

DATE : FEB 19 1999

FROM : Sharon O'Callaghan, ^{MSC}CSO,
 Division of Inspections and Surveillance (HFM-650)

SUBJECT: ERROR AND ACCIDENT REPORTS - ANNUAL SUMMARY FOR FY-98

TO : Acting, Director, Division of Inspections and Surveillance (HFM-650) *J. Balwani*

Between October 1, 1997 and September 30, 1998, the Division of Inspections and Surveillance received 6,035 error and accident reports from the American Red Cross (ARC), 5,819 error and accident reports from non-ARC licensed blood establishments, 211 error and accident reports from unlicensed registered blood establishments, 19 error and accident reports from transfusion services, 1103 error and accident reports from plasma centers, 17 error and accident reports from blood derivative manufacturers, 19 error and accident report from in-vitro diagnostic manufacturers, 3 error and accident reports from vaccine manufacturers, 3 error and accident reports from allergenic manufacturers, and 3 error and accident reports from therapeutic manufacturers. A total of 13,232 error and accident reports were received. There were 1,692 (12.8%) 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, 903 (6.8%) 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 are as follows:

REPORTABLE ERRORS/ACCIDENTS

Donor Suitability - 72.4%	
Post Donation Information	65.0%
Donor Screening	6.7%
Donor Deferral	0.7%
Storage and Distribution	10.3%
Labeling	9.0%
Product Testing - 5.2%	
Routine Testing	3.1%
Viral Testing	2.1%
Component Preparation	2.1%
Collection	0.8%
Miscellaneous	0.2%

NON-REPORTABLE ERRORS/ACCIDENTS

Miscellaneous	42.3%
Labeling	20.1%
Donor Suitability - 18.4%	
Donor Screening	12.3%
Post Donation Information	5.8%
Donor Deferral	0.3%
Storage and Distribution	11.9%
Collection	5.3%
Product Testing - 1.3%	
Viral Testing	1.0%
Routine Testing	0.3%
Component Preparation	0.7%

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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 (65.0%), Storage and Distribution (10.3%), Labeling (9.0%), and Donor Screening (6.7%) and for Non-Reportables: Miscellaneous (42.3%), Labeling (20.1%), Donor Screening (12.3%), and Storage and Distribution (11.9%). A table and graphs are also provided that illustrate the distribution of the reporting time, i.e., time from the date 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 travelling to a malarial endemic area or having a history of malaria.

Of the 7986 post donation information reports received, 6342 (79.4%) reports involved the donor providing the information at a subsequent donation, 1176 (14.7%) reports involved the donor calling back to the center within a few days of donating, and 468 (5.9%) reports involved a third party providing the information.

INFORMATION RECEIVED BY:	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	PLASMA CENTERS	TOTAL	
SUBSEQUENT DONATION	3223	2441	33	645	6342	79.4%
TELEPHONE CALL	634	524	4	14	1176	14.7%
THIRD PARTY	139	106	0	223	468	5.9%
TOTAL	3996	3071	37	882	7986	100.0%

Of the 7986 post donation information reports received, 6262 (78.4%) 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. 1724 (21.6%) 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	3072	2359	32	799	6262	78.4%
NOT KNOWN AT TIME OF DONATION	924	712	5	83	1724	21.6%
Total	3996	3071	37	882	7986	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 - Tables - Types of Errors/Accidents for Blood and Plasma Manufacturers
 - Reportable Errors/Accidents
 - Non-Reportable Errors/Accidents
- 4 - Table - Types of Errors/Accidents for Non-Blood Manufacturers
- 5 (2 pages) - Tables - Detailed Listing of Errors/Accidents for Non-Blood Manufacturers
- 6- Tables - Types of Errors/Accidents - American Red Cross
 - Reportable Errors/Accidents
 - Non-Reportable Errors/Accidents
 - Total Errors/Accidents
- 7 - Tables - Types of Errors/Accidents - Non-ARC Licensed Blood Banks
 - Reportable Errors/Accidents
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 - Total Errors/Accidents
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- 16 (5 pages) - Tables - Post Donation Information Reports
- 17 (3 pages) - Tables - Storage/Distribution Errors/Accidents
- 18 (2 pages) - Tables - Labeling Errors/Accidents
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- 28 - Table - Reporting Time
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- 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 (10 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 (2 pages) - Table - Number of Non-Reportable Errors/Accident by Establishments

**ERROR AND ACCIDENT REPORTS
RECEIVED 10/1/97 - 9/30/98**

	TOTAL REPORTS	POTENTIAL RECALLS	%RECALLS
AMERICAN RED CROSS	6035	528	8.7%
NON-ARC LICENSED BLOOD BANKS	5819	1045	18.0%
UNLICENSED BLOOD BANKS	211	18	8.5%
TRANSFUSION SERVICES	19	0	0.0%
PLASMA CENTERS	1103	86	7.8%
BLOOD DERIVATIVE MANUFACTURER	17	0	0.0%
IN-VITRO DIAGNOSTIC MANUFACTURER	19	12	66.7%
VACCINE MANUFACTURER	3	0	0.0%
ALLERGENICS MANUFACTURER	3	3	100.0%
THERAPEUTIC MANUFACTURER	3	0	0.0%
<i>TOTAL</i>	13232	1692	12.8%

	TOTAL REPORTS	REPORTABLE	%REPORTABLE
AMERICAN RED CROSS	6035	5622	93.2%
NON-ARC LICENSED BLOOD BANKS	5819	5441	93.5%
UNLICENSED BLOOD BANKS	211	160	75.8%
TRANSFUSION SERVICES	19	17	89.5%
PLASMA CENTERS	1103	1046	94.8%
BLOOD DERIVATIVE MANUFACTURER	17	16	94.1%
IN-VITRO DIAGNOSTIC MANUFACTURER	19	18	94.7%
VACCINE MANUFACTURER	3	3	100.0%
ALLERGENICS MANUFACTURER	3	3	0.0%
THERAPEUTIC MANUFACTURER	3	3	100.0%
<i>TOTAL</i>	13232	12329	93.2%

	TOTAL REPORTS	NON- REPORTABLES	%NON- REPORTABLE
AMERICAN RED CROSS	6035	413	6.8%
NON-ARC LICENSED BLOOD BANKS	5819	378	6.5%
UNLICENSED BLOOD BANKS	211	51	24.2%
TRANSFUSION SERVICES	19	2	10.5%
PLASMA CENTERS	1103	57	5.2%
BLOOD DERIVATIVE MANUFACTURER	17	1	5.9%
IN-VITRO DIAGNOSTIC MANUFACTURER	19	1	5.6%
VACCINE MANUFACTURER	3	0	0.0%
ALLERGENICS MANUFACTURER	3	0	0.0%
THERAPEUTIC MANUFACTURER	3	0	0.0%
<i>TOTAL</i>	13232	903	6.8%

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	126	234	20	3	0	383	2.9%
VIRAL TESTING	41	218	7	0	6	272	2.1%
COLLECTION	93	52	2	0	2	149	1.1%
COMPONENT PREPARATION	117	138	5	2	0	262	2.0%
LABELING	599	643	30	0	10	1282	9.7%
DONOR SCREENING	313	542	11	0	69	935	7.1%
DONOR DEFERRAL	23	48	4	0	13	88	0.7%
POST DONATION INFO	4009	3107	39	0	883	8038	61.0%
STORAGE/DISTRIBUTION	557	688	53	12	58	1368	10.4%
MISCELLANEOUS	157	149	40	2	62	410	3.1%
TOTAL	6035	5819	211	19	1103	13187	100%

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	0	6	0	0	0	6	0.4%
VIRAL TESTING	17	182	2	0	2	203	12.1%
COLLECTION	31	26	0	0	1	58	3.5%
COMPONENT PREPARATION	73	93	0	0	0	166	9.9%
LABELING	69	109	5	0	2	185	11.0%
DONOR SCREENING	170	309	4	0	33	516	30.8%
DONOR DEFERRAL	20	40	4	0	12	76	4.5%
POST DONATION INFO	29	16	0	0	5	50	3.0%
STORAGE/DISTRIBUTION	119	263	3	0	31	416	24.8%
MISCELLANEOUS	0	1	0	0	0	1	0.1%
TOTAL	528	1045	18	0	86	1677	100%

**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	126	231	20	3	0	380	3.1%
VIRAL TESTING	40	210	7	0	6	263	2.1%
COLLECTION	52	46	1	0	2	101	0.8%
COMPONENT PREPARATION	117	132	5	2	0	256	2.1%
LABELING	499	565	28	0	9	1101	9.0%
DONOR SCREENING	268	487	10	0	59	824	6.7%
DONOR DEFERRAL	22	46	4	0	13	85	0.7%
POST DONATION INFO	3996	3071	37	0	882	7986	65.0%
STORAGE/DISTRIBUTION	499	650	47	12	53	1261	10.3%
MISCELLANEOUS	3	3	1	0	22	29	0.2%
TOTAL	5622	5441	160	17	1046	12286	100%

**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	0	3	0	0	0	3	0.3%
VIRAL TESTING	1	8	0	0	0	9	1.0%
COLLECTION	41	6	1	0	0	48	5.3%
COMPONENT PREPARATION	0	6	0	0	0	6	0.7%
LABELING	100	78	2	0	1	181	20.1%
DONOR SCREENING	45	55	1	0	10	111	12.3%
DONOR DEFERRAL	1	2	0	0	0	3	0.3%
POST DONATION INFO	13	36	2	0	1	52	5.8%
STORAGE/DISTRIBUTION	58	38	6	0	5	107	11.9%
MISCELLANEOUS	154	146	39	2	40	381	42.3%
TOTAL	413	378	51	2	57	901	100%

NON-BLOOD MANUFACTURERS

TYPE OF ERROR/ACCIDENT	DERIVATIVE		IN-VITRO DIAGNOSTIC		VACCINE		ALLERGENIC		THERAPEUTIC		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	2.2%	1	6.7%
STERILITY COMPROMISED	1	0	1	1	0	0	0	0	2	0	4	8.9%	1	6.7%
LABELING	1	0	8	5	2	0	3	3	0	0	14	31.1%	8	53.3%
STORAGE/DISTRIBUTION	4	0	3	1	0	0	0	0	1	0	8	17.8%	1	6.7%
MISCELLANEOUS	10	0	5	4	1	0	0	0	0	0	16	35.6%	4	26.7%
NON-REPORTABLE	1	0	1	0	0	0	0	0	0	0	2	4.4%	0	0.0%
TOTAL	17	0	19	12	3	0	3	3	3	0	45	100%	15	100%

NON-BLOOD MANUFACTURERS

DERIVATIVES

ERROR/ACCIDENT	#REPORTS
<i>STERILITY COMPROMISED</i>	1
Air contamination during lyophilization	1
<i>LABELING</i>	1
Package insert incorrect	1
<i>STORAGE/DISTRIBUTION</i>	4
Products released that were manufactured from source material that was improperly tested	1
Failure to quarantine product whose source material was withdrawn due to CJD risk	1
Product released prior to completion of required testing - sterility testing not performed on bulk sample	1
Product shipped or stored at incorrect temperature	1
<i>MISCELLANEOUS</i>	10
Source material withdrawn due to CJD risk	5
Decrease in potency due to an underfill of final container vials	1
Pre-bulk pH specifications were not consistent with product license application	1
Product subjected to a second complete heat cycle	1
Stability testing failed	2
<i>NON-REPORTABLE</i>	1
Albumin labeled as being derived from blood collected from specific donors instead of volunteer donors - product quality not affected	1
<i>TOTAL</i>	17

IN-VITRO DIAGNOSTICS

ERROR/ACCIDENT	#REPORTS
<i>REAGENT PERFORMANCE</i>	1
Reagent may exhibit positive DAT when the gel test is used	1
<i>STERILITY COMPROMISED</i>	1
Bacterial contamination	1
<i>LABELING</i>	8
Package insert incorrect	3
Product label incorrect	4
Lot number missing or incorrect	1
<i>STORAGE/DISTRIBUTION</i>	3
Failure to quarantine product with an extended expiration date	1
Product released prior to completion of required testing	1
Product shipped or stored at incorrect temperature	1
<i>MISCELLANEOUS</i>	5
Decrease in potency	3
Reagent panel cells packaged with ficin solution having a shorter expiration date than panel cells	1
Stability testing failed	1
<i>NON-REPORTABLE</i>	1
Fire in sterilization room - no products available for distribution	1
<i>TOTAL</i>	19

NON-BLOOD MANUFACTURERS

VACCINES

ERROR/ACCIDENT	#REPORTS
<i>LABELING</i>	2
Product label incorrect	1
Expiration date extended	1
<i>MISCELLANEOUS</i>	1
Seed passage used not approved as part of product license	1
<i>TOTAL</i>	3

ALLERGENICS

ERROR/ACCIDENT	#REPORTS
<i>LABELING</i>	3
Product label incorrect	1
Expiration date extended	1
Lot number missing or incorrect	1
<i>TOTAL</i>	3

THERAPEUTICS

ERROR/ACCIDENT	#REPORTS
<i>STERILITY COMPROMISED</i>	2
Contaminated with phenolic compounds during filling	1
White polyurethane elastomer	1
<i>STORAGE AND DISTRIBUTION</i>	1
Product released prior to completion of required testing	1
<i>TOTAL</i>	3

AMERICAN RED CROSS

REPORTABLE ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	31	35	29	31	126	2.2%
VIRAL TESTING	6	11	6	17	40	0.7%
COLLECTION	14	11	10	17	52	0.9%
COMPONENT PREPARATION	38	37	22	20	117	2.1%
LABELING	124	127	124	124	499	8.9%
DONOR SCREENING	82	58	75	53	268	4.8%
DONOR DEFERRAL	7	6	6	3	22	0.4%
POST DONATION INFO	959	841	974	1222	3996	71.1%
STORAGE/DISTRIBUTION	135	122	123	119	499	8.9%
MISCELLANEOUS	1	1	1	0	3	0.1%
TOTAL	1397	1249	1370	1606	5622	100.0%

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	1	0	1	0.2%
COLLECTION	10	8	7	16	41	9.9%
COMPONENT PREPARATION	0	0	0	0	0	0.0%
LABELING	32	20	24	24	100	24.2%
DONOR SCREENING	16	4	15	10	45	10.9%
DONOR DEFERRAL	0	0	0	1	1	0.2%
POST DONATION INFO	2	2	3	6	13	3.1%
STORAGE/DISTRIBUTION	19	20	2	17	58	14.0%
MISCELLANEOUS	43	36	35	40	154	37.3%
TOTAL	122	90	87	114	413	100.0%

TOTAL ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	31	35	29	31	126	2.1%
VIRAL TESTING	6	11	7	17	41	0.7%
COLLECTION	24	19	17	33	93	1.5%
COMPONENT PREPARATION	38	37	22	20	117	1.9%
LABELING	156	147	148	148	599	9.9%
DONOR SCREENING	98	62	90	63	313	5.2%
DONOR DEFERRAL	7	6	6	4	23	0.4%
POST DONATION INFO	961	843	977	1228	4009	66.4%
STORAGE/DISTRIBUTION	154	142	125	136	557	9.2%
MISCELLANEOUS	44	37	36	40	157	2.6%
TOTAL	1519	1339	1457	1720	6035	100.0%

NON-ARC LICENSED BLOOD BANKS**REPORTABLE ERRORS AND ACCIDENTS**

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	67	75	38	51	231	4.2%
VIRAL TESTING	17	37	21	135	210	3.9%
COLLECTION	12	10	14	10	46	0.8%
COMPONENT PREPARATION	33	49	27	23	132	2.4%
LABELING	137	152	128	148	565	10.4%
DONOR SCREENING	131	119	121	116	487	9.0%
DONOR DEFERRAL	14	13	11	8	46	0.8%
POST DONATION INFO	720	800	802	749	3071	56.4%
STORAGE/DISTRIBUTION	109	145	240	156	650	11.9%
MISCELLANEOUS	1	1	0	1	3	0.1%
TOTAL	1241	1401	1402	1397	5441	100.0%

NON-REPORTABLE ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	0	0	2	1	3	0.8%
VIRAL TESTING	7	0	1	0	8	2.1%
COLLECTION	0	4	1	1	6	1.6%
COMPONENT PREPARATION	1	1	3	1	6	1.6%
LABELING	17	23	26	12	78	20.6%
DONOR SCREENING	13	16	12	14	55	14.6%
DONOR DEFERRAL	1	0	1	0	2	0.5%
POST DONATION INFO	15	11	6	4	36	9.5%
STORAGE/DISTRIBUTION	17	5	4	12	38	10.1%
MISCELLANEOUS	44	22	42	38	146	38.6%
TOTAL	115	82	98	83	378	100.0%

TOTAL ERRORS AND ACCIDENTS

TOTAL	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	67	75	40	52	234	4.0%
VIRAL TESTING	24	37	22	135	218	3.7%
COLLECTION	12	14	15	11	52	0.9%
COMPONENT PREPARATION	34	50	30	24	138	2.4%
LABELING	154	175	154	160	643	11.1%
DONOR SCREENING	144	135	133	130	542	9.3%
DONOR DEFERRAL	15	13	12	8	48	0.8%
POST DONATION INFO	735	811	808	753	3107	53.4%
STORAGE/DISTRIBUTION	126	150	244	168	688	11.8%
MISCELLANEOUS	45	23	42	39	149	2.6%
TOTAL	1356	1483	1500	1480	5819	100.0%

UNLICENSED BLOOD BANKS

REPORTABLE ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	7 ²	6 ¹	8	2	23	13.0%
VIRAL TESTING	2	1	1	3	7	4.0%
COLLECTION	0	1	0	0	1	0.6%
COMPONENT PREPARATION	1	3	1 ¹	2 ¹	7	4.0%
LABELING	3	5	11	9	28	15.8%
DONOR SCREENING	1	2	5	2	10	5.6%
DONOR DEFERRAL	0	0	2	2	4	2.3%
POST DONATION INFO	6	8	13	10	37	20.9%
STORAGE/DISTRIBUTION	8 ³	11 ²	22 ¹	18 ⁶	59	33.3%
MISCELLANEOUS	0	0	0	1	1	0.6%
TOTAL	28	37	63	49	177	100.0%

^{1,2,3,6} 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	0	0	0.0%
VIRAL TESTING	0	0	0	0	0	0.0%
COLLECTION	0	0	0	1	1	1.9%
COMPONENT PREPARATION	0	0	0	0	0	0.0%
LABELING	0	0	1	1	2	3.8%
DONOR SCREENING	0	0	1	0	1	1.9%
DONOR DEFERRAL	0	0	0	0	0	0.0%
POST DONATION INFO	1	0	1	0	2	3.8%
STORAGE/DISTRIBUTION	1	2	1	2	6	11.3%
MISCELLANEOUS	4 ¹	15 ¹	11	11	41	77.4%
TOTAL ⁴¹	6	17	15	15	53	100.0%

¹ Number of reports included from transfusion services

TOTAL ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	7 ²	6 ¹	8	2	23	10.0%
VIRAL TESTING	2	1	1	3	7	3.0%
COLLECTION	0	1	0	1	2	0.9%
COMPONENT PREPARATION	1	3	1 ¹	2 ¹	7	3.0%
LABELING	3	5	12	10	30	13.0%
DONOR SCREENING	1	2	6	2	11	4.8%
DONOR DEFERRAL	0	0	2	2	4	1.7%
POST DONATION INFO	7	8	14	10	39	17.0%
STORAGE/DISTRIBUTION	9 ³	13 ²	23 ¹	20 ⁶	65	28.3%
MISCELLANEOUS	4 ¹	15 ¹	11	12	42	18.3%
TOTAL	34	54	78	64	230	100.0%

^{1,2,3,6} 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	0	0	0	0	0.0%
VIRAL TESTING	1	3	1	1	6	0.6%
COLLECTION	1	0	1	0	2	0.2%
COMPONENT PREPARATION	0	0	0	0	0	0.0%
LABELING	1	1	7	0	9	0.9%
DONOR SCREENING	12	10	16	21	59	5.6%
DONOR DEFERRAL	1	4	2	6	13	1.2%
POST DONATION INFO	196	269	214	203	882	84.3%
STORAGE/DISTRIBUTION	13	20	8	12	53	5.1%
MISCELLANEOUS	8	4	8	2	22	2.1%
TOTAL	233	311	257	245	1046	100.0%

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	1	0	0	0	1	1.8%
DONOR SCREENING	4	3	3	0	10	17.5%
DONOR DEFERRAL	0	0	0	0	0	0.0%
POST DONATION INFO	0	0	1	0	1	1.8%
STORAGE/DISTRIBUTION	0	2	1	2	5	8.8%
MISCELLANEOUS	1	8	9	22	40	70.2%
TOTAL	6	13	14	24	57	100.0%

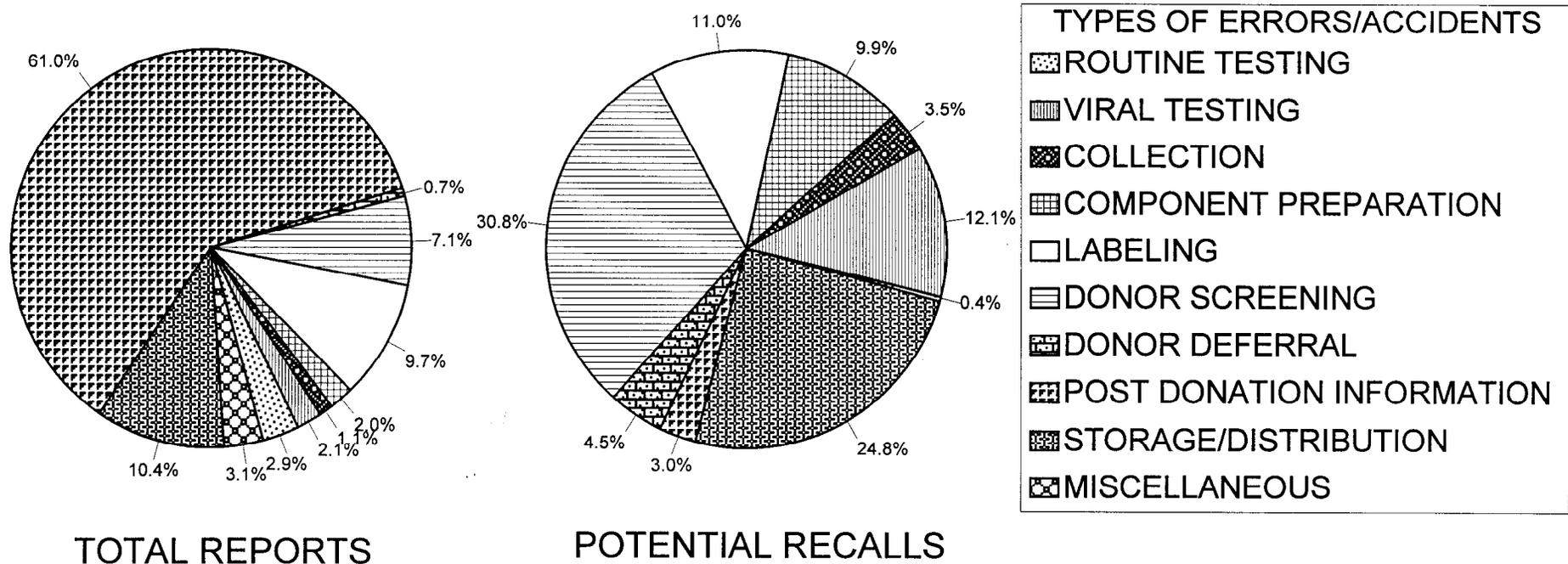
TOTAL ERROR AND ACCIDENT REPORTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	0	0	0	0	0	0.0%
VIRAL TESTING	1	3	1	1	6	0.5%
COLLECTION	1	0	1	0	2	0.2%
COMPONENT PREPARATION	0	0	0	0	0	0.0%
LABELING	2	1	7	0	10	0.9%
DONOR SCREENING	16	13	19	21	69	6.3%
DONOR DEFERRAL	1	4	2	6	13	1.2%
POST DONATION INFO	196	269	215	203	883	80.1%
STORAGE/DISTRIBUTION	13	22	9	14	58	5.3%
MISCELLANEOUS	9	12	17	24	62	5.6%
TOTAL	239	324	271	269	1103	100.0%

ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

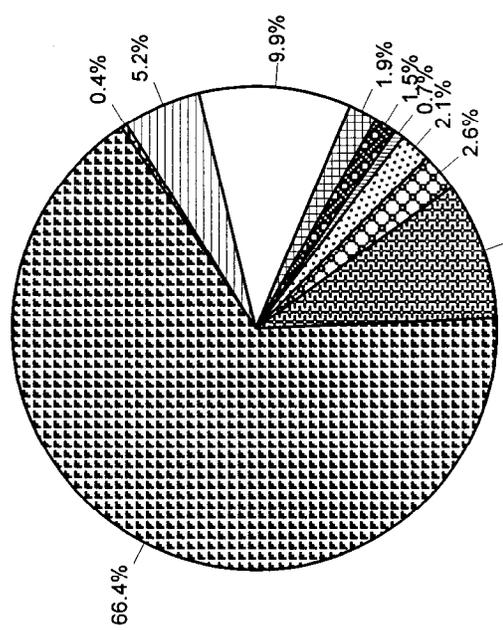
FY98



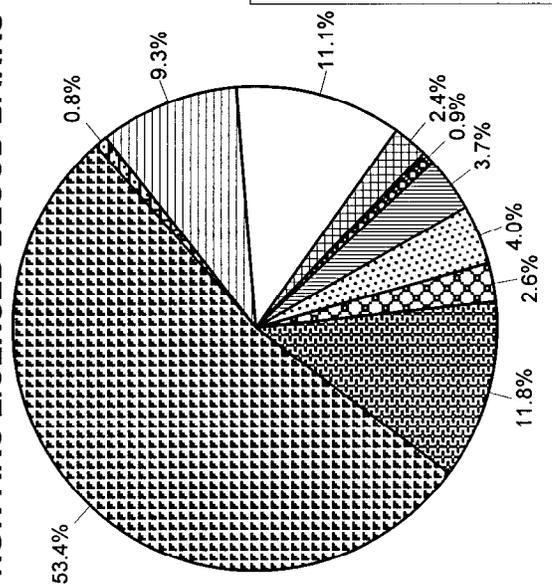
TOTAL REPORTS RECEIVED (10/1/97 - 9/30/98) = 13,187
 POTENTIAL RECALLS = 1,677

ERROR AND ACCIDENT REPORTS FY98

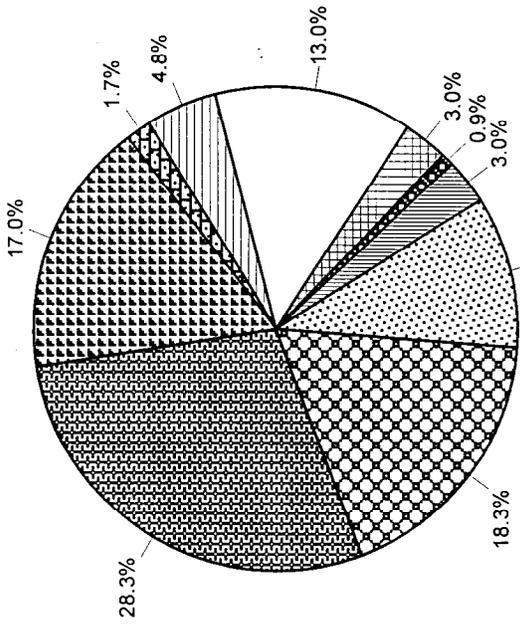
AMERICAN RED CROSS



NON-ARC LICENSED BLOOD BANKS

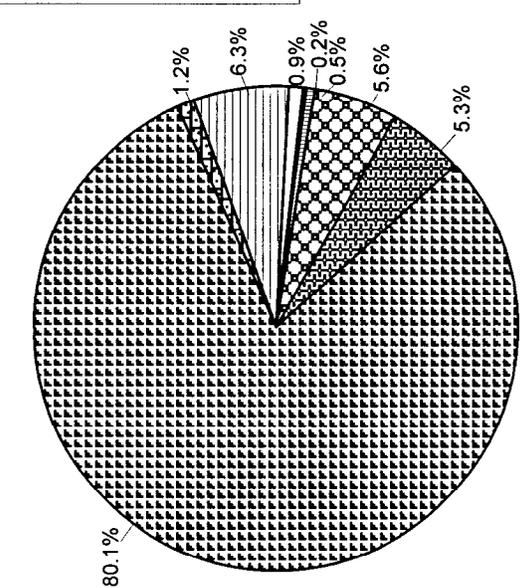


- TYPES OF ERRORS/ACCIDENTS**
- ROUTINE TESTING
 - VIRAL TESTING
 - COLLECTION
 - COMPONENT PREPARATION
 - LABELING
 - DONOR SCREENING
 - DONOR DEFERRAL
 - POST DONATION INFORMATION
 - STORAGE/DISTRIBUTION
 - MISCELLANEOUS



UNLICENSED BLOOD BANKS

PLASMA CENTERS

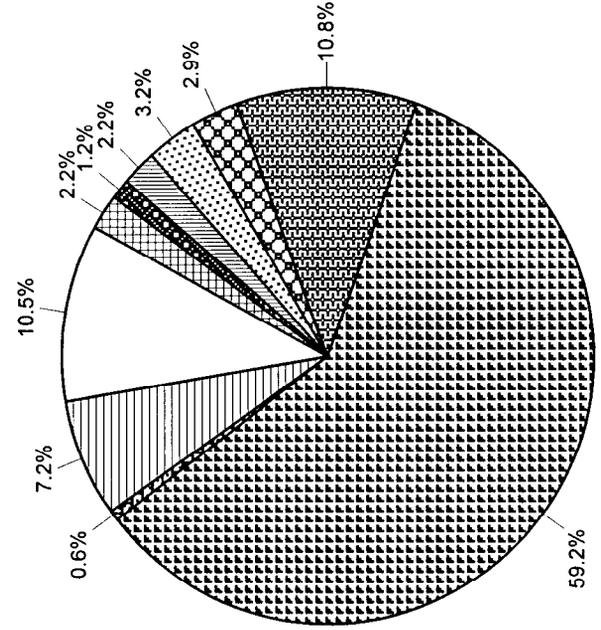


REPORTS RECEIVED (10/1/97 - 9/30/98) = 13,187

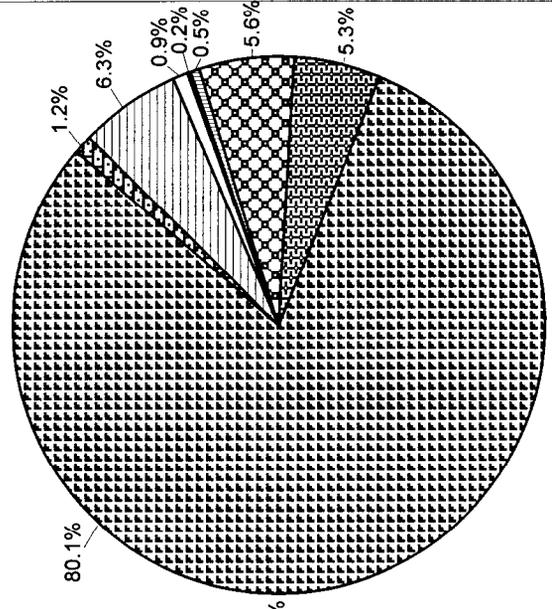
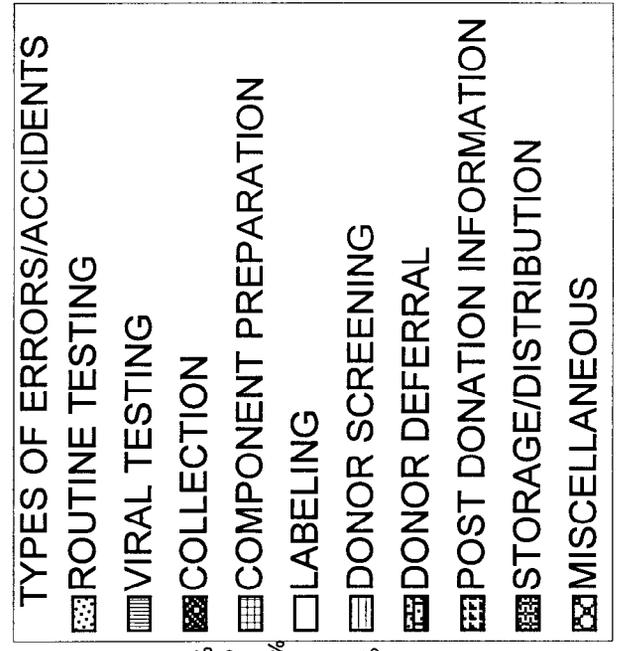
ARC = 6,035; NON-ARC LICENSED BLOOD BANKS = 5,819; UNLICENSED BLOOD BANKS = 230; PLASMA CENTERS = 1103

ERROR AND ACCIDENT REPORTS BLOOD BANKS VERSUS PLASMA CENTERS

FY98



BLOOD BANKS

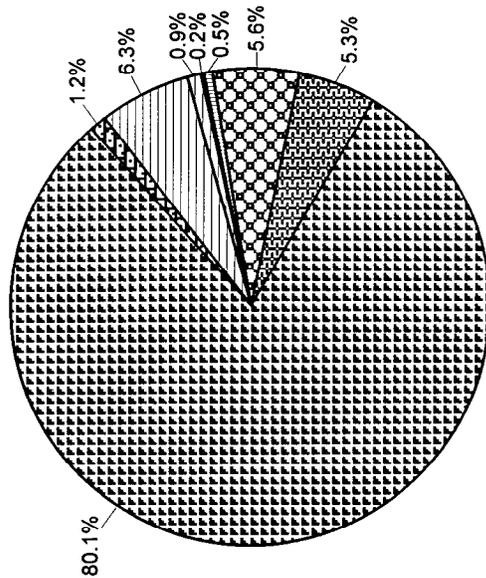
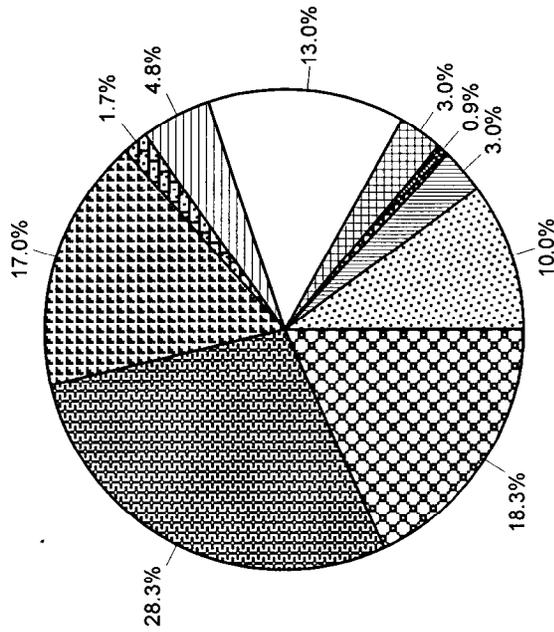
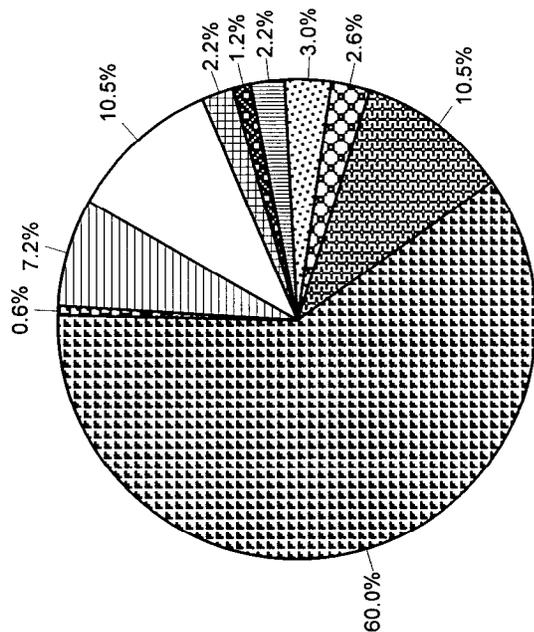


PLASMA CENTERS

REPORTS RECEIVED 10/1/97 - 9/30/98
 BLOOD BANKS = 12,084
 PLASMA CENTERS = 1103

ERROR AND ACCIDENT REPORTS BLOOD BANKS VERSUS PLASMA CENTERS

FY98



LICENSED BLOOD BANKS UNLICENSED BLOOD BANKS PLASMA CENTERS

TYPES OF ERRORS/ACCIDENTS

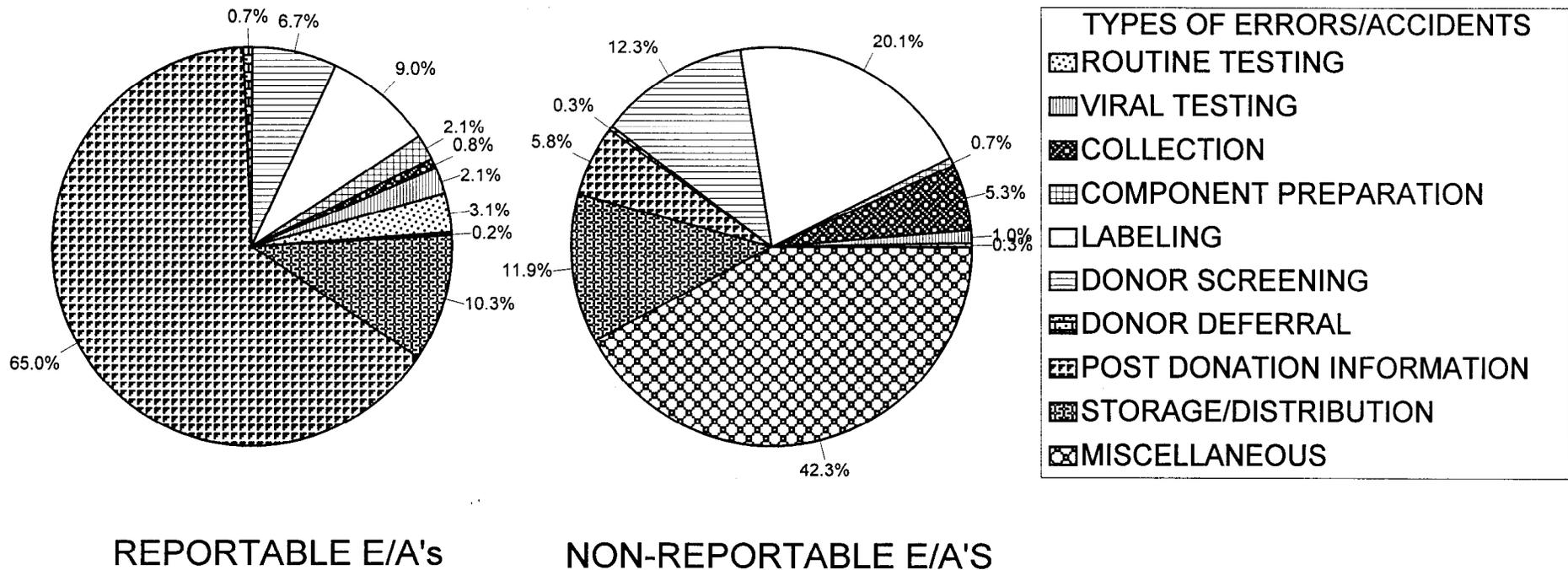
- ROUTINE TESTING
- COMPONENT PREPARATION
- DONOR DEFERRAL
- MISCELLANEOUS
- VIRAL TESTING
- LABELING
- POST DONATION INFORMATION
- STORAGE/DISTRIBUTION
- COLLECTION
- DONOR SCREENING

REPORTS RECEIVED 10/1/97 - 9/30/98
 LICENSED BLOOD BANKS = 11,854
 UNLICENSED BLOOD BANKS = 230
 PLASMA CENTERS = 1103

ERROR AND ACCIDENT REPORTS

ALL BLOOD AND PLASMA ESTABLISHMENTS

FY98



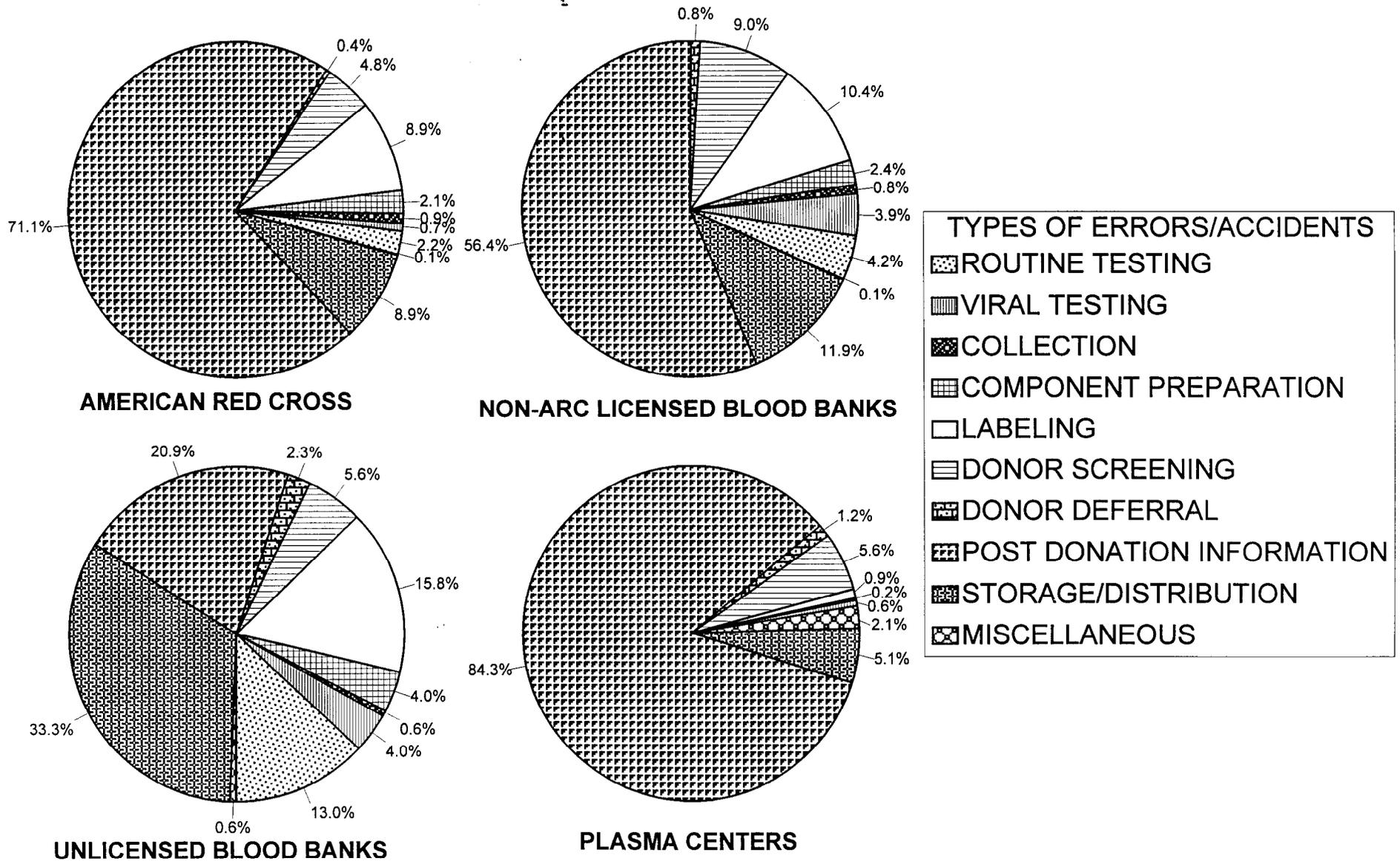
REPORTS RECEIVED (10/1/97 - 9/30/98)

REPORTABLE ERRORS/ACCIDENTS = 12,286

NON-REPORTABLE ERRORS/ACCIDENTS = 901

ERROR AND ACCIDENT REPORTS

REPORTABLE ERRORS/ACCIDENTS-FY98



REPORTS RECEIVED (10/1/97 - 9/30/98) = 12,286

ARC = 5622; NON-ARC LICENSED BLOOD BANKS = 5441; UNLICENSED BLOOD BANKS = 177; PLASMA CENTERS = 1046

Of the 12,286 reportable error and accident reports received from blood and plasma establishments, 7986 (65.0%) reports involved post donation information. 7104 (89.0%) reports were submitted by blood establishments and 882 (11.0%) 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	
TRAVEL TO MALARIAL ENDEMIC AREA	1255	17.7%	1	0.1%	1256	15.7%
TATTOO, EARPIERCING, NEEDLESTICK, TRANSFUSION	978	13.8%	183	20.7%	1161	14.5%
ILLNESS (NOT AIDS OR HEPATITIS RELATED)	948	13.3%	2	0.2%	950	11.9%
HISTORY OF CANCER	778	11.0%	11	1.2%	789	9.9%
HISTORY OF DISEASE/SURGERY	389	5.5%	5	0.6%	394	4.9%
IV DRUG USE	274	3.9%	114	12.9%	388	4.9%
SEX PARTNER TESTS POSITIVE FOR HEPATITIS	369	5.2%	15	1.7%	384	4.8%
HIGH RISK BEHAVIOR-NOT SPECIFIED	145	2.0%	152	17.2%	297	3.7%
MALE TO MALE SEX	216	3.0%	47	5.3%	263	3.3%
HISTORY OF HEPATITIS B/C OR JAUNDICE	230	3.2%	10	1.1%	240	3.0%
TRAVEL TO OR IMMIGRATION FROM HIGH RISK AREA (HEPATITIS OR AIDS)	190	2.7%	6	0.7%	196	2.5%
SEX WITH AN IV DRUG USER	169	2.4%	25	2.8%	194	2.4%
HISTORY OF INCARCERATION	26	0.4%	161	18.3%	187	2.3%
NON-SEXUAL EXPOSURE TO HEPATITIS B/C	166	2.3%	6	0.7%	172	2.2%
RECEIVED MEDICATION OR ANTIBIOTICS	134	1.9%	4	0.5%	138	1.7%
RISK FACTOR ASSOCIATED WITH CJD	125	1.8%	1	0.1%	126	1.6%
RECEIVED PROSCAR, TEGISON, OR ACCUTANE	115	1.6%	1	0.1%	116	1.5%
HEPATITIS RELATED ILLNESS	78	1.1%	20	2.3%	98	1.2%
SEX PARTNER TESTS POSITIVE FOR HIV/HTLV	45	0.6%	37	4.2%	82	1.0%
EXPOSURE TO HEPATITIS A	62	0.9%	8	0.9%	70	0.9%
INFORMATION NOT RELATED TO HEPATITIS OR AIDS	38	0.5%	25	2.8%	63	0.8%
EXCHANGED SEX FOR DRUGS/MONEY	40	0.6%	18	2.0%	58	0.7%
RECEIVED VACCINE OR IMMUNE GLOBULIN	46	0.6%	7	0.8%	53	0.7%
HISTORY OF HEPATITIS A	46	0.6%	5	0.6%	51	0.6%
RECEIVED GROWTH HORMONE	48	0.7%	2	0.2%	50	0.6%
DO NOT USE MY BLOOD	49	0.7%	0	0.0%	49	0.6%
FEMALE HAD SEX WITH MALE WHO HAD SEX WITH ANOTHER MALE	42	0.6%	4	0.5%	46	0.6%
AIDS RELATED ILLNESS	21	0.3%	6	0.7%	27	0.3%
SEXUALLY TRANSMITTED DISEASE/POSITIVE STS	22	0.3%	2	0.2%	24	0.3%
RECEIVED METHOTREXATE	20	0.3%	0	0.0%	20	0.3%
EXPOSURE TO A DISEASE	18	0.3%	0	0.0%	18	0.2%
SEX PARTNER HAS SEXUALLY TRANSMITTED DISEASE	9	0.1%	0	0.0%	9	0.1%
RESIDED IN REHABILITATION CENTER	4	0.1%	3	0.3%	7	0.1%
NON-SEXUAL EXPOSURE TO HIV	5	0.1%	1	0.1%	6	0.1%
HISTORY OF CJD	4	0.1%	0	0.0%	4	0.1%
TOTAL	7104	100.0%	882	100.0%	7986	100.0%

POST DONATION INFORMATION REPORTS - TABLE 2

POST DONATION INFORMATION RECEIVED	BLOOD ESTABLISHMENTS		TOTAL	
TRAVEL TO MALARIAL ENDEMIC AREA	1255	17.7%	1256	15.7%
TATTOO, EARPIERCING, NEEDLESTICK, TRANSFUSION	978	13.8%	1161	14.5%
ILLNESS (NOT AIDS OR HEPATITIS RELATED)	948	13.3%	950	11.9%
HISTORY OF CANCER	778	11.0%	789	9.9%
HISTORY OF DISEASE/SURGERY	389	5.5%	394	4.9%
SEX PARTNER TESTS POSITIVE FOR HEPATITIS	369	5.2%	384	4.8%
IV DRUG USE	274	3.9%	388	4.9%
HISTORY OF HEPATITIS B/C OR JAUNDICE	230	3.2%	240	3.0%
MALE TO MALE SEX	216	3.0%	263	3.3%
TRAVEL TO OR IMMIGRATION FROM HIGH RISK AREA (HEPATITIS OR AIDS)	190	2.7%	196	2.5%
SEX WITH AN IV DRUG USER	169	2.4%	194	2.4%
NON-SEXUAL EXPOSURE TO HEPATITIS B/C	166	2.3%	172	2.2%
HIGH RISK BEHAVIOR-NOT SPECIFIED	145	2.0%	297	3.7%
RECEIVED MEDICATION OR ANTIBIOTICS	134	1.9%	138	1.7%
RISK FACTOR ASSOCIATED WITH CJD	125	1.8%	126	1.6%
RECEIVED PROSCAR, TEGISON, OR ACCUTANE	115	1.6%	116	1.5%
HEPATITIS RELATED ILLNESS	78	1.1%	98	1.2%
EXPOSURE TO HEPATITIS A	62	0.9%	70	0.9%
DO NOT USE MY BLOOD	49	0.7%	49	0.6%
RECEIVED GROWTH HORMONE	48	0.7%	50	0.6%
RECEIVED VACCINE OR IMMUNE GLOBULIN	46	0.6%	53	0.7%
HISTORY OF HEPATITIS A	46	0.6%	51	0.6%
SEX PARTNER TESTS POSITIVE FOR HIV/HTLV	45	0.6%	82	1.0%
FEMALE HAD SEX WITH MALE WHO HAD SEX WITH ANOTHER MALE	42	0.6%	46	0.6%
EXCHANGED SEX FOR DRUGS/MONEY	40	0.6%	58	0.7%
INFORMATION NOT RELATED TO HEPATITIS OR AIDS	38	0.5%	63	0.8%
HISTORY OF INCARCERATION	26	0.4%	187	2.3%
SEXUALLY TRANSMITTED DISEASE/POSITIVE STS	22	0.3%	24	0.3%
AIDS RELATED ILLNESS	21	0.3%	27	0.3%
RECEIVED METHOTREXATE	20	0.3%	20	0.3%
EXPOSURE TO A DISEASE	18	0.3%	18	0.2%
SEX PARTNER HAS SEXUALLY TRANSMITTED DISEASE	9	0.1%	9	0.1%
NON-SEXUAL EXPOSURE TO HIV	5	0.1%	6	0.1%
HISTORY OF CJD	4	0.1%	4	0.1%
RESIDED IN REHABILITATION CENTER	4	0.1%	7	0.1%
TOTAL	7104	100.0%	7986	100.0%

POST DONATION INFORMATION REPORTS - TABLE 3

POST DONATION INFORMATION RECEIVED	PLASMA CENTERS		TOTAL	
TATTOO, EARPIERCING, NEEDLESTICK, TRANSFUSION	183	20.7%	1161	14.5%
HISTORY OF INCARCERATION	161	18.3%	187	2.3%
HIGH RISK BEHAVIOR-NOT SPECIFIED	152	17.2%	297	3.7%
IV DRUG USE	114	12.9%	388	4.9%
MALE TO MALE SEX	47	5.3%	263	3.3%
SEX PARTNER TESTS POSITIVE FOR HIV/HTLV	37	4.2%	82	1.0%
INFORMATION NOT RELATED TO HEPATITIS OR AIDS	25	2.8%	63	0.8%
SEX WITH AN IV DRUG USER	25	2.8%	194	2.4%
HEPATITIS RELATED ILLNESS	20	2.3%	98	1.2%
EXCHANGED SEX FOR DRUGS/MONEY	18	2.0%	58	0.7%
SEX PARTNER TESTS POSITIVE FOR HEPATITIS	15	1.7%	384	4.8%
HISTORY OF CANCER	11	1.2%	789	9.9%
HISTORY OF HEPATITIS B/C OR JAUNDICE	10	1.1%	240	3.0%
EXPOSURE TO HEPATITIS A	8	0.9%	70	0.9%
RECEIVED VACCINE OR IMMUNE GLOBULIN	7	0.8%	53	0.7%
AIDS RELATED ILLNESS	6	0.7%	27	0.3%
TRAVEL TO OR IMMIGRATION FROM HIGH RISK AREA (HEPATITIS OR AIDS)	6	0.7%	196	2.5%
NON-SEXUAL EXPOSURE TO HEPATITIS B/C	6	0.7%	172	2.2%
HISTORY OF DISEASE/SURGERY	5	0.6%	394	4.9%
HISTORY OF HEPATITIS A	5	0.6%	51	0.6%
FEMALE HAD SEX WITH MALE WHO HAD SEX WITH ANOTHER MALE	4	0.5%	46	0.6%
RECEIVED MEDICATION OR ANTIBIOTICS	4	0.5%	138	1.7%
RESIDED IN REHABILITATION CENTER	3	0.3%	7	0.1%
ILLNESS (NOT AIDS OR HEPATITIS RELATED)	2	0.2%	950	11.9%
SEXUALLY TRANSMITTED DISEASE/POSITIVE STS	2	0.2%	24	0.3%
RECEIVED GROWTH HORMONE	2	0.2%	50	0.6%
NON-SEXUAL EXPOSURE TO HIV	1	0.1%	6	0.1%
TRAVEL TO MALARIAL ENDEMIC AREA	1	0.1%	1256	15.7%
RISK FACTOR ASSOCIATED WITH CJD	1	0.1%	126	1.6%
RECEIVED PROSCAR, TEGISON, OR ACCUTANE	1	0.1%	116	1.5%
DO NOT USE MY BLOOD	0	0.0%	49	0.6%
SEX PARTNER HAS SEXUALLY TRANSMITTED DISEASE	0	0.0%	9	0.1%
HISTORY OF CJD	0	0.0%	4	0.1%
EXPOSURE TO A DISEASE	0	0.0%	18	0.2%
RECEIVED METHOTREXATE	0	0.0%	20	0.3%
TOTAL	882	100.0%	7986	100.0%

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	
TRAVEL TO MALARIAL ENDEMIC AREA	1254	23.0%	1	0.1%	1255	20.0%
TATTOO, EARPIERCING, NEEDLESTICK, TRANSFUSION	978	17.9%	183	22.9%	1161	18.5%
HISTORY OF CANCER	598	10.9%	8	1.0%	606	9.7%
HISTORY OF DISEASE/SURGERY	388	7.1%	5	0.6%	393	6.3%
IV DRUG USE	274	5.0%	114	14.3%	388	6.2%
HIGH RISK BEHAVIOR-NOT SPECIFIED	145	2.7%	152	19.0%	297	4.7%
MALE TO MALE SEX	216	4.0%	47	5.9%	263	4.2%
HISTORY OF HEPATITIS B/C OR JAUNDICE	229	4.2%	10	1.3%	239	3.8%
TRAVEL TO OR IMMIGRATION FROM HIGH RISK AREA (HEPATITIS OR AIDS)	190	3.5%	6	0.8%	196	3.1%
SEX WITH AN IV DRUG USER	169	3.1%	25	3.1%	194	3.1%
HISTORY OF INCARCERATION	26	0.5%	161	20.2%	187	3.0%
TOTAL	4467	81.8%	712	89.1%	5179	82.7%

Table 2

POST DONATION INFORMATION	BLOOD ESTABLISHMENTS		TOTAL	
TRAVEL TO MALARIAL ENDEMIC AREA	1254	23.0%	1255	20.0%
TATTOO, EARPIERCING, NEEDLESTICK, TRANSFUSION	978	17.9%	1161	18.5%
HISTORY OF CANCER	598	10.9%	606	9.7%
HISTORY OF DISEASE/SURGERY	388	7.1%	393	6.3%
IV DRUG USE	274	5.0%	388	6.2%
HISTORY OF HEPATITIS B/C OR JAUNDICE	229	4.2%	239	3.8%
MALE TO MALE SEX	216	4.0%	263	4.2%
TRAVEL TO OR IMMIGRATION FROM HIGH RISK AREA (HEPATITIS OR AIDS)	190	3.5%	196	3.1%
SEX WITH AN IV DRUG USER	169	3.1%	194	3.1%
NON-SEXUAL EXPOSURE TO HEPATITIS B/C	165	3.0%	171	2.7%
TOTAL	4461	81.7%	4866	77.7%

Table 3

POST DONATION INFORMATION	PLASMA CENTERS		TOTAL	
TATTOO, EARPIERCING, NEEDLESTICK, TRANSFUSION	183	22.9%	1161	18.5%
HISTORY OF INCARCERATION	161	20.2%	187	3.0%
HIGH RISK BEHAVIOR-NOT SPECIFIED	152	19.0%	297	4.7%
IV DRUG USE	114	14.3%	388	6.2%
MALE TO MALE SEX	47	5.9%	263	4.2%
TOTAL	657	82.2%	2296	36.7%

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)	948	57.8%	2	2.4%	950
SEX PARTNER TESTS POSITIVE FOR HEPATITIS	369	22.5%	15	18.1%	384	22.3%
DIAGNOSIS OF CANCER, POST DONATION	180	11.0%	3	3.6%	183	10.6%
TOTAL	1497	91.2%	20	1.2%	1517	88.0%

Table 2

POST DONATION INFORMATION	BLOOD ESTABLISHMENTS		TOTAL	
	ILLNESS (NOT AIDS OR HEPATITIS RELATED)	948	57.8%	950
SEX PARTNER TESTS POSITIVE FOR HEPATITIS	369	22.5%	384	22.3%
DIAGNOSIS OF CANCER, POST DONATION	180	11.0%	183	10.6%
TOTAL	1497	91.2%	1517	88.0%

Table 3

POST DONATION INFORMATION	PLASMA CENTERS		TOTAL	
	SEX PARTNER TESTS POSITIVE FOR HIV/HTLV	37	44.6%	82
HEPATITIS RELATED ILLNESS	16	19.3%	66	3.8%
SEX PARTNER TESTS POSITIVE FOR HEPATITIS	15	18.1%	384	22.3%
AIDS RELATED ILLNESS	5	6.0%	18	1.0%
TOTAL	73	88.0%	550	31.9%

Of the 12,286 reportable error and accident reports received from blood and plasma establishments, 1261 (10.3%) reports were storage and distribution errors or accidents. 1208 (95.8%) reports were submitted by blood establishments and 53 (4.2%) 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	392	32.5%	0	0.0%	392
SHIPPED/STORED AT INCORRECT TEMPERATURE	251	20.8%	2	3.8%	253	20.1%
FAILURE TO QUARANTINE UNIT DUE TO TESTING NOT PERFORMED OR DOCUMENTED	145	12.0%	30	56.6%	175	13.9%
FAILURE TO QUARANTINE UNIT DUE TO INCORRECT, INCOMPLETE, OR POSITIVE TESTING	113	9.4%	9	17.0%	122	9.7%
INAPPROPRIATE RELEASE	108	8.9%	0	0.0%	108	8.6%
FAILURE TO QUARANTINE UNIT DUE TO MEDICAL HISTORY	88	7.3%	11	20.8%	99	7.9%
IMPROPER TRANSFUSION SERVICE PRACTICE	64	5.3%	0	0.0%	64	5.1%
INTERSTATE SHIPMENT OF UNLICENSED PRODUCT	47	3.9%	1	1.9%	48	3.8%
TOTAL	1208	100.0%	53	100.0%	1261	100.0%

STORAGE/DISTRIBUTION - TABLE 2

STORAGE AND DISTRIBUTION ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		Total	
	UNSUITABLE PRODUCT	392	32.5%	392
SHIPPED/STORED AT INCORRECT TEMPERATURE	251	20.8%	253	20.1%
FAILURE TO QUARANTINE UNIT DUE TO TESTING NOT PERFORMED OR DOCUMENTED	145	12.0%	175	13.9%
FAILURE TO QUARANTINE UNIT DUE TO INCORRECT, INCOMPLETE, OR POSITIVE TESTING	113	9.4%	122	9.7%
INAPPROPRIATE RELEASE	108	8.9%	108	8.6%
FAILURE TO QUARANTINE UNIT DUE TO MEDICAL HISTORY	88	7.3%	99	7.9%
IMPROPER TRANSFUSION SERVICE PRACTICE	64	5.3%	64	5.1%
INTERSTATE SHIPMENT OF UNLICENSED PRODUCT	47	3.9%	48	3.8%
TOTAL	1208	100.0%	1261	100.0%

STORAGE/DISTRIBUTION - TABLE 3

STORAGE AND DISTRIBUTION ERRORS/ACCIDENTS	PLASMA CENTERS		TOTAL	
	FAILURE TO QUARANTINE UNIT DUE TO TESTING NOT PERFORMED OR DOCUMENTED	30	56.6%	175
FAILURE TO QUARANTINE UNIT DUE TO MEDICAL HISTORY	11	20.8%	99	7.9%
FAILURE TO QUARANTINE UNIT DUE TO INCORRECT, INCOMPLETE, OR POSITIVE TESTING	9	17.0%	122	9.7%
SHIPPED/STORED AT INCORRECT TEMPERATURE	2	3.8%	253	20.1%
INTERSTATE SHIPMENT OF UNLICENSED PRODUCT	1	1.9%	48	3.8%
INAPPROPRIATE RELEASE	0	0.0%	108	8.6%
UNSUITABLE PRODUCT	0	0.0%	392	31.1%
IMPROPER TRANSFUSION SERVICE PRACTICE	0	0.0%	64	5.1%
TOTAL	53	100.0%	1261	100.0%

STORAGE/DISTRIBUTION - TABLE 2A

STORAGE AND DISTRIBUTION ERRORS/ACCIDENTS (DETAILED)	BLOOD ESTABLISHMENTS		TOTAL	
<i>UNSUITABLE PRODUCT</i>				
UNIT CONTAINED CLOTS	282	23.4%	282	22.4%
BROKEN/DAMAGED UNIT	55	4.6%	55	4.4%
OTHER ¹	31	2.6%	31	2.5%
UNIT/SEGMENT HEMOLYZED	24	2.0%	24	1.9%
<i>SHIPPED/STORED AT INCORRECT TEMPERATURE</i>	251	20.8%	253	20.1%
<i>FAILURE TO QUARANTINE UNIT DUE TO TESTING NOT PERFORMED OR DOCUMENTED FOR:</i>				
ANTI-HBc	99	8.2%	99	7.9%
OTHER REASONS ²	24	2.0%	39	3.1%
<i>FAILURE TO QUARANTINE UNIT DUE TO INCORRECT, INCOMPLETE, OR POSITIVE TESTING FOR:</i>				
ANTI-HBc	31	2.6%	31	2.5%
OTHER REASONS ³	22	1.8%	23	1.8%
ANTIBODY SCREEN	17	1.4%	17	1.3%
<i>INAPPROPRIATE RELEASE</i>				
OTHER ⁴	89	7.4%	89	7.1%
OUTDATED PRODUCT	17	1.4%	17	1.3%
<i>FAILURE TO QUARANTINE UNIT DUE TO MEDICAL HISTORY</i>				
OTHER REASONS ⁵	54	4.5%	55	4.4%
<i>IMPROPER TRANSFUSION SERVICE PRACTICE</i>				
IMPROPER ABO/Rh TYPE SELECTED FOR PATIENT	24	2.0%	24	1.9%
<i>INTERSTATE SHIPMENT OF UNLICENSED PRODUCT</i>	47	3.9%	48	3.8%
TOTAL	1067	88.3%	1088	86.3%

¹ - Includes unit underweight; particulate matter in product

² - Includes all viral markers; DAT; anti-CMV; compatibility testing

³ - Includes DAT; platelet count; anti-CMV

⁴ - Includes failure to quarantine during investigation of discrepancies

⁵ - 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 TESTING NOT PERFORMED OR DOCUMENTED FOR:</i>				
OTHER REASONS ¹	15	28.3%	39	3.1%
SYPHILIS	14	26.4%	20	1.6%
<i>FAILURE TO QUARANTINE UNIT DUE TO INCORRECT, INCOMPLETE, OR POSITIVE TESTING FOR:</i>				
ANTI-HCV	3	5.7%	8	0.6%
ALT	4	7.5%	6	0.5%
OTHER REASONS ²	1	1.9%	23	1.8%
<i>FAILURE TO QUARANTINE UNIT DUE TO MEDICAL HISTORY</i>				
SEXUAL PARTNER TESTING POSITIVE FOR HEPATITIS	3	5.7%	4	0.3%
TATTOO, EARPIERCING, NEEDLESTICK, OR TRANSFUSION	2	3.8%	7	0.6%
NON-SEXUAL EXPOSURE TO HEPATITIS B OR C	2	3.8%	3	0.2%
TOTAL	44	83.0%	110	8.7%

1 - Includes all viral markers

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

Of the 12,286 reportable error and accident reports received from blood and plasma establishments, 1101 (9.0%) reports were labeling errors or accidents. 1092 (99.2%) reports were submitted by blood establishments and 9 (0.8%) 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	269	24.6%	0	0.0%	269	24.4%
EXTENDED EXPIRATION DATE	211	19.3%	0	0.0%	211	19.2%
INCORRECT ABO AND/OR Rh LABEL OR TAG	107	9.8%	1	11.1%	108	9.8%
MISSING/INCORRECT DONOR NUMBER	97	8.9%	6	66.7%	103	9.4%
INCORRECT PRODUCT LABEL OR TAG	99	9.1%	2	22.2%	101	9.2%
<i>MISSING/INCORRECT LABEL OR TAG</i>						
ANTIGEN/ANTIBODY	71	6.5%	0	0.0%	71	6.4%
CMV	60	5.5%	0	0.0%	60	5.4%
CROSSMATCH	30	2.7%	0	0.0%	30	2.7%
OTHER ¹	28	2.6%	0	0.0%	28	2.5%
BIOHAZARD/TEST STATUS	22	2.0%	0	0.0%	22	2.0%
IRRADIATION	20	1.8%	0	0.0%	20	1.8%
PLATELET COUNT	11	1.0%	0	0.0%	11	1.0%
RECIPIENT NUMBER	10	0.9%	0	0.0%	10	0.9%
ANTICOAGULANT	9	0.8%	0	0.0%	9	0.8%
UNLICENSED PRODUCT LABELED WITH LICENSE NUMBER	48	4.4%	0	0.0%	48	4.4%
TOTAL	1092	100.0%	9	100.0%	1101	100.0%

¹ - Includes Hemoglobin S; ALT; HLA

LABELING - TABLE 2

LABELING ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		TOTAL	
	MISSING/INCORRECT LABEL OR TAG-AUTOLOGOUS LABELING	269	24.6%	269
EXTENDED EXPIRATION DATE	211	19.3%	211	19.2%
INCORRECT ABO AND/OR Rh LABEL OR TAG	107	9.8%	108	9.8%
INCORRECT PRODUCT LABEL OR TAG	99	9.1%	101	9.2%
<i>MISSING/INCORRECT LABEL OR TAG</i>				
DONOR NUMBER	97	8.9%	103	9.4%
ANTIGEN/ANTIBODY	71	6.5%	71	6.4%
CMV	60	5.5%	60	5.4%
CROSSMATCH	30	2.7%	30	2.7%
OTHER ¹	28	2.6%	28	2.5%
BIOHAZARD/TEST STATUS	22	2.0%	22	2.0%
IRRADIATION	20	1.8%	20	1.8%
PLATELET COUNT	11	1.0%	11	1.0%
RECIPIENT NUMBER	10	0.9%	10	0.9%
ANTICOAGULANT	9	0.8%	9	0.8%
UNLICENSED PRODUCT LABELED WITH LICENSE NUMBER	48	4.4%	48	4.4%
TOTAL	1092	100.0%	1101	100.0%

¹ - Includes Hemoglobin S; ALT; HLA

LABELING - TABLE 3

LABELING ERRORS/ACCIDENTS	PLASMA CENTERS		TOTAL	
	MISSING/INCORRECT DONOR NUMBER	6	66.7%	103
INCORRECT PRODUCT LABEL OR TAG	2	22.2%	101	9.2%
INCORRECT ABO AND/OR Rh LABEL OR TAG	1	11.1%	108	9.8%
TOTAL	9	100.0%	312	28.3%

Of the 12,286 reportable error and accident reports received from blood and plasma establishments, 824 (6.7%) reports were donor screening errors or accidents. 765 (92.8%) reports were submitted by blood establishments and 59 (7.2%) 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	421	55.0%	9	15.3%	430
DONOR RECORD INCOMPLETE/INCORRECT/NOT REVIEWED	196	25.6%	16	27.1%	212	25.7%
INCORRECT ID USED DURING DEFERRAL SEARCH, DONOR PREVIOUSLY DEFERRED	54	7.1%	9	15.3%	63	7.6%
DEFERRAL SCREENING NOT DONE, DONOR PREVIOUSLY DEFERRED	43	5.6%	18	30.5%	61	7.4%
DONOR DID NOT MEET ACCEPTANCE CRITERIA	51	6.7%	7	11.9%	58	7.0%
TOTAL	765	100.0%	59	100.0%	824	100.0%

DONOR SCREENING - TABLE 2

DONOR SCREENING ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		TOTAL	
	DONOR GAVE HISTORY WHICH WARRANTED DEFERRAL AND WAS NOT DEFERRED	421	55.0%	430
DONOR RECORD INCOMPLETE/INCORRECT/NOT REVIEWED	196	25.6%	212	25.7%
INCORRECT ID USED DURING DEFERRAL SEARCH, DONOR PREVIOUSLY DEFERRED	54	7.1%	63	7.6%
DONOR DID NOT MEET ACCEPTANCE CRITERIA	51	6.7%	58	7.0%
DEFERRAL SCREENING NOT DONE, DONOR PREVIOUSLY DEFERRED	43	5.6%	61	7.4%
TOTAL	765	100.0%	824	100.0%

DONOR SCREENING - TABLE 3

DONOR SCREENING ERRORS/ACCIDENTS	PLASMA CENTERS		TOTAL	
	DEFERRAL SCREENING NOT DONE, DONOR PREVIOUSLY DEFERRED	18	30.5%	61
DONOR RECORD INCOMPLETE/INCORRECT/NOT REVIEWED	16	27.1%	212	25.7%
INCORRECT ID USED DURING DEFERRAL SEARCH, DONOR PREVIOUSLY DEFERRED	9	15.3%	63	7.6%
DONOR GAVE HISTORY WHICH WARRANTED DEFERRAL AND WAS NOT DEFERRED	9	15.3%	430	52.2%
DONOR DID NOT MEET ACCEPTANCE CRITERIA	7	11.9%	58	7.0%
TOTAL	59	100.0%	824	100.0%

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 MALARIAL ENDEMIC AREA	160	20.9%	160	19.4%
HISTORY OF DISEASE/SURGERY	49	6.4%	51	6.2%
HISTORY OF CANCER	43	5.6%	43	5.2%
RECEIVED MEDICATION OR ANTIBIOTICS	41	5.4%	42	5.1%
HEPATITIS RELATED RISK	21	2.7%	21	2.5%
RECEIVED TATTOO, EARPIERCING, NEEDLESTICK, OR TRANSFUSION	16	2.1%	20	2.4%
<i>DONOR RECORD INCOMPLETE/INCORRECT/NOT REVIEWED</i>				
HIGH RISK BEHAVIOR QUESTIONS/INFORMATION	79	10.3%	82	10.0%
MEDICAL HISTORY QUESTIONS	66	8.6%	73	8.9%
OTHER ¹	24	3.1%	27	3.3%
DONOR SIGNATURE	22	2.9%	22	2.7%
<i>INCORRECT ID USED DURING DEFERRAL SEARCH, DONOR PREVIOUSLY DEFERRED DUE TO</i>				
RECEIVING TATTOO, EARPIERCING, NEEDLESTICK, OR TRANSFUSION	15	2.0%	16	1.9%
HIV REACTIVITY	8	1.0%	10	1.2%
ANTI-HBc REACTIVITY	7	0.9%	7	0.8%
<i>DONOR DID NOT MEET ACCEPTANCE CRITERIA</i>				
TEMPERATURE UNACCEPTABLE OR NOT DOCUMENTED	28	3.7%	28	3.4%
HEMOGLOBIN/HEMATOCRIT (<11.0g/dl OR <33%) OR NOT DOCUMENTED	21	2.7%	21	2.5%
<i>DEFERRAL SCREENING NOT DONE, DONOR PREVIOUSLY DEFERRED DUE TO</i>				
HIV REACTIVITY	22	2.9%	26	3.2%
HBsAg REACTIVITY OR HISTORY OF HEPATITIS	6	0.8%	7	0.8%
TOTAL	628	82.1%	656	79.6%

¹ - Includes arm inspection; cue sticker missing

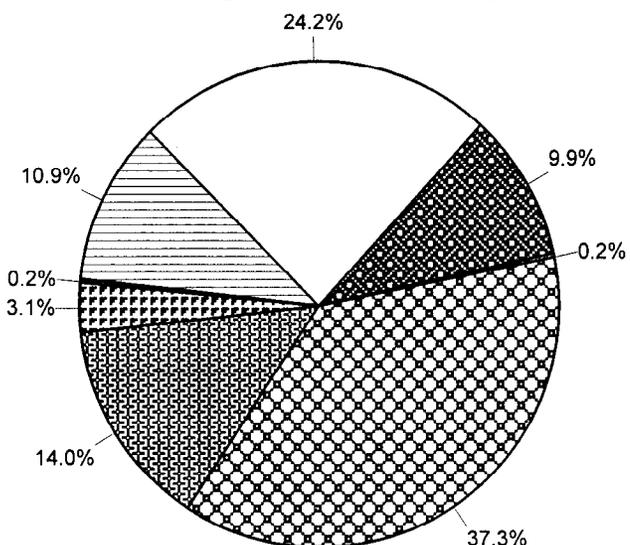
DONOR SCREENING - TABLE 3A

DONOR SCREENING ERRORS/ACCIDENTS (DETAILED)	PLASMA CENTERS		TOTAL	
<i>DEFERRAL SCREENING NOT DONE, DONOR PREVIOUSLY DEFERRED DUE TO</i>				
HIGH RISK BEHAVIOR-NOT SPECIFIED	6	10.2%	7	0.8%
HIV REACTIVITY	4	6.8%	26	3.2%
OTHER REASONS ¹	2	3.4%	4	0.5%
HBsAg REACTIVITY OR HISTORY OF HEPATITIS	1	1.7%	7	0.8%
ANTI-HBc	1	1.7%	1	0.1%
ALT REACTIVITY	1	1.7%	1	0.1%
SEXUALLY TRANSMITTED DISEASE OR POSITIVE STS	1	1.7%	1	0.1%
HISTORY OF DISEASE/SURGERY	1	1.7%	1	0.1%
INCARCERATED	1	1.7%	1	0.1%
<i>DONOR RECORD INCOMPLETE/INCORRECT/NOT REVIEWED</i>				
MEDICAL HISTORY QUESTIONS	7	11.9%	73	8.9%
OTHER REASONS ²	3	5.1%	27	3.3%
DONOR IDENTIFICATION	3	5.1%	8	1.0%
HIGH RISK BEHAVIOR QUESTIONS/INFORMATION	3	5.1%	82	10.0%
<i>INCORRECT ID USED DURING DEFERRAL SEARCH, DONOR PREVIOUSLY DEFERRED DUE TO</i>				
HIGH RISK BEHAVIOR-NOT SPECIFIED	4	6.8%	6	0.7%
HIV REACTIVITY	2	3.4%	10	1.2%
HBsAg REACTIVITY OR HISTORY OF HEPATITIS	1	1.7%	3	0.4%
OTHER REASONS ³	1	1.7%	6	0.7%
RECEIVED TATTOO, EARPIERCING, NEEDLESTICK, OR TRANSFUSION	1	1.7%	16	1.9%
<i>DONOR GAVE HISTORY WHICH WARRANTED DEFERRAL AND WAS NOT DEFERRED</i>				
RECEIVED TATTOO, EARPIERCING, NEEDLESTICK, OR TRANSFUSION	4	6.8%	20	2.4%
HISTORY OF DISEASE/SURGERY	2	3.4%	51	6.2%
OTHER REASONS ⁴	1	1.7%	3	0.4%
TRAVEL/IMMIGRATION - HIGH RISK AREA	1	1.7%	9	1.1%
RECEIVED MEDICATION OR ANTIBIOTICS	1	1.7%	42	5.1%
<i>DONOR DID NOT MEET ACCEPTANCE CRITERIA</i>				
MEDICAL REVIEW OR PHYSICAL NOT PERFORMED OF INADEQUATE	6	10.2%	6	0.7%
UNEXPLAINED WEIGHT LOSS	1	1.7%	1	0.1%
TOTAL	59	100.0%	412	100.0%

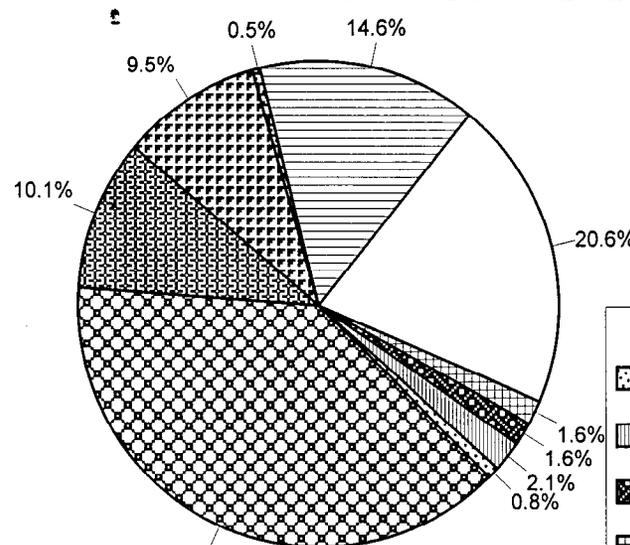
¹ - Includes positive drug screen² - Includes donor provided false information³ - Includes donor rejected at another center; unsuitable history³ - Includes marijuana use

ERROR AND ACCIDENT REPORTS

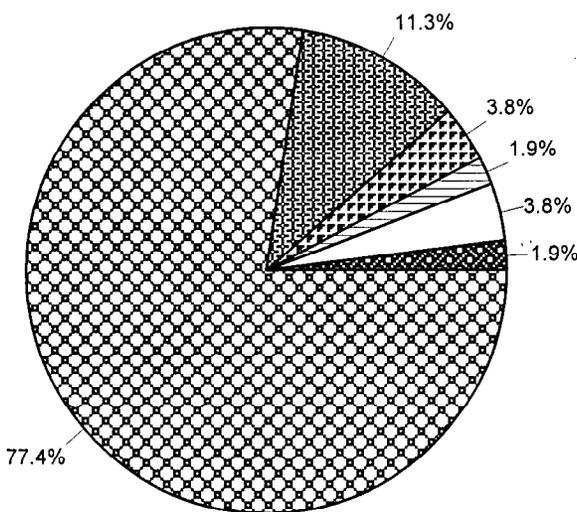
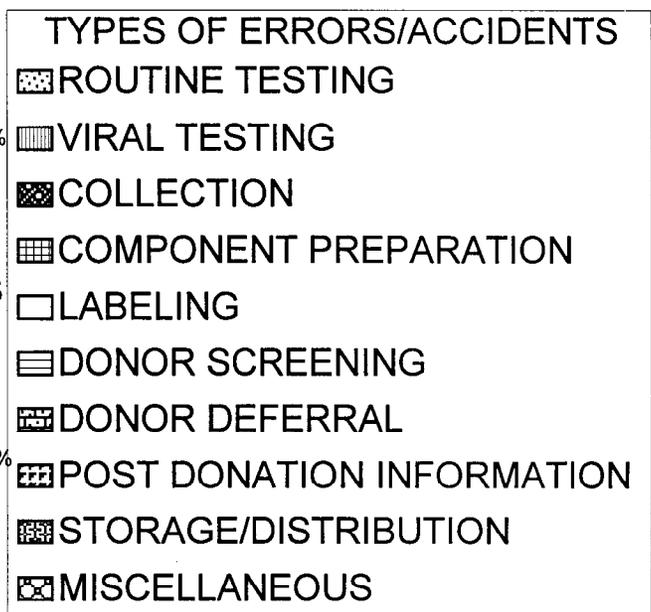
NON-REPORTABLE ERRORS/ACCIDENTS-FY98



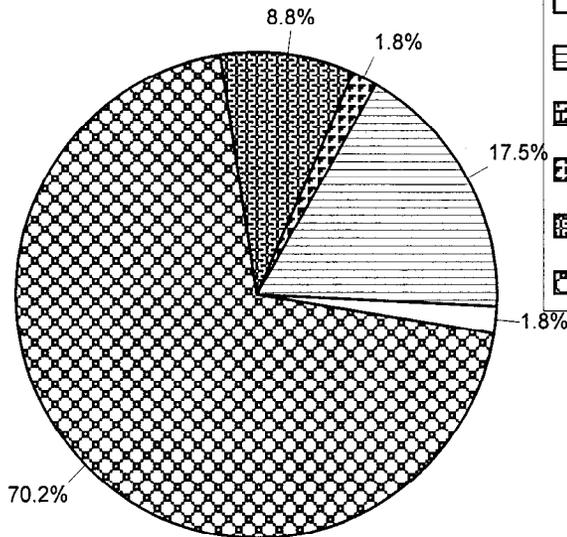
AMERICAN RED CROSS



NON-ARC LICENSED BLOOD BANKS



UNLICENSED BLOOD BANKS



PLASMA CENTERS

REPORTS RECEIVED (10/1/97 - 9/30/98) = 901
 ARC = 413; NON-ARC LICENSED BLOOD BANKS = 378; UNLICENSED BLOOD BANKS = 53; PLASMA CENTERS = 57

Of the 901 non-reportable error and accident reports received from blood and plasma establishments, 381 (42.3%) reports were miscellaneous errors or accidents. 341 (89.5%) reports were submitted by blood establishments and 40 (10.5%) 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	134	39.3%	13	32.5%	147	38.6%
RECORDKEEPING ERROR/ACCIDENT (TESTING AND LABELING ARE ACCEPTABLE)	57	16.7%	4	10.0%	61	16.0%
MISCELLANEOUS*	37	10.9%	20	50.0%	57	15.0%
RECORDS DESTROYED OR LOST/DESTRUCTION RECORDS INCOMPLETE/FINAL DISPOSITION UNKNOWN	50	14.7%	2	5.0%	52	13.6%
QC NOT PERFORMED OR INADEQUATE (OTHER THAN VIRAL MARKER, ABO/Rh)	31	9.1%	1	2.5%	32	8.4%
RECIPIENT REACTION	27	7.9%	0	0.0%	27	7.1%
EMERGENCY RELEASED UNIT NOT TESTED PRIOR TO RELEASE AND FOUND POSITIVE, LABELED APPROPRIATELY	5	1.5%	0	0.0%	5	1.3%
TOTAL	341	100.0%	40	100.0%	381	100.0%

MISCELLANEOUS - TABLE 2

MISCELLANEOUS ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		TOTAL	
NO PRODUCTS MADE AVAILABLE FOR DISTRIBUTION	134	39.3%	147	38.6%
RECORDKEEPING ERROR/ACCIDENT (TESTING AND LABELING ARE ACCEPTABLE)	57	16.7%	61	16.0%
RECORDS DESTROYED OR LOST/DESTRUCTION RECORDS INCOMPLETE/FINAL DISPOSITION UNKNOWN	50	14.7%	52	13.6%
MISCELLANEOUS*	37	10.9%	57	15.0%
QC NOT PERFORMED OR INADEQUATE (OTHER THAN VIRAL MARKER, ABO/Rh)	31	9.1%	32	8.4%
RECIPIENT REACTION	27	7.9%	27	7.1%
EMERGENCY RELEASED UNIT NOT TESTED PRIOR TO RELEASE AND FOUND POSITIVE, LABELED APPROPRIATELY	5	1.5%	5	1.3%
TOTAL	341	100.0%	381	100.0%

MISCELLANEOUS - TABLE 3

MISCELLANEOUS ERRORS/ACCIDENTS	PLASMA CENTERS		TOTAL	
MISCELLANEOUS*	20	50.0%	57	15.0%
NO PRODUCTS MADE AVAILABLE FOR DISTRIBUTION	13	32.5%	147	38.6%
RECORDKEEPING ERROR/ACCIDENT (TESTING AND LABELING ARE ACCEPTABLE)	4	10.0%	61	16.0%
RECORDS DESTROYED OR LOST/DESTRUCTION RECORDS INCOMPLETE/FINAL DISPOSITION UNKNOWN	2	5.0%	52	13.6%
QC NOT PERFORMED OR INADEQUATE (OTHER THAN VIRAL MARKER, ABO/Rh)	1	2.5%	32	8.4%
TOTAL	40	100.0%	349	91.6%

*Includes- recall, notification or lookback procedures not followed

Of the 901 non-reportable error and accident reports received from blood and plasma establishments, 181 (20.1%) reports were labeling errors or accidents. 180 (99.4%) reports were submitted by blood establishments and 1 (0.6%) 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	62	34.4%	1	100.0%	63	34.8%
UNIT MISSING LABEL FOR ABO&/OR Rh, PRODUCT OR EXPIRATION DATE	44	24.4%	0	0.0%	44	24.3%
UNIT LABELED WITH SHORTENED EXPIRATION DATE	37	20.6%	0	0.0%	37	20.4%
DIRECTED UNIT, SUITABLE FOR HOMOLOGOUS USE, LABELED WITH INCORRECT NAME, SSN, OR DOB	31	17.2%	0	0.0%	31	17.1%
MISCELLANEOUS*	6	3.3%	0	0.0%	6	3.3%
TOTAL	180	100.0%	1	100.0%	181	100.0%

*Includes - unit irradiated but not labeled as irradiated; unit not irradiated, but labeled with Rad-Sure label indicating not irradiated; directed donation tie tag attached to homologous unit

Of the 901 non-reportable error and accident reports received from blood and plasma establishments, 111 (12.3%) reports were donor screening errors or accidents. 101 (91.0%) reports were submitted by blood establishments and 10 (9.0%) were submitted from plasma centers. The following 3 tables represent the type of donor screening errors or accidents reported in order of prevalence.

DONOR SCREENING - TABLE 1

DONOR SCREENING ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
ACCEPTANCE CRITERIA NOT MET - TIME INTERVAL BETWEEN DONATIONS	42	41.6%	0	0.0%	42	37.8%
ACCEPTANCE CRITERIA NOT MET - AGE	29	28.7%	0	0.0%	29	26.1%
MISCELLANEOUS*	16	15.8%	1	10.0%	17	15.3%
ACCEPTANCE CRITERIA NOT MET -TOTAL PROTEIN OR SPE	1	1.0%	8	80.0%	9	8.1%
ACCEPTANCE CRITERIA NOT MET - BLOOD PRESSURE OR PULSE	8	7.9%	0	0.0%	8	7.2%
UNIT COLLECTED FROM ELIGIBLE DONOR, DONOR DEFERRAL LIST NOT CHECKED OR CHECKED WITH INCORRECT INFORMATION	2	2.0%	1	10.0%	3	2.7%
PHERESIS DONOR DID NOT MEET ACCEPTANCE CRITERIA FOR PLATELET COUNT, PRODUCT ACCEPTABLE	2	2.0%	0	0.0%	2	1.8%
ACCEPTANCE CRITERIA NOT MET -HEMOGLOBIN/HEMATOCRIT (Hgb>=11.0G/DL OR Hct>=33%)	1	1.0%	0	0.0%	1	0.9%
TOTAL	101	100.0%	10	100.0%	111	100.0%

DONOR SCREENING - TABLE 2

DONOR SCREENING ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		TOTAL	
ACCEPTANCE CRITERIA NOT MET - TIME INTERVAL BETWEEN DONATIONS	42	41.6%	42	37.8%
ACCEPTANCE CRITERIA NOT MET - AGE	29	28.7%	29	26.1%
MISCELLANEOUS*	16	15.8%	17	15.3%
ACCEPTANCE CRITERIA NOT MET - BLOOD PRESSURE OR PULSE	8	7.9%	8	7.2%
UNIT COLLECTED FROM ELIGIBLE DONOR, DONOR DEFERRAL LIST NOT CHECKED OR CHECKED WITH INCORRECT INFORMATION	2	2.0%	3	2.7%
PHERESIS DONOR DID NOT MEET ACCEPTANCE CRITERIA FOR PLATELET COUNT, PRODUCT ACCEPTABLE	2	2.0%	2	1.8%
ACCEPTANCE CRITERIA NOT MET -HEMOGLOBIN/HEMATOCRIT (Hgb>=11.0G/DL OR Hct>=33%)	1	1.0%	1	0.9%
ACCEPTANCE CRITERIA NOT MET -TOTAL PROTEIN OR SPE	1	1.0%	9	8.1%
TOTAL	101	100.0%	111	100.0%

DONOR SCREENING - TABLE 3

DONOR SCREENING ERRORS/ACCIDENTS	PLASMA CENTERS		TOTAL	
ACCEPTANCE CRITERIA NOT MET -TOTAL PROTEIN OR SPE	8	80.0%	9	8.1%
UNIT COLLECTED FROM ELIGIBLE DONOR, DONOR DEFERRAL LIST NOT CHECKED OR CHECKED WITH INCORRECT INFORMATION	1	10.0%	3	2.7%
MISCELLANEOUS*	1	10.0%	17	15.3%
TOTAL	10	100.0%	29	26.1%

*Includes - explained weight loss - due to supervised diet; donor met HBsAg reentry criteria; plasma products not affected by malarial exposure

Of the 901 non-reportable error and accident reports received from blood and plasma establishments, 107 (11.9%) reports involved storage and distribution errors or accidents. 102 (95.3%) reports were submitted by blood establishments and 5 (4.7%) 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

TYPE OF STORAGE AND DISTRIBUTION ERROR/ACCIDENT	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
	Count	Percentage	Count	Percentage	Count	Percentage
DISCREPANCY BETWEEN SHIPPING FORM AND SHIPMENT	49	48.0%	0	0.0%	49	45.8%
MISCELLANEOUS*	15	14.7%	5	100.0%	20	18.7%
IRRADIATED UNIT REQUESTED, UNI NOT IRRADIATED, <i>LABELED APPROPRIATELY</i>	14	13.7%	0	0.0%	14	13.1%
RELEASE OF PRODUCT OTHER THAN THAT WHICH WAS ORDERED, <i>LABELED APPROPRIATELY</i>	7	6.9%	0	0.0%	7	6.5%
SHIPMENT TO INCORRECT FACILITY	6	5.9%	0	0.0%	6	5.6%
ANTI-CMV NEGATIVE UNIT REQUESTED, UNIT NOT TESTED FOR ANTI-CMV, <i>LABELED APPROPRIATELY</i>	4	3.9%	0	0.0%	4	3.7%
UNIT LOST OR SHIPMENT NEVER RECEIVED	2	2.0%	0	0.0%	2	1.9%
SPECIAL ANTIGEN TESTING REQUESTED, UNIT NOT TESTED FOR SPECIAL ANTIGEN, <i>LABELED APPROPRIATELY</i>	2	2.0%	0	0.0%	2	1.9%
SPECIFIC ABO/Rh TYPE REQUESTED, INCORRECT ABO/Rh RELEASED, <i>LABELED APPROPRIATELY</i>	2	2.0%	0	0.0%	2	1.9%
DISTRIBUTION OF UNIT WITH NO SEGMENTS	1	1.0%	0	0.0%	1	0.9%
TOTAL	102	100.0%	5	100.0%	107	100.0%

STORAGE AND DISTRIBUTION - TABLE 2

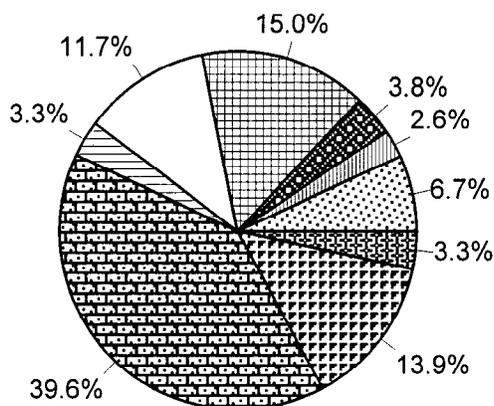
TYPE OF STORAGE AND DISTRIBUTION ERROR/ACCIDENT	BLOOD ESTABLISHMENTS		TOTAL	
	Count	Percentage	Count	Percentage
DISCREPANCY BETWEEN SHIPPING FORM AND SHIPMENT	49	48.0%	49	45.8%
MISCELLANEOUS*	15	14.7%	20	18.7%
IRRADIATED UNIT REQUESTED, UNI NOT IRRADIATED, <i>LABELED APPROPRIATELY</i>	14	13.7%	14	13.1%
RELEASE OF PRODUCT OTHER THAN THAT WHICH WAS ORDERED, <i>LABELED APPROPRIATELY</i>	7	6.9%	7	6.5%
SHIPMENT TO INCORRECT FACILITY	6	5.9%	6	5.6%
ANTI-CMV NEGATIVE UNIT REQUESTED, UNIT NOT TESTED FOR ANTI-CMV, <i>LABELED APPROPRIATELY</i>	4	3.9%	4	3.7%
UNIT LOST OR SHIPMENT NEVER RECEIVED	2	2.0%	2	1.9%
SPECIAL ANTIGEN TESTING REQUESTED, UNIT NOT TESTED FOR SPECIAL ANTIGEN, <i>LABELED APPROPRIATELY</i>	2	2.0%	2	1.9%
SPECIFIC ABO/Rh TYPE REQUESTED, INCORRECT ABO/Rh RELEASED, <i>LABELED APPROPRIATELY</i>	2	2.0%	2	1.9%
DISTRIBUTION OF UNIT WITH NO SEGMENTS	1	1.0%	1	0.9%
TOTAL	102	100.0%	107	100.0%

STORAGE AND DISTRIBUTION - TABLE 3

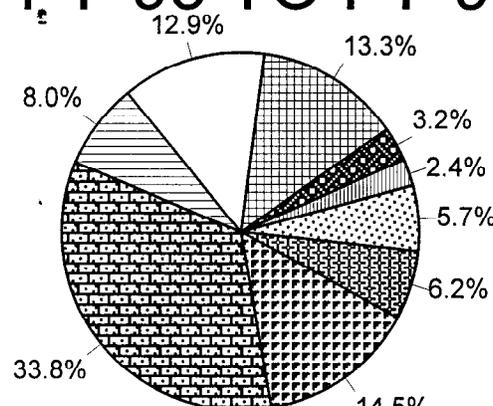
TYPE OF STORAGE AND DISTRIBUTION ERROR/ACCIDENT	PLASMA CENTERS		TOTAL	
	Count	Percentage	Count	Percentage
MISCELLANEOUS*	5	100.0%	20	18.7%
TOTAL	5	100.0%	20	18.7%

* includes applicant donor unit shipped prior to collection of confirming unit, unit suitable; unit determined to be out of monitored storage less than 30 minutes; allogeneic unit issued when autologous unit was available; unit returned at acceptable temperature, acceptable for use

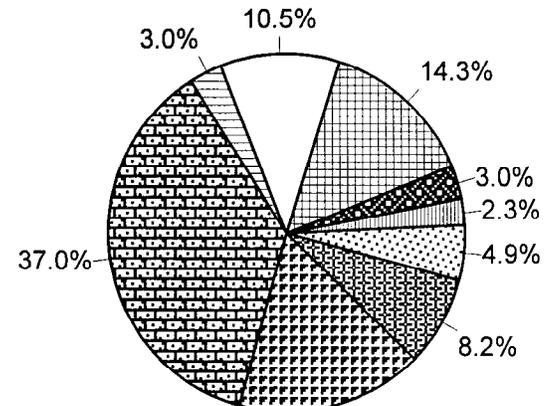
ERROR AND ACCIDENT REPORTS FY-93 TO FY-98



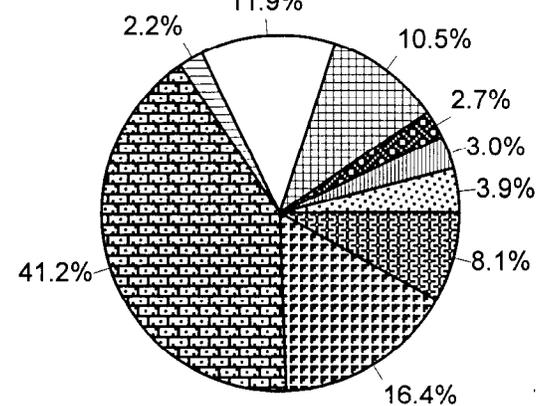
FY-93



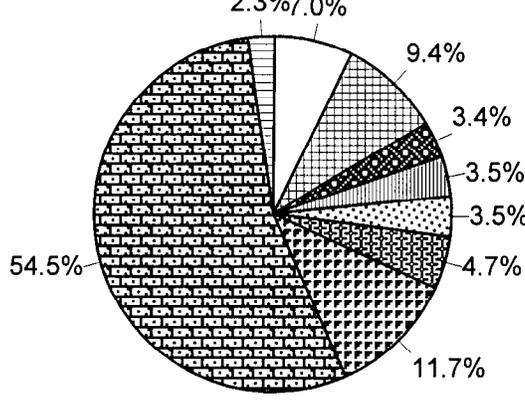
FY-94



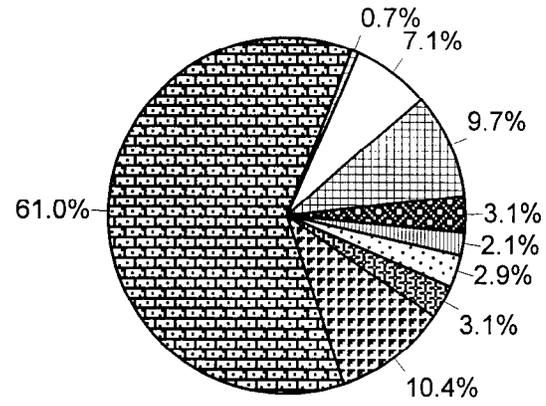
FY-95



FY-96



FY-97



FY-98

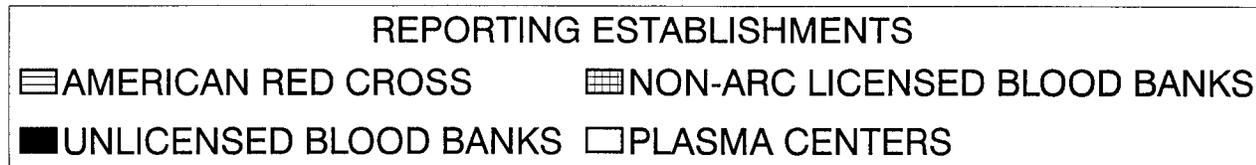
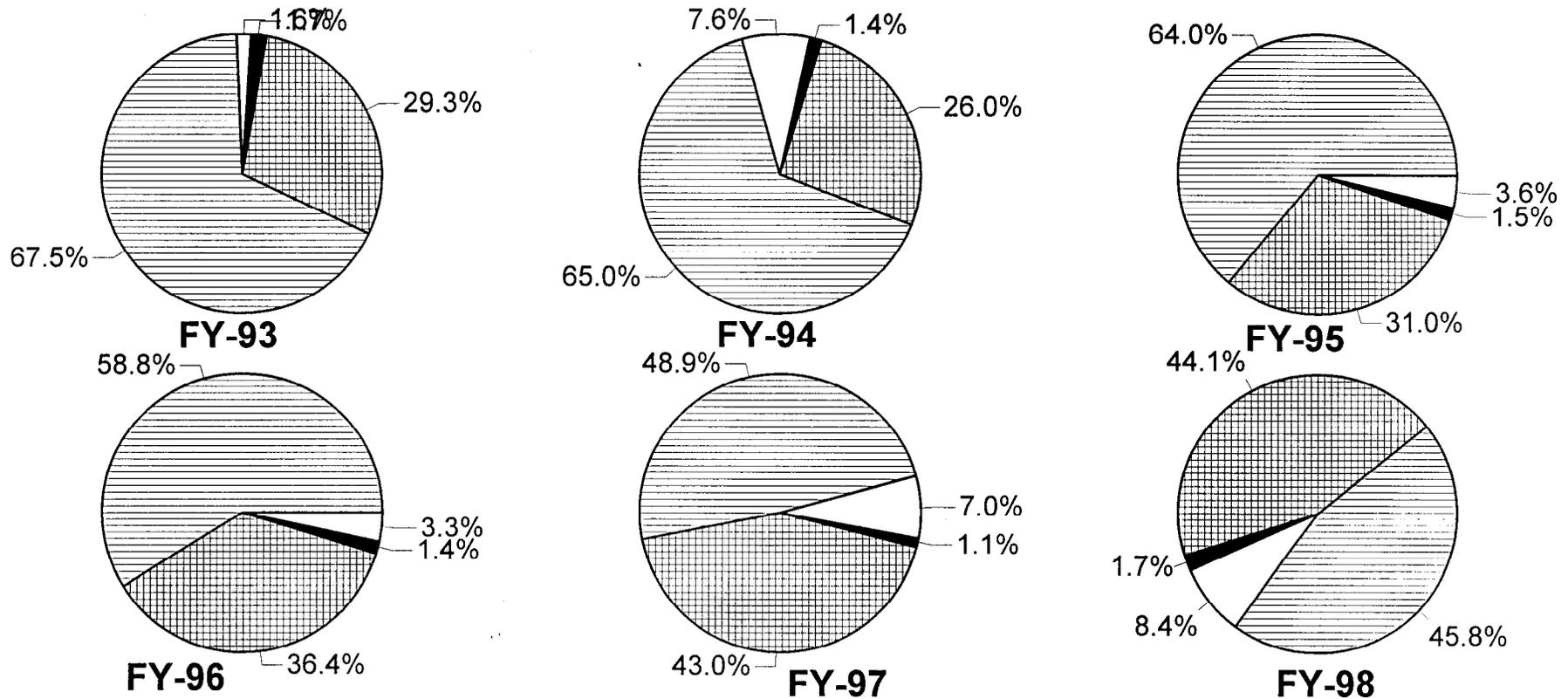
TYPES OF ERRORS/ACCIDENTS					
	ROUTINE TESTING		VIRAL TESTING		COLLECT/COMP. PREPARATION
	LABELING		DONOR SCREENING		DONOR DEFERRAL
	POST DONATION INFORMATION		STORAGE/DISTRIBUTION		MISCELLANEOUS

REPORTS RECEIVED 10/1/92 - 9/30/98

FY-93 = 8,988; FY-94 = 11,292; FY-95 = 12,923; FY-96 = 14,034; FY-97 = 12,421; FY98 = 12,187

ERROR AND ACCIDENT REPORTS

ALL REPORTING BLOOD ESTABLISHMENTS

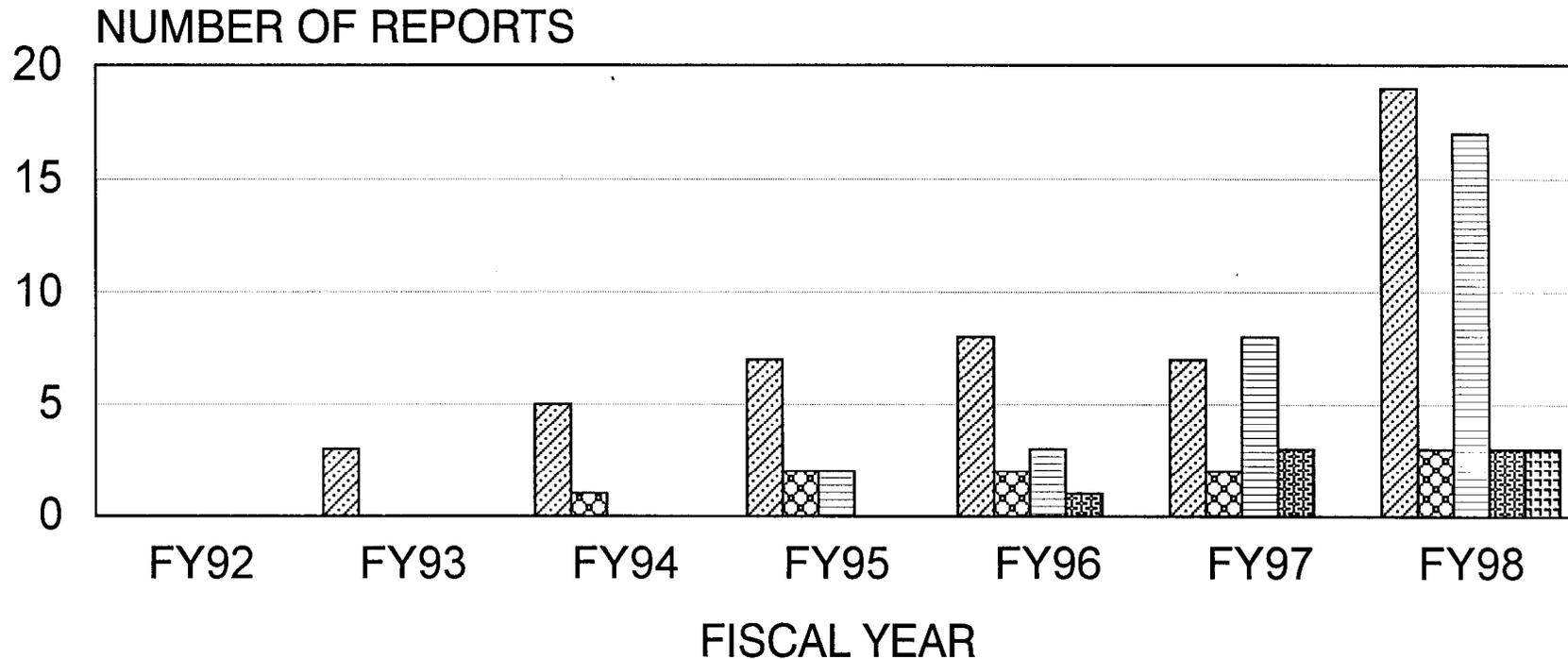


REPORTS RECEIVED 10/1/92 - 9/30/98

FY-93 = 8,988; FY-94 = 11,292; FY-95 = 12,923; FY-96 = 14,034; FY-97 = 12,421; FY98 = 12187

ERROR AND ACCIDENT REPORTS

ALL REPORTING NON-BLOOD ESTABLISHMENTS



REPORTS RECEIVED 10/1/91 - 9/30/98

FY-92 = 0; FY-93 = 3; FY-94 = 6; FY-95 = 11; FY-96 = 14; FY-97 = 20; FY98 = 45

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 10/1/97 - 9/30/98

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

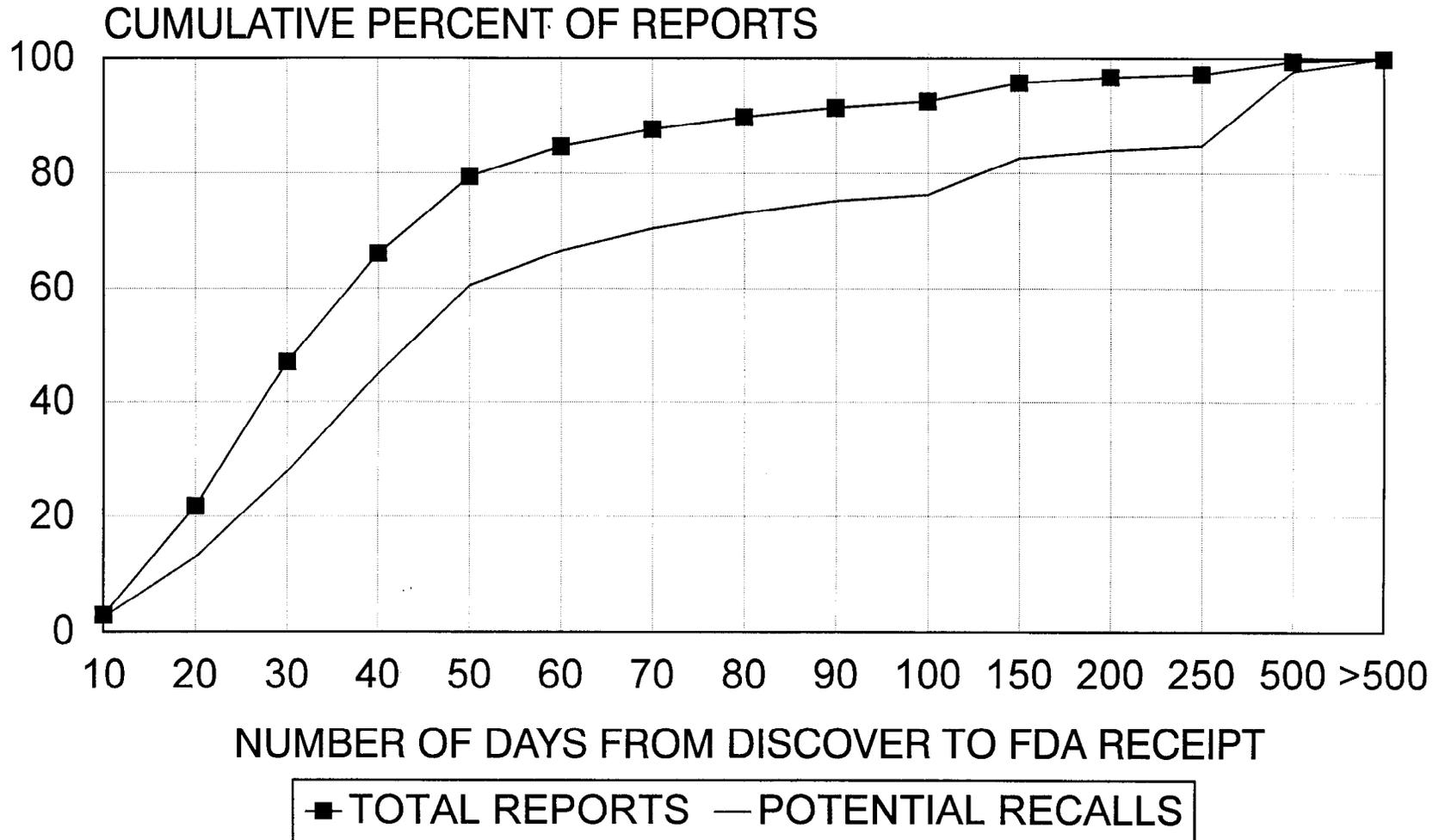
CUMULATIVE PERCENT OF REPORTS	ARC (DAYS)	NON-ARC LICENSED (DAYS)	UNLICENSED (DAYS)	PLASMA (DAYS)	TOTAL (DAYS)
25%	21	21	14	18	21
50%	29	34	24	33	31
75%	40	62	48	71	47
90%	48	119	81	133	80
# REPORTS	5622	5437	176	1046	12281
RANGE	5-708	4-1132	4-727	3-559	3-1132

ERROR AND ACCIDENT REPORTS

REPORTING TIME

ALL REPORTING BLOOD ESTABLISHMENTS

FY98

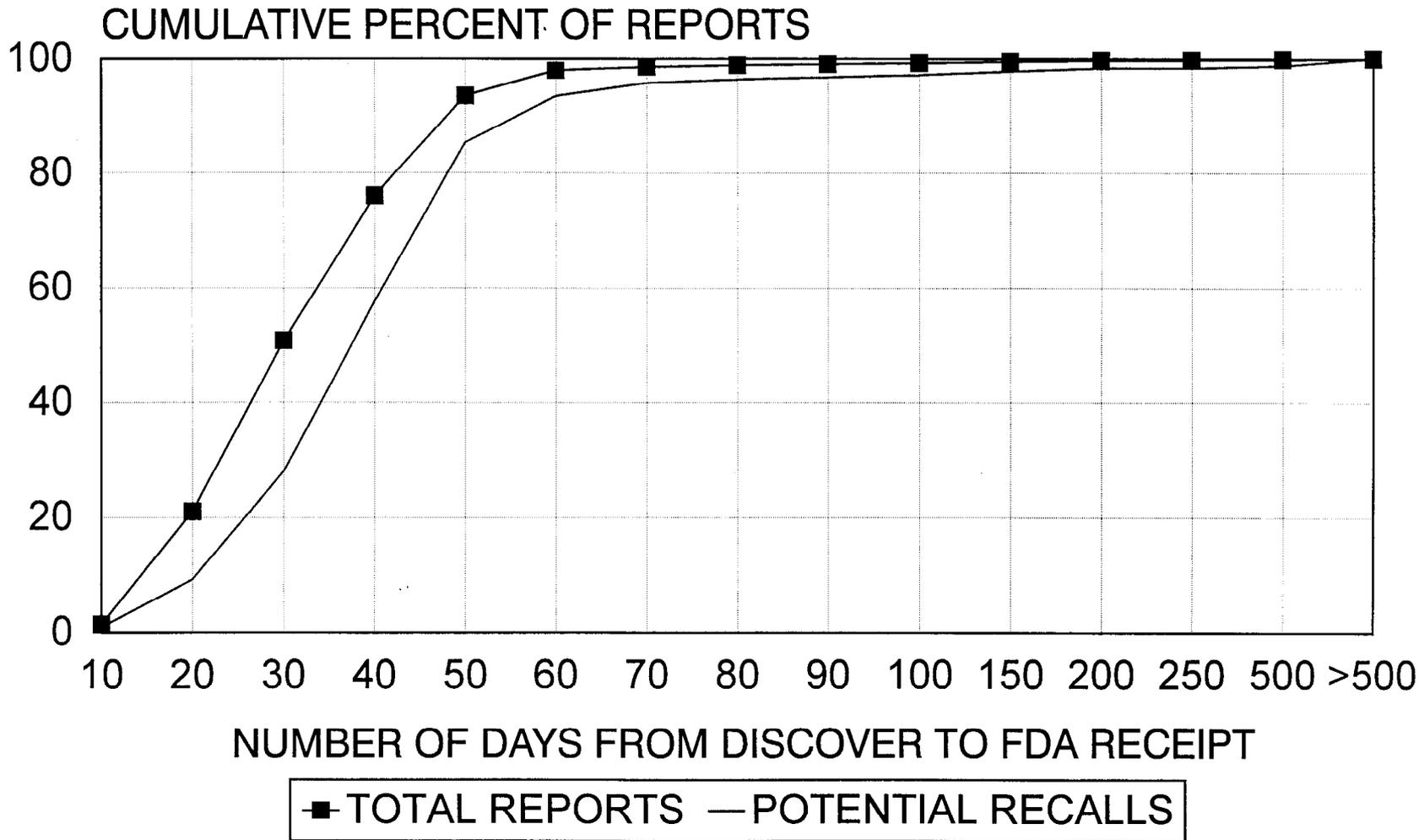


TOTAL REPORTS = 12,281

POTENTIAL RECALLS = 1676

ERROR AND ACCIDENT REPORTS

REPORTING TIME AMERICAN RED CROSS FY98



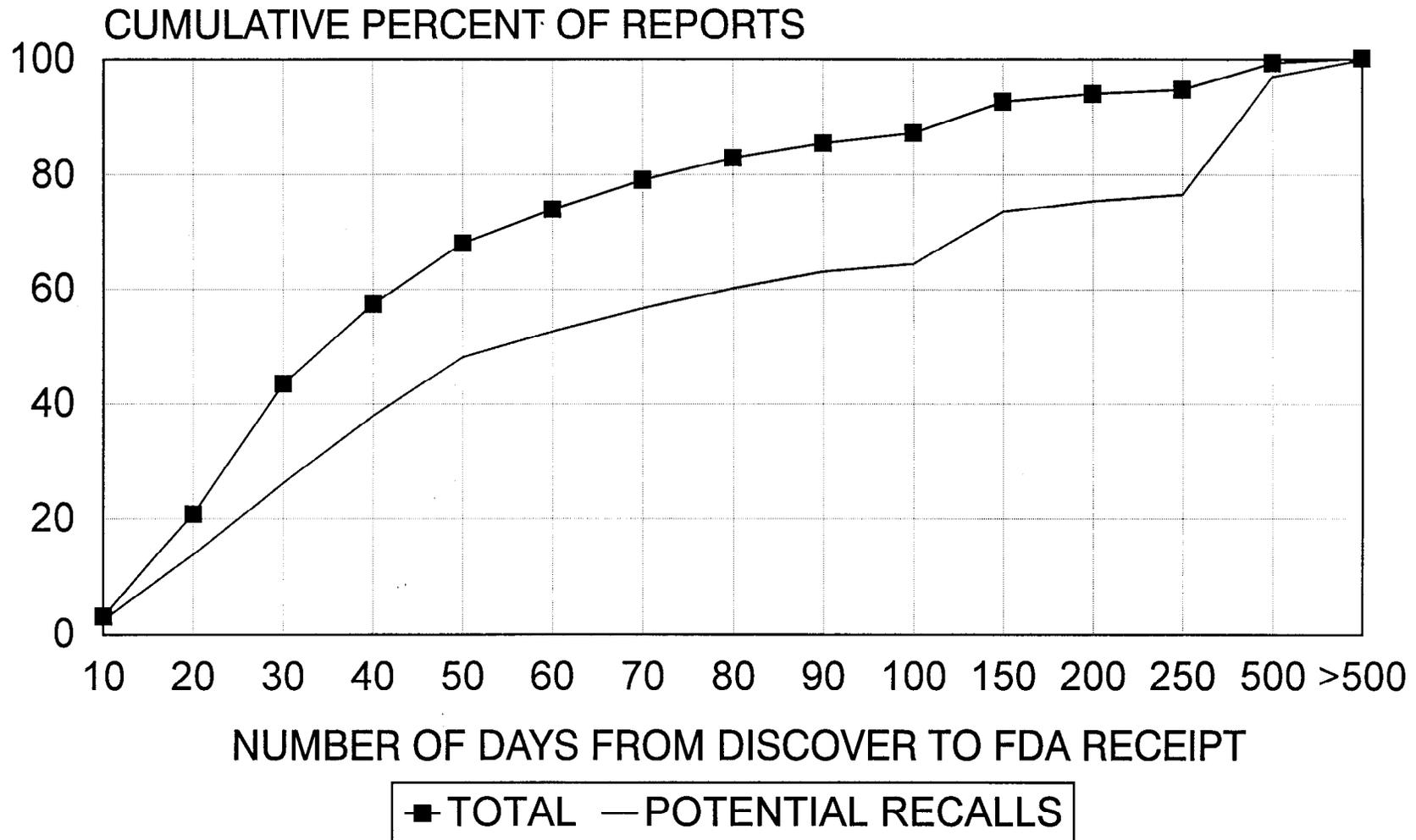
TOTAL REPORTS = 5622
POTENTIAL RECALLS = 528

ERROR AND ACCIDENT REPORTS

REPORTING TIME

NON-ARC LICENSED BLOOD BANKS

FY98



TOTAL REPORTS = 5437

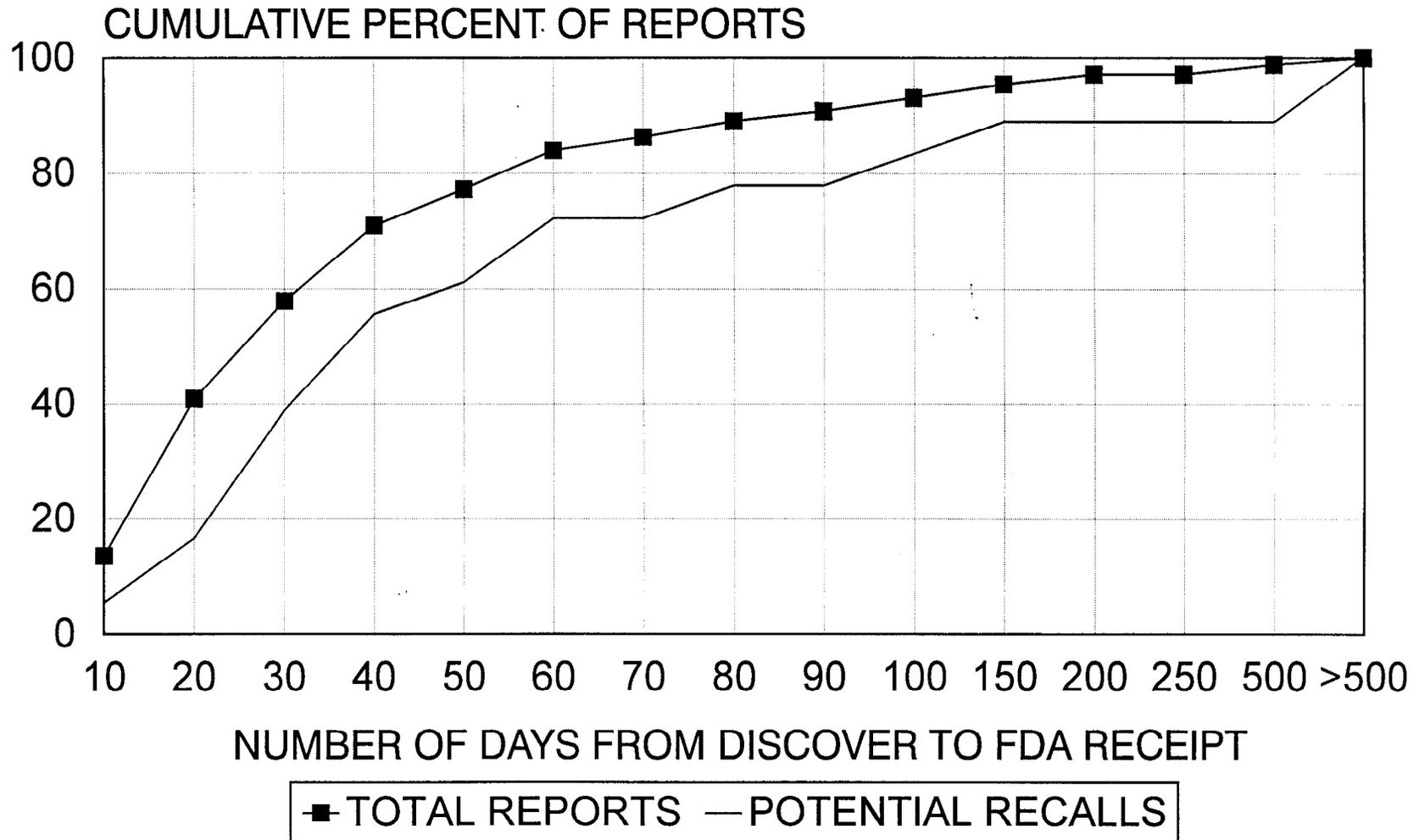
POTENTIAL RECALLS = 1044

ERROR AND ACCIDENT REPORTS

REPORTING TIME

UNLICENSED BLOOD BANKS

FY98



TOTAL REPORTS = 176

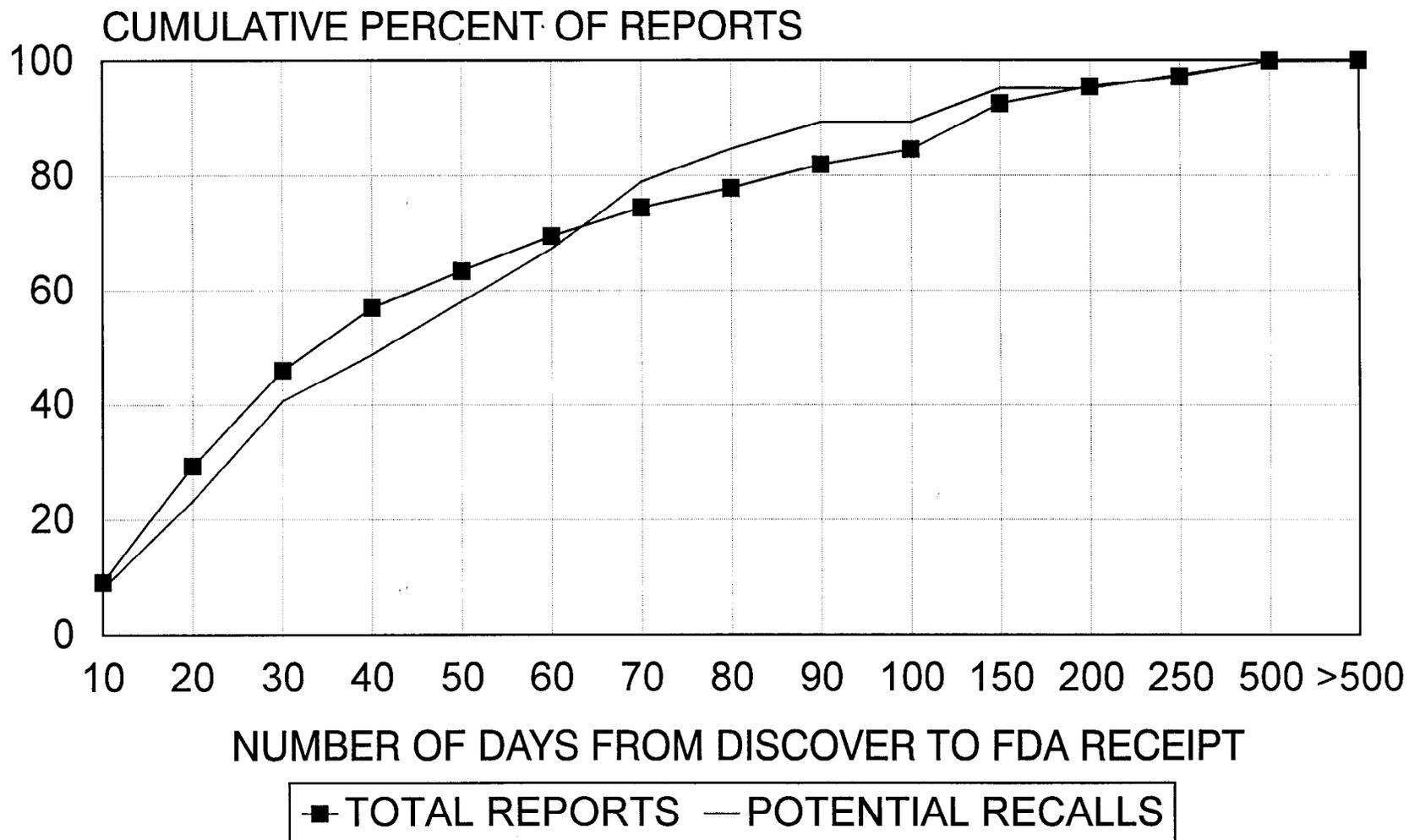
POTENTIAL RECALLS = 18

ERROR AND ACCIDENT REPORTS

REPORTING TIME

PLASMA CENTERS

FY98

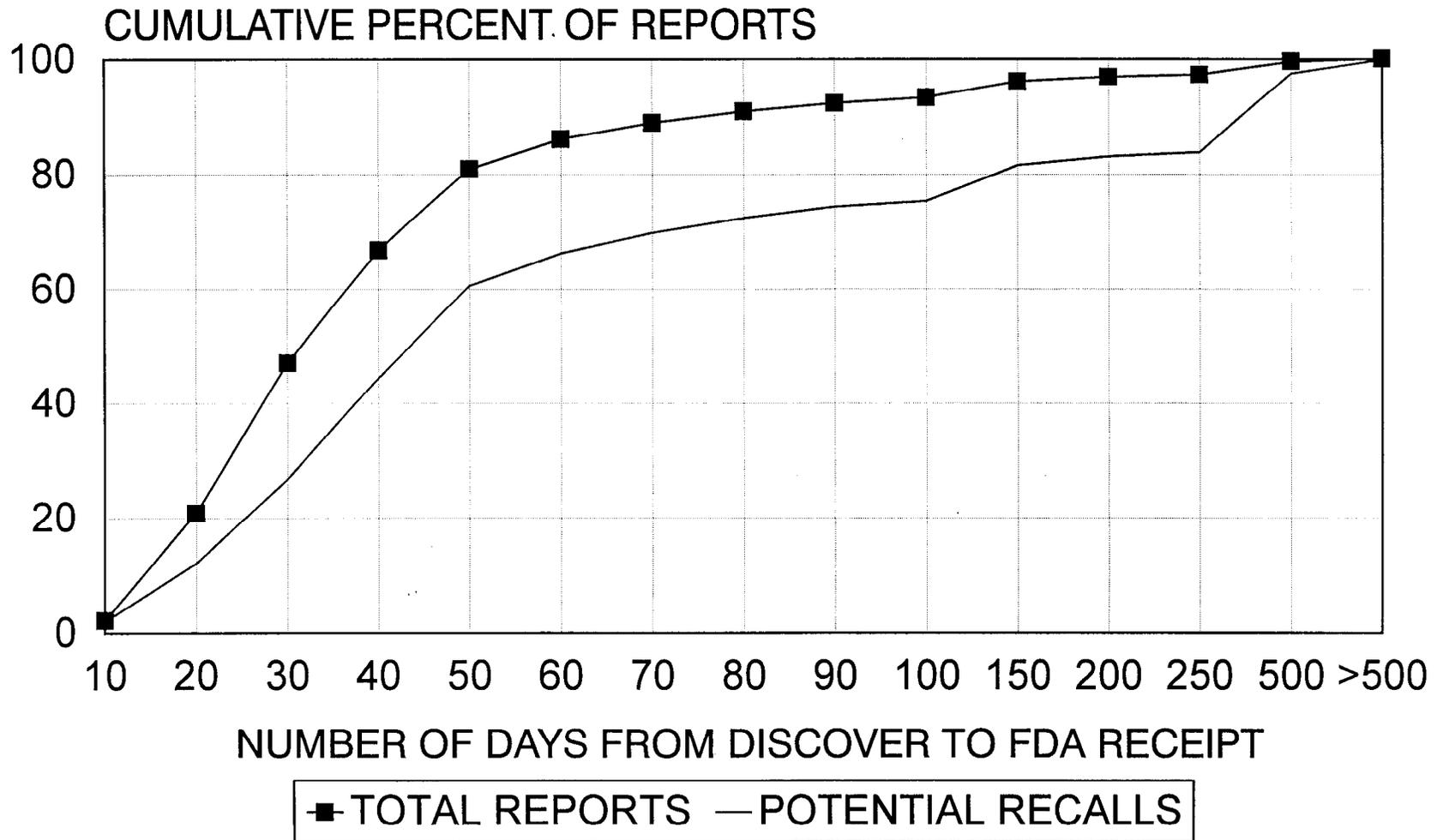


TOTAL REPORTS = 1046

POTENTIAL RECALLS = 86

ERROR AND ACCIDENT REPORTS

REPORTING TIME ALL LICENSED BLOOD BANKS FY98



TOTAL REPORTS = 11,059

POTENTIAL RECALLS = 1572

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***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*)- *arm inspection/preparation documentation*- *cue sticker missing*- *male donor answered questions intended for female donor***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*)- *donor previously self-deferred*- *positive drug screen***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**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*)
 - *CMV positive*
 - *donor previously self-deferred*
 - *donor implicated in transfusion related disease*
 - 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
 - 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*)
 - donor had flu symptoms at time of donation
 - marijuana use
 - 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
 - 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
 - 5522 - Travel to malaria endemic area/history of malaria
 - 5523 - History of disease/surgery
 - 5524 - History of cancer
 - 5525 - History of Creutzfeldt-Jakob Disease
 - 5526 - Risk factors associated with Creutzfeldt-Jakob Disease
 - 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 involved twice in cases of post transfusion hepatitis
 - skin lesion biopsy pending
 - 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*)
 - *reason unknown*
 - 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
 - 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
- 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)
 - 6304 - Post donation HBV or HCV related illness or positive hepatitis marker
 - 6305 - Post donation AIDS or related illness or positive test for HIV, or anti-HTLV-I
 - 6306 - Information not related to hepatitis B/C, HIV, HTLV-1, or STD (*see remarks*)
 - donor called back for test results
 - non-IV drug use
 - sex change operation
 - 6307 - History of hepatitis B/C or jaundice
 - 6308 - Sexually transmitted disease, or positive STS
 - 6309 - Sexual partner having sexually transmitted disease
 - 6310 - Sexual partner testing positive for HIV
 - 6311 - Sexual partner testing positive for Hepatitis marker
 - 6312 - Male donor had sex with another man
 - 6313 - Female had sex with a man who has had sex with another man
 - 6314 - IV drug use
 - 6315 - Sex with IV drug user
 - 6316 - Travel/immigration - high risk area
 - 6317 - Exchanged sex for drugs/money
 - 6318 - Received tattoo, earpiercing, needlestick, transfusion
 - 6319 - Non-sexual exposure to HIV
 - 6320 - Non-sexual exposure to hepatitis B or C
 - 6321 - High risk behavior, but does not specify what type
 - 6322 - Travel to malaria endemic area/history of malaria
 - 6323 - History of disease/surgery
 - 6324 - History of cancer
 - 6325 - History of Creutzfeldt-Jakob Disease
 - 6326 - Risk factors associated with Creutzfeldt-Jakob Disease
 - 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
- 6333 - Resided in a rehabilitation center or psychiatric hospital
- 6334 - Received Methotrexate
- 6335 - History of Hepatitis A
- 6336 - Exposure to Hepatitis A

BC - BLOOD COLLECTION

- BC3000 - Miscellaneous (*see remarks*)
 - *blood collection set lot number not recorded on blood donation record*
- BC31 - Sterility compromised
 - 3100 - Other (*see remarks*)
 - *blood collected from rash area on donor arm*
 - 3101 - Bacterial contamination
 - 3102 - Air contamination
 - 3103 - Arm prep not performed or performed inappropriately
- 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*
 - 3401 - Collection time extended, discrepant, or not documented
 - 3402 - Overbleed
- BC35 - Collection device
 - 3500 - Device defect

CP - COMPONENT PREPARATION

- CP8000 - Miscellaneous (*see remarks*)
 - *Hemasure filter associated with adverse reaction*
 - *platelets and FFP prepared in centrifuge with unacceptable acceleration*
- CP8100 - Components prepared more than 8 hours after collection
- CP8200 - Additive not added or added inappropriately
- CP8300 - Sterility compromised
 - 8301 - Other
 - 8302 - Bacterial contamination
 - 8303 - Air contamination
- CP8400 - Incorrect/inappropriate preparation of platelets
 - 8400 - Other (*see remarks*)
 - *centrifuge not validated*
 - *insufficient plasma for high yield platelets*
 - *saline added instead of plasma*
 - 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*)
 - *component filtered or leukoreduced inappropriately*
 - *extended or difficult collection*
- 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*)
 - *CMV*
 - *Hemoglobin*
 - *Hematocrit*
 - *sickle cell screen*

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
- 2109** - ALT
- 2110** - Anti-HCV
- 2111** - More than 1 test
- 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*)- *emergency release label*- *"for autologous use only" label*- *autologous unit labeled as homologous*

4208 - Anticoagulant

4209 - Donor number

4210 - Recipient number

4211 - Biohazard/Test status

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 answered no to, "are you feeling well today?"*- *donor self-deferred*- *post donation illness (information received prior to release of products)*

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

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

- 7122 - Travel to malaria endemic area/history of malaria
- 7123 - History of disease/surgery
- 7124 - History of cancer
- 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
- 7130 - Received vaccine or immune globulin
- 7131 - Exposure to a disease
- 7132 - Incarcerated
- 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
 - 7202 - HBsAg
 - 7203 - Anti-HBc
 - 7204 - Anti-HCV
 - 7205 - Anti-HTLV-I
 - 7206 - ALT
 - 7207 - Other reasons (*see remarks*)
 - *Chagas*
 - *CMV*
 - *DAT*
 - 7208 - ABO
 - 7209 - Rh
 - 7210 - Antibody screen
 - 7211 - Antigen screen
 - 7212 - Syphilis
- SD73** - Failure to quarantine unit due to testing not performed or documented for:
 - 7301 - Anti-HIV/HIV antigen
 - 7302 - HBsAg
 - 7303 - Anti-HBc
 - 7304 - Anti-HCV
 - 7305 - Anti-HTLV-I
 - 7306 - ALT
 - 7307 - Other reasons (*see remarks*)
 - *CMV*
 - *compatibility testing*
 - *crossmatch*
 - 7308 - ABO
 - 7309 - Rh
 - 7310 - Antibody screen
 - 7311 - Antigen screen
 - 7312 - Syphilis

SD74 - Inappropriate release**7400** - Other (*see remarks*)- *associated component unsuitable (clots, hemolyzed)*- *product released prior to investigation of discrepancy***7401** - Outdated product**7402** - Autologous unit not meeting homologous criteria**SD75** - Unsuitable product**7500** - Other (*see remarks*)- *particulate matter in product*- *possible contamination*- *unit had pinhole leak in tubing***7501** - Unit contained clots or would not flow through filter**7502** - Unit/segment hemolyzed**7503** - Broken/damaged unit**SD7600** - Shipped/stored at incorrect temperature**SD7700** - Shipment of unlicensed product labeled with license number**SD7800** - Improper transfusion service practices**7800** - Miscellaneous (*see remarks*)- *wrong phenotype*- *patient transfused prior to repeating crossmatch***7801** - Unit requiring irradiation was not irradiated**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*)- *malaria*- *babesiosis***9500** - 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	
DONOR SCREENING						824	6.71%
DS5103	10	10	1	0	0	21	0.17%
DS5104	7	21	0	0	0	28	0.23%
DS5105	0	2	0	0	0	2	0.02%
DS5106	0	0	0	0	6	6	0.05%
DS5109	0	0	0	0	1	1	0.01%
DS5200	13	10	1	0	3	27	0.22%
DS5201	2	2	1	0	3	8	0.07%
DS5202	7	15	0	0	0	22	0.18%
DS5203	19	46	1	0	7	73	0.59%
DS5204	15	64	0	0	3	82	0.67%
DS5301	19	2	1	0	4	26	0.21%
DS5302	5	1	0	0	1	7	0.06%
DS5303	0	0	0	0	1	1	0.01%
DS5304	0	3	0	0	0	3	0.02%
DS5305	0	0	1	0	0	1	0.01%
DS5306	0	0	0	0	1	1	0.01%
DS5307	0	2	0	0	2	4	0.03%
DS5308	0	0	0	0	1	1	0.01%
DS5310	0	1	0	0	0	1	0.01%
DS5314	2	0	0	0	0	2	0.02%
DS5318	0	2	0	0	0	2	0.02%
DS5320	0	1	0	0	0	1	0.01%
DS5321	0	1	0	0	6	7	0.06%
DS5322	0	1	1	0	0	2	0.02%
DS5323	0	0	0	0	1	1	0.01%
DS5332	0	0	0	0	1	1	0.01%
DS5401	3	5	0	0	2	10	0.08%
DS5402	0	2	0	0	1	3	0.02%
DS5403	1	6	0	0	0	7	0.06%
DS5404	1	1	0	0	0	2	0.02%
DS5405	1	1	0	0	0	2	0.02%
DS5406	2	0	0	0	0	2	0.02%
DS5407	2	3	0	0	1	6	0.05%
DS5410	0	1	0	0	0	1	0.01%
DS5412	1	0	0	0	0	1	0.01%
DS5414	1	1	0	0	0	2	0.02%
DS5417	0	1	0	0	0	1	0.01%
DS5418	5	10	0	0	1	16	0.13%
DS5420	0	1	0	0	0	1	0.01%
DS5421	1	1	0	0	4	6	0.05%
DS5422	1	1	0	0	0	2	0.02%
DS5424	0	1	0	0	0	1	0.01%
DS5501	1	2	0	0	0	3	0.02%
DS5502	8	13	0	0	0	21	0.17%
DS5507	0	2	0	0	1	3	0.02%
DS5510	0	1	0	0	0	1	0.01%
DS5511	10	4	0	0	0	14	0.11%
DS5512	0	2	0	0	0	2	0.02%
DS5514	0	1	1	0	0	2	0.02%
DS5515	0	2	0	0	0	2	0.02%

ERROR CODE	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
DS5516	2	6	0	0	1	9	0.07%
DS5518	3	12	1	0	4	20	0.16%
DS5520	4	5	0	0	0	9	0.07%
DS5521	1	1	0	0	0	2	0.02%
DS5522	46	113	1	0	0	160	1.30%
DS5523	15	34	0	0	2	51	0.42%
DS5524	24	19	0	0	0	43	0.35%
DS5526	0	1	0	0	0	1	0.01%
DS5527	0	2	0	0	0	2	0.02%
DS5528	3	10	0	0	0	13	0.11%
DS5529	18	23	0	0	1	42	0.34%
DS5530	3	4	0	0	0	7	0.06%
DS5534	10	5	0	0	0	15	0.12%
DS5535	1	5	0	0	0	6	0.05%
DS5536	1	1	0	0	0	2	0.02%
DONOR DEFERRAL						85	0.69%
DD6101	5	7	2	0	0	14	0.11%
DD6102	2	1	0	0	1	4	0.03%
DD6103	1	5	0	0	0	6	0.05%
DD6105	2	1	0	0	0	3	0.02%
DD6106	1	0	0	0	0	1	0.01%
DD6107	2	0	0	0	0	2	0.02%
DD6108	0	0	0	0	3	3	0.02%
DD6112	1	0	0	0	0	1	0.01%
DD6118	1	5	0	0	1	7	0.06%
DD6121	0	1	0	0	1	2	0.02%
DD6122	0	3	0	0	0	3	0.02%
DD6123	1	0	0	0	0	1	0.01%
DD6124	0	1	0	0	0	1	0.01%
DD6130	0	1	0	0	0	1	0.01%
DD6132	0	0	0	0	3	3	0.02%
DD6201	6	11	0	0	0	17	0.14%
DD6202	0	1	0	0	0	1	0.01%
DD6203	0	1	0	0	0	1	0.01%
DD6204	0	5	0	0	0	5	0.04%
DD6207	0	1	0	0	1	2	0.02%
DD6208	0	1	0	0	0	1	0.01%
DD6218	0	0	2	0	2	4	0.03%
DD6223	0	0	0	0	1	1	0.01%
DD6224	0	1	0	0	0	1	0.01%
POST DONATION INFORMATION						7986	65.00%
DD6301	21	27	1	0	0	49	0.40%
DD6303	524	420	4	0	2	950	7.73%
DD6304	54	24	0	0	20	98	0.80%
DD6305	13	8	0	0	6	27	0.22%
DD6306	4	34	0	0	25	63	0.51%
DD6307	156	73	1	0	10	240	1.95%
DD6308	12	10	0	0	2	24	0.20%
DD6309	4	5	0	0	0	9	0.07%
DD6310	27	18	0	0	37	82	0.67%
DD6311	266	102	1	0	15	384	3.13%
DD6312	154	61	1	0	47	263	2.14%
DD6313	28	14	0	0	4	46	0.37%

ERROR CODE	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
DD6314	123	147	4	0	114	388	3.16%
DD6315	124	45	0	0	25	194	1.58%
DD6316	132	58	0	0	6	196	1.60%
DD6317	23	16	1	0	18	58	0.47%
DD6318	621	352	5	0	183	1161	9.45%
DD6319	4	1	0	0	1	6	0.05%
DD6320	116	50	0	0	6	172	1.40%
DD6321	42	101	2	0	152	297	2.42%
DD6322	488	759	8	0	1	1256	10.22%
DD6323	226	162	1	0	5	394	3.21%
DD6324	442	332	4	0	11	789	6.42%
DD6325	2	2	0	0	0	4	0.03%
DD6326	72	52	1	0	1	126	1.03%
DD6327	30	18	0	0	2	50	0.41%
DD6328	74	41	0	0	1	116	0.94%
DD6329	89	45	0	0	4	138	1.12%
DD6330	34	11	1	0	7	53	0.43%
DD6331	8	10	0	0	0	18	0.15%
DD6332	11	14	1	0	161	187	1.52%
DD6333	3	0	1	0	3	7	0.06%
DD6334	18	2	0	0	0	20	0.16%
DD6335	18	28	0	0	5	51	0.42%
DD6336	33	29	0	0	8	70	0.57%
COLLECTION						101	0.82%
BC3000	1	0	0	0	0	1	0.01%
BC3100	3	0	0	0	0	3	0.02%
BC3101	11	23	0	0	0	34	0.28%
BC3102	12	10	0	0	1	23	0.19%
BC3103	5	2	1	0	1	9	0.07%
BC3201	1	1	0	0	0	2	0.02%
BC3202	0	2	0	0	0	2	0.02%
BC3400	11	0	0	0	0	11	0.09%
BC3401	7	8	0	0	0	15	0.12%
BC3402	1	0	0	0	0	1	0.01%
COMPONENT PREPARATION						256	2.08%
CP8000	2	0	0	0	0	2	0.02%
CP8100	1	10	0	0	0	11	0.09%
CP8200	3	4	0	0	0	7	0.06%
CP8301	0	0	1	0	0	1	0.01%
CP8302	8	7	0	0	0	15	0.12%
CP8303	1	1	0	0	0	2	0.02%
CP8400	19	10	0	1	0	30	0.24%
CP8401	14	9	0	0	0	23	0.19%
CP8402	3	11	0	0	0	14	0.11%
CP8403	0	4	0	0	0	4	0.03%
CP8404	0	2	0	0	0	2	0.02%
CP8405	2	4	0	0	0	6	0.05%
CP8406	6	6	0	0	0	12	0.10%
CP8407	26	14	0	0	0	40	0.33%
CP8500	11	36	0	1	0	48	0.39%
CP8501	0	0	1	0	0	1	0.01%
CP8502	4	6	0	0	0	10	0.08%
CP8503	0	1	1	0	0	2	0.02%

ERROR CODE	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
SD7127	1	0	0	0	0	1	0.01%
SD7128	0	2	0	0	0	2	0.02%
SD7129	2	4	0	0	0	6	0.05%
SD7130	0	1	0	0	0	1	0.01%
SD7201	1	4	2	0	1	8	0.07%
SD7202	5	5	0	0	0	10	0.08%
SD7203	3	25	3	0	0	31	0.25%
SD7204	1	4	0	0	3	8	0.07%
SD7205	0	4	0	0	0	4	0.03%
SD7206	0	1	1	0	4	6	0.05%
SD7207	16	6	0	0	1	23	0.19%
SD7208	2	2	0	0	0	4	0.03%
SD7209	1	1	0	0	0	2	0.02%
SD7210	8	9	0	0	0	17	0.14%
SD7212	1	7	1	0	0	9	0.07%
SD7301	0	0	0	0	1	1	0.01%
SD7303	0	97	2	0	0	99	0.81%
SD7305	0	4	0	0	0	4	0.03%
SD7307	11	11	2	0	15	39	0.32%
SD7310	2	6	0	0	0	8	0.07%
SD7311	1	3	0	0	0	4	0.03%
SD7312	1	5	0	0	14	20	0.16%
SD7400	49	39	1	0	0	89	0.72%
SD7401	6	9	1	1	0	17	0.14%
SD7402	0	2	0	0	0	2	0.02%
SD7500	7	24	0	0	0	31	0.25%
SD7501	100	182	0	0	0	282	2.30%
SD7502	11	13	0	0	0	24	0.20%
SD7503	47	6	2	0	0	55	0.45%
SD7600	164	78	7	2	2	253	2.06%
SD7700	20	26	1	0	1	48	0.39%
SD7800	1	5	2	1	0	9	0.07%
SD7801	0	5	8	2	0	15	0.12%
SD7802	0	7	3	1	0	11	0.09%
SD7803	0	3	1	1	0	5	0.04%
SD7804	1	9	10	4	0	24	0.20%
MISCELLANEOUS						29	0.24%
MI9202	1	0	1	0	0	2	0.02%
MI9203	2	2	0	0	0	4	0.03%
MI9501	0	0	0	0	5	5	0.04%
MI9502	0	0	0	0	4	4	0.03%
MI9503	0	0	0	0	13	13	0.11%
MI9504	0	1	0	0	0	1	0.01%
TOTAL	5622	5441	160	17	1046	12286	100%

Non-Reportable Errors and Accidents

ERROR CODES	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
DONOR SCREENING						111	12.32%
DS1	24	5	0	0	0	29	3.22%
DS2	0	1	0	0	0	1	0.11%
DS3	4	4	0	0	0	8	0.89%
DS4	9	32	1	0	0	42	4.66%
DS6	1	1	0	0	1	3	0.33%
DS7	0	2	0	0	0	2	0.22%
DS8	0	1	0	0	8	9	1.00%
miscellaneous (MI5)	7	9	0	0	1	17	1.89%
DONOR DEFERRAL						3	0.33%
miscellaneous (MI5)	1	2	0	0	0	3	0.33%
POST DONATION INFORMATION						52	5.77%
DS5	11	34	2	0	0	47	5.22%
miscellaneous (MI5)	2	2	0	0	1	5	0.55%
COLLECTION						46	5.11%
BC1	5	3	0	0	0	8	0.89%
BC2	2	0	0	0	0	2	0.22%
BC3	34	1	1	0	0	36	4.00%
miscellaneous (MI5)	0	2	0	0	0	2	0.22%
COMPONENT PREPARATION						6	0.67%
miscellaneous (MI5)	0	6	0	0	0	6	0.67%
ROUTINE TESTING						3	0.33%
miscellaneous (MI5)	0	3	0	0	0	3	0.33%
VIRAL TESTING						9	1.00%
miscellaneous (MI5)	1	8	0	0	0	9	1.00%
LABELING						181	20.09%
LA1	13	22	2	0	0	37	4.11%
LA2	26	18	0	0	0	44	4.88%
LA3	22	9	0	0	0	31	3.44%
LA4	37	25	0	0	1	63	6.99%
miscellaneous (MI5)	2	4	0	0	0	6	0.67%
STORAGE/DISTRIBUTION						107	11.88%
DI1	34	14	1	0	0	49	5.44%
DI2	1	6	0	0	0	7	0.78%
DI3	2	3	1	0	0	6	0.67%
DI4	0	1	0	0	0	1	0.11%
DI5	2	0	0	0	0	2	0.22%
DI6	9	4	1	0	0	14	1.55%
DI7	3	1	0	0	0	4	0.44%
DI8	2	0	0	0	0	2	0.22%
DI9	1	1	0	0	0	2	0.22%
miscellaneous (MI5)	4	8	3	0	5	20	2.22%

ERROR CODES	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
MISCELLANEOUS						452	50.17%
MI1	33	17	0	0	2	52	5.77%
MI2	3	2	0	0	0	5	0.55%
MI3	30	25	2	0	4	61	6.77%
MI4	11	88	33	2	13	147	16.32%
MI5	30	5	2	0	20	128	14.21%
MI6	25	2	0	0	0	27	3.00%
QC1	22	7	2	0	1	32	3.55%
TOTAL	413	378	51	2	57	901	100%