOD ESTABLISHMENTS		TOTAL	
<i>Donor gave history which warranted deferral and was not deferred</i>				
Travel to malaria endemic area/history of malaria	178	28.7%	178	24.3%
History of cancer	52	8.4%	52	7.1%
Received medication or antibiotics	46	7.4%	48	6.5%
History of disease or surgery	34	5.5%	36	4.9%
Hepatitis related risk	21	3.4%	22	3.0%
Received tattoo, earpiercing, accidental needlestick, transfusion	16	2.6%	23	3.1%
<i>Donor record incomplete/incorrect/not reviewed</i>				
Medical history questions	48	7.7%	67	9.1%
High risk behavior questions/information	48	7.7%	56	7.6%
<i>Donor did not meet acceptance criteria</i>				
Temperature unacceptable or not documented	21	3.4%	28	3.8%
Hemoglobin <11.0g/dl, Hematocrit <33%, or Hgb/Hct not documented	13	2.1%	13	1.8%
<i>Incorrect ID used during deferral search, donor previously deferred due to:</i>				
HBsAg reactivity or history of hepatitis	6	1.0%	6	0.8%
HIV reactivity	5	0.8%	5	0.7%
Travel to malaria endemic area/history of malaria	4	0.6%	4	0.5%
<i>Deferral screening not done, donor previously deferred due to</i>				
HBsAg reactivity or history of hepatitis	4	0.6%	8	1.1%
Anti-HBc reactivity	4	0.6%	4	0.5%
Anti-HCV reactivity	4	0.6%	8	1.1%
<b>TOTAL</b>	<b>504</b>	<b>81.2%</b>	<b>558</b>	<b>76.1%</b>



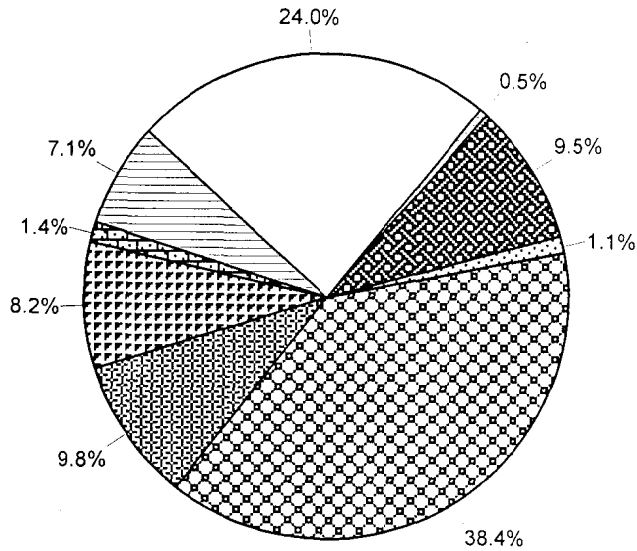
## DONOR SCREENING - TABLE 3A

DONOR SCREENING ERRORS/ACCIDENTS (DETAILED)	PLASMA CENTERS		TOTAL	
<i>Donor record incomplete/incorrect/not reviewed</i>				
Medical history questions	19	17.0%	67	9.1%
High risk behavior questions/information	8	7.1%	56	7.6%
<i>Deferral screening not done, donor previously deferred due to:</i>				
Other reasons <sup>1</sup>	6	5.4%	8	1.1%
HBsAg reactivity or history of hepatitis	4	3.6%	8	1.1%
Anti-HCV reactivity	4	3.6%	8	1.1%
High risk behavior-not specified	4	3.6%	5	0.7%
Sex with IV drug user	3	2.7%	4	0.5%
Incarcerated	3	2.7%	3	0.4%
<i>Donor gave history which warranted deferral and was not deferred</i>				
Received vaccine or immune globulin	9	8.0%	17	2.3%
Received tattoo, earpiercing, accidental needlestick, or transfusion	7	6.3%	23	3.1%
High risk behavior, but does not specify what type	2	1.8%	3	0.4%
History of disease or surgery	2	1.8%	36	4.9%
Received medication or antibiotics	2	1.8%	48	6.5%
<i>Donor did not meet acceptance criteria</i>				
Medical review or physical not performed or inadequate	8	7.1%	8	1.1%
Temperature unacceptable or not documented	7	6.3%	28	3.8%
<i>Incorrect id used during deferral search, donor previously deferred due to:</i>				
High risk behavior-not specified	2	1.8%	2	0.3%
Incarcerated	2	1.8%	2	0.3%
<b>TOTAL</b>	<b>92</b>	<b>82.1%</b>	<b>326</b>	<b>44.5%</b>

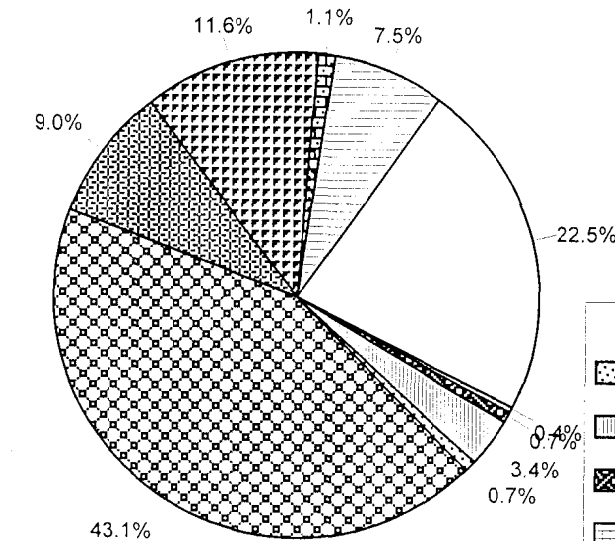
<sup>1</sup> - Includes positive drug screen

# ERROR AND ACCIDENT REPORTS

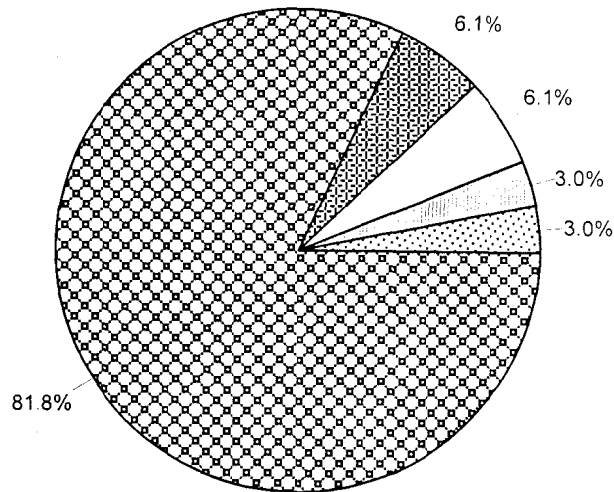
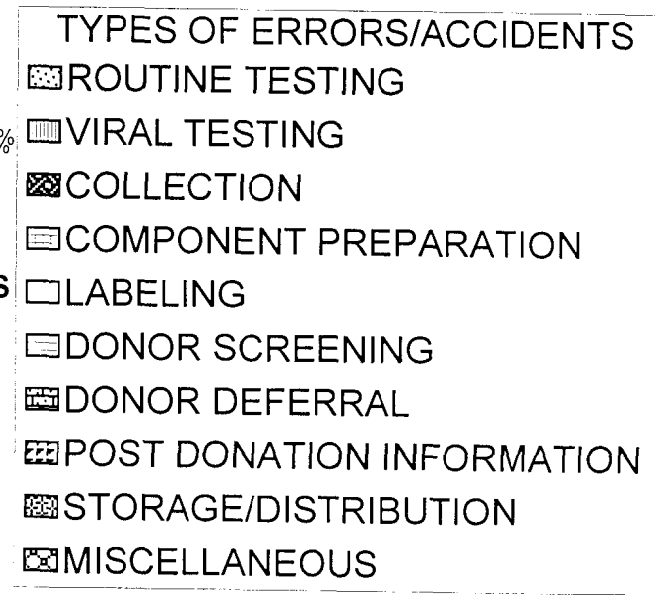
## NON-REPORTABLE ERRORS/ACCIDENTS-FY99



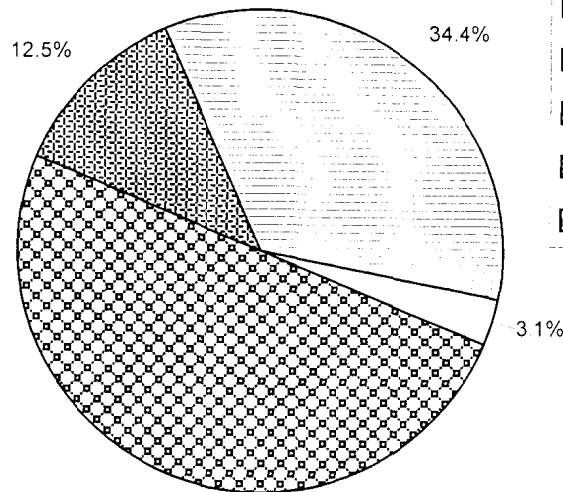
**AMERICAN RED CROSS**



**NON-ARC LICENSED BLOOD BANKS**



**UNLICENSED BLOOD BANKS**



**PLASMA CENTERS**

REPORTS RECEIVED (10/1/98 - 9/30/99) = 701

ARC = 367; NON-ARC LICENSED BLOOD BANKS = 267; UNLICENSED BLOOD BANKS = 35; PLASMA CENTERS = 32

Of the 701 non-reportable error and accident reports received from blood and plasma establishments, 301 (42.9%) reports were miscellaneous errors or accidents. 285 (94.7%) reports were submitted by blood establishments and 16 (5.3%) were submitted from plasma centers. The following 3 tables represent the type of miscellaneous errors or accidents reported in order of prevalence.

MISCELLANEOUS - TABLE 1

MISCELLANEOUS ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
No products made available for distribution	92	32.3%	6	37.5%	98	32.6%
Miscellaneous*	50	17.5%	7	43.8%	57	18.9%
QC not performed or inadequate (other than viral marker, ABO/Rh)	51	17.9%	0	0.0%	51	16.9%
Recordkeeping error/accident (testing and labeling are acceptable)	43	15.1%	1	6.3%	44	14.6%
Records destroyed or lost, destruction records incomplete, or final disposition unknown	29	10.2%	2	12.5%	31	10.3%
Recipient reaction	17	6.0%	0	0.0%	17	5.6%
Emergency released unit not tested prior to release and found positive, labeled appropriately	3	1.1%	0	0.0%	3	1.0%
<b>TOTAL</b>	<b>285</b>	<b>100.0%</b>	<b>16</b>	<b>100.0%</b>	<b>301</b>	<b>100.0%</b>

MISCELLANEOUS - TABLE 2

MISCELLANEOUS ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		TOTAL	
No products made available for distribution	92	32.3%	98	32.6%
QC not performed or inadequate (other than viral marker, ABO/Rh)	51	17.5%	51	16.9%
Miscellaneous*	50	17.9%	57	18.9%
Recordkeeping error/accident (testing and labeling are acceptable)	43	15.1%	44	14.6%
Records destroyed or lost, destruction records incomplete, or final disposition unknown	29	10.2%	31	10.3%
Recipient reaction	17	6.0%	17	5.6%
Emergency released unit not tested prior to release and found positive, labeled appropriately	3	1.1%	3	1.0%
<b>TOTAL</b>	<b>285</b>	<b>100.0%</b>	<b>301</b>	<b>100.0%</b>

MISCELLANEOUS - TABLE 3

MISCELLANEOUS ERRORS/ACCIDENTS	PLASMA CENTERS		TOTAL	
Miscellaneous*	7	43.8%	57	18.9%
No products made available for distribution	6	37.5%	98	32.6%
Records destroyed or lost, destruction records incomplete, or final disposition unknown	2	12.5%	31	10.3%
Recordkeeping error/accident (testing and labeling are acceptable)	1	6.3%	44	14.6%
QC not performed or inadequate (other than viral marker, ABO/Rh)	0	0.0%	51	16.9%
<b>TOTAL</b>	<b>16</b>	<b>100.0%</b>	<b>281</b>	<b>93.4%</b>

\*Includes notification, retrieval, or lookback procedures not followed

Of the 701 non-reportable error and accident reports received from blood and plasma establishments, 151 (21.5%) reports were labeling errors or accidents. 150 (99.3%) reports were submitted by blood establishments and 1 (0.7%) was submitted from a plasma center. The following table represents the type of labeling errors or accidents reported in order of prevalence.

LABELING - TABLE 1

LABELING ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
Unit labeled with missing/incorrect weight, volume, collection date, or facility identifiers; unit acceptable	50	33.3%	1	100.0%	51	33.8%
Unit labeled with shortened expiration date	37	24.7%	0	0.0%	37	24.5%
Unit missing label for ABO and/or Rh, product or expiration date	30	20.0%	0	0.0%	30	19.9%
Directed unit, suitable for homologous use, labeled with incorrect name, SSN, or DOB	27	18.0%	0	0.0%	27	17.9%
Miscellaneous*	6	4.0%	0	0.0%	6	3.9%
<b>TOTAL</b>	<b>150</b>	<b>100.0%</b>	<b>1</b>	<b>100.0%</b>	<b>151</b>	<b>100.0%</b>

\*Includes – unlicensed product labeled with license number crossed off; biohazard label missing but determined that label was not required; recovered plasma with extended expiration date

Of the 701 non-reportable error and accident reports received from blood and plasma establishments, 66 (9.4%) reports involved storage and distribution errors or accidents. 62 (93.9%) reports were submitted by blood establishments and 4 (6.1%) were submitted from plasma centers. The following 3 tables represent the type of storage and distribution errors or accidents reported in order of prevalence.

STORAGE AND DISTRIBUTION - TABLE 1

STORAGE AND DISTRIBUTION ERROR/ACCIDENT	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
Miscellaneous*	28	45.2%	2	50.0%	30	45.5%
Discrepancy between shipping form and shipment	10	16.1%	2	50.0%	12	18.2%
Irradiated unit requested, unit not irradiated, labeled appropriately	9	14.5%	0	0.0%	9	13.6%
Shipment to incorrect facility	5	8.1%	0	0.0%	5	7.6%
Unit lost or shipment never received	4	6.5%	0	0.0%	4	6.1%
Anti-CMV negative unit requested, unit not tested for anti-CMV, labeled appropriately	3	4.8%	0	0.0%	3	4.5%
Release of product other than that which was ordered, labeled appropriately	1	1.6%	0	0.0%	1	1.5%
Special antigen testing requested, unit not tested for special antigen, labeled appropriately	1	1.6%	0	0.0%	1	1.5%
Specific ABO/Rh type requested, incorrect ABO/Rh released, labeled appropriately	1	1.6%	0	0.0%	1	1.5%
<b>TOTAL</b>	<b>62</b>	<b>100.0%</b>	<b>4</b>	<b>100.0%</b>	<b>66</b>	<b>100.0%</b>

\* includes - failure to quarantine unit after receipt of post donation information regarding cold or flu symptoms; allogeneic unit issued when autologous unit was available; unit released using emergency release procedures; applicant donor unit shipped prior to collection of confirming unit, unit suitable

STORAGE AND DISTRIBUTION - TABLE 2

STORAGE AND DISTRIBUTION ERROR/ACCIDENT	BLOOD ESTABLISHMENTS		TOTAL	
Miscellaneous*	28	45.2%	30	45.5%
Discrepancy between shipping form and shipment	10	16.1%	12	18.2%
Irradiated unit requested, unit not irradiated, labeled appropriately	9	14.5%	9	13.6%
Shipment to incorrect facility	5	8.1%	5	7.6%
Unit lost or shipment never received	4	6.5%	4	6.1%
Anti-CMV negative unit requested, unit not tested for anti-CMV, labeled appropriately	3	4.8%	3	4.5%
Release of product other than that which was ordered, labeled appropriately	1	1.6%	1	1.5%
Special antigen testing requested, unit not tested for special antigen, labeled appropriately	1	1.6%	1	1.5%
Specific ABO/Rh type requested, incorrect ABO/Rh released, labeled appropriately	1	1.6%	1	1.5%
<b>TOTAL</b>	<b>62</b>	<b>100.0%</b>	<b>66</b>	<b>100.0%</b>

\* includes - failure to quarantine unit after receipt of post donation information regarding cold or flu symptoms; allogeneic unit issued when autologous unit was available; unit released using emergency release procedures

STORAGE AND DISTRIBUTION - TABLE 3

TYPE OF STORAGE AND DISTRIBUTION ERROR/ACCIDENT	PLASMA CENTERS		TOTAL	
Miscellaneous*	2	50.0%	30	45.5%
Discrepancy between shipping form and shipment	2	50.0%	12	18.2%
<b>TOTAL</b>	<b>4</b>	<b>100.0%</b>	<b>42</b>	<b>63.6%</b>

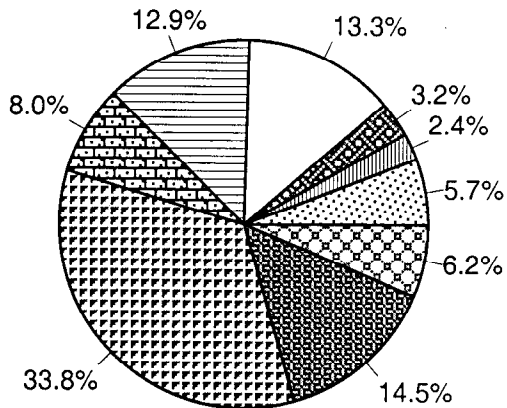
\* includes -applicant donor unit shipped prior to collection of confirming unit, unit suitable

Of the 701 non-reportable error and accident reports received from blood and plasma establishments, 61 (8.7%) reports involve post donation information. Blood establishments submitted all reports. The following table represents the type of donor screening errors or accidents reported in order of prevalence.

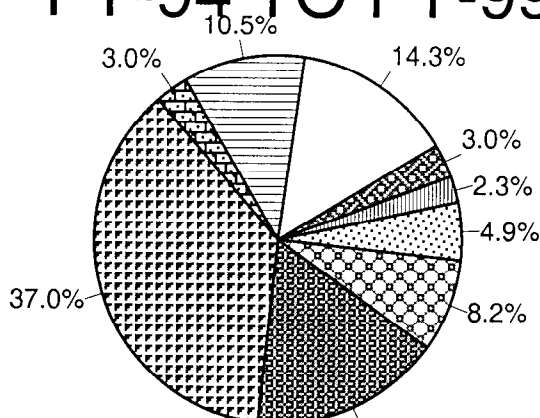
#### POST DONATION INFORMATION

POST DONATION INFORMATION RECEIVED	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
Post donation cold or flu symptoms	56	91.8%	0	0.0%	56	91.8%
Donor pregnant	4	6.6%	0	0.0%	4	6.6%
Discrepancy in information; unit determined to be suitable	1	1.6%	0	0.0%	1	1.6%
<b>TOTAL</b>	<b>61</b>	<b>100.0%</b>	<b>0</b>	<b>0.0%</b>	<b>61</b>	<b>100.0%</b>

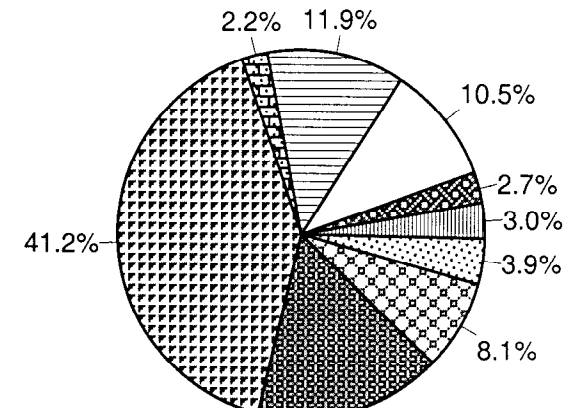
# ERROR AND ACCIDENT REPORTS FY-94 TO FY-99



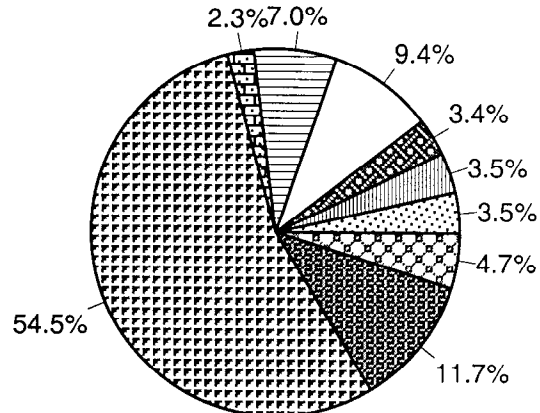
**FY-94**



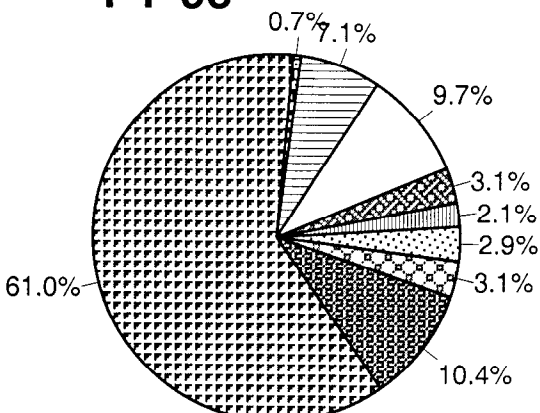
**FY-95**



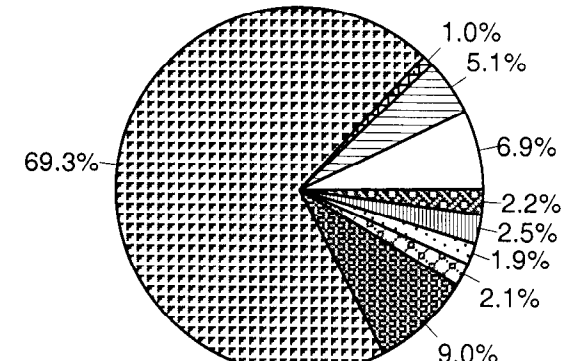
**FY-96**



**FY-97**



**FY-98**



**FY-99**

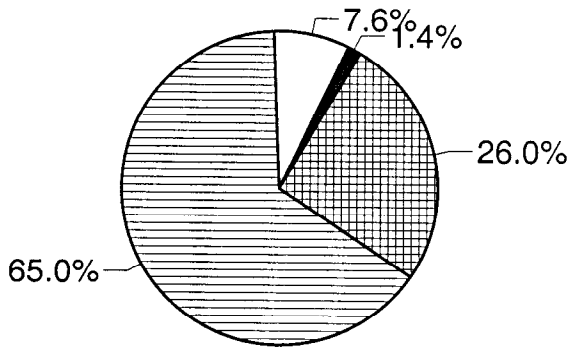
TYPES OF ERRORS/ACCIDENTS		
ROUTINE TESTING	VIRAL TESTING	COLLECT/COMP. PREPARATION
LABELING	DONOR SCREENING	DONOR DEFERRAL
POST DONATION INFORMATION	STORAGE/DISTRIBUTION	MISCELLANEOUS

REPORTS RECEIVED 10/1/92 - 9/30/99

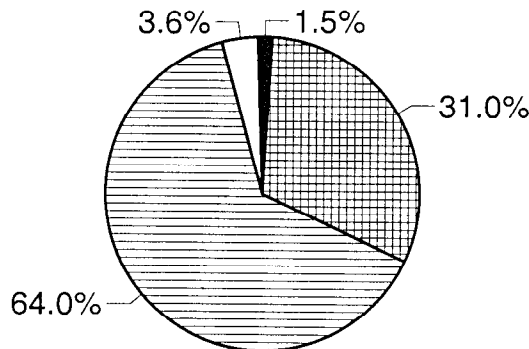
FY-94 = 11,292; FY-95 = 12,923; FY-96 = 14,034, FY-97 = 12,421; FY98 = 13,187; FY99=15,434

# ERROR AND ACCIDENT REPORTS

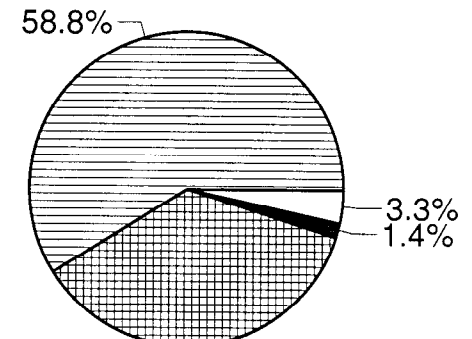
## ALL REPORTING BLOOD ESTABLISHMENTS



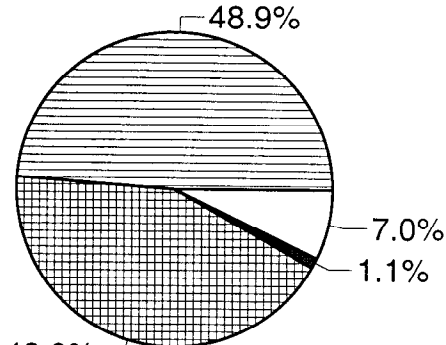
**FY-94**



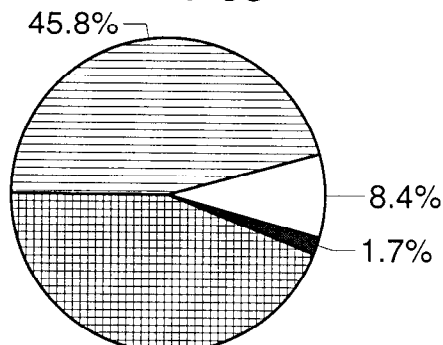
**FY-95**



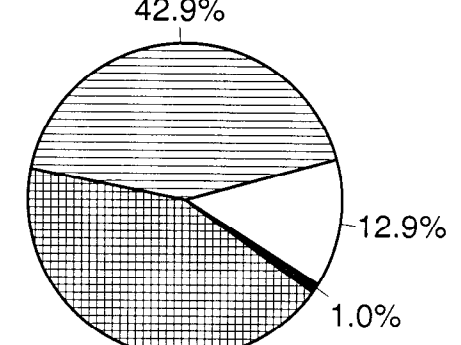
**FY-96**



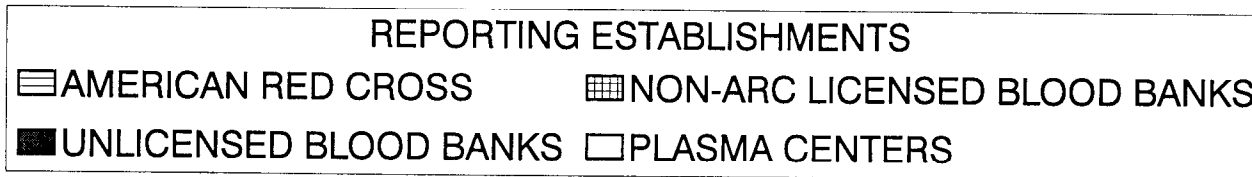
**FY-97**



**FY-98**



**FY-99**



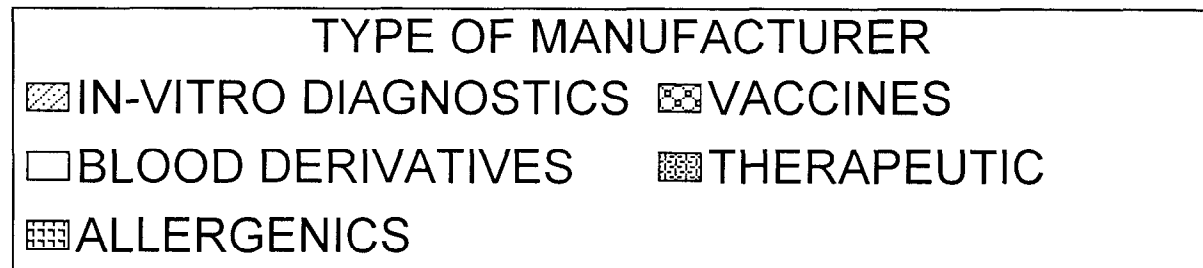
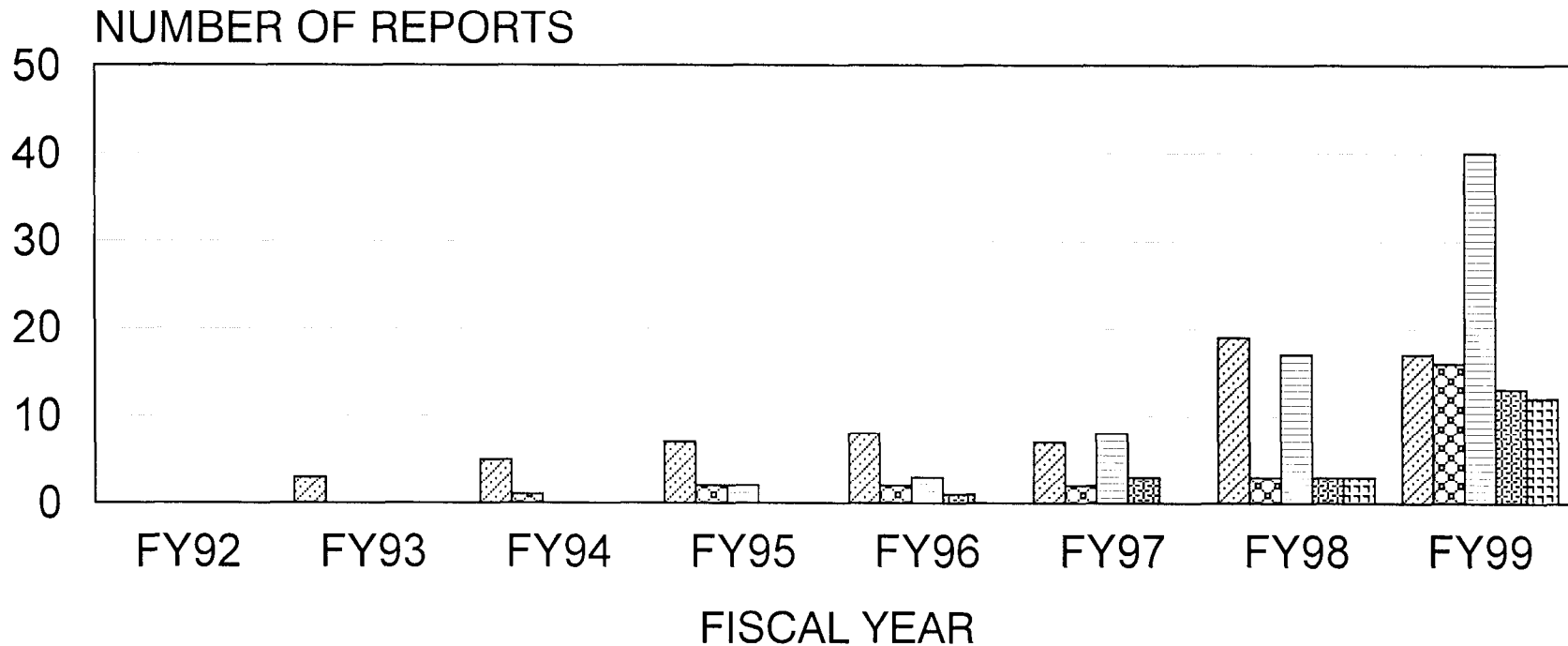
REPORTS RECEIVED 10/1/93 - 9/30/99

FY94 = 11,292; FY95 = 12,923; FY96 = 14,034; FY97 = 12,421; FY98 = 13,187; FY99 = 14,733



# ERROR AND ACCIDENT REPORTS

## ALL REPORTING NON-BLOOD ESTABLISHMENTS



REPORTS RECEIVED 10/1/91 - 9/30/99

FY92 = 0; FY93 = 3; FY94 = 6; FY95 = 11; FY96 = 14; FY97 = 20; FY98 = 45; FY99 = 98

The following table and graphs show the time periods in which the reports were received by CBER. The evaluation of timeliness is limited to only reports that met the threshold for reporting.

**ERROR AND ACCIDENT REPORTS  
RECEIVED 10/1/98 - 9/30/99**

**NUMBER OF DAYS FROM DATE E/A DISCOVERED TO FDA RECEIVED  
BLOOD ESTABLISHMENTS**

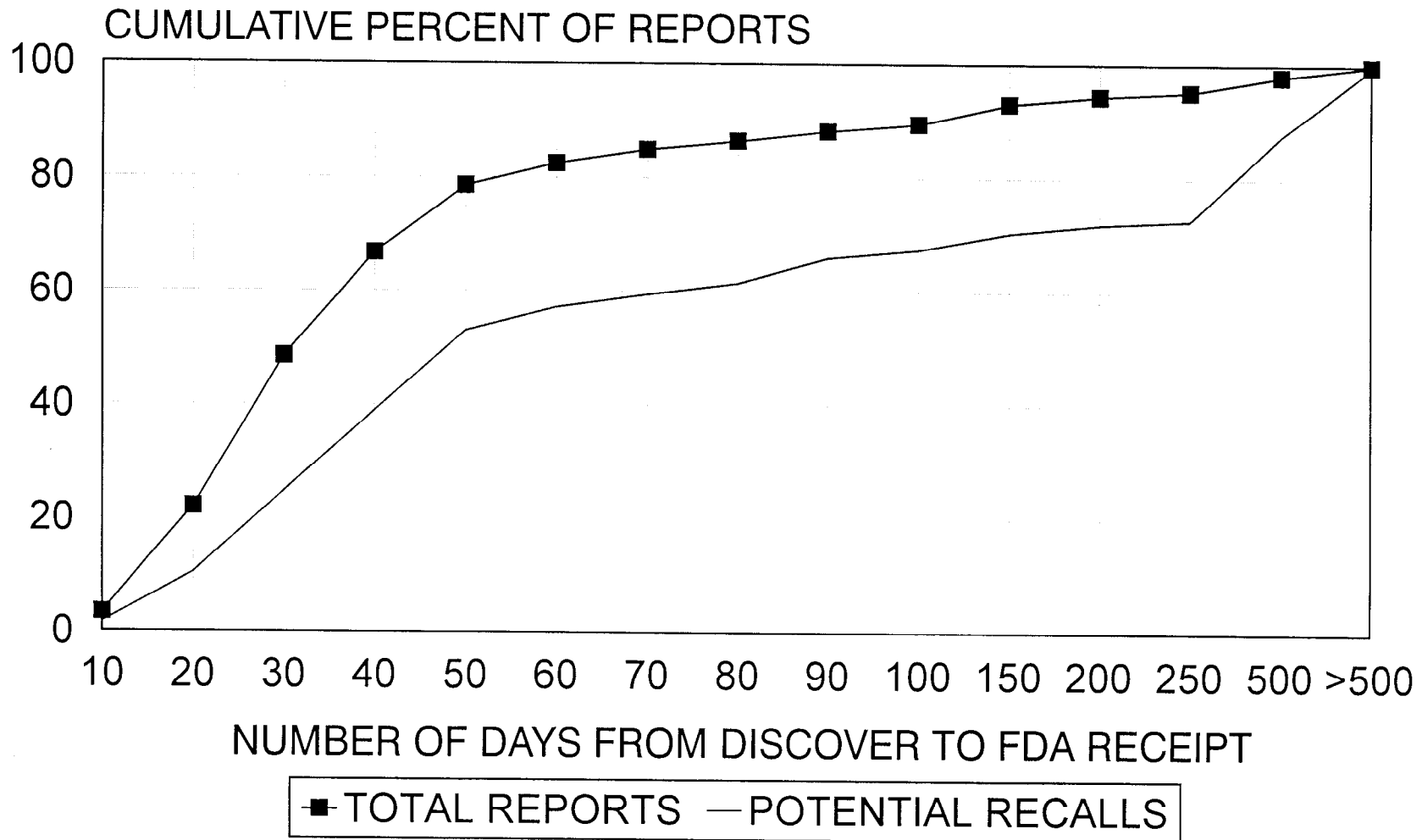
CUMULATIVE PERCENT OF REPORTS	ARC (DAYS)	NON-ARC LICENSED (DAYS)	UNLICENSED (DAYS)	PLASMA (DAYS)	TOTAL (DAYS)
10%	16	15	7	12	14
25%	21	22	14	17	21
50%	29	34	31	28	331
75%	39	79	79	54	47
90%	47	214	197	118	104
# REPORTS	6249	6397	122	1965	14733
RANGE	1-383	3-2385	1-831	3-1221	1-2385

# ERROR AND ACCIDENT REPORTS

## REPORTING TIME

### ALL REPORTING BLOOD ESTABLISHMENTS

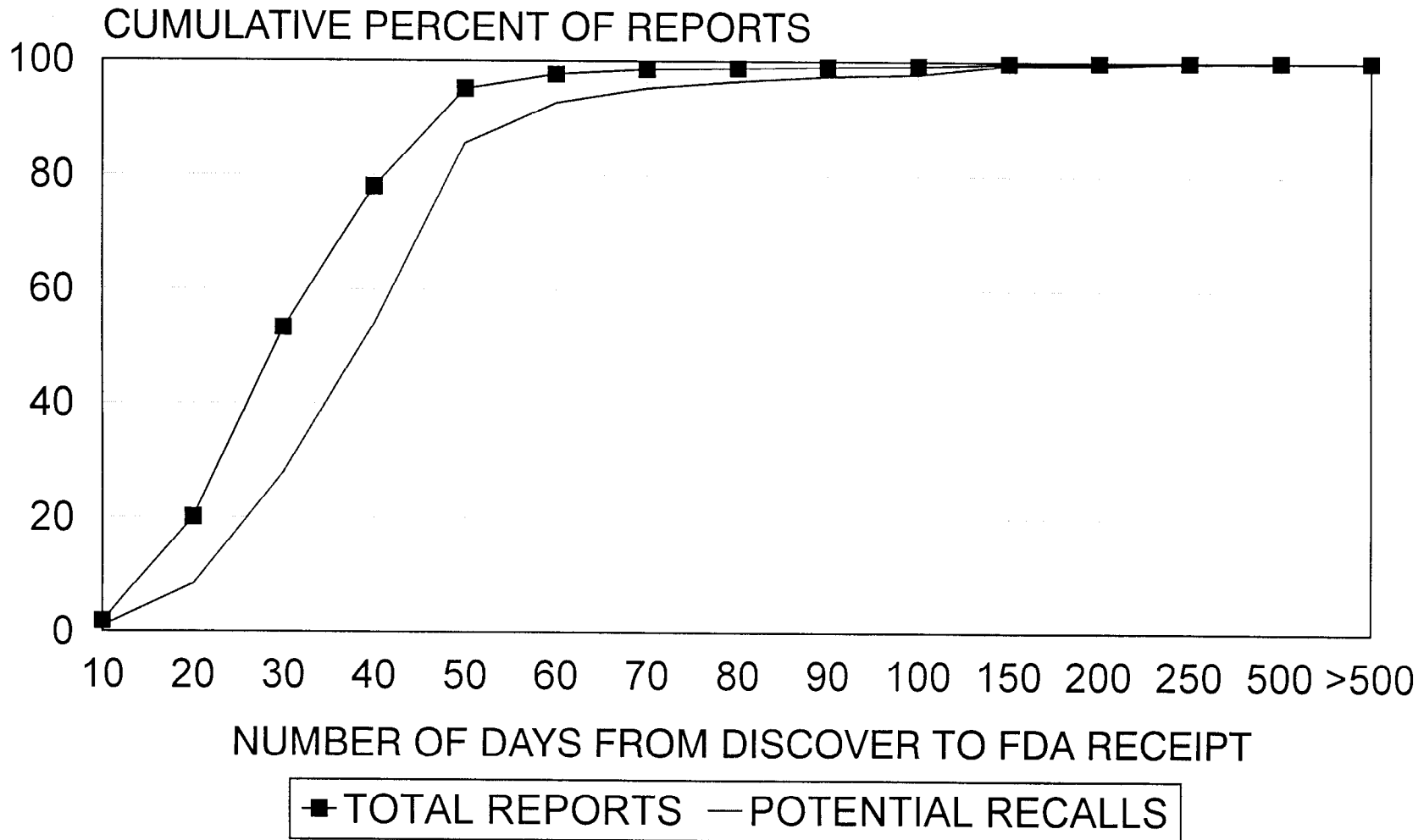
FY-99



TOTAL REPORTS = 14,733  
 POTENTIAL RECALLS = 1724

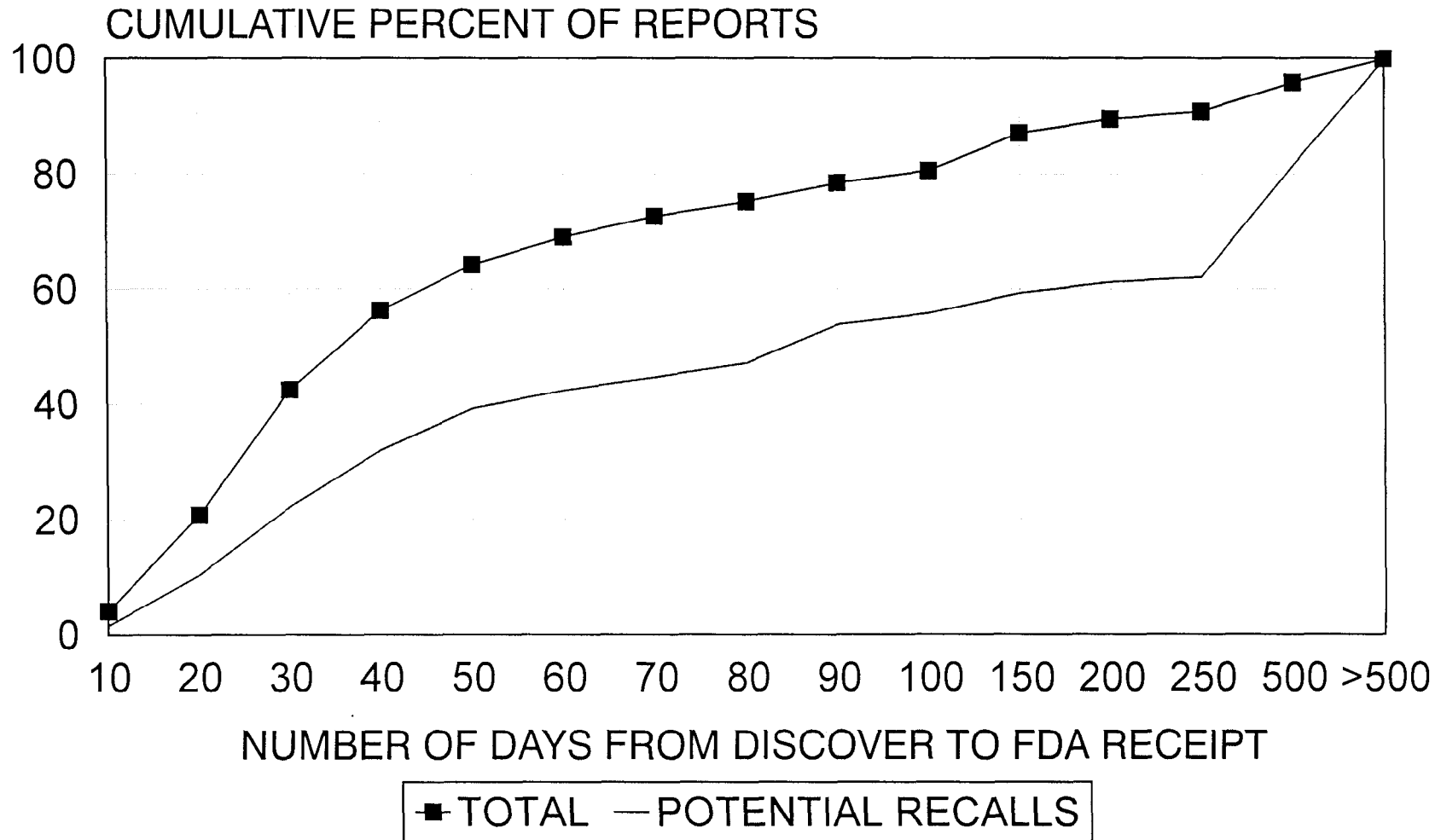
# ERROR AND ACCIDENT REPORTS

## REPORTING TIME AMERICAN RED CROSS *FY-99*



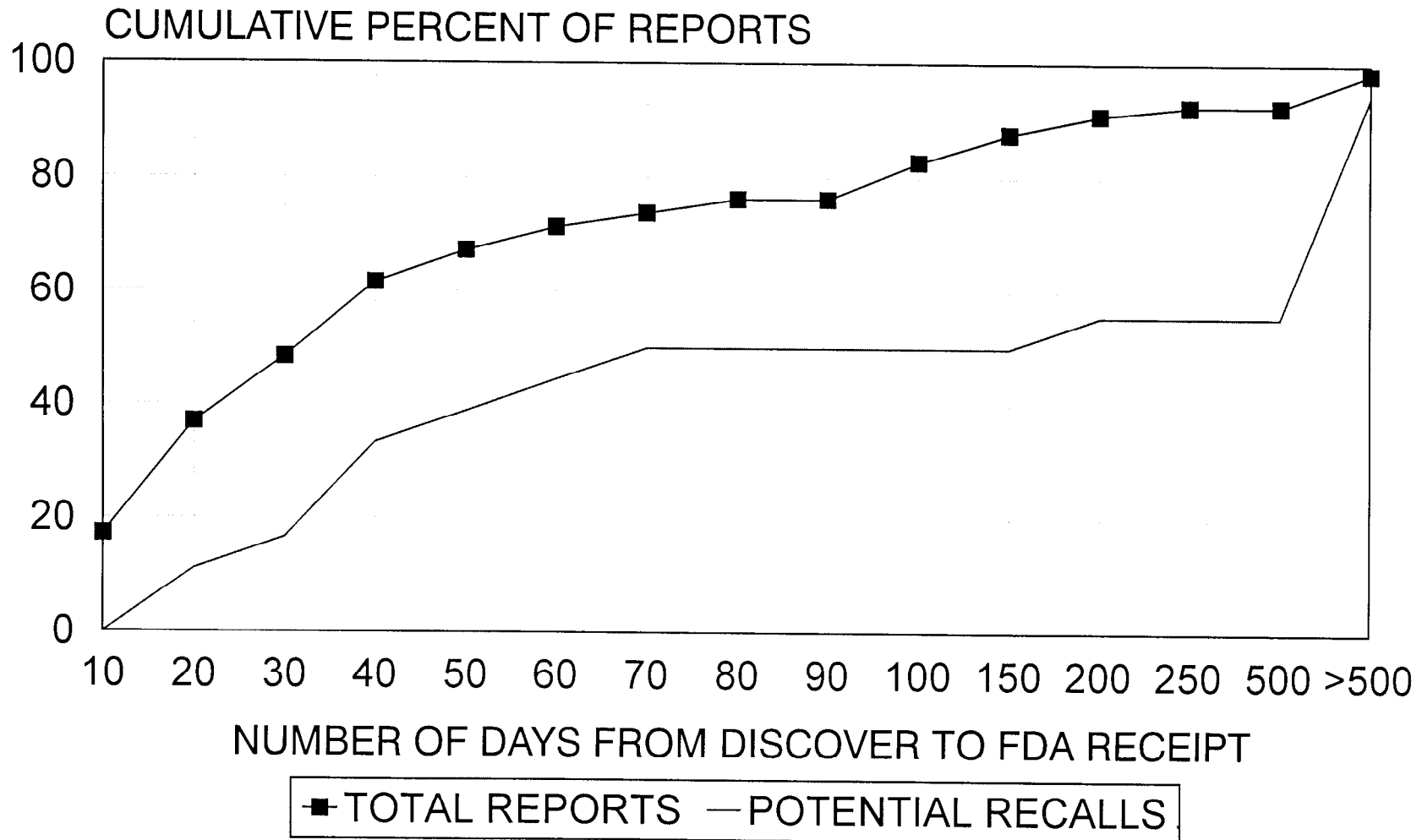
TOTAL REPORTS = 6249  
POTENTIAL RECALLS = 480

# ERROR AND ACCIDENT REPORTS REPORTING TIME NON-ARC LICENSED BLOOD BANKS FY-99



TOTAL REPORTS = 6397  
POTENTIAL RECALLS = 1081

# ERROR AND ACCIDENT REPORTS REPORTING TIME UNLICENSED BLOOD BANKS *FY-99*



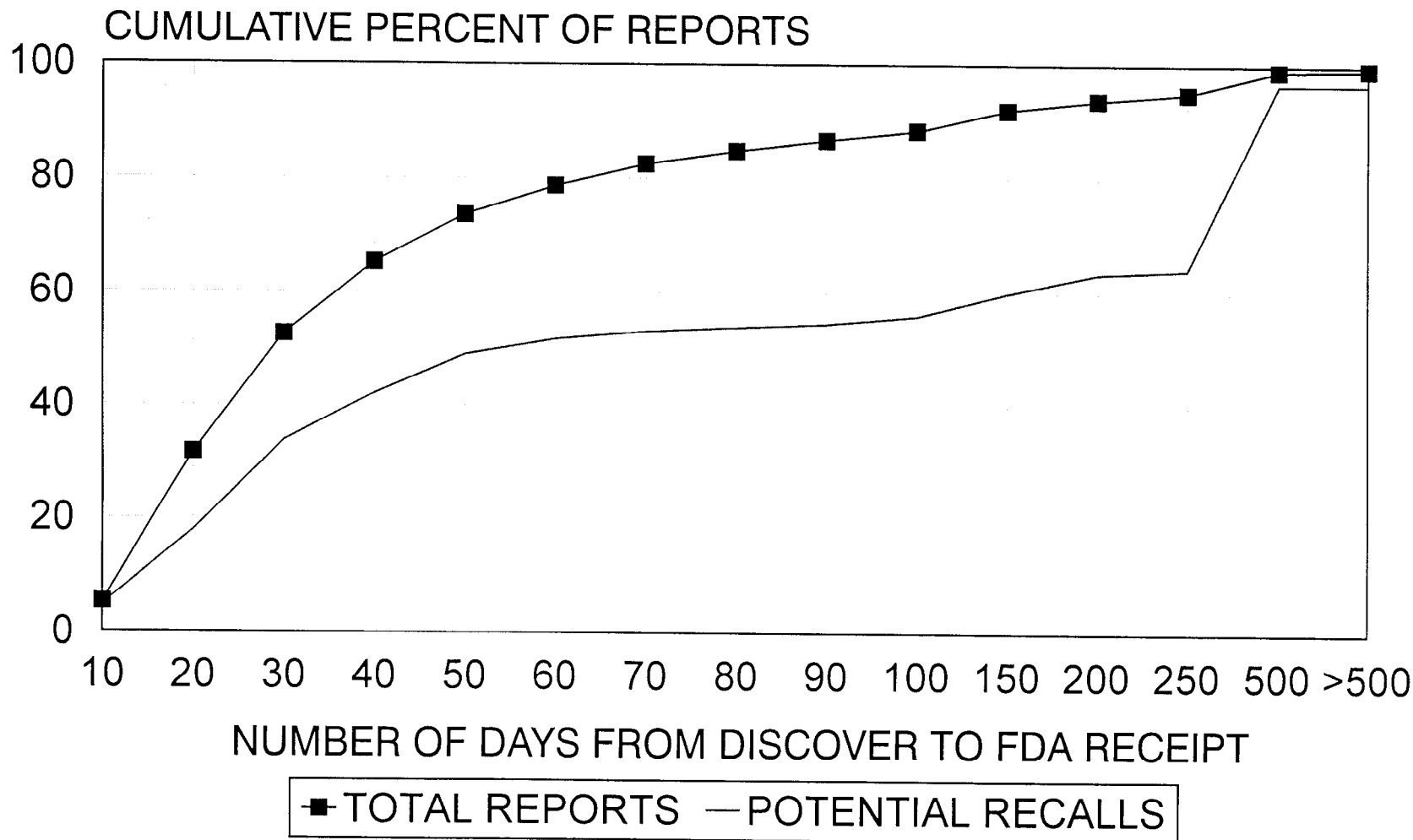
TOTAL REPORTS = 122  
POTENTIAL RECALLS = 18

# ERROR AND ACCIDENT REPORTS

## REPORTING TIME

### PLASMA CENTERS

FY-99

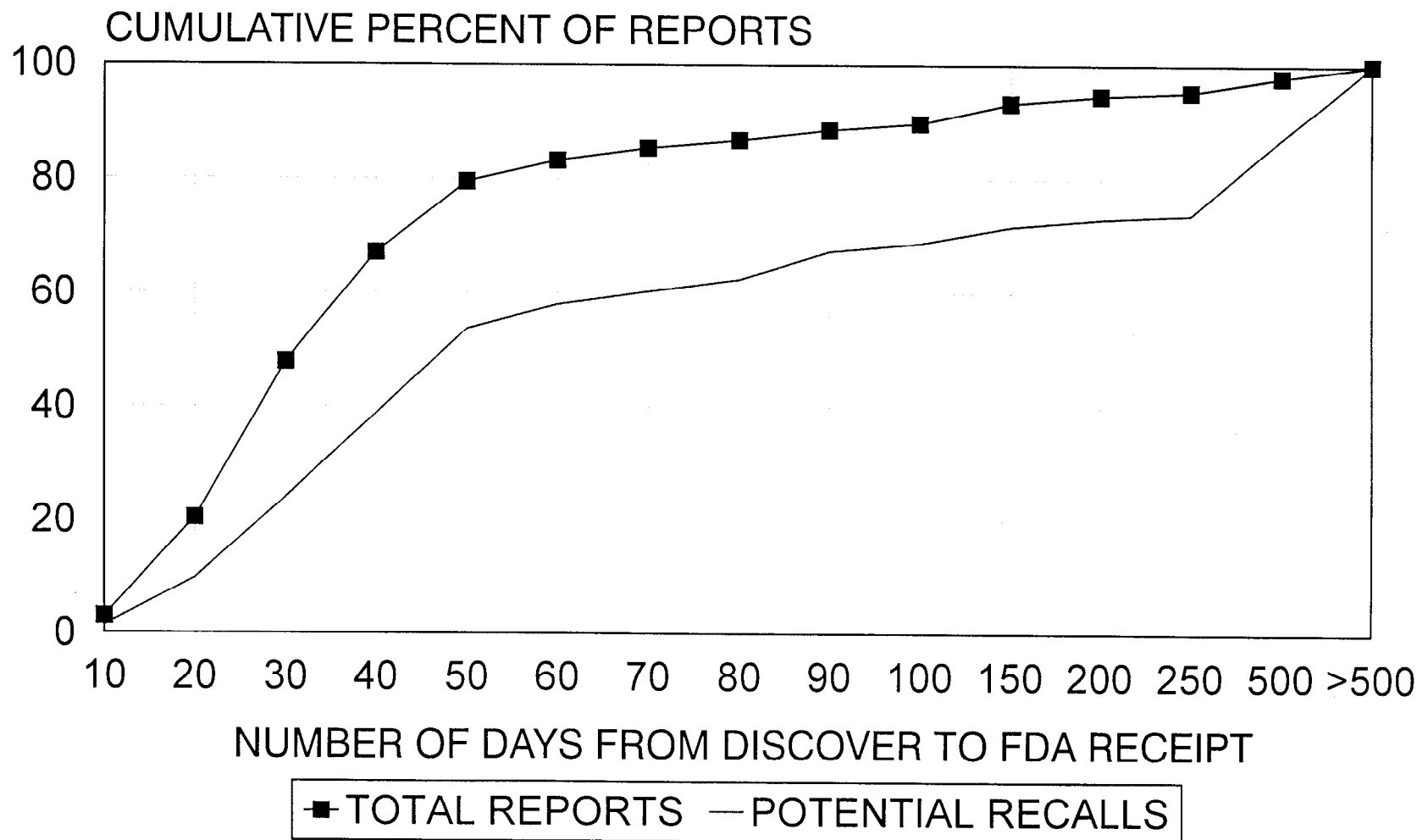


TOTAL REPORTS = 1965  
 POTENTIAL RECALLS = 145

# ERROR AND ACCIDENT REPORTS

## REPORTING TIME ALL LICENSED BLOOD BANKS

FY-99



TOTAL REPORTS = 12,646  
POTENTIAL RECALLS = 1561



**REPORTABLE ERROR/ACCIDENT CODES****DS/DD - DONOR SUITABILITY****DS** - Donor Screening**DS5000** - Miscellaneous**DS51** - Donor did not meet acceptance criteria**5103** - Hemoglobin <11.0g/dl, Hematocrit <33%, or Hgb/Hct not documented**5104** - Temperature unacceptable or not documented**5105** - Other (*see remarks*)

WBC count, no documented WBC count for unit

**5106** - Medical review or physical not performed or inadequate**5107** - Platelet count, no documented platelet count for unit**5109** - Unexplained weight loss**DS52** - Donor record incomplete/incorrect/not reviewed**5200** - Other (*see remarks*)

Answers to comprehension questions on self-administered health history not documented

Arm inspection

Blood donor record completed by donor's mother

Both CUE stickers on BDR

Breach in donor confidentiality

"Do you have any questions?" was not answered

Donor interviews were shortened

Donor reported CUE procedure performed by screener

Donor reported all questions were not asked during screening

Donor screener marked answers to high risk questions before asking donor the questions

Health history questions were self-administered; donors were employees

Newly trained employee performed health histories without supervision

No donor consent form

Outdated Spanish donor record used for screening

**5201** - Donor identification**5202** - Donor signature**5203** - Medical history questions**5204** - High risk behavior questions/information**DS53** - Deferral screening not done, donor previously deferred due to:**5301** - HIV reactivity**5302** - HBsAg reactivity or history of hepatitis**5303** - Anti-HBc reactivity**5304** - Anti-HCV reactivity**5305** - Anti-HTLV-I reactivity**5306** - ALT reactivity**5307** - Other reasons (*see remarks*)

Anti-D

Donor previously self-deferred

IV drug use or hemochromatosis

Positive drug screen

Positive glucose test

**5308** - Sexually transmitted disease, or positive STS**5309** - Sexual partner having sexually transmitted disease**5310** - Sexual partner testing positive for HIV**5311** - Sexual partner testing positive for Hepatitis marker**5312** - Male had sex with another man**5313** - Female had sex with a man who has had sex with another man**5314** - IV drug use

- 5315 - Sex with IV drug user
- 5316 - Travel/immigration - high risk area
- 5317 - Exchanged sex for drugs/money
- 5318 - Received tattoo, earpiercing, needlestick, transfusion
- 5319 - Non-sexual exposure to HIV
- 5320 - Non-sexual exposure to hepatitis B or C
- 5321 - High risk behavior, but does not specify what type
  - Donor rejected at another center
  - Non-IV drug use
- 5322 - Travel to malaria endemic area/history of malaria
- 5323 - History of disease/surgery
- 5324 - History of cancer
- 5325 - History of Creutzfeldt-Jakob Disease
- 5326 - Risk factors associated with Creutzfeldt-Jakob Disease
- 5327 - Received growth hormone
- 5328 - Received Proscar, Tegison or Accutane
- 5329 - Received medication or antibiotics
- 5330 - Received vaccine or immune globulin
- 5331 - Exposure to a disease
- 5332 - Incarcerated
- 5333 - Resided in a rehabilitation center or psychiatric hospital
- 5334 - Received Methotrexate
- 5335 - History of Hepatitis A
- 5336 - Exposure to Hepatitis A
- DS54 - Incorrect ID used during deferral search, donor previously deferred due to:
  - 5401 - HIV reactivity
  - 5402 - HBsAg reactivity or history of hepatitis
  - 5403 - Anti-HBc reactivity
  - 5404 - Anti-HCV reactivity
  - 5405 - Anti-HTLV-I reactivity
  - 5406 - ALT reactivity
  - 5407 - Other reasons (*see remarks*)
    - Donor previously self-deferred
  - 5408 - Sexually transmitted disease, or positive STS
  - 5409 - Sexual partner having sexually transmitted disease
  - 5410 - Sexual partner testing positive for HIV
  - 5411 - Sexual partner testing positive for Hepatitis marker
  - 5412 - Male had sex with another man
  - 5413 - Female had sex with a man who has had sex with another man
  - 5414 - IV drug use
  - 5415 - Sex with IV drug user
  - 5416 - Travel/immigration - high risk area
  - 5417 - Exchanged sex for drugs/money
  - 5418 - Received tattoo, earpiercing, needlestick, transfusion
  - 5419 - Non-sexual exposure to HIV
  - 5420 - Non-sexual exposure to hepatitis B or C
  - 5421 - High risk behavior, but does not specify what type
    - Donor rejected at another center
  - 5422 - Travel to malaria endemic area/history of malaria
  - 5423 - History of disease/surgery
  - 5424 - History of cancer

- 5425 - History of Creutzfeldt-Jakob Disease
- 5426 - Risk factors associated with Creutzfeldt-Jakob Disease
- 5427 - Received growth hormone
- 5428 - Received Proscar, Tegison or Accutane
- 5429 - Received medication or antibiotics
- 5430 - Received vaccine or immune globulin
- 5431 - Exposure to a disease
- 5432 - Incarcerated
- 5433 - Resided in a rehabilitation center or psychiatric hospital
- 5434 - Received Methotrexate
- 5435 - History of Hepatitis A
- 5436 - Exposure to Hepatitis A
- DS55 - Donor gave history which warranted deferral and was not deferred
  - 5501 - AIDS related risk
  - 5502 - Hepatitis related risk
  - 5507 - Other reasons (*see remarks*)
    - Previously deferred at another center due to elevated liver enzymes
  - 5508 - Sexually transmitted disease, or positive STS
  - 5509 - Sexual partner having sexually transmitted disease
  - 5510 - Sexual partner testing positive for HIV
  - 5511 - Sexual partner testing positive for Hepatitis marker
  - 5512 - Male had sex with another man
  - 5513 - Female had sex with a man who has had sex with another man
  - 5514 - IV drug use
  - 5515 - Sex with IV drug user
  - 5516 - Travel/immigration - high risk area
    - Central African Republic
    - Congo
    - Gabon
    - Nigeria
    - Panama-Chagas risk
    - Sex partner lived in Nigeria
    - Sex partner lived in an HIV Group O risk area
  - 5517 - Exchanged sex for drugs/money
  - 5518 - Received tattoo, earpiercing, needlestick, transfusion
  - 5519 - Non-sexual exposure to HIV
  - 5520 - Non-sexual exposure to hepatitis B or C
  - 5521 - High risk behavior, but does not specify what type
    - Non-IV drug use
  - 5522 - Travel to malaria endemic area/history of malaria
    - Subsequently diagnosed with malaria
  - 5523 - History of disease/surgery
  - 5524 - History of cancer
  - 5525 - History of Creutzfeldt-Jakob Disease
  - 5526 - Risk factors associated with Creutzfeldt-Jakob Disease
    - Brain surgery
    - Family history - (*family member*)
  - 5527 - Received growth hormone
  - 5528 - Received Proscar, Tegison or Accutane
  - 5529 - Received medication or antibiotics
  - 5530 - Received vaccine or immune globulin
  - 5531 - Exposure to a disease

- 5532 - Incarcerated
- 5533 - Resided in a rehabilitation center or psychiatric hospital
- 5534 - Received Methotrexate
- 5535 - History of Hepatitis A
- 5536 - Exposure to Hepatitis A

**DD - Donor Deferral****DD6000 - Miscellaneous****DD61 - Donor missing or incorrectly identified on deferral list, donor previously deferred due to:**

- 6101 - HIV reactivity
- 6102 - HBsAg reactivity or history of hepatitis
- 6103 - Anti-HBc reactivity
- 6104 - Anti-HCV reactivity
- 6105 - Anti-HTLV-I reactivity
- 6106 - ALT reactivity
- 6107 - Other reasons (*see remarks*)
  - Donor admitted to previous dishonesty
  - High risk behavior questions unanswered
  - Reason not identified
- 6108 - Sexually transmitted disease, or positive STS
- 6109 - Sexual partner having sexually transmitted disease
- 6110 - Sexual partner testing positive for HIV
- 6111 - Sexual partner testing positive for Hepatitis marker
- 6112 - Male had sex with another man
- 6113 - Female had sex with a man who has had sex with another man
- 6114 - IV drug use
- 6115 - Sex with IV drug user
- 6116 - Travel/immigration - high risk area
- 6117 - Exchanged sex for drugs/money
- 6118 - Received tattoo, earpiercing, needlestick, transfusion
- 6119 - Non-sexual exposure to HIV
- 6120 - Non-sexual exposure to hepatitis B or C
- 6121 - High risk behavior, but does not specify what type
- 6122 - Travel to malaria endemic area/history of malaria
- 6123 - History of disease/surgery
- 6124 - History of cancer
- 6125 - History of Creutzfeldt-Jakob Disease
- 6126 - Risk factors associated with Creutzfeldt-Jakob Disease
- 6127 - Received growth hormone
- 6128 - Received Proscar, Tegison or Accutane
- 6129 - Received medication or antibiotics
- 6130 - Received vaccine or immune globulin
- 6131 - Exposure to a disease
- 6132 - Incarcerated
- 6133 - Resided in a rehabilitation center or psychiatric hospital
- 6134 - Received Methotrexate
- 6135 - History of Hepatitis A
- 6136 - Exposure to Hepatitis A

**DD62 - Donor deleted from deferral list/donor not reentered properly, donor previously deferred due to:**

- 6201 - HIV reactivity
- 6202 - HBsAg reactivity or history of hepatitis
- 6203 - Anti-HBc reactivity

- 6204 - Anti-HCV reactivity
- 6205 - Anti-HTLV-I reactivity
- 6206 - ALT reactivity
- 6207 - Other reasons (*see remarks*)
- 6208 - Sexually transmitted disease, or positive STS
- 6209 - Sexual partner having sexually transmitted disease
- 6210 - Sexual partner testing positive for HIV
- 6211 - Sexual partner testing positive for Hepatitis marker
- 6212 - Male donor had sex with another man
- 6213 - Female had sex with a man who has had sex with another man
- 6214 - IV drug use
- 6215 - Sex with IV drug user
- 6216 - Travel/immigration - high risk area  
Previous deferral for response to HIV Group O risk questions
- 6217 - Exchanged sex for drugs/money
- 6218 - Received tattoo, earpiercing, needlestick, transfusion
- 6219 - Non-sexual exposure to HIV
- 6220 - Non-sexual exposure to hepatitis B or C
- 6221 - High risk behavior, but does not specify what type
- 6222 - Travel to malaria endemic area/history of malaria
- 6223 - History of disease/surgery  
Therapeutic donor
- 6224 - History of cancer
- 6225 - History of Creutzfeldt-Jakob Disease
- 6226 - Risk factors associated with Creutzfeldt-Jakob Disease
- 6227 - Received growth hormone
- 6228 - Received Proscar, Tegison or Accutane
- 6229 - Received medication or antibiotics
- 6230 - Received vaccine or immune globulin
- 6231 - Exposure to a disease
- 6232 - Incarcerated
- 6233 - Resided in a rehabilitation center or psychiatric hospital
- 6234 - Received Methotrexate
- 6235 - History of Hepatitis A
- 6236 - Exposure to Hepatitis A

**DD63** - Post donation information

- 6301 - Donor does not want their blood used
- 6303 - Post donation illness (not hepatitis, HIV, HTLV-I, STD, or cold/flu related)  
Parvovirus B19
- 6304 - Post donation HBV or HCV related illness or positive hepatitis marker  
Also an IV drug user, had sex with an IV drug user, had tattoo, and exchanged sex for drugs or money  
Also diagnosed with hepatitis A  
Also used IV drugs and has history of Hepatitis B  
Donor rejected at another center  
Tested positive prior to donation  
Tested positive prior to donation; also has history of hepatitis  
Tested positive prior to donation; also has history of jaundice

- 6305** - Post donation AIDS or related illness or positive test for HIV, or anti-HTLV-I  
 Also an IV drug user  
 Also had sex with another man  
 Also received growth hormone  
 HTLV-I/II  
 Tested positive for anti-HTLV-1 prior to donation  
 Tested positive prior to donation  
 Tested positive prior to donation; also tested positive for syphilis
- 6306** - Information not related to hepatitis B/C, HIV, HTLV-1, or STD (*see remarks*)  
 Blood donor record completed by donor's wife  
 Donated to be tested  
 Donor believed to have given unreliable health history  
 Donor called back for test results  
 Donor exhibited erratic behavior  
 Donor mentally retarded  
 Donor received dog bite from stray dog  
 Donor used false identification  
 Students may have donated for grade credit
- 6307** - History of hepatitis B/C or jaundice  
 Also taking proscar
- 6308** - Sexually transmitted disease, or positive STS  
 Also reported exposure to HIV  
 Diagnosed post donation
- 6309** - Sexual partner having sexually transmitted disease  
 Diagnosed post donation
- 6310** - Sexual partner testing positive for HIV  
 Also received a tattoo  
 Also received needlestick from HIV positive person  
 And Hepatitis  
 Diagnosed post donation  
 HTLV-I/II; diagnosed post donation  
 HTLV-I; diagnosed post donation  
 Tested positive prior to donation
- 6311** - Sexual partner testing positive for Hepatitis marker  
 Also has multiple sclerosis  
 Diagnosed post donation  
 Sex partner also an IV drug user  
 Sex partner also tested positive for HTLV  
 Sex partner has jaundice
- 6312** - Male donor had sex with another man  
 Also an IV drug user  
 Also answered yes to questions regarding exchange of sex for money or drugs and sex with someone having  
 AIDS or testing positive for the AIDS virus  
 Also exchanged sex for drugs or money  
 Also received a tattoo  
 Also took accutane  
 Also traveled to malarial endemic area
- 6313**- Female had sex with a man who had sex with another man  
 Also has father with Hepatitis  
 Sex partner also an IV drug user  
 Sex partner also exchanged sex for drugs or money
- 6314** - IV drug use  
 Also exchanged sex for drugs or money  
 Sex partner also an IV drug user

- 6315 - Sex with IV drug user**  
 Also exchanged sex for drugs or money  
 Sex partner also an IV drug user  
 Sex partner also exchanged sex for drugs or money  
 Sex partner also has Hepatitis C  
 Sex partner also has hepatitis  
 Sex partner also positive for HCV
- 6316 - Travel/immigration - high risk area**  
 Algeria  
 Cameroon  
 Cameroon, Chad, Niger, Nigeria, and Central African Republic  
 Central African Republic  
 Central African Republic and Nigeria  
 Chad  
 Congo  
 HIV Group O risk area  
 Lived in Brazil-Chagas risk  
 Malaysia  
 Niger  
 Nigeria  
 Sex partner also lived in Africa  
 Sex partner lived in Africa  
 Sex partner lived in Cameroon  
 Sex partner lived in Central African Republic  
 Sex partner lived in Chad  
 Sex partner lived in Congo  
 Sex partner lived in Gabon  
 Sex partner lived in Niger  
 Sex partner lived in Nigeria  
 Sex partner lived in an HIV Group O risk area  
 South Africa
- 6317- Exchanged sex for drugs/money**  
 Sex partner  
 Sex partner also an IV drug user  
 Sex partner also exchanged sex for drugs/money  
 Sex partner also lived in Central African Republic  
 Sex partner also lived in an HIV Group O risk area
- 6318- Received tattoo, earpiercing, needlestick, transfusion**  
 Also had sex with an IV drug user and sex with someone who lived in Central African Republic  
 Also incarcerated  
 Also inquired about test results  
 Sex partner  
 Sex partner also exchanged sex for drugs or money  
 Sex partner also lived an HIV Group O risk area
- 6319 - Non-sexual exposure to HIV**  
 Same household member also tested positive for HBsAg
- 6320 - Non-sexual exposure to hepatitis B or C**  
 Diagnosed post donation

- 6321 - High risk behavior, but does not specify what type**  
 Alcohol abuse  
 Cocaine use  
 Donor expressed concern about gonorrhea  
 Donor refused to sign donor history form  
 Donor rejected at another center  
 Donor unable to understand high risk donor history questions  
 Exposure to mother's blood; mother has Hepatitis  
 Ingested urine  
 Non-IV drug use  
 Positive drug screen  
 Positive viral marker test results; also an IV drug user  
 Rape  
 Sex offender  
 Sex partner also HIV positive  
 Sex partner had high risk behavior  
 Sex partner had sex with an HIV positive person  
 Sex partner has positive drug screen  
 Sex partner previously rejected  
 Sex partner received clotting factor  
 Sex partner rejected at another center  
 Sex partner rejected due to laboratory test results  
 Sex partner used non-IV drugs  
 Unprotected sex
- 6322 - Travel to malaria endemic area/history of malaria**  
 Also a history of liver inflammation  
 Also has history of jaundice  
 Diagnosed post donation
- 6323 - History of disease/surgery**  
 Also diagnosed with cancer post donation  
 Also household exposure to Hepatitis C  
 Also took clotting factor concentrates  
 Diagnosed post donation  
 Roommate also has Hepatitis A
- 6324 - History of cancer**  
 Also high risk behavior  
 Diagnosed post donation
- 6325 - History of Creutzfeldt-Jakob Disease**
- 6326 - Risk factors associated with Creutzfeldt-Jakob Disease**  
 Brain surgery  
 Family history  
 Lived in United Kingdom (nvCJD)
- 6327 - Received growth hormone**
- 6328 - Received Proscar, Tegison or Accutane**
- 6329 - Received medication or antibiotics**
- 6330 - Received vaccine or immune globulin**
- 6331 - Exposure to a disease**
- 6332 - Incarcerated**  
 Sex partner
- 6333 - Resided in a rehabilitation center or psychiatric hospital**  
 Also incarcerated
- 6334 - Received Methotrexate**
- 6335 - History of Hepatitis A**  
 Diagnosed post donation
- 6336 - Exposure to Hepatitis A**  
 Also has history of liver disease  
 Diagnosed post donation  
 Sex partner also diagnosed with Hepatitis C



**BC - BLOOD COLLECTION****BC3000** - Miscellaneous (*see remarks*)

- Expired needles
- Incorrect prime solution used
- Regionally unapproved bags (450 ml) were used using procedures for 500 ml bags
- Sampling device attached before collection process complete

**BC31** - Sterility compromised**3100** - Other (*see remarks*)

- Disposable apheresis set used for collection greater than 24 hours after installation
- Phlebotomist touched needle prior to venipuncture
- Venipuncture performed on arm with skin condition

**3101** - Bacterial contamination**3102** - Air contamination**3103** - Arm prep not performed or performed inappropriately

- Also high risk questions not asked by screener

**BC32** - Collection bag**3201** - Blood drawn into outdated bag**3202** - Bag mix up**3203** - Anticoagulant - used inappropriately/expired**BC33** - Donor/patient**3301** - Wrong patient drawn**3303** - Wrong cell infusion**BC34** - Collection process**3400** - Other (*see remarks*)

- Collection status not documented
- Inappropriate concurrent collection of plasma with platelets
- Underweight unit

**3401** - Collection time extended, discrepant, or not documented**3402** - Overbleed**BC35** - Collection device**3500** - Device defect**CP - COMPONENT PREPARATION****CP8000** - Miscellaneous (*see remarks*)**CP8100** - Components prepared more than 8 hours after collection**CP8200** - Additive not added or added inappropriately**CP8300** - Sterility compromised**8301** - Other

- Weld inspection not performed

**8302** - Bacterial contamination**8303** - Air contamination**CP8400** - Incorrect/inappropriate preparation of platelets**8400** - Other (*see remarks*)

- Additional bag not sterile docked to units which exceeded acceptable platelet count
- Centrifuge not calibrated for volume reduction
- Collection procedure was begun more than 4 hours after pheresis kit was primed
- Combined into one bag or exceeded concentration limit
- Insufficient plasma volume
- No procedure for volume reduction of pheresis platelets
- Prepared from whole blood unit collected at unacceptable or undocumented temperature
- Procedure for leukoreduction not followed
- Processed at incorrect centrifuge speed
- Underweight component
- Underweight unit
- Volume not reduced

**8401** - Extended collection time

**8402** - Unit collected from donor who took aspirin within 72 hours of donation

**8403** - Prepared at incorrect temperature

**8404** - Resting time requirements not met

**8405** - Platelets not agitated

**8406** - Difficult collection

**8407** - Platelet count or platelet yield not acceptable or platelet count not performed on product

**CP8500** - Incorrect/inappropriate preparation of product other than platelets

**8500** - Other (*see remarks*)

Blood collection time discrepancy

Centrifuge rpm during cryo production not recorded

Component prepared from low volume whole blood unit

Component prepared from overweight unit

Cryo-poor plasma converted to Fresh Frozen Plasma

Difficult/extended collection

FFP exceeded maximum preparation limits

Incorrect centrifuge speed and time settings

Incorrect segments attached to unit

Insufficient plasma volume and excessive thawing time

Leukoreduced twice

Plasma improperly transferred from one pooling bottle to another

Prepared from whole blood unit collected at unacceptable or undocumented temperature

Procedure for filtration not followed

Procedure for leukoreduction not followed

Procedure for leukoreduction not followed and procedure for addition of additive not followed

Procedure not followed for glycerolization of RBC

RBC with antibody not washed as required by SOP

Unacceptable WBC count

Unacceptable concentration of cryopreservative

Unapproved procedure

Underweight component

Units collected into 450 ml bags using 500 ml setting

**8501** - Expired reagents used

**8502** - Freezing time requirements not met or not documented

**8503** - Prepared at incorrect temperature

**8504** - Excess plasma removed

**CP8600** - Overweight component

**CP8700** - Irradiation not performed or performed inappropriately

**RT/VT** - LABORATORY TESTING

**RT** - ROUTINE TESTING

**RT1000** - Miscellaneous

**RT11** - Incorrectly tested for:

**1101** - ABO

**1102** - Rh

**1103** - ABO & Rh

**1104** - Antibody screening

**1105** - Antigen typing

**1106** - Other (*see remarks*)

ABO, Rh, anti-Fya

Hemoglobin S

**1107** - Platelet count

**1108** - Compatibility

**RT12** - Sample identification

**1201** - Incorrect sample tested/sample misidentified

**VT - VIRAL TESTING****VT2000 - Miscellaneous****VT21 - Incorrectly tested for:**

- 2101 - HBsAg**
- 2102 - Anti-HIV-1**
- 2103 - Anti-HIV-2**
- 2104 - Anti-HIV-1/2**
- 2105 - HIV Antigen**
- 2106 - Syphilis**
- 2107 - Anti-HTLV-I**
- 2108 - Anti-HBc**  
Also, one unit not tested for HBsAg
- 2109 - ALT**
- 2110 - Anti-HCV**
- 2111 - More than 1 test**  
ABO/Rh, CMV and syphilis  
All viral markers  
Anti-HBc and HBsAg  
HBsAg and anti-HIV-1/2  
HIV antigen and ALT  
Syphilis and ABO/Rh  
Syphilis and ALT
- 2112 - Cytomegalovirus**

**LA - LABELING****LA4000 - Miscellaneous****LA41 - Incorrect label or tag**

- 4101 - ABO and/or Rh**
- 4102 - Product**
- 4103 - Extended expiration date**

**LA42 - Missing/incorrect label or tag**

- 4201 - Autologous labeling**
- 4202 - CMV**
- 4203 - Antigen/antibody**
- 4204 - Irradiation**
- 4205 - Platelet count**
- 4206 - Crossmatch**
- 4207 - Other (*see remarks*)**  
Autologous  
Directed donation labeled autologous  
Fresh Frozen Plasma, donor retested  
HLA  
Labeled as being prepared from 500ml instead of 450ml  
Leukoreduced  
Random equivalents  
Volume of anticoagulant  
WBC count  
WBC count, labeled with count but not performed  
Washed
- 4208 - Anticoagulant**
- 4209 - Donor number**
- 4210 - Recipient number**
- 4211 - Biohazard/Test status**  
NAT testing

**LA43** - License number

**4300** - Unlicensed product labeled with license number

**SD** - STORAGE/DISTRIBUTION**SD7000** - Miscellaneous**SD71** - Failure to quarantine unit due to medical history:

**7101** - Previous HIV reactivity

**7102** - Previous HBsAg reactivity or history of hepatitis

**7103** - Previous Anti-HBc reactivity

**7104** - Previous Anti-HCV reactivity

**7105** - Previous Anti-HTLV-I reactivity

**7106** - Previous ALT reactivity

**7107** - Other reasons (*see remarks*)

Donor self-excluded post donation

Elevated temperature

HCV lookback

Post donation illness

Post donation increase in hemoglobin

Post donation infection

Post donation information

Post donation report of elevated liver enzymes; Hepatitis testing negative

Reason not identified

**7108** - Sexually transmitted disease, or positive STS

**7109** - Sexual partner having sexually transmitted disease

**7110** - Sexual partner testing positive for HIV

**7111** - Sexual partner testing positive for Hepatitis marker

**7112** - Male donor had sex with another man

**7113** - Female donor had sex with a man who has had sex with another man

**7114** - IV drug use

**7115** - Sex with IV drug user

**7116** - Travel/immigration - high risk area

**7117** - Exchanged sex for drugs/money

**7118** - Received tattoo, earpiercing, needlestick, transfusion

Information received post donation, prior to release of products

**7119** - Non-sexual exposure to HIV

**7120** - Non-sexual exposure to hepatitis B or C

**7121** - High risk behavior, but does not specify what type

Information received post donation, prior to release of products

**7122** - Travel to malaria endemic area/history of malaria

**7123** - History of disease/surgery

**7124** - History of cancer

Information received post donation, prior to release of products

**7125** - History of Creutzfeldt-Jakob Disease

**7126** - Risk factors associated with Creutzfeldt-Jakob Disease

**7127** - Received growth hormone

**7128** - Received Proscar, Tegison or Accutane

**7129** - Received medication or antibiotics

Second donor requested test results

**7130** - Received vaccine or immune globulin

Information received post donation, prior to release of products

**7131** - Exposure to a disease

**7132** - Incarcerated

Information received post donation, prior to release of products

**7133** - Resided in a rehabilitation center or psychiatric hospital

- 7134 - Received Methotrexate
- 7135 - History of Hepatitis A
- 7136 - Exposure to Hepatitis A
- SD72 - Failure to quarantine unit due to incorrect, incomplete, or positive testing for:
  - 7201 - Anti-HIV/HIV Antigen  
Subsequent unit tested positive
  - 7202 - HBsAg  
Subsequent unit tested positive
  - 7203 - Anti-HBc
  - 7204 - Anti-HCV  
NAT  
Previous unit tested positive  
Subsequent unit tested positive
  - 7205 - Anti-HTLV-I  
Subsequent unit tested positive
  - 7206 - ALT
  - 7207 - Other reasons (*see remarks*)  
ALT and Syphilis  
All viral markers  
Anti-HBc and anti-HCV  
Anti-HIV-1/2, HBsAg  
Anti-HIV-Ag, HBsAg  
DAT  
HLA  
Platelet count  
Previous units tested positive for various viral markers  
Various viral markers; subsequent units tested positive
  - 7208 - ABO
  - 7209 - Rh
  - 7210 - Antibody screen  
DAT also positive
  - 7211 - Antigen screen
  - 7212 - Syphilis  
Previous unit tested positive
- SD73 - Failure to quarantine unit due to testing not performed or documented for:
  - 7301 - Anti-HIV/HIV antigen
  - 7302 - HBsAg  
Anti-HBc testing also performed incorrectly  
Anti-HIV-1 testing also performed incorrectly
  - 7303 - Anti-HBc
  - 7304 - Anti-HCV  
NAT
  - 7305 - Anti-HTLV-I
  - 7306 - ALT
  - 7307 - Other reasons (*see remarks*)  
AHG crossmatch  
AHG testing for anti-A not performed on non-group O unit for infant  
All viral markers  
CMV  
Chagas antibody  
Crossmatch  
DAT  
Hemoglobin S  
NAT  
Opiates  
Platelet and WBC count

Platelet count  
 Syphilis and antibody screen  
 WBC count  
 pH

**7308 - ABO**

Patient ABO/Rh not documented

**7309 - Rh****7310 - Antibody screen****7311 - Antigen screen**

Compatibility testing also incomplete

**7312 - Syphilis**

And ATYA

**SD74 - Inappropriate release****7400 - Other (see remarks)**

"Do not use" indicated by donor

ABO incompatible

ALT testing not done on previous unit

Anti-HBc reactive autologous units shipped without physician approval

Arm inspection/arm prep not documented or unacceptable

Associated product contained clots

Associated product had abnormal appearance and small volume

Autologous recovered plasma

BDR missing

Both CUE stickers on BDR

CUE

CUE code removed

CUE sticker missing

Collection end time not documented

Collection status not documented

Collection time discrepancy

Disposable apheresis set used for collection greater than 24 hours after installation

Donor accepted with transient address

Donor history questions paraphrased

Donor signature missing

Donor temperature not documented

Hematocrit QC not performed

Hematocrit not documented

Incomplete donor history

Incorrect probe covers used with electronic thermometers

Incorrect version of BDR used

Initial RBC recovery miscalculated as unacceptable and unit made available; recalculation was acceptable

Inspection of units not documented prior to reissue

Not stored under continuous agitation

Observation of antecubital area for skin disease marked "yes" on BDR

PPC failed drift test

PPC instrument QC failed

Platelets from donor who took aspirin within 3 days of donation used as a sole source

Potential break in positive donor identification

Previous unit tested CMV positive

Procedure for confidential unit exclusion not followed

Procedure for filtration not followed

Procedure for leukoreduction not followed

Product QC not performed

Product from slow bleed not inspected for clots

Product returned due to possible cold agglutinin

Product released prior to revalidation of freezer

QC records missing

RBC from extended collection not inspected for clots prior to release

Scale used to weigh questionable units failed QC-units not reweighed

Segments reattached to primary container

Segments reattached to wrong unit  
 Shortdated unit-expired at time of receipt  
 Sterile weld suitability not documented  
 Storage temperatures not recorded and temperature chart stopped during storage  
 System pressure monitor check not documented  
 Testing samples not collected at time of unit collection  
 Unacceptable hematocrit QC  
 Unacceptable platelet QC  
 Unit distributed prior to receipt of viral marker test results  
 Unit from extended collection not inspected for clots  
 Unit not washed or volume reduced  
 Unit released prior to cell separator validation  
 Unit released prior to completion of validation testing; platelet yield and WBC count  
 Unit released prior to completion of validation testing; WBC count was unacceptable  
 Unit released prior to receiving platelet count results  
 Unit released prior to resolution of discrepancy  
 Units received greater than 24 hours after release were distributed without swirl testing  
 Viral marker test results reported under voided bleed number  
 WBC count not performed after receiving message during apheresis

**7401 - Outdated product**

Emergency release procedures not followed

**7402 - Autologous unit not meeting homologous criteria**

**SD75 - Unsuitable product**

**7500 - Other (see remarks)**

Air contaminated  
 Bloody appearance  
 Crossmatch samples not included with products  
 Emergency released granulocytes product contained no granulocytes  
 Excess plasma removed  
 Extended collection  
 Foreign material observed in unit  
 Hemoglobin not documented  
 Icteric unit  
 Lipemic  
 Low volume  
 Low-yield product  
 Microgram issued instead of full dose RhoGam  
 Overweight unit  
 Phlebotomy end time not documented  
 Plasma contained greenish fibrin threads and foam  
 Plasma recalled due to Parvovirus was redistributed  
 Positive for Parvovirus  
 Unacceptable RBC recovery  
 Unacceptable WBC count  
 Unacceptable hematocrit  
 Unacceptable pH  
 Unacceptable platelet count  
 Unacceptable platelet count, WBC count and/or pH  
 Unacceptable volume  
 Underweight component  
 Unit contained unidentified white flocculent material  
 Unit in transit for more than 24 hours, not agitated  
 Unit released prior to completion of platelet count; count unacceptable  
 Unit released prior to filtration  
 Units considered unsuitable after deglycerolization  
 Units irradiated at facilities with inadequate SOP  
 Written approval for release of autologous HCV reactive unit not received prior to distribution

**7501 - Unit contained clots or would not flow through filter**

Unit returned and re-released

**7502 - Unit/segment hemolyzed**

**7503** - Broken/damaged unit

Units returned and made available for distribution

**SD7600** - Shipped/stored at incorrect temperature

**SD7700** - Shipment of unlicensed product labeled with license number

**SD7800** - Improper transfusion service practices

**7800** - Miscellaneous (*see remarks*)

CMV positive platelets transfused to CMV negative patient

E positive RBC transfused to patient with history of anti-E

Product not leukoreduced as required

**7801** - Unit requiring irradiation was not irradiated

Unit also not leukoreduced or CMV negative as required

**7802** - Unit issued to wrong patient

**7803** - Improper product selected for patient

**7804** - Improper ABO or Rh type selected for patient

**MI** - Miscellaneous

**MI90** - Miscellaneous

**9000** - Miscellaneous

**MI92** - Donor implicated in transfusion associated disease

**9201** - HIV

**9202** - Hepatitis

**9203** - Other (*see remarks*)

**MI9500** - Lookback; subsequent unit tested

**9501** - HIV antibody positive

**9502** - HBsAg positive

**9503** - HCV positive

**9504** - HTLV-I positive

**9505** - HIV antigen positive



**NON-REPORTABLE ERROR/ACCIDENT CODES****Donor Suitability - DS**

- DS1 - Donor did not meet acceptance criteria for Age
- DS2 - Donor did not meet acceptance criteria for Hemoglobin/Hematocrit  
(Hgb $\geq$ 11.0g/dl, Hct $\geq$ 33%)
- DS3 - Donor did not meet acceptance criteria for Blood pressure or pulse
- DS4 - Donor did not meet acceptance criteria for time interval between donations  
(i.e., too short)
- DS5 - Post donation information reports of cold and/or flu symptoms
- DS6 - Unit collected from eligible donor but, donor deferral list not checked or checked  
with incorrect information
- DS7 - Pheresis donor did not meet acceptance criteria for platelet count, product  
acceptable
- DS8 - Donor did not meet acceptance criteria for total protein or SPE

**Labeling - LA**

- LA1 - Unit labeled with shortened expiration date
- LA2 - Unit missing label for ABO &/or Rh, product, or expiration date (illegible date)
- LA3 - Directed unit, suitable for homologous use, labeled with incorrect name, SSN, or  
DOB
- LA4 - Unit labeled with missing/incorrect weight, volume, collection date, or facility  
identifiers - unit acceptable (e.g., name/Registration number)

**Distribution - DI**

- DI1 - Discrepancy between shipping form and shipment  
(e.g., 10 units listed on shipping form, but only 9 units in box)
- DI2 - Release of product other than that which was ordered, labeled appropriately  
(e.g., FFP instead of platelets)
- DI3 - Shipment to incorrect facility
- DI4 - Distribution of unit with no segments
- DI5 - Unit lost or shipment never received
- DI6 - Irradiated unit requested, unit not irradiated, labeled appropriately
- DI7 - Anti-CMV negative unit requested, unit not tested for anti-CMV, labeled  
appropriately
- DI8 - Special antigen testing requested, unit not tested for special antigens, labeled  
appropriately
- DI9 - Specific ABO/Rh type requested, incorrect ABO/Rh released, labeled  
appropriately

**Other - MI**

- MI1 - Records destroyed or lost / Destruction records incomplete or final disposition of  
product unknown (with assumption that unit was suitable at time of distribution  
and the work was performed)
- MI2 - Emergency released unit not tested prior to release and found positive for viral  
marker test or incompatible, as long as it was labeled as not tested or crossmatch not  
completed {606.151(e), 606.121(h)}
- MI3 - Recordkeeping error/accident (manual or computer) - record is incorrect or not  
reviewed, testing and labeling acceptable
- MI4 - no products made available for distribution

MI5 - miscellaneous - product quality not affected

MI6 - Recipient reaction

**Quality Control - QC**

QC1 - QC not performed or inadequate, other than viral marker, ABO/Rh  
(e.g., centrifuge, sterile connecting device, scale)

**Blood Collection - BC**

BC1 - Phlebotomist signature missing from donor record

BC2 - Wrong bag used (wrong anticoagulant, wrong bag configuration) - correct expiration  
date

BC3 - Donor reaction

**Laboratory Testing - LT**

LT1 - Testing not routinely performed, unit tested positive for Direct Antiglobulin

LT2 - Testing not routinely performed, unit tested positive for Bilirubin

LT3 - Testing not routinely performed, unit tested positive for Sickle Cell

**NON-BLOOD ERROR/ACCIDENT CODES****NB10 - Reagent performance**

- 1010 - Other**
- 1020 - Anti-HIV test kit**
- 1030 - HIV antigen test kit**
- 1040 - HBsAg test kit**
- 1050 - Anti-HBc test kit**
- 1060 - Anti-HCV test kit**
- 1070 - Anti-HTLV-1 test kit**
- 1080 - Syphilis test kit**
- 1090 - Blood Group Reagent**

**NB20 - Sterility compromised**

- 2010 - Other**
- 2020 - Bacterial contamination**

**NB30 - Labeling**

- 3010 - Other**
- 3020 - Package insert incorrect**
- 3030 - Product label incorrect**
- 3040 - Expiration date extended**
- 3050 - Lot number missing/incorrect**
- 3060 - Storage temperature missing/incorrect**
- 3070 - Administration route missing/incorrect**

**NB40 - Storage and Distribution**

- 4010 - Other**
- 4020 - Product released prior to completion of required testing**
- 4030 - Product released prior to Lot Release approval**
- 4040 - Outdated product**
- 4050 - Product shipped/stored at incorrect temperature**

**NB50 - Miscellaneous**

- 5010 - Other**
- 5020 - Stability testing**

## Reportable Errors and Accidents

ERROR CODE	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
<b>DONOR SCREENING</b>						<b>733</b>	<b>4.98%</b>
DS5103	6	7	0	0	0	13	0.09%
DS5104	4	16	1	0	7	28	0.19%
DS5105	0	1	0	0	0	1	0.01%
DS5106	0	0	0	0	8	8	0.05%
DS5200	12	11	0	0	1	24	0.16%
DS5201	1	1	0	0	3	5	0.03%
DS5202	1	3	0	0	0	4	0.03%
DS5203	8	40	0	0	19	67	0.45%
DS5204	5	41	2	0	8	56	0.38%
DS5301	1	2	0	0	1	4	0.03%
DS5302	2	2	0	0	4	8	0.05%
DS5303	0	4	0	0	0	4	0.03%
DS5304	0	4	0	0	4	8	0.05%
DS5306	1	0	0	0	1	2	0.01%
DS5307	0	2	0	0	4	6	0.04%
DS5308	0	1	0	0	0	1	0.01%
DS5314	0	0	0	0	2	2	0.01%
DS5318	0	1	0	0	3	4	0.03%
DS5321	0	1	0	0	6	7	0.05%
DS5322	0	1	0	0	0	1	0.01%
DS5323	0	0	0	0	2	2	0.01%
DS5329	0	1	0	0	0	1	0.01%
DS5332	0	0	0	0	3	3	0.02%
DS5401	1	4	0	0	0	5	0.03%
DS5402	3	3	0	0	0	6	0.04%
DS5403	0	2	0	0	0	2	0.01%
DS5404	1	2	0	0	1	4	0.03%
DS5406	1	1	0	0	1	3	0.02%
DS5407	0	1	0	0	0	1	0.01%
DS5414	2	0	0	0	1	3	0.02%
DS5417	0	0	0	0	1	1	0.01%
DS5418	0	1	0	0	1	2	0.01%
DS5421	0	0	0	0	2	2	0.01%
DS5422	2	2	0	0	0	4	0.03%
DS5423	0	1	0	0	0	1	0.01%
DS5432	0	0	0	0	2	2	0.01%
DS5502	12	9	0	0	1	22	0.15%
DS5507	0	1	0	0	0	1	0.01%
DS5511	3	3	0	0	1	7	0.05%
DS5513	1	0	0	0	0	1	0.01%
DS5514	0	2	0	0	0	2	0.01%
DS5515	1	1	0	0	0	2	0.01%
DS5516	5	4	0	0	1	10	0.07%
DS5518	2	14	0	0	7	23	0.16%
DS5520	3	2	0	0	0	5	0.03%
DS5521	0	1	0	0	2	3	0.02%
DS5522	71	106	1	0	0	178	1.21%
DS5523	13	21	0	0	2	36	0.24%
DS5524	25	27	0	0	0	52	0.35%
DS5526	0	3	0	0	1	4	0.03%

ERROR CODE	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
DS5528	1	3	0	0	0	4	0.03%
DS5529	7	38	1	0	2	48	0.33%
DS5530	5	3	0	0	9	17	0.12%
DS5532	0	2	0	0	1	3	0.02%
DS5534	7	2	0	0	0	9	0.06%
DS5535	7	4	0	0	0	11	0.07%
<b>DONOR DEFERRAL</b>						<b>153</b>	<b>1.04%</b>
DD6101	3	78	0	0	0	81	0.55%
DD6102	1	8	0	0	0	9	0.06%
DD6103	0	2	0	0	0	2	0.01%
DD6104	5	5	0	0	0	10	0.07%
DD6105	0	3	0	0	0	3	0.02%
DD6106	1		0	0	0	1	0.01%
DD6107	0	4	0	0	0	4	0.03%
DD6108	0	1	0	0	2	3	0.02%
DD6111	0		0	0	1	1	0.01%
DD6114	0	2	0	0	0	2	0.01%
DD6118	1	3	0	0	0	4	0.03%
DD6120	0	0	0	0	2	2	0.01%
DD6121	1	0	0	0	1	2	0.01%
DD6122	1	0	0	0	0	1	0.01%
DD6123	0	1	0	0	0	1	0.01%
DD6124	0	1	0	0	0	1	0.01%
DD6129	1	2	0	0	0	3	0.02%
DD6130	0	0	0	0	1	1	0.01%
DD6132	0	0	0	0	1	1	0.01%
DD6201	0	14	0	0	0	14	0.10%
DD6203	0	1	0	0	0	1	0.01%
DD6205	1	0	0	0	0	1	0.01%
DD6206	0	1	0	0	0	1	0.01%
DD6216	0	1	0	0	0	1	0.01%
DD6218	0	0	0	0	1	1	0.01%
DD6223	0	1	0	0	0	1	0.01%
DD6236	0	1	0	0	0	1	0.01%
<b>POST DONATION INFORMATION</b>						<b>10639</b>	<b>72.21%</b>
DD6301	9	27	0	0	1	37	0.25%
DD6303	547	460	0	0	5	1012	6.87%
DD6304	85	32	0	0	17	134	0.91%
DD6305	19	13	0	0	3	35	0.24%
DD6306	6	53	0	0	4	63	0.43%
DD6307	148	100	1	0	12	261	1.77%
DD6308	10	23	0	0	5	38	0.26%
DD6309	0	3	0	0	0	3	0.02%
DD6310	36	20	0	0	22	78	0.53%
DD6311	421	128	0	0	33	582	3.95%
DD6312	174	67	0	0	47	288	1.95%
DD6313	44	12	0	0	2	58	0.39%
DD6314	131	173	0	0	103	407	2.76%
DD6315	152	91	0	0	17	260	1.76%
DD6316	89	70	1	0	3	163	1.11%
DD6317	51	28	0	0	14	93	0.63%
DD6318	678	463	2	0	773	1916	13.00%
DD6319	1	1	0	0	0	2	0.01%

ERROR CODE	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
DD6320	202	78	0	0	15	295	2.00%
DD6321	29	92	2	0	249	372	2.52%
DD6322	590	886	3	0	1	1480	10.05%
DD6323	344	259	1	0	17	621	4.22%
DD6324	735	557	5	0	11	1308	8.88%
DD6325	2	5	0	0	1	8	0.05%
DD6326	61	62	0	0	2	125	0.85%
DD6327	19	13	0	0	0	32	0.22%
DD6328	76	31	0	0	2	109	0.74%
DD6329	114	120	0	0	9	243	1.65%
DD6330	36	17	0	0	24	77	0.52%
DD6331	13	12	0	0	1	26	0.18%
DD6332	7	25	0	0	311	343	2.33%
DD6333	2	1	0	0	10	13	0.09%
DD6334	32	0	0	0	0	32	0.22%
DD6335	28	51	1	0	4	84	0.57%
DD6336	25	14	0	0	2	41	0.28%
<b>COLLECTION</b>						<b>126</b>	<b>0.86%</b>
BC3000	2	2	0	0	0	4	0.03%
BC3100	2	5	0	0	0	7	0.05%
BC3101	13	20	0	0	0	33	0.22%
BC3102	17	9	0	0	1	27	0.18%
BC3103	2	9	0	0	0	11	0.07%
BC3201	7	1	0	0	0	8	0.05%
BC3400	13	2	0	0	0	15	0.10%
BC3401	12	7	0	0	0	19	0.13%
BC3402	1	1	0	0	0	2	0.01%
<b>COMPONENT PREPARATION</b>						<b>170</b>	<b>1.15%</b>
CP8100	2	4	0	0	0	6	0.04%
CP8200	0	1	0	0	0	1	0.01%
CP8301	1	0	0	0	0	1	0.01%
CP8302	6	5	0	0	0	11	0.07%
CP8303	1	0	0	0	0	1	0.01%
CP8400	8	11	0	0	0	19	0.13%
CP8401	3	7	1	0	0	11	0.07%
CP8402	5	8	0	0	0	13	0.09%
CP8403	0	5	0	0	0	5	0.03%
CP8404	0	5	0	0	0	5	0.03%
CP8405	1	0	0	0	0	1	0.01%
CP8406	1	2	0	0	0	3	0.02%
CP8407	7	14	0	0	0	21	0.14%
CP8500	19	21	1	0	1	42	0.29%
CP8501	0	3	1	0	0	4	0.03%
CP8502	1	4	0	0	0	5	0.03%
CP8503	0	1	0	0	0	1	0.01%
CP8504	1	0	0	0	0	1	0.01%
CP8600	7	5	1	0	0	13	0.09%
CP8700	3	3	0	0	0	6	0.04%
<b>ROUTINE TESTING</b>						<b>280</b>	<b>1.90%</b>
RT1101	18	35	0	0	1	54	0.37%
RT1102	39	51	1	2	0	93	0.63%
RT1103	4	7	0	0	0	11	0.07%
RT1104	11	26	3	0	0	40	0.27%

ERROR CODE	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
RT1105	20	31	0	1	0	52	0.35%
RT1106	2	1	0	0	0	3	0.02%
RT1108	1	1	0	0	0	2	0.01%
RT1201	1	20	1	2	1	25	0.17%
<b>VIRAL TESTING</b>						<b>382</b>	<b>2.59%</b>
VT2101	6	42	0	0	0	48	0.33%
VT2102	0	10	0	0	0	10	0.07%
VT2104	3	3	0	0	2	8	0.05%
VT2105	4	6	0	0	2	12	0.08%
VT2106	2	8	0	0	0	10	0.07%
VT2107	0	3	0	0	0	3	0.02%
VT2108	2	247	8	0	0	257	1.74%
VT2109	1	2	0	0	2	5	0.03%
VT2110	3	8	0	0	2	13	0.09%
VT2111	3	3	0	0	1	7	0.05%
VT2112	4	4	1	0	0	9	0.06%
<b>LABELING</b>						<b>912</b>	<b>6.19%</b>
LA4101	27	55	3	0	0	85	0.58%
LA4102	19	35	2	0	0	56	0.38%
LA4103	44	125	9	1	0	179	1.21%
LA4201	118	74	3	0	0	195	1.32%
LA4202	41	12	0	1	0	54	0.37%
LA4203	21	24	0	0	0	45	0.31%
LA4204	7	16	1	0	0	24	0.16%
LA4205	6	16	0	0	0	22	0.15%
LA4206	3	4	1	1	0	9	0.06%
LA4207	22	36	1	1	0	60	0.41%
LA4208	2	4	0	0	1	7	0.05%
LA4209	31	54	4	3	1	93	0.63%
LA4210	7	21	3	0	0	31	0.21%
LA4211	11	4	0	0	0	15	0.10%
LA4300	26	11	0	0	0	37	0.25%
<b>STORAGE/DISTRIBUTION</b>						<b>1319</b>	<b>8.95%</b>
SD7107	16	14	0	1	1	32	0.22%
SD7110	0	0	0	0	1	1	0.01%
SD7111	0	0	0	0	1	1	0.01%
SD7118	1	4	0	0	1	6	0.04%
SD7120	2	0	0	0	0	2	0.01%
SD7121	1	2	0	0	2	5	0.03%
SD7122	1	4	0	0	0	5	0.03%
SD7123	1	1	0	0	0	2	0.01%
SD7124	2	3	0	0	1	6	0.04%
SD7129	1	3	0	0	0	4	0.03%
SD7130	3	0	0	0	3	6	0.04%
SD7132	0	0	0	0	1	1	0.01%
SD7135	0	1	0	0	0	1	0.01%
SD7201	2	7	0	0	5	14	0.10%
SD7202	0	5	3	0	2	10	0.07%
SD7203	0	24	1	0	0	25	0.17%
SD7204	2	13	1	0	4	20	0.14%
SD7205	1	4	1	0	0	6	0.04%
SD7206	0	6	1	0	1	8	0.05%
SD7207	4	8	0	0	47	59	0.40%

ERROR CODE	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
SD7209	0	2	0	0	0	2	0.01%
SD7210	11	12	0	0	0	23	0.16%
SD7211	0	2	0	0	0	2	0.01%
SD7212	0	6	1	0	2	9	0.06%
SD7301	0	1	0	0	0	1	0.01%
SD7302	0	55	0	0	0	55	0.37%
SD7303	0	4	0	0	0	4	0.03%
SD7304	0	1	1	0	2	4	0.03%
SD7306	0	0	1	0	1	2	0.01%
SD7307	14	19	1	0	13	47	0.32%
SD7308	0	2	0	0	0	2	0.01%
SD7310	2	8	0	0	2	12	0.08%
SD7311	4	5	3	0	0	12	0.08%
SD7312	0	0	0	0	3	3	0.02%
SD7400	54	50	0	0	5	109	0.74%
SD7401	13	21	3	2	0	39	0.26%
SD7500	53	47	0	0	0	100	0.68%
SD7501	65	206	0	0	0	271	1.84%
SD7502	10	40	0	0	0	50	0.34%
SD7503	43	9	0	0	0	52	0.35%
SD7600	137	69	0	3	2	211	1.43%
SD7700	13	26	1	0	0	40	0.27%
SD7800	1	3	2	0	0	6	0.04%
SD7801	0	4	2	3	0	9	0.06%
SD7802	0	10	4	1	0	15	0.10%
SD7803	0	3	0	3	0	6	0.04%
SD7804	1	13	2	3	0	19	0.13%
<b>MISCELLANEOUS</b>						<b>19</b>	<b>0.13%</b>
MI9202	0	2	0	0	0	2	0.01%
MI9501	1	2	0	0	3	6	0.04%
MI9502	0	0	0	0	3	3	0.02%
MI9503	1	1	0	0	2	4	0.03%
MI9504	0	3	0	0	0	3	0.02%
MI9505	0	0	0	0	1	1	0.01%
<b>TOTAL</b>	<b>6249</b>	<b>6397</b>	<b>94</b>	<b>28</b>	<b>1965</b>	<b>14733</b>	<b>100.00%</b>



## Non-Reportable Errors and Accidents

ERROR CODES	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
<b>DONOR SCREENING</b>						<b>57</b>	<b>8.13%</b>
DS1	15	0	0	0	1	16	2.28%
DS2	0	1	0	0	2	3	0.43%
DS3	2	1	0	0	0	3	0.43%
DS4	3	13	0	0	6	22	3.14%
DS6	2	3	0	0	0	5	0.71%
DS7	1	2	0	0	0	3	0.43%
DS8	0	0	0	0	2	2	0.29%
Miscellaneous (MI5)	3	0	0	0	0	3	0.43%
<b>DONOR DEFERRAL</b>						<b>8</b>	<b>1.14%</b>
Miscellaneous (MI5)	5	3	0	0	0	8	1.14%
<b>POST DONATION INFORMATION</b>						<b>61</b>	<b>8.70%</b>
DS5	27	29	0	0	0	56	7.99%
miscellaneous (MI5)	3	2	0	0	0	5	0.71%
<b>COLLECTION</b>						<b>37</b>	<b>5.28%</b>
BC1	1	0	0	0	0	1	0.14%
BC2	4	0	0	0	0	4	0.57%
BC3	30	1	0	0	0	31	4.42%
miscellaneous (MI5)	0	1	0	0	0	1	0.14%
<b>COMPONENT PREPARATION</b>						<b>3</b>	<b>0.43%</b>
miscellaneous (MI5)	2	1	0	0	0	3	0.43%
<b>ROUTINE TESTING</b>						<b>7</b>	<b>1.00%</b>
LT1	4	2	0	0	0	6	0.86%
miscellaneous (MI5)	0	0	1	0	0	1	0.14%
<b>VIRAL TESTING</b>						<b>10</b>	<b>1.43%</b>
LT4	0	9	1	0	0	10	1.43%
<b>LABELING</b>						<b>151</b>	<b>21.54%</b>
LA1	21	14	2	0	0	37	5.28%
LA2	15	15	0	0	0	30	4.28%
LA3	23	4	0	0	0	27	3.85%
LA4	27	23	0	0	1	51	7.28%
miscellaneous (MI5)	2	4	0	0	0	6	0.86%
<b>STORAGE/DISTRIBUTION</b>						<b>66</b>	<b>9.42%</b>
DI1	8	2	0	0	2	12	1.71%
DI2	0	1	0	0	0	1	0.14%
DI3	3	2	0	0	0	5	0.71%
DI5	4	0	0	0	0	4	0.57%
DI6	2	7	0	0	0	9	1.28%
DI7	3	0	0	0	0	3	0.43%
DI8	1	0	0	0	0	1	0.14%
DI9	1	0	0	0	0	1	0.14%
miscellaneous (MI5)	14	12	2	0	2	30	4.28%
<b>MISCELLANEOUS</b>						<b>301</b>	<b>42.94%</b>
MI1	18	11	0	0	2	31	4.42%
MI2	2	1	0	0	0	3	0.43%
MI3	21	21	1	0	1	44	6.28%
MI4	11	59	21	1	6	98	13.98%
MI5	35	10	5	0	7	57	8.13%
MI6	13	3	0	1	0	17	2.43%
QC1	41	10	0	0	0	51	7.28%
<b>TOTAL</b>	<b>367</b>	<b>267</b>	<b>33</b>	<b>2</b>	<b>32</b>	<b>701</b>	<b>100.00%</b>