

DATE : FEB 19 1998

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

SUBJECT: ERROR AND ACCIDENT REPORTS - ANNUAL SUMMARY FOR FY-97

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

Bevd Jogle
2/23/98

Between October 1, 1996 and September 30, 1997, the Division of Inspections and Surveillance received 6,069 error and accident reports from the American Red Cross (ARC), 5,345 error and accident reports from non-ARC licensed blood establishments, 123 error and accident reports from unlicensed registered blood establishments, 13 error and accident reports from transfusion services, 871 error and accident reports from plasma centers, 8 error and accident reports from blood derivative manufacturers, 7 error and accident report from in-vitro diagnostic manufacturers (IVD), 2 error and accident reports from vaccine manufacturers, and 3 error and accident reports from therapeutic manufacturers. A total of 12,441 error and accident reports were received. There were 1,484 (11.9%) 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, 1,345 (10.8%) 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.

As requested, the categories of errors and accidents were grouped by manufacturing systems, and the distribution of reports are as follows:

REPORTABLE ERRORS/ACCIDENTS

Donor Suitability - 68.2%	
Post Donation Information	60.1%
Donor Screening	6.5%
Donor Deferral	1.6%
Storage and Distribution	12.2%
Labeling	8.6%
Product Testing - 7.6%	
Routine Testing	3.9%
Viral Testing	3.7%
Component Preparation	2.3%
Collection	0.8%
Miscellaneous	0.3%

NON-REPORTABLE ERRORS/ACCIDENTS

Miscellaneous	41.0%
Donor Suitability - 26.7%	
Donor Screening	11.0%
Donor Deferral	7.9%
Post Donation Information	7.8%
Labeling	16.5%
Storage and Distribution	7.7%
Collection	5.4%
Product Testing - 2.3%	
Viral Testing	2.0%
Routine Testing	0.3%
Component Preparation	0.3%

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 (60.1%), Storage and Distribution (12.2%), Labeling (8.6%), and Donor Screening (6.5%) and for Non-Reportables: Miscellaneous (41.0%), Labeling (16.5%), Donor Screening (11.0%), and Post Donation Information (7.9%). 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.

As requested, 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 having received a tattoo, ear or body piercing, transfusion, or needlestick injury within one year of donation.

Of the 6658 post donation information reports received, 5251 (78.9%) reports involved the donor providing the information at a subsequent donation, 995 (14.9%) reports involved the donor calling back to the center within a few days of donating, and 412 (6.2%) reports involved a third party providing the information.

INFORMATION RECEIVED BY:	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	PLASMA CENTERS	TOTAL	
SUBSEQUENT DONATION	2764	1959	23	505	5251	78.9%
TELEPHONE CALL	613	365	11	6	995	14.9%
THIRD PARTY	167	93	4	148	412	6.2%
TOTAL	3544	2417	38	659	6658	100.0%

Of the 6658 post donation information reports received, 5274 (79.2%) reports involved information in which the donor should have known at the time of donation, such as participating in a high risk group, having a tattoo or body piercing, travel outside the United States, taking medication, etc. 1384 (20.8%) reports involved information in which the donor was not aware, such as exposure to disease, sex partner participated in high risk behavior or tested positive, post donation illness, etc.

INFORMATION	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	PLASMA CENTERS	TOTAL	
AVAILABLE, NOT PROVIDED	2765	1915	31	563	5274	79.2%
NOT KNOWN AT TIME OF DONATION	779	502	7	96	1384	20.8%
Total	3544	2417	38	659	6658	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 - Tables - Types of Errors/Accidents - American Red Cross
 - Reportable Errors/Accidents
 - Non-Reportable Errors/Accidents
 - Total Errors/Accidents
- 6 - Tables - Types of Errors/Accidents - Non-ARC Licensed Blood Banks
 - Reportable Errors/Accidents
 - Non-Reportable Errors/Accidents
 - Total Errors/Accidents
- 7 - Tables - Types of Errors/Accidents - Unlicensed Registered Blood Banks
 - Reportable Errors/Accidents
 - Non-Reportable Errors/Accidents
 - Total Errors/Accidents
- 8 - Tables - Types of Errors/Accidents - Plasma Centers
 - Reportable Errors/Accidents
 - Non-Reportable Errors/Accidents
 - Total Errors/Accidents
- 9 - Pie chart - All Blood and Plasma Establishments
 - Total Reports
 - Potential Recalls
- 10 - Pie charts - Types of Total Errors/Accidents by Establishment
- 11 - Pie charts - Blood Banks versus Plasma Centers
- 12 - Pie charts - Blood Banks versus Plasma Centers
 - Licensed Blood Banks, Unlicensed Blood Banks, Plasma Centers
- 13 - Pie charts - Reportable versus Non-Reportable Errors/Accidents
- 14 - Pie charts - Types of Reportable Errors/Accidents by Establishment
- 15 (5 pages) - Tables - Post Donation Information Reports
- 16 (3 pages) - Tables - Storage/Distribution Errors/Accidents
- 17 (2 pages) - Tables - Labeling Errors/Accidents
- 18 (3 pages) - Tables - Donor Screening Errors/Accidents
- 19 - Pie charts - Non-Reportable Errors/Accident by Establishment
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- 28 - Line graph - Reporting Time - All Blood Establishments
- 29 - Line graph - Reporting Time - American Red Cross
- 30 - Line graph - Reporting Time - Non-ARC Licensed Blood Banks
- 31 - Line graph - Reporting Time - Unlicensed Blood Banks
- 32 - Line graph - Reporting Time - Plasma Centers
- 33 - Line graph - Reporting Time - All Licensed Blood Banks
- 34 (10 pages) - List of Reportable Error/Accident Codes
- 35 (2 pages) - List of Non-Reportable Error/Accident Codes
- 36 (6 pages) - Table - Number of Reportable Errors/Accidents by Establishment
- 37 (2 pages) - Table - Number of Non-Reportable Errors/Accident by Establishments

**ERROR AND ACCIDENT REPORTS
RECEIVED 10/1/96 - 9/30/97**

	TOTAL REPORTS	POTENTIAL RECALLS	% RECALLS
AMERICAN RED CROSS	6069	416	6.9%
NON-ARC LICENSED BLOOD BANKS	5345	949	17.8%
UNLICENSED BLOOD BANKS	123	12	9.1%
TRANSFUSION SERVICES	13	1	11.1%
PLASMA CENTERS	871	100	11.5%
BLOOD DERIVATIVE MANUFACTURER	8	3	37.5%
IN-VITRO DIAGNOSTIC MANUFACTURER	7	3	42.9%
VACCINE MANUFACTURER	2	0	0.0%
ALLERGENICS MANUFACTURER	0	0	0.0%
THERAPEUTIC MANUFACTURER	3	0	0.0%
TOTAL	12441	1484	11.9%

	TOTAL REPORTS	REPORTABLE	%REPORT
AMERICAN RED CROSS	6069	5566	91.7%
NON-ARC LICENSED BLOOD BANKS	5345	4545	85.0%
UNLICENSED BLOOD BANKS	123	108	87.8%
TRANSFUSION SERVICES	13	13	100.0%
PLASMA CENTERS	871	844	96.9%
BLOOD DERIVATIVE MANUFACTURER	8	8	100.0%
IN-VITRO DIAGNOSTIC MANUFACTURER	7	7	100.0%
VACCINE MANUFACTURER	2	2	100.0%
ALLERGENICS MANUFACTURER	0	0	0.0%
THERAPEUTIC MANUFACTURER	3	3	100.0%
TOTAL	12441	11096	89.2%

	TOTAL REPORTS	NON- REPORTABLE	% NON- REPORTABLE
AMERICAN RED CROSS	6069	503	8.3%
NON-ARC LICENSED BLOOD BANKS	5345	800	15.0%
UNLICENSED BLOOD BANKS	123	15	12.2%
TRANSFUSION SERVICES	13	0	0.0%
PLASMA CENTERS	871	27	3.1%
BLOOD DERIVATIVE MANUFACTURER	8	0	0.0%
IN-VITRO DIAGNOSTIC MANUFACTURER	7	0	0.0%
VACCINE MANUFACTURER	2	0	0.0%
ALLERGENICS MANUFACTURER	0	0	0.0%
THERAPEUTIC MANUFACTURER	3	0	0.0%
TOTAL	12441	1345	10.8%

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

BLOOD AND PLASMA MANUFACTURERS
TOTAL ERRORS AND ACCIDENTS

	ARC	NON-ARC LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
TYPE OF ERROR/ACCIDENT							
ROUTINE TESTING	212	200	15	2	2	431	3.5%
VIRAL TESTING	42	387	5	0	6	440	3.5%
COLLECTION	118	40	5	0	3	166	1.3%
COMPONENT PREPARATION	132	121	2	1	0	256	2.1%
LABELING	559	591	12	4	3	1169	9.4%
DONOR SCREENING	344	455	7	0	61	867	7.0%
DONOR DEFERRAL	43	225	2	0	12	282	2.3%
POST DONATION INFO	3581	2481	38	0	664	6764	54.5%
STORAGE/DISTRIBUTION	829	516	28	6	78	1457	11.7%
MISCELLANEOUS	209	329	9	0	42	589	4.7%
TOTAL	6069	5345	123	13	871	12421	100%

BLOOD AND PLASMA MANUFACTURERS
POTENTIAL RECALLS

	ARC	NON-ARC LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
TYPE OF ERROR/ACCIDENT							
ROUTINE TESTING	4	3	0	0	0	7	0.5%
VIRAL TESTING	13	313	0	0	5	331	22.4%
COLLECTION	17	18	0	0	1	36	2.4%
COMPONENT PREPARATION	78	76	1	1	0	156	10.6%
LABELING	40	100	0	0	1	141	9.5%
DONOR SCREENING	162	190	3	0	26	381	25.8%
DONOR DEFERRAL	33	115	0	0	4	152	10.3%
POST DONATION INFO	1	0	0	0	0	1	0.1%
STORAGE/DISTRIBUTION	68	134	8	0	63	273	18.5%
MISCELLANEOUS	0	0	0	0	0	0	0.0%
TOTAL	416	949	12	1	100	1478	100.0%

BLOOD AND PLASMA MANUFACTURERS
REPORTABLE ERRORS AND ACCIDENTS

	ARC	NON-ARC LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
TYPE OF ERROR/ACCIDENT							
ROUTINE TESTING	210	198	15	2	2	427	3.9%
VIRAL TESTING	40	362	5	0	6	413	3.7%
COLLECTION	51	35	5	0	2	93	0.8%
COMPONENT PREPARATION	132	118	1	1	0	252	2.3%
LABELING	468	462	10	4	3	947	8.6%
DONOR SCREENING	291	368	5	0	56	720	6.5%
DONOR DEFERRAL	43	121	2	0	10	176	1.6%
POST DONATION INFO	3544	2417	38	0	659	6658	60.1%
STORAGE/DISTRIBUTION	785	457	27	6	78	1353	12.2%
MISCELLANEOUS	2	7	0	0	28	37	0.3%
TOTAL	5566	4545	108	13	844	11076	100.0%

BLOOD AND PLASMA MANUFACTURERS
NON-REPORTABLE ERRORS AND ACCIDENTS

	ARC	NON-ARC LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
TYPE OF ERROR/ACCIDENT							
ROUTINE TESTING	2	2	0	0	0	4	0.3%
VIRAL TESTING	2	25	0	0	0	27	2.0%
COLLECTION	67	5	0	0	1	73	5.4%
COMPONENT PREPARATION	0	3	1	0	0	4	0.3%
LABELING	91	129	2	0	0	222	16.5%
DONOR SCREENING	53	88	2	0	5	148	11.0%
DONOR DEFERRAL	0	104	0	0	2	106	7.9%
POST DONATION INFO	37	63	0	0	5	105	7.8%
STORAGE/DISTRIBUTION	44	59	1	0	0	104	7.7%
MISCELLANEOUS	207	322	9	0	14	552	41.0%
TOTAL	503	800	15	0	27	1345	100%

NON-BLOOD MANUFACTURERS

TYPE OF ERROR/ACCIDENT	IN-VITRO DIAGNOSTIC		DERIVATIVE		VACCINE		THERAPEUTIC		TOTAL REPORTS		POTENTIAL RECALL	
	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL	TOTAL	RECALL				
REAGENT PERFORMANCE	6	3	0	0	0	0	0	0	6	30.0%	3	50.0%
STERILITY COMPROMISED	0	0	2	1	1	0	1	0	4	20.0%	1	16.7%
LABELING	1	0	1	1	0	0	0	0	2	10.0%	1	16.7%
MISCELLANEOUS	0	0	5	1	1	0	2	0	8	40.0%	1	16.7%
TOTAL	7	3	8	3	2	0	3	0	20	100.0%	6	100.0%

*MISCELLANEOUS include:

Source material withdrawn due to CJD risk

Reconstituted conjugate expiration dating problem

Temperature deviations during solvent detergent treatment

Product specification below acceptable range

Decrease in potency

AMERICAN RED CROSS
REPORTABLE ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	58	68	45	39	210	3.8%
VIRAL TESTING	14	13	7	6	40	0.7%
COLLECTION	18	13	10	10	51	0.9%
COMPONENT PREPARATION	33	42	27	30	132	2.4%
LABELING	131	112	113	112	468	8.4%
DONOR SCREENING	59	64	70	98	291	5.2%
DONOR DEFERRAL	11	10	13	9	43	0.8%
POST DONATION INFO	972	824	866	882	3544	63.7%
STORAGE/DISTRIBUTION	372	186	124	103	785	14.1%
MISCELLANEOUS	0	0	2	0	2	0.0%
TOTAL	1668	1332	1277	1289	5566	100.0%

AMERICAN RED CROSS
NON-REPORTABLE ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	2	0	0	0	2	0.4%
VIRAL TESTING	2	0	0	0	2	0.4%
COLLECTION	15	12	23	17	67	13.3%
COMPONENT PREPARATION	0	0	0	0	0	0.0%
LABELING	25	27	21	18	91	18.1%
DONOR SCREENING	19	17	11	6	53	10.5%
DONOR DEFERRAL	0	0	0	0	0	0.0%
POST DONATION INFO	16	10	9	2	37	7.4%
STORAGE/DISTRIBUTION	14	16	6	8	44	8.7%
MISCELLANEOUS	73	48	48	38	207	41.2%
TOTAL	166	130	118	89	503	100.0%

AMERICAN RED CROSS
TOTAL ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	60	68	45	39	212	3.5%
VIRAL TESTING	16	13	7	6	42	0.7%
COLLECTION	33	25	33	27	118	1.9%
COMPONENT PREPARATION	33	42	27	30	132	2.2%
LABELING	156	139	134	130	559	9.2%
DONOR SCREENING	78	81	81	104	344	5.7%
DONOR DEFERRAL	11	10	13	9	43	0.7%
POST DONATION INFO	988	834	875	884	3581	59.0%
STORAGE/DISTRIBUTION	386	202	130	111	829	13.7%
MISCELLANEOUS	73	48	50	38	209	3.4%
TOTAL	1834	1462	1395	1378	6069	100.0%

NON-ARC LICENSED BLOOD BANKS
REPORTABLE ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	57	50	42	49	198	4.4%
VIRAL TESTING	126	88	99	49	362	8.0%
COLLECTION	16	7	3	9	35	0.8%
COMPONENT PREPARATION	42	36	20	20	118	2.6%
LABELING	111	144	96	111	462	10.2%
DONOR SCREENING	82	92	93	101	368	8.1%
DONOR DEFERRAL	44	16	31	30	121	2.7%
POST DONATION INFO	576	569	636	636	2417	53.2%
STORAGE/DISTRIBUTION	99	125	121	112	457	10.1%
MISCELLANEOUS	4	0	2	1	7	0.2%
TOTAL	1157	1127	1143	1118	4545	100.0%

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

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	0	2	0	0	2	0.3%
VIRAL TESTING	12	3	9	1	25	3.1%
COLLECTION	1	2	0	2	5	0.6%
COMPONENT PREPARATION	2	0	1	0	3	0.4%
LABELING	36	47	26	20	129	16.1%
DONOR SCREENING	33	21	21	13	88	11.0%
DONOR DEFERRAL	94	6	2	2	104	13.0%
POST DONATION INFO	14	24	19	6	63	7.9%
STORAGE/DISTRIBUTION	14	16	13	16	59	7.4%
MISCELLANEOUS	221	42	27	32	322	40.3%
TOTAL	427	163	118	92	800	100.0%

NON-ARC LICENSED BLOOD BANKS
TOTAL ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	57	52	42	49	200	3.7%
VIRAL TESTING	138	91	108	50	387	7.2%
COLLECTION	17	9	3	11	40	0.7%
COMPONENT PREPARATION	44	36	21	20	121	2.3%
LABELING	147	191	122	131	591	11.1%
DONOR SCREENING	115	113	114	114	456	8.5%
DONOR DEFERRAL	138	22	33	32	225	4.2%
POST DONATION INFO	590	593	655	642	2480	46.4%
STORAGE/DISTRIBUTION	113	141	134	128	516	9.7%
MISCELLANEOUS	225	42	29	33	329	6.2%
TOTAL	1584	1290	1261	1210	5345	100.0%

UNLICENSED BLOOD BANKS
REPORTABLE ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	6**	7	3	1	17	14.0%
VIRAL TESTING	1	0	3	1	5	4.1%
COLLECTION	2	0	1	2	5	4.1%
COMPONENT PREPARATION	0	0	2*	0	2	1.7%
LABELING	2	3	8***	1	14	11.6%
DONOR SCREENING	1	0	1	3	5	4.1%
DONOR DEFERRAL	0	1	1	0	2	1.7%
POST DONATION INFO	15	7	10	6	38	31.4%
STORAGE/DISTRIBUTION	9*	10**	7*	7**	33	27.3%
MISCELLANEOUS	0	0	0	0	0	0.0%
TOTAL	36	28	36	21	121	100.0%

*Includes 1 report from transfusion services **Includes 2 reports from transfusion services *** Includes 4 reports from transfusion services

UNLICENSED BLOOD BANKS
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	1	0	0	1	6.7%
LABELING	1	0	1	0	2	13.3%
DONOR SCREENING	0	0	1	1	2	13.3%
DONOR DEFERRAL	0	0	0	0	0	0.0%
POST DONATION INFO	0	0	0	0	0	0.0%
STORAGE/DISTRIBUTION	1	0	0	0	1	6.7%
MISCELLANEOUS	3	3	2	1	9	60.0%
TOTAL	5	4	4	2	15	100.0%

UNLICENSED BLOOD BANKS
TOTAL ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	6**	7	3	1	17	12.5%
VIRAL TESTING	1	0	3	1	5	3.7%
COLLECTION	2	0	1	2	5	3.7%
COMPONENT PREPARATION	0	1	2*	0	3	2.2%
LABELING	3	3	9***	1	16	11.8%
DONOR SCREENING	1	0	2	4	7	5.1%
DONOR DEFERRAL	0	1	1	0	2	1.5%
POST DONATION INFO	15	7	10	6	38	27.9%
STORAGE/DISTRIBUTION	10*	10**	7*	7**	34	25.0%
MISCELLANEOUS	3	3	2	1	9	6.6%
TOTAL	41	32	40	23	136	100.0%

*Includes 1 report from transfusion services **Includes 2 reports from transfusion services *** Includes 4 reports from transfusion services

PLASMA CENTERS
REPORTABLE ERRORS AND ACCIDENTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	1	0	0	1	2	0.2%
VIRAL TESTING	1	1	1	3	6	0.7%
COLLECTION	0	0	1	1	2	0.2%
COMPONENT PREPARATION	0	0	0	0	0	0.0%
LABELING	0	0	1	2	3	0.4%
DONOR SCREENING	18	8	12	18	56	6.6%
DONOR DEFERRAL	6	3	0	1	10	1.2%
POST DONATION INFO	105	162	187	205	659	78.1%
STORAGE/DISTRIBUTION	20	16	11	31	78	9.2%
MISCELLANEOUS	8	4	6	10	28	3.3%
TOTAL	159	194	219	272	844	100.0%

PLASMA CENTERS
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	1	0	1	3.7%
COMPONENT PREPARATION	0	0	0	0	0	0.0%
LABELING	0	0	0	0	0	0.0%
DONOR SCREENING	0	0	2	3	5	18.5%
DONOR DEFERRAL	1	0	0	0	1	3.7%
POST DONATION INFO	2	0	3	1	6	22.2%
STORAGE/DISTRIBUTION	0	0	0	0	0	0.0%
MISCELLANEOUS	9	2	2	1	14	51.9%
TOTAL	12	2	8	5	27	100.0%

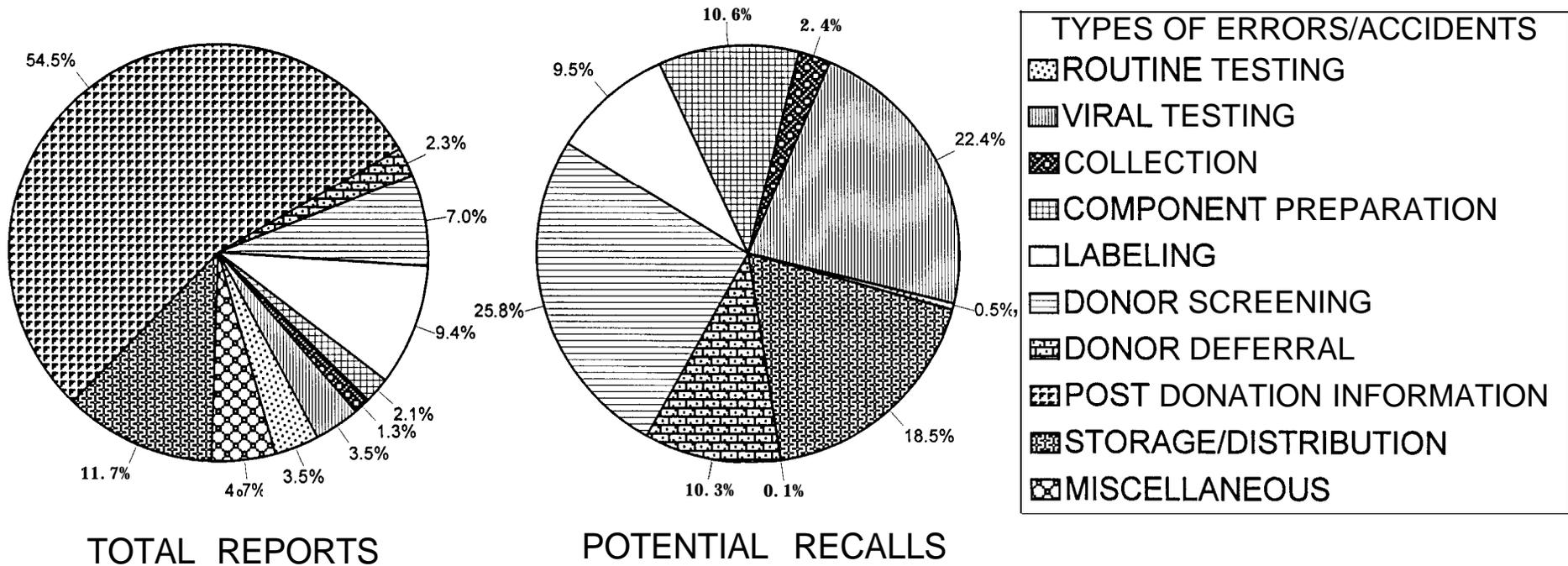
PLASMA CENTERS
TOTAL ERROR AND ACCIDENT REPORTS

TYPE OF ERROR/ACCIDENT	QUARTER				TOTAL	PERCENT
	FIRST	SECOND	THIRD	FOURTH		
ROUTINE TESTING	1	0	0	1	2	0.2%
VIRAL TESTING	1	1	1	3	6	0.7%
COLLECTION	0	0	2	1	3	0.3%
COMPONENT PREPARATION	0	0	0	0	0	0.0%
LABELING	0	0	1	2	3	0.3%
DONOR SCREENING	18	8	14	21	61	7.0%
DONOR DEFERRAL	7	3	0	1	11	1.3%
POST DONATION INFO	107	162	190	206	665	76.3%
STORAGE/DISTRIBUTION	20	16	11	31	78	9.0%
MISCELLANEOUS	17	6	8	11	42	4.8%
TOTAL	171	196	227	277	871	100.0%

ERROR AND ACCIDENT REPORTS

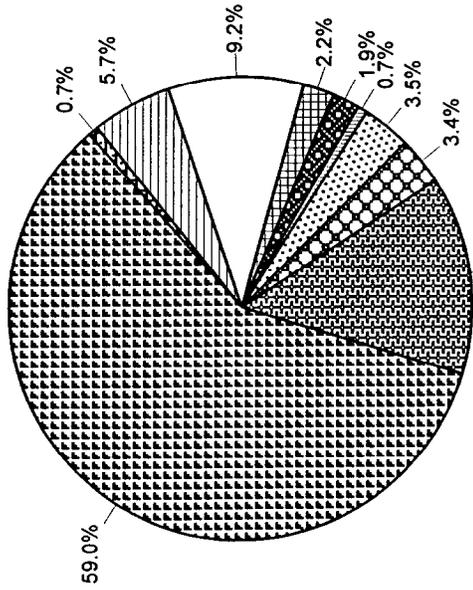
ALL BLOOD AND PLASMA ESTABLISHMENTS

FY97

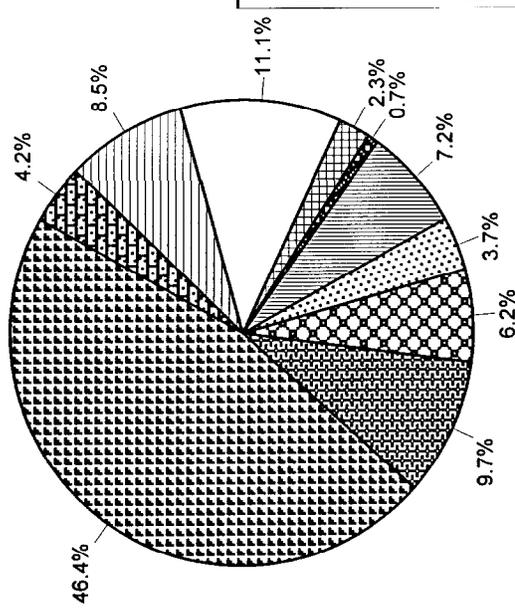


TOTAL REPORTS RECEIVED (10/1/96 - 9/30/97) = 72,427
 POTENTIAL RECALLS = 7,478

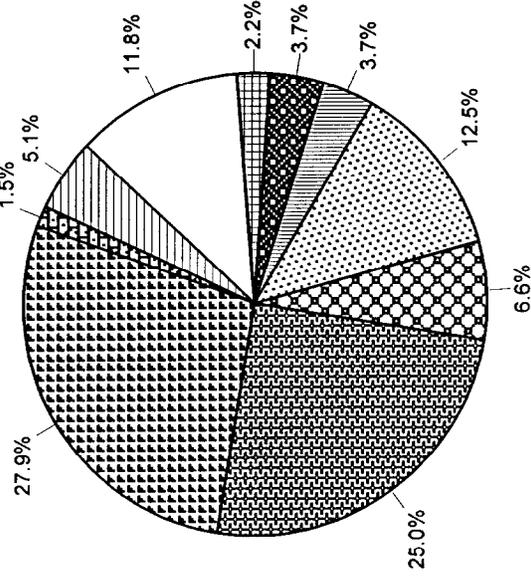
ERROR AND ACCIDENT REPORTS FY97



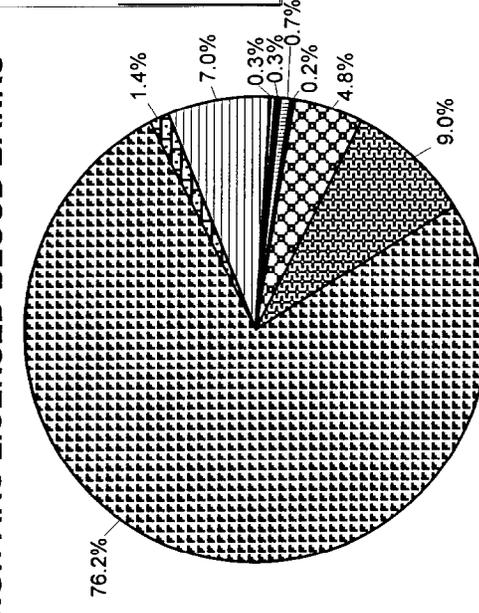
AMERICAN RED CROSS



NON-ARC LICENSED BLOOD BANKS



UNLICENSED BLOOD BANKS



PLASMA CENTERS

TYPES OF ERRORS/ACCIDENTS

ROUTINE TESTING

VIRAL TESTING

COLLECTION

COMPONENT PREPARATION

LABELING

DONOR SCREENING

DONOR DEFERRAL

POST DONATION INFORMATION

STORAGE/DISTRIBUTION

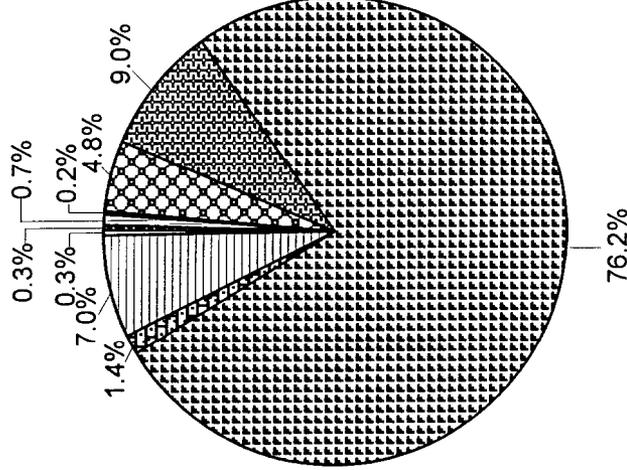
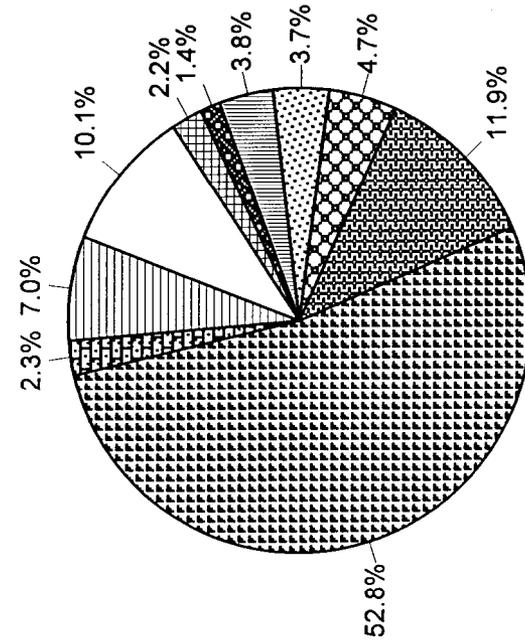
MISCELLANEOUS

REPORTS RECEIVED (10/1/96 - 9/30/97) = 12,421

ARC = 6,069; NON-ARC LICENSED BLOOD BANKS = 5,345; UNLICENSED BLOOD BANKS = 136; PLASMA CENTERS = 871

ERROR AND ACCIDENT REPORTS BLOOD BANKS VERSUS PLASMA CENTERS

FY97



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

BLOOD BANKS

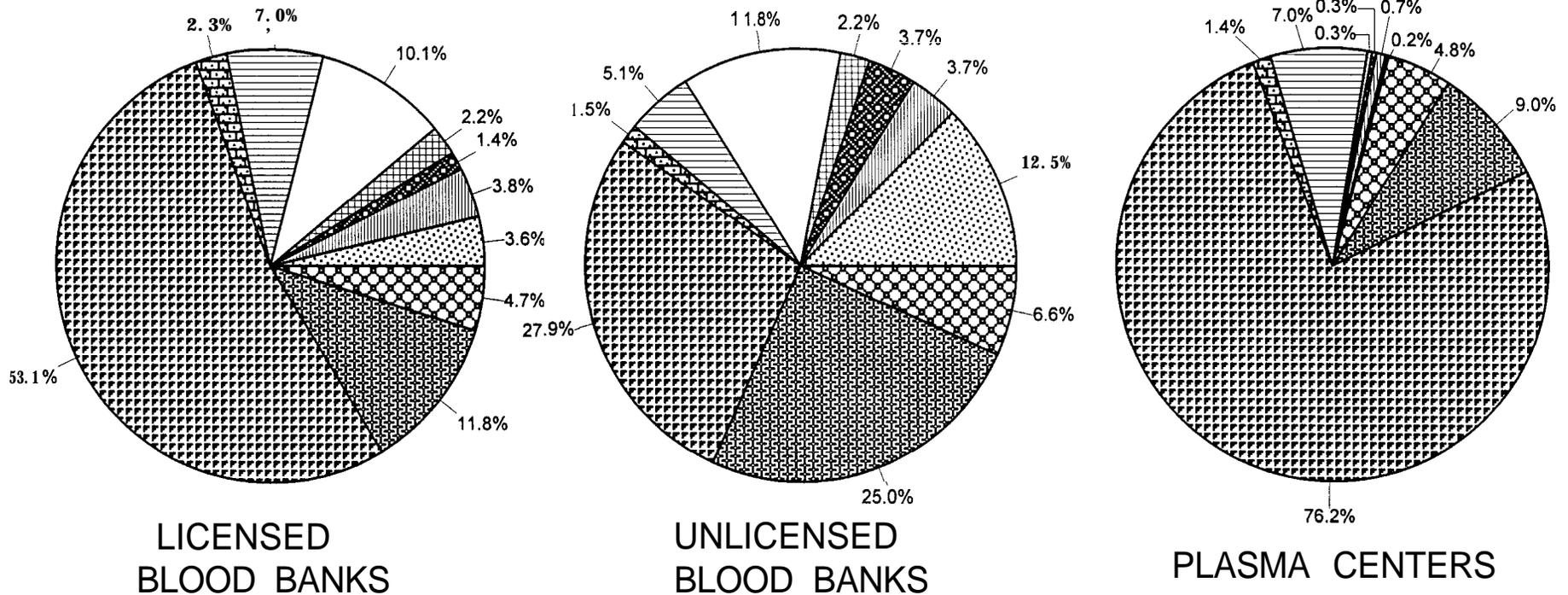
PLASMA CENTERS

REPORTS RECEIVED 10/1/96 - 9/30/97
 BLOOD BANKS = 11,550
 PLASMA CENTERS = 871

ERROR AND ACCIDENT REPORTS

BLOOD BANKS VERSUS PLASMA CENTERS

FY97



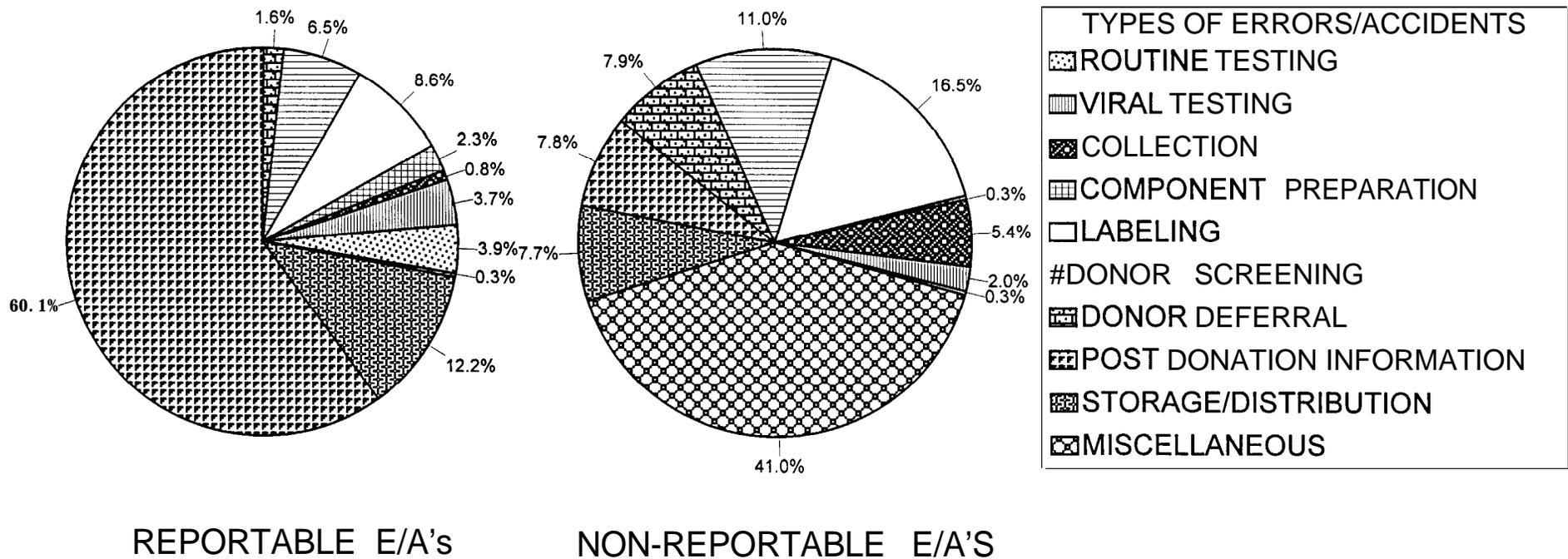
TYPES OF ERRORS/ACCIDENTS			
	ROUTINE TESTING		VIRAL TESTING
	COMPONENT PREPARATION		LABELING
	DONOR DEFERRAL		POST DONATION INFORMATION
	MISCELLANEOUS		STORAGE/DISTRIBUTION
			COLLECTION
			DONOR SCREENING

REPORTS RECEIVED 10/1/96 - 9/30/97
 LICENSED BLOOD BANKS = 71,414
 UNLICENSED BLOOD BANKS = 736
 PLASMA CENTERS = 871

ERROR AND ACCIDENT REPORTS

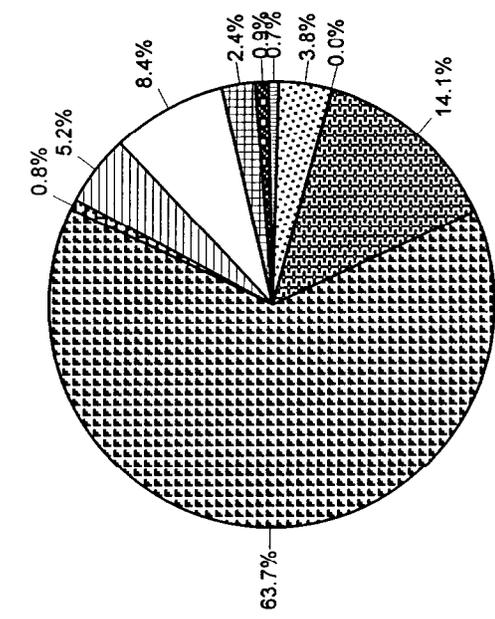
ALL BLOOD AND PLASMA ESTABLISHMENTS

FY97

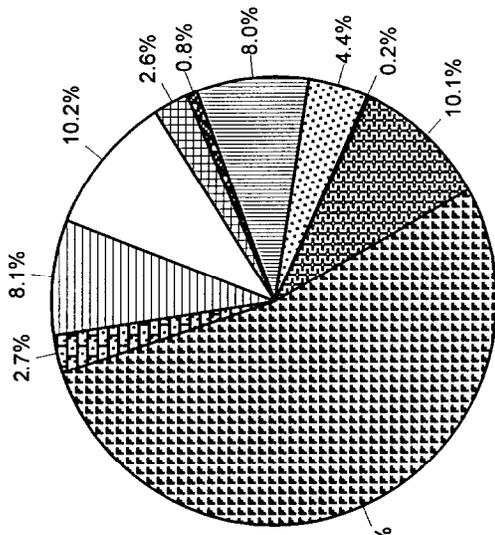


REPORTS RECEIVED (10/1/96 - 9/30/97)
 REPORTABLE ERRORS/ACCIDENTS = 1 7,076
 NON-REPORTABLE ERRORS/ACCIDENTS = 1345

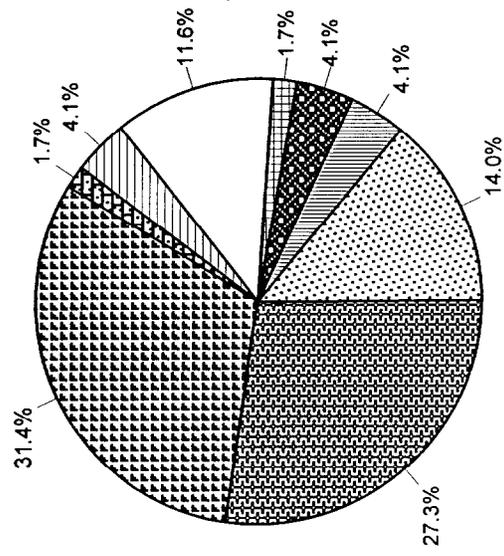
ERROR AND ACCIDENT REPORTS REPORTABLE ERRORS/ACCIDENTS-FY97



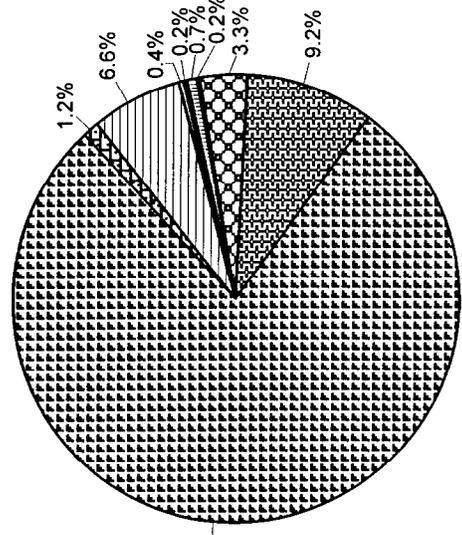
AMERICAN RED CROSS



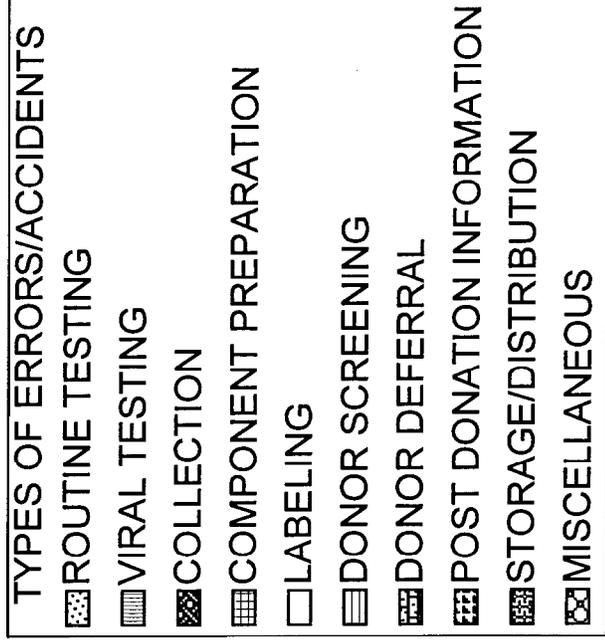
NON-ARC LICENSED BLOOD BANKS



UNLICENSED BLOOD BANKS



PLASMA CENTERS



REPORTS RECEIVED (10/1/96 - 9/30/97) = 11,076
 ARC = 5566; NON-ARC LICENSED BLOOD BANKS = 4545; UNLICENSED BLOOD BANKS = 121; PLASMA CENTERS = 844

Of the 11,076 reportable error and accident reports received from blood and plasma establishments, 6658 (60.1%) reports involved post donation information. 5999 (90.1%) reports were submitted by blood establishments and 659 (9.9%) were submitted from plasma centers. The following 3 tables represent the type of post donation information reported in order of prevalence.

POST DONATION INFORMATION REPORTS - TABLE 1

POST DONATION INFORMATION RECEIVED	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
TATTOO, EARPIERCING, NEEDLESTICK, TRANSFUSION	965	16.1%	131	19.9%	1096	16.5%
TRAVEL TO MALARIAL ENDEMIC AREA	848	14.1%	2	0.3%	850	12.8%
ILLNESS (NOT AIDS OR HEPATITIS RELATED)	784	13.1%	2	0.3%	786	11.8%
HISTORY OF CANCER	581	9.7%	6	0.9%	587	8.8%
IV DRUG USE	340	5.7%	80	12.1%	420	6.3%
HISTORY OF DISEASE/SURGERY	340	5.7%	5	0.8%	345	5.2%
MALE TO MALE SEX	211	3.5%	28	4.2%	239	3.6%
RISK FACTOR ASSOCIATED WITH CJD	237	4.0%	2	0.3%	239	3.6%
HISTORY OF HEPATITIS B/C OR JAUNDICE	209	3.5%	22	3.3%	231	3.5%
HIGH RISK BEHAVIOR-NOT SPECIFIED	123	2.1%	87	13.2%	210	3.2%
SEX PARTNER TESTS POSITIVE FOR HEPATITIS	182	3.0%	18	2.7%	200	3.0%
SEX WITH AN IV DRUG USER	153	2.6%	20	3.0%	173	2.6%
HISTORY OF INCARCERATION	23	0.4%	150	22.8%	173	2.6%
RECEIVED MEDICATION OR ANTIBIOTICS	129	2.2%	3	0.5%	132	2.0%
NON-SEXUAL EXPOSURE TO HEPATITIS B/C	118	2.0%	5	0.8%	123	1.8%
RECEIVED PROSCAR, TEGISON, OR ACCUTANE	111	1.9%	0	0.0%	111	1.7%
EXPOSURE TO HEPATITIS A	95	1.6%	2	0.3%	97	1.5%
TRAVEL TO OR IMMIGRATION FROM HIGH RISK AREA (HEPATITIS OR AIDS)	63	1.1%	17	2.6%	80	1.2%
HISTORY OF HEPATITIS A	62	1.0%	7	1.1%	69	1.0%
SEX PARTNER TESTS POSITIVE FOR HIV/HTLV	38	0.6%	27	4.1%	65	1.0%
EXCHANGED SEX FOR DRUGS/MONEY	51	0.9%	13	2.0%	64	1.0%
HEPATITIS RELATED ILLNESS	52	0.9%	8	1.2%	60	0.9%
RECEIVED VACCINE OR IMMUNE GLOBULIN	51	0.9%	1	0.2%	52	0.8%
"DO NOT USE MY BLOOD"	48	0.8%	0	0.0%	48	0.7%
FEMALE HAD SEX WITH MALE WHO HAD SEX WITH ANOTHER MALE	42	0.7%	2	0.3%	44	0.7%
RECEIVED GROWTH HORMONE	38	0.6%	1	0.2%	39	0.6%
SEXUALLY TRANSMITTED DISEASE/POSITIVE STS	28	0.5%	3	0.5%	31	0.5%
AIDS RELATED ILLNESS	19	0.3%	4	0.6%	23	0.3%
INFORMATION NOT RELATED TO HEPATITIS OR AIDS	14	0.2%	7	1.1%	21	0.3%
EXPOSURE TO A DISEASE	13	0.2%	2	0.3%	15	0.2%
RESIDED IN REHABILITATION CENTER	11	0.2%	3	0.5%	14	0.2%
NON-SEXUAL EXPOSURE TO HIV	7	0.1%	0	0.0%	7	0.1%
RECEIVED METHOTREXATE	6	0.1%	0	0.0%	6	0.1%
SEX PARTNER HAS SEXUALLY TRANSMITTED DISEASE	3	0.1%	1	0.2%	4	0.1%
HISTORY OF CJD	4	0.1%	0	0.0%	4	0.1%
TOTAL	5999	100.0%	659	100.0%	6658	100.0%

POST DONATION INFORMATION REPORTS - TABLE 2

POST DONATION INFORMATION RECEIVED	BLOOD ESTABLISHMENTS		TOTAL	
TATTOO, EARPIERCING, NEEDLESTICK, TRANSFUSION	965	16.1%	1096	16.5%
TRAVEL TO MALARIAL ENDEMIC AREA	848	14.1%	850	12.8%
ILLNESS (NOT AIDS OR HEPATITIS RELATED)	784	13.1%	786	11.8%
HISTORY OF CANCER	581	9.7%	587	8.8%
IV DRUG USE	340	5.7%	420	6.3%
HISTORY OF DISEASE/SURGERY	340	5.7%	345	5.2%
RISK FACTOR ASSOCIATED WITH CJD	237	4.0%	239	3.6%
MALE TO MALE SEX	211	3.5%	239	3.6%
HISTORY OF HEPATITIS B/C OR JAUNDICE	209	3.5%	231	3.5%
SEX PARTNER TESTS POSITIVE FOR HEPATITIS	182	3.0%	200	3.0%
SEX WITH AN IV DRUG USER	153	2.6%	173	2.6%
RECEIVED MEDICATION OR ANTIBIOTICS	129	2.2%	132	2.0%
HIGH RISK BEHAVIOR-NOT SPECIFIED	123	2.1%	210	3.2%
NON-SEXUAL EXPOSURE TO HEPATITIS B/C	118	2.0%	123	1.8%
RECEIVED PROSCAR, TEGISON, OR ACCUTANE	111	1.9%	111	1.7%
EXPOSURE TO HEPATITIS A	95	1.6%	97	1.5%
TRAVEL TO OR IMMIGRATION FROM HIGH RISK AREA (HEPATITIS OR AIDS)	63	1.1%	80	1.2%
HISTORY OF HEPATITIS A	62	1.0%	69	1.0%
HEPATITIS RELATED ILLNESS	52	0.9%	60	0.9%
EXCHANGED SEX FOR DRUGS/MONEY	51	0.9%	64	1.0%
RECEIVED VACCINE OR IMMUNE GLOBULIN	51	0.9%	52	0.8%
"DO NOT USE MY BLOOD"	48	0.8%	48	0.7%
FEMALE HAD SEX WITH MALE WHO HAD SEX WITH ANOTHER MALE	42	0.7%	44	0.7%
SEX PARTNER TESTS POSITIVE FOR HIV/HTLV	38	0.6%	65	1.0%
RECEIVED GROWTH HORMONE	38	0.6%	39	0.6%
SEXUALLY TRANSMITTED DISEASE/POSITIVE STS	28	0.5%	31	0.5%
HISTORY OF INCARCERATION	23	0.4%	173	2.6%
AIDS RELATED ILLNESS	19	0.3%	23	0.3%
INFORMATION NOT RELATED TO HEPATITIS OR AIDS	14	0.2%	21	0.3%
EXPOSURE TO A DISEASE	13	0.2%	15	0.2%
RESIDED IN REHABILITATION CENTER	11	0.2%	14	0.2%
NON-SEXUAL EXPOSURE TO HIV	7	0.1%	7	0.1%
RECEIVED METHOTREXATE	6	0.1%	6	0.1%
HISTORY OF CJD	4	0.1%	4	0.1%
SEX PARTNER HAS SEXUALLY TRANSMITTED DISEASE	3	0.1%	4	0.1%
TOTAL	5999	100.0%	6658	100.0%

POST DONATION INFORMATION REPORTS - TABLE 3

POST DONATION INFORMATION RECEIVED	PLASMA CENTERS		TOTAL	
HISTORY OF INCARCERATION	150	22.8%	173	2.6%
TATTOO, EARPIERCING, NEEDLESTICK, TRANSFUSION	131	19.9%	1096	16.5%
HIGH RISK BEHAVIOR-NOT SPECIFIED	87	13.2%	210	3.2%
IV DRUG USE	80	12.1%	420	6.3%
MALE TO MALE SEX	28	4.2%	239	3.6%
SEX PARTNER TESTS POSITIVE FOR HIV/HTLV	27	4.1%	65	1.0%
HISTORY OF HEPATITIS B/C OR JAUNDICE	22	3.3%	231	3.5%
SEX WITH AN IV DRUG USER	20	3.0%	173	2.6%
SEX PARTNER TESTS POSITIVE FOR HEPATITIS	18	2.7%	200	3.0%
TRAVEL TO OR IMMIGRATION FROM HIGH RISK AREA (HEPATITIS OR AIDS)	17	2.6%	80	1.2%
EXCHANGED SEX FOR DRUGS/MONEY	13	2.0%	64	1.0%
HEPATITIS RELATED ILLNESS	8	1.2%	60	0.9%
INFORMATION NOT RELATED TO HEPATITIS OR AIDS	7	1.1%	21	0.3%
HISTORY OF HEPATITIS A	7	1.1%	69	1.0%
HISTORY OF CANCER	6	0.9%	587	8.8%
NON-SEXUAL EXPOSURE TO HEPATITIS B/C	5	0.8%	123	1.8%
HISTORY OF DISEASE/SURGERY	5	0.8%	345	5.2%
AIDS RELATED ILLNESS	4	0.6%	23	0.3%
SEXUALLY TRANSMITTED DISEASE/POSITIVE STS	3	0.5%	31	0.5%
RECEIVED MEDICATION OR ANTIBIOTICS	3	0.5%	132	2.0%
RESIDED IN REHABILITATION CENTER	3	0.5%	14	0.2%
ILLNESS (NOT AIDS OR HEPATITIS RELATED)	2	0.3%	786	11.8%
FEMALE HAD SEX WITH MALE WHO HAD SEX WITH ANOTHER MALE	2	0.3%	44	0.7%
TRAVEL TO MALARIAL ENDEMIC AREA	2	0.3%	850	12.8%
RISK FACTOR ASSOCIATED WITH CJD	2	0.3%	239	3.6%
EXPOSURE TO A DISEASE	2	0.3%	15	0.2%
EXPOSURE TO HEPATITIS A	2	0.3%	97	1.5%
SEX PARTNER HAS SEXUALLY TRANSMITTED DISEASE	1	0.2%	4	0.1%
RECEIVED GROWTH HORMONE	1	0.2%	39	0.6%
RECEIVED VACCINE OR IMMUNE GLOBULIN	1	0.2%	52	0.8%
"DO NOT USE MY BLOOD"	0	0.0%	48	0.7%
NON-SEXUAL EXPOSURE TO HIV	0	0.0%	7	0.1%
HISTORY OF CJD	0	0.0%	4	0.1%
RECEIVED PROSCAR, TEGISON, OR ACCUTANE	0	0.0%	111	1.7%
RECEIVED METHOTREXATE	0	0.0%	6	0.1%
TOTAL	659	100.0%	6658	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	
TATTOO, EAR/BODY PIERCING, NEEDLESTICK, OR TRANSFUSION	962	20.4%	130	23.1%	1092	20.7%
TRAVEL TO MALARIAL ENDEMIC AREA	845	17.9%	2	0.4%	847	16.1%
HISTORY OF CANCER	451	9.6%	3	0.5%	454	8.6%
IV DRUG USE	340	7.2%	79	14.0%	419	7.9%
HISTORY OF DISEASE/SURGERY	328	7.0%	5	0.9%	333	6.3%
MALE TO MALE SEX	211	4.5%	28	5.0%	239	4.5%
HISTORY OF HEPATITIS B/C OR JAUNDICE	205	4.4%	21	3.7%	226	4.3%
RISK FACTOR ASSOCIATED WITH CJD	200	4.2%	1	0.2%	201	3.8%
HISTORY OF INCARCERATION	23	0.5%	150	26.6%	173	3.3%
HIGH RISK BEHAVIOR, NOT SPECIFIED	108	2.3%	60	10.7%	168	3.2%
SEX WITH AN IV DRUG USER	132	2.8%	16	2.8%	148	2.8%
TOTAL	3805	80.8%	495	87.9%	4300	81.5%

Table 2

POST DONATION INFORMATION	BLOOD ESTABLISHMENTS		TOTAL	
TATTOO, EAR/BODY PIERCING, NEEDLESTICK, OR TRANSFUSION	962	20.4%	1092	20.7%
TRAVEL TO MALARIAL ENDEMIC AREA	845	17.9%	847	16.1%
HISTORY OF CANCER	451	9.6%	454	8.6%
IV DRUG USE	340	7.2%	419	7.9%
HISTORY OF DISEASE/SURGERY	328	7.0%	333	6.3%
MALE TO MALE SEX	211	4.5%	239	4.5%
HISTORY OF HEPATITIS B/C OR JAUNDICE	205	4.4%	226	4.3%
RISK FACTOR ASSOCIATED WITH CJD	200	4.2%	201	3.8%
SEX WITH AN IV DRUG USER	132	2.8%	148	2.8%
RECEIVED MEDICATION OR ANTIBIOTICS	127	2.7%	130	2.5%
TOTAL	3801	80.7%	4089	77.5%

Table 3

POST DONATION INFORMATION	PLASMA CENTERS		TOTAL	
HISTORY OF INCARCERATION	150	26.6%	173	3.3%
TATTOO, EAR/BODY PIERCING, NEEDLESTICK, OR TRANSFUSION	130	23.1%	1092	20.7%
IV DRUG USE	79	14.0%	419	7.9%
HIGH RISK BEHAVIOR-NOT SPECIFIED	60	10.7%	168	3.2%
MALE TO MALE SEX	28	5.0%	239	4.5%
HISTORY OF HEPATITIS B/C OR JAUNDICE	21	3.7%	226	4.3%
TOTAL	468	83.1%	2317	43.9%

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)	770	59.8%	2	2.1%	772	55.8%
DIAGNOSIS OF CANCER, POST DONATION	130	10.1%	3	3.1%	133	9.6%
SEX PARTNER TESTS POSITIVE FOR HEPATITIS	62	4.8%	11	11.5%	73	5.3%
SEX PARTNER TESTS POSITIVE FOR HIV/HTLV	31	2.4%	22	22.9%	53	3.8%
HEPATITIS RELATED ILLNESS OR POSITIVE HEPATITIS MARKER	41	3.2%	6	6.3%	47	3.4%
EXPOSURE TO HEPATITIS A	42	3.3%	1	1.0%	43	3.1%
TOTAL	1076	83.5%	45	46.9%	1121	81.0%

Table 2

POST DONATION INFORMATION	BLOOD ESTABLISHMENTS		TOTAL	
ILLNESS (NOT AIDS OR HEPATITIS RELATED)	770	59.8%	772	55.8%
DIAGNOSIS OF CANCER, POST DONATION	130	10.1%	133	9.6%
SEX PARTNER TESTS POSITIVE FOR HEPATITIS	62	4.8%	73	5.3%
EXPOSURE TO HEPATITIS A	42	3.3%	43	3.1%
HEPATITIS RELATED ILLNESS OR POSITIVE HEPATITIS MARKER	41	3.2%	47	3.4%
TOTAL	1045	81.1%	1068	77.2%

Table 3

POST DONATION INFORMATION	PLASMA CENTERS		TOTAL	
HIGH RISK BEHAVIOR-NOT SPECIFIED	27	28.1%	42	3.0%
SEX PARTNER TESTS POSITIVE FOR HIV/HTLV	22	22.9%	53	3.8%
SEX PARTNER TESTS POSITIVE FOR HEPATITIS	11	11.5%	73	5.3%
HEPATITIS RELATED ILLNESS OR POSITIVE HEPATITIS MARKER	6	6.3%	47	3.4%
HISTORY OF HEPATITIS A	5	5.2%	32	2.3%
AIDS RELATED ILLNESS OR POSITIVE TEST FOR HIV	4	4.2%	17	1.2%
SEX WITH AN IV DRUG USER	4	4.2%	25	1.8%
TOTAL	79	82.3%	289	20.9%

Of the 11,076 reportable error and accident reports received from blood and plasma establishments, 1353 (12.2%) reports were storage and distribution errors or accidents. 1275 (94.2%) reports were submitted by blood establishments and 78 (5.8%) 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	728	57.1%	0	0.0%	728	53.8%
SHIPPED/STORED AT INCORRECT TEMPERATURE	179	14.0%	3	3.8%	182	13.5%
FAILURE TO QUARANTINE UNIT DUE TO MEDICAL HISTORY	97	7.6%	21	26.9%	118	8.7%
FAILURE TO QUARANTINE UNIT DUE TO INCORRECT, INCOMPLETE, OR POSITIVE TESTING	78	6.1%	21	26.9%	99	7.4%
FAILURE TO QUARANTINE UNIT DUE TO TESTING NOT PERFORMED OR DOCUMENTED	57	4.5%	31	39.7%	88	6.5%
INAPPROPRIATE RELEASE	60	4.7%	0	0.0%	60	4.4%
IMPROPER TRANSFUSION SERVICE PRACTICE	45	3.5%	0	0.0%	45	3.3%
INTERSTATE SHIPMENT OF UNLICENSED PRODUCT	30	2.4%	2	2.6%	32	2.4%
MISCELLANEOUS	1	0.1%	0	0.0%	1	0.1%
TOTAL	1275	100.0%	78	100.0%	1353	100.0%

STORAGE/DISTRIBUTION - TABLE 2

STORAGE AND DISTRIBUTION ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		TOTAL	
UNSUITABLE PRODUCT	728	57.1%	728	53.8%
SHIPPED/STORED AT INCORRECT TEMPERATURE	179	14.0%	182	13.5%
FAILURE TO QUARANTINE UNIT DUE TO MEDICAL HISTORY	97	7.6%	118	8.7%
FAILURE TO QUARANTINE UNIT DUE TO INCORRECT, INCOMPLETE, OR POSITIVE TESTING	78	6.1%	99	7.3%
INAPPROPRIATE RELEASE	60	4.7%	60	4.4%
FAILURE TO QUARANTINE UNIT DUE TO TESTING NOT PERFORMED OR DOCUMENTED	57	4.5%	88	6.5%
IMPROPER TRANSFUSION SERVICE PRACTICE	45	3.5%	45	3.3%
INTERSTATE SHIPMENT OF UNLICENSED PRODUCT	30	2.4%	32	2.4%
MISCELLANEOUS	1	0.1%	1	0.1%
TOTAL	1275	100.0%	1353	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	31	39.7%	88	6.5%
FAILURE TO QUARANTINE UNIT DUE TO MEDICAL HISTORY	21	26.9%	118	8.7%
FAILURE TO QUARANTINE UNIT DUE TO INCORRECT, INCOMPLETE, OR POSITIVE TESTING	21	26.9%	99	7.3%
SHIPPED/STORED AT INCORRECT TEMPERATURE	3	3.8%	182	13.5%
INTERSTATE SHIPMENT OF UNLICENSED PRODUCT	2	2.6%	32	2.4%
MISCELLANEOUS	0	0.0%	1	0.1%
INAPPROPRIATE RELEASE	0	0.0%	60	4.4%
UNSUITABLE PRODUCT	0	0.0%	728	53.8%
IMPROPER TRANSFUSION SERVICE PRACTICE	0	0.0%	45	3.3%
TOTAL	78	100.0%	1353	100.0%

STORAGE/DISTRIBUTION - TABLE 2A

STORAGE AND DISTRIBUTION ERRORS/ACCIDENTS (DETAILED)	BLOOD ESTABLISHMENTS		TOTAL	
<i>UNSUITABLE PRODUCT</i>				
UNIT CONTAINED CLOTS	524	41.1%	524	38.7%
UNIT/SEGMENT HEMOLYZED	114	8.9%	114	8.4%
OTHER ¹	46	3.6%	46	3.4%
BROKEN/DAMAGED UNIT	44	3.5%	44	3.3%
SHIPPED/STORED AT INCORRECT TEMPERATURE	179	14.0%	182	13.5%
<i>FAILURE TO QUARANTINE UNIT DUE TO MEDICAL HISTORY</i>				
OTHER REASONS ²	64	5.0%	66	4.9%
<i>INAPPROPRIATE RELEASE</i>				
OUTDATED PRODUCT	37	2.9%	37	2.7%
OTHER ³	21	1.6%	21	1.6%
INTERSTATE SHIPMENT OF UNLICENSED PRODUCT	30	2.4%	32	2.4%
<i>FAILURE TO QUARANTINE UNIT DUE TO TESTING NOT PERFORMED OR DOCUMENTED FOR:</i>				
OTHER REASONS ⁴	18	1.4%	34	2.5%
<i>IMPROPER TRANSFUSION SERVICE PRACTICE</i>				
IMPROPER ABO/Rh TYPE SELECTED FOR PATIENT	16	1.3%	16	1.2%
<i>FAILURE TO QUARANTINE UNIT DUE TO INCORRECT, INCOMPLETE, OR POSITIVE TESTING FOR:</i>				
OTHER REASONS ⁵	15	1.2%	16	1.2%
ANTIBODY SCREEN	14	1.1%	14	1.0%
ANTI-HBc	13	1.0%	13	1.0%
TOTAL	1135	89.0%	1159	85.7%

¹ - Includes icteric unit; lipemic unit; air contamination

² - Includes donor self deferred; post donation illness, information received prior to release of product

³ - Includes associated product contained clots; donor record incomplete

⁴ - Includes all viral markers; DAT, anti-CMV

⁵ - Includes DAT; platelet count

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	16	20.5%	34	2.5%
SYPHILIS	8	10.3%	15	1.1%
ANTI-HIV/HIV ANTIGEN	6	7.7%	13	1.0%
<i>FAILURE TO QUARANTINE UNIT DUE TO INCORRECT, INCOMPLETE, OR POSITIVE TESTING FOR:</i>				
ANTI-HCV	12	15.4%	18	1.3%
ALT	6	7.7%	9	0.7%
<i>FAILURE TO QUARANTINE UNIT DUE TO MEDICAL HISTORY</i>				
TATTOO, EARPIERCING, NEEDLESTICK, OR TRANSFUSION	7	9.0%	10	0.7%
HISTORY OF INCARCERATION	4	5.1%	5	0.4%
PREVIOUS HIV REACTIVITY	2	2.6%	5	0.4%
SEXUAL PARTNER TESTING POSITIVE FOR HEPATITIS	2	2.6%	2	0.1%
OTHER REASONS ²	2	2.6%	66	4.9%
SHIPPED/STORED AT INCORRECT TEMPERATURE	3	3.8%	182	13.5%
INTERSTATE SHIPMENT OF UNLICENSED PRODUCT	2	2.6%	32	2.4%
TOTAL	70	89.7%	391	28.9%

¹ - Includes all viral markers

² - Includes post donation illness, information received prior to release of product

Of the 11,076 reportable error and accident reports received from blood and plasma establishments, 947 (8.6%) reports were labeling errors or accidents. 944 (99.7%) reports were submitted by blood establishments and 3 (0.3%) 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	302	32.0%	0	0.0%	302	31.9%
EXTENDED EXPIRATION DATE	160	16.9%	1	33.3%	161	17.0%
INCORRECT ABO AND/OR Rh LABEL OR TAG	96	10.2%	0	0.0%	96	10.1%
INCORRECT PRODUCT LABEL OR TAG	90	9.5%	0	0.0%	90	9.5%
<i>MISSING/INCORRECT LABEL OR TAG</i>						
DONOR NUMBER	70	7.4%	1	33.3%	71	7.5%
CMV	60	6.4%	0	0.0%	60	6.3%
ANTIGEN/ANTIBODY	58	6.1%	0	0.0%	58	6.1%
BIOHAZARD/TEST STATUS	36	3.8%	0	0.0%	36	3.8%
IRRADIATION	14	1.5%	0	0.0%	14	1.5%
OTHER ¹	13	1.4%	0	0.0%	13	1.4%
CROSSMATCH	10	1.1%	0	0.0%	10	1.1%
ANTICOAGULANT	5	0.5%	1	33.3%	6	0.6%
PLATELET COUNT	4	0.4%	0	0.0%	4	0.4%
RECIPIENT NUMBER	3	0.3%	0	0.0%	3	0.3%
UNLICENSED PRODUCT LABELED WITH LICENSE NUMBER	23	2.4%	0	0.0%	23	2.4%
TOTAL	944	100.0%	3	100.0%	947	100.0%

¹ - Includes Hemoglobin S; ALT; DAT

LABELING - TABLE 2

LABELING ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		TOTAL	
	MISSING/INCORRECT LABEL OR TAG-AUTOLOGOUS LABELING	302	32.0%	302
EXTENDED EXPIRATION DATE	160	16.9%	161	17.0%
INCORRECT ABO AND/OR Rh LABEL OR TAG	96	10.2%	96	10.1%
INCORRECT PRODUCT LABEL OR TAG	90	9.5%	90	9.5%
<i>MISSING/INCORRECT LABEL OR TAG</i>				
DONOR NUMBER	70	7.4%	71	7.5%
CMV	60	6.4%	60	6.3%
ANTIGEN/ANTIBODY	58	6.1%	58	6.1%
BIOHAZARD/TEST STATUS	36	3.8%	36	3.8%
IRRADIATION	14	1.5%	14	1.5%
OTHER ¹	13	1.4%	13	1.4%
CROSSMATCH	10	1.1%	10	1.1%
ANTICOAGULANT	5	0.5%	6	0.6%
PLATELET COUNT	4	0.4%	4	0.4%
RECIPIENT NUMBER	3	0.3%	3	0.3%
UNLICENSED PRODUCT LABELED WITH LICENSE NUMBER	23	2.4%	23	2.4%
TOTAL	944	100.0%	947	100.0%

¹ - Includes Hemoglobin S; ALT; DAT

LABELING - TABLE 3

LABELING ERRORS/ACCIDENTS	PLASMA CENTERS		TOTAL	
	EXTENDED EXPIRATION DATE	1	33.3%	161
MISSING/INCORRECT LABEL OR TAG-ANTICOAGULANT	1	33.3%	6	0.6%
MISSING/INCORRECT LABEL OR TAG-DONOR NUMBER	1	33.3%	71	7.5%
TOTAL	3	100.0%	238	25.1%

Of the **11,076** reportable error and accident reports received from blood and plasma establishments, 720 (6.5%) reports were donor screening errors or accidents. 664 (92.2%) reports were submitted by blood establishments and 56 (7.8%) 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	375	56.5%	13	23.2%	388	53.9%
DONOR RECORD INCOMPLETE/INCORRECT	128	19.3%	4	7.1%	132	18.3%
DEFERRAL SCREENING NOT DONE, DONOR PREVIOUSLY DEFERRED	73	11.0%	29	51.8%	102	14.2%
INCORRECT ID USED DURING DEFERRAL SEARCH, DONOR PREVIOUSLY DEFERRED	47	7.1%	8	14.3%	55	7.6%
DONOR DID NOT MEET ACCEPTANCE CRITERIA	41	6.2%	2	3.6%	43	6.0%
TOTAL	664	100.0%	56	100.0%	720	100.0%

DONOR SCREENING - TABLE 2

DONOR SCREENING ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		TOTAL	
DONOR GAVE HISTORY WHICH WARRANTED DEFERRAL AND WAS NOT DEFERRED	375	56.5%	388	53.9%
DONOR RECORD INCOMPLETE/INCORRECT	128	19.3%	132	18.3%
DEFERRAL SCREENING NOT DONE, DONOR PREVIOUSLY DEFERRED	73	11.0%	102	14.2%
INCORRECT ID USED DURING DEFERRAL SEARCH, DONOR PREVIOUSLY DEFERRED	47	7.1%	55	7.6%
DONOR DID NOT MEET ACCEPTANCE CRITERIA	41	6.2%	43	6.0%
TOTAL	664	100.0%	720	100.0%

DONOR SCREENING - TABLE 3

DONOR SCREENING ERRORS/ACCIDENTS	PLASMA CENTERS		TOTAL	
DEFERRAL SCREENING NOT DONE, DONOR PREVIOUSLY DEFERRED	29	51.8%	102	14.2%
DONOR GAVE HISTORY WHICH WARRANTED DEFERRAL AND WAS NOT DEFERRED	13	23.2%	388	53.9%
INCORRECT ID USED DURING DEFERRAL SEARCH, DONOR PREVIOUSLY DEFERRED	8	14.3%	55	7.6%
DONOR RECORD INCOMPLETE/INCORRECT	4	7.1%	132	18.3%
DONOR DID NOT MEET ACCEPTANCE CRITERIA	2	3.6%	43	6.0%
TOTAL	56	100.0%	720	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	143	21.5%	143	19.9%
HISTORY OF CANCER	53	8.0%	54	7.5%
RECEIVED MEDICATION OR ANTIBIOTICS	39	5.9%	40	5.6%
HISTORY OF DISEASE/SURGERY	29	4.4%	29	4.0%
RECEIVED TATTOO, EARPIERCING, NEEDLESTICK, OR TRANSFUSION	26	3.9%	28	3.9%
HEPATITIS RELATED RISK	19	2.9%	21	2.9%
RECEIVED PROSCAR, TEGISON, OR ACCUTANE	11	1.7%	11	1.5%
RISK FACTOR ASSOCIATED WITH CJD	9	1.4%	12	1.7%
RECEIVED METHOTREXATE	9	1.4%	9	1.3%
HISTORY OF HEPATITIS A	8	1.2%	10	1.4%
NON-SEXUAL EXPOSURE TO HEPATITIS	3	0.5%	3	0.4%
HIGH RISK-NOT SPECIFIED	3	0.5%	5	0.7%
<i>DONOR RECORD INCOMPLETE/INCORRECT</i>				
MEDICAL HISTORY QUESTIONNAIRE	51	7.7%	54	7.5%
HIGH RISK BEHAVIOR QUESTIONS/INFORMATION	46	6.9%	46	6.4%
OTHER ¹	13	2.0%	13	1.8%
DONOR SIGNATURE	10	1.5%	10	1.4%
<i>DONOR DID NOT MEET ACCEPTANCE CRITERIA</i>				
TEMPERATURE	23	3.5%	23	3.2%
HEMOGLOBIN/HEMATOCRIT (<11.0g/dl OR <33%)	16	2.4%	16	2.2%
DEFERRAL SCREENING NOT DONE, DONOR PREVIOUSLY DEFERRED DUE TO HIV REACTIVITY	37	5.6%	38	5.3%
INCORRECT ID USED DURING DEFERRAL SEARCH, DONOR PREVIOUSLY DEFERRED DUE TO HIV REACTIVITY	11	1.7%	12	1.7%
TOTAL	559	84.2%	577	80.1%

¹ - Includes arm inspection

DONOR SCREENING - TABLE 3A

DONOR SCREENMG ERRORS/ACCIDENTS (DETAILED)	PLASMA CENTERS		TOTAL	
<i>DEFERRAL SCREENING NOT DONE, DONOR PREVIOUSLY DEFERRED DUE TO</i>				
OTHER REASONS ¹	14	25.0%	21	2.9%
HBsAg REACTIVITY OR HISTORY OF HEPATITIS	5	8.9%	10	1.4%
ANTI-HCV REACTIVITY	4	7.1%	5	0.7%
RECEIVED TATTOO, EARPIERCING, NEEDLESTICK OR TRANSFUSION	2	3.6%	7	1.0%
HIV REACTIVITY	1	1.8%	38	5.3%
HIGH RISK BEHAVIOR-NOT SPECIFIED	1	1.8%	1	0.1%
SEX PARTNER TESTS POSITIVE FOR HIV	1	1.8%	1	0.1%
NON-SEXUAL EXPOSURE TO HEPATITIS B/C	1	1.8%	1	0.1%
<i>DONOR GAVE HISTORY WHICH WARRANTED DEFERRAL AND WAS NOT DEFERRED</i>				
RISK FACTOR ASSOCIATED WITH CJD	3	5.4%	12	1.7%
RECEIVED TATTOO, EARPIERCING, NEEDLESTICK, OR TRANSFUSION	2	3.6%	28	3.9%
HEPATITIS RELATED RISK	2	3.6%	21	2.9%
HIGH RISK-NOT SPECIFIED	2	3.6%	5	0.7%
HISTORY OF HEPATITIS A	2	3.6%	10	1.4%
HISTORY OF CANCER	1	1.8%	54	7.5%
RECEIVED MEDICATION OR ANTIBIOTICS	1	1.8%	40	5.6%
<i>DONOR RECORD INCOMPLETE/INCORRECT</i>				
MEDICAL HISTORY QUESTIONNAIRE	3	5.4%	54	7.5%
DONOR IDENTIFICATION	1	1.8%	9	1.3%
<i>INCORRECT ID USED DURING DEFERRAL SEARCH, DONOR PREVIOUSLY DEFERRED DUE TO</i>				
HBsAg REACTIVITY OR HISTORY OF HEPATITIS	2	3.6%	8	1.1%
ANTI-HCV REACTIVITY	2	3.6%	8	1.1%
ALT REACTIVITY	1	1.8%	3	0.4%
HIV REACTIVITY	1	1.8%	12	1.7%
OTHER REASONS ²	1	1.8%	4	0.6%
SEXUALLY TRANSMITTED DISEASE/POSITIVE STS	1	1.8%	2	0.3%
<i>DONOR DID NOT MEET ACCEPTANCE CRITERIA</i>				
MISCELLANEOUS ³	1	1.8%	2	0.3%
UNEXPLAINED WEIGHT LOSS	1	1.8%	1	0.1%
TOTAL	56	100.0%	357	49.6%

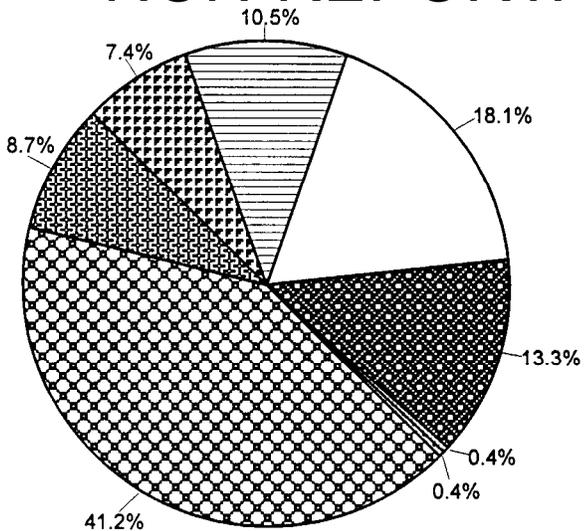
¹ . Includes donor rejected at another center; unsuitable history

² - Includes donor provided false information

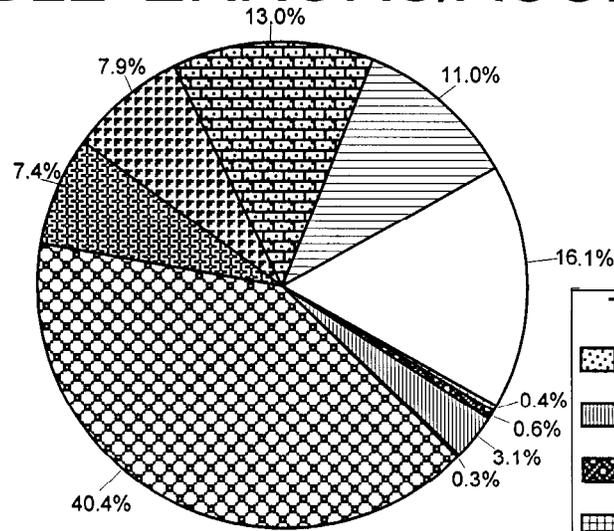
³ - Includes syphilis testing not performed on a new donor

ERROR AND ACCIDENT REPORTS

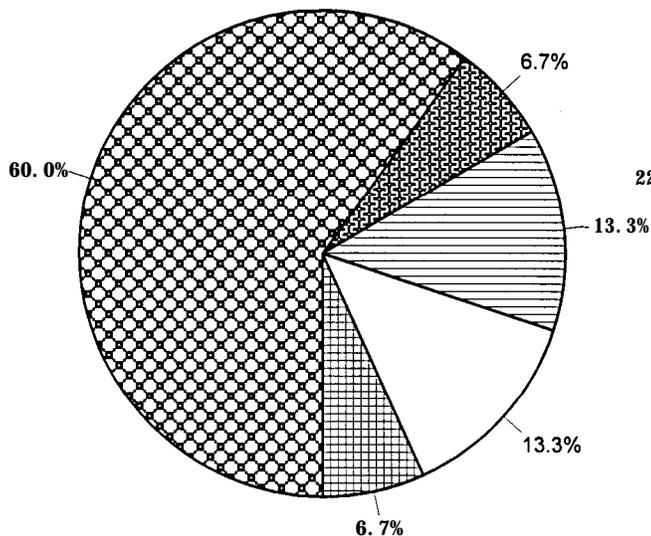
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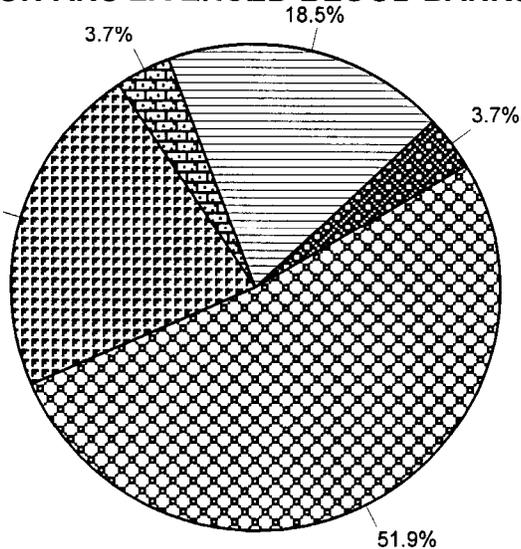
AMERICAN RED CROSS



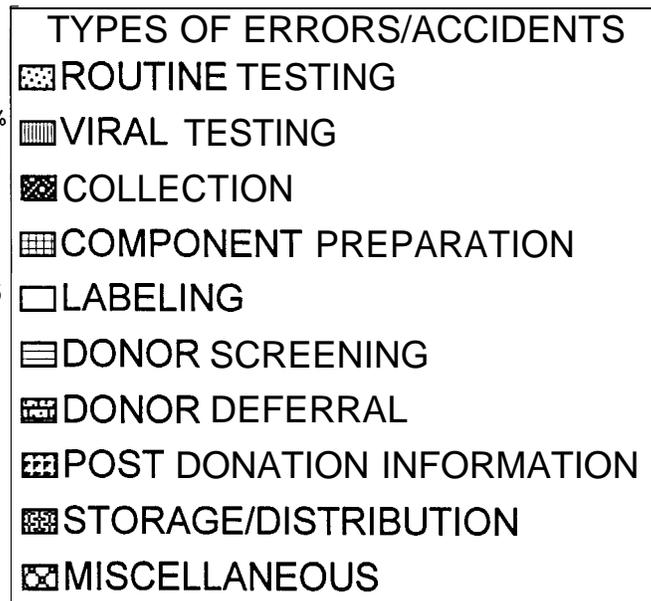
NON-ARC LICENSED BLOOD BANKS



UNLICENSED BLOOD BANKS



PLASMA CENTERS



REPORTS RECEIVED (10/1/96 - 9/30/97) = 1345

ARC = 503; NON-ARC LICENSED BLOOD BANKS = 800; UNLICENSED BLOOD BANKS = 15; PLASMA CENTERS = 27

Of the 1345 non-reportable error and accident reports received from blood and plasma establishments, 552 (41 .0%) reports were miscellaneous errors or accidents. 538 (97.5%) reports were submitted by blood establishments and 14 (2.5%) 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	243	45.2%	11	78.6%	254	46.0%
RECORDKEEPING ERROR/ACCIDENT	93	17.3%	2	14.3%	95	17.2%
RECORDS DESTROYED OR LOST/DESTRUCTION RECORDS INCOMPLETE/FINAL DISPOSITION UNKNOWN	88	16.4%	1	7.1%	89	16.1%
QC NOT PERFORMED OR INADEQUATE (OTHER THAN VIRAL MARKER, ABO/Rh)	60	11.2%	0	0.0%	60	10.9%
MISCELLANEOUS*	27	5.0%	0	0.0%	27	4.9%
RECIPIENT REACTION	17	3.2%	0	0.0%	17	3.1%
EMERGENCY RELEASED UNIT NOT TESTED PRIOR TO RELEASE AND FOUND POSITIVE, LABELED APPROPRIATELY	10	1.9%	0	0.0%	10	1.8%
TOTAL	538	100.0%	14	100.0%	552	100.0%

MISCELLANEOUS - TABLE 2

MISCELLANEOUS ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		TOTAL	
NO PRODUCTS MADE AVAILABLE FOR DISTRIBUTION	243	45.2%	254	46.0%
RECORDKEEPING ERROR/ACCIDENT	93	17.3%	95	17.2%
RECORDS DESTROYED OR LOST/DESTRUCTION RECORDS INCOMPLETE/FINAL DISPOSITION UNKNOWN	88	16.4%	89	16.1%
QC NOT PERFORMED OR INADEQUATE(OTHER THAN VIRAL MARKER, ABO/Rh)	60	11.2%	60	10.9%
MISCELLANEOUS*	27	5.0%	27	4.9%
RECIPIENT REACTION	17	3.2%	17	3.1%
EMERGENCY RELEASED UNIT NOT TESTED PRIOR TO RELEASE AND FOUND POSITIVE, LABELED APPROPRIATELY	10	1.9%	10	1.8%
TOTAL	538	100.0%	552	100.0%

MISCELLANEOUS - TABLE 3

MISCELLANEOUS ERRORS/ACCIDENTS	A	S	M	A
NO PRODUCTS MADE AVAILABLE FOR DISTRIBUTION	11	78.6%	254	46.0%
RECORDKEEPING ERROR/ACCIDENT	2	14.3%	95	17.2%
RECORDS DESTROYED OR LOST/DESTRUCTION RECORDS INCOMPLETE/FINAL DISPOSITION UNKNOWN	1	7.1%	89	16.1%
EMERGENCY RELEASED UNIT NOT TESTED PRIOR TO RELEASE AND FOUND POSITIVE, LABELED APPROPRIATELY	0	0.0%	10	1.8%
MISCELLANEOUS*	0	0.0%	27	4.9%
RECIPIENT REACTION	0	0.0%	17	3.1%
QC NOT PERFORMED OR INADEQUATE(OTHER THAN VIRAL MARKER, ABO/Rh)	0	0.0%	60	10.9%
TOTAL	14	100.0%	552	100.0%

*Includes- recall/notification procedures not followed; correction to records not made appropriately

Of the **3094** non-reportable error and accident reports received from blood and plasma establishments, 222 (16.5%) reports were labeling errors or accidents. 222 (100%) reports were submitted by blood establishments and 0 (0%) were submitted from plasma centers. 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 MISSING LABEL FOR ABO&/OR Rh, PRODUCT OR EXPIRATION DATE	68	30.6%	0	0	68	30.6%
UNIT LABELED WITH MISSING/INCORRECT WEIGHT, VOLUME, COLLECTION DATE, OR FACILITY IDENTIFIERS; UNIT ACCEPTABLE	62	27.9%	0	0	62	27.9%
UNIT LABELED WITH SHORTENED EXPIRATION DATE	49	22.1%	0	0	49	22.1%
DIRECTED UNIT, SUITABLE FOR HOMOLOGOUS USE, LABELED WITH INCORRECT NAME, SSN, OR DOB	30	13.5%	0	0	30	13.5%
MISCELLANEOUS*	13	5.9%	0	0	13	5.9%
TOTAL	222	100.0%	0	0	222	100.0%

*Includes - autologous unit labeled with ABO/Rh; unit irradiated but not labeled as irradiated; directed unit labeled as autologous

Of the 1345 non-reportable error and accident reports received from blood and plasma establishments, 148 (11.0%) reports were donor screening errors or accidents. 143 (96.6%) reports were submitted by blood establishments and 5 (3.4%) 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	84	58.7%	0	0.0%	84	56.8%
ACCEPTANCE CRITERIA NOT MET - AGE	19	13.3%	2	40.0%	21	14.2%
ACCEPTANCE CRITERIA NOT MET - BLOOD PRESSURE OR PULSE	19	13.3%	0	0.0%	19	12.8%
MISCELLANEOUS*	14	9.8%	0	0.0%	14	9.5%
UNIT COLLECTED FROM ELIGIBLE DONOR, DONOR DEFERRAL LIST NOT CHECKED OR CHECKED WITH INCORRECT INFORMATION	5	3.5%	0	0.0%	5	3.4%
ACCEPTANCE CRITERIA NOT MET -TOTAL PROTEIN OR SPE	0	0.0%	3	60.0%	3	2.0%
ACCEPTANCE CRITERIA NOT MET -HEMOGLOBIN/HEMATOCRIT	2	1.4%	0	0.0%	2	1.4%
PHERESIS DONOR DID NOT MEET ACCEPTANCE CRITERIA FOR PLATELET COUNT, PRODUCT ACCEPTABLE	0	0.0%	0	0.0%	0	0.0%
TOTAL	143	100.0%	5	100.0%	148	100.0%

DONOR SCREENING - TABLE 2

DONOR SCREENING ERRORS/ACCIDENTS	BLOOD ESTABLISHMENTS		TOTAL	
ACCEPTANCE CRITERIA NOT MET-TIME INTERVAL BETWEEN DONATIONS	84	58.7%	84	56.8%
ACCEPTANCE CRITERIA NOT MET - AGE	19	13.3%	21	14.2%
ACCEPTANCE CRITERIA NOT MET - BLOOD PRESSURE OR PULSE	19	13.3%	19	12.8%
MISCELLANEOUS*	14	9.8%	14	9.5%
UNIT COLLECTED FROM ELIGIBLE DONOR, DONOR DEFERRAL LIST NOT CHECKED OR CHECKED WITH INCORRECT INFORMATION	5	3.5%	5	3.4%
ACCEPTANCE CRITERIA NOT MET -HEMOGLOBIN/HEMATOCRIT	2	1.4%	2	1.4%
PHERESIS DONOR DID NOT MEET ACCEPTANCE CRITERIA FOR PLATELET COUNT, PRODUCT ACCEPTABLE	0	0.0%	0	0.0%
ACCEPTANCE CRITERIA NOT MET - TOTAL PROTEIN OR SPE	0	0.0%	3	2.0%
TOTAL	143	100.0%	148	100.0%

DONOR SCREENING - TABLE 3

DONOR SCREENING ERRORS/ACCIDENTS	PLASMA CENTERS		TOTAL	
ACCEPTANCE CRITERIA NOT MET - TOTAL PROTEIN OR SPE	3	60.0%	3	2.0%
ACCEPTANCE CRITERIA NOT MET - AGE	2	40.0%	21	14.2%
TOTAL	5	100.0%	24	16.2%

*Includes - donor gave incorrect birthdate; autologous donor donated too soon before surgery

Of the 1345 non-reportable error and accident reports received from blood and plasma establishments, 106 (7.9%) reports involved post donation information. 165 (98.8%) reports were submitted by blood establishments and 2 (1.2%) were submitted from plasma centers. The following 3 tables represent the type of post donation information reported in order of prevalence.

POST DONATION INFORMATION - TABLE 1

TYPE OF POST DONATION INFORMATION	BLOOD ESTABLISHMENTS		PLASMA CENTERS		TOTAL	
POST DONATION COLD/FLU SYMPTOMS	93	93.0%	0	0.0%	93	87.7%
MISCELLANEOUS*	6	6.0%	4	66.7%	10	9.4%
DONOR PREGNANT	1	1.0%	2	33.3%	3	2.8%
TOTAL	100	100.0%	6	100.0%	106	100.0%

POST DONATION INFORMATION - TABLE 2

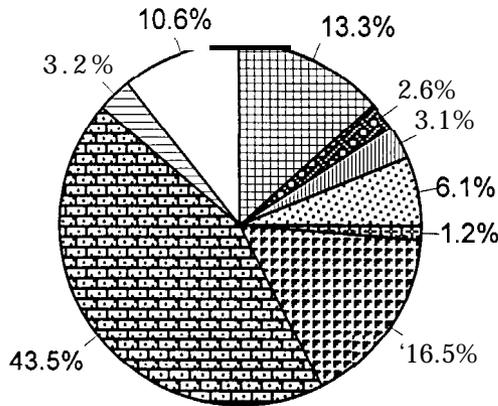
TYPE OF POST DONATION INFORMATION	BLOOD ESTABLISHMENTS		TOTAL	
POST DONATION COLD/FLU SYMPTOMS	93	93.0%	93	87.7%
MISCELLANEOUS*	6	6.0%	10	9.4%
DONOR PREGNANT	1	1.0%	3	2.8%
TOTAL	100	100.0%	106	100.0%

POST DONATION INFORMATION - TABLE 3

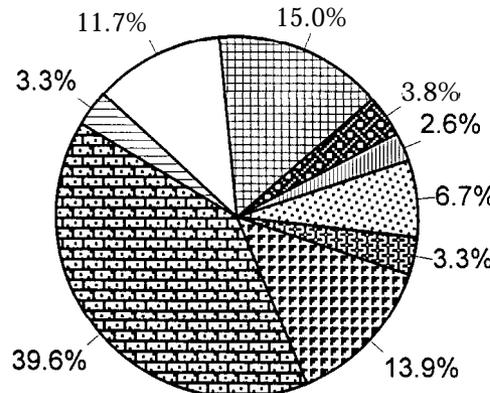
TYPE OF POST DONATION INFORMATION	PLASMA CENTERS		TOTAL	
POST DONATION COLD/FLU SYMPTOMS	0	0.0%	93	87.7%
MISCELLANEOUS*	4	66.7%	10	9.4%
DONOR PREGNANT	2	33.3%	3	2.8%
TOTAL	6	100.0%	106	100.0%

* includes: malaria risk - only recovered plasma available; third party information determined to be false; donor had heart attack after donation; donor under house arrest, not in correctional institution

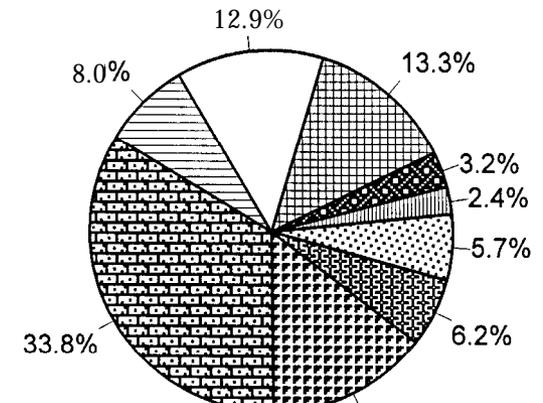
ERROR AND ACCIDENT REPORTS FY-92 TO FY-97



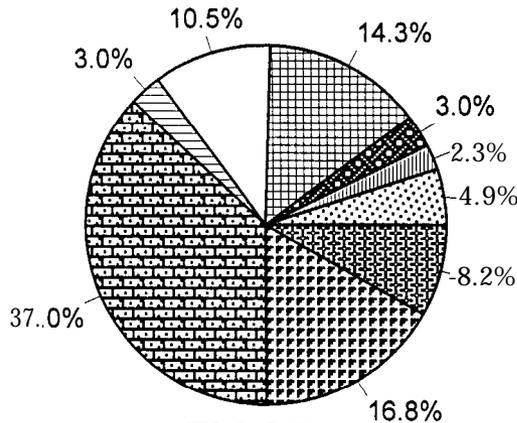
FY-92



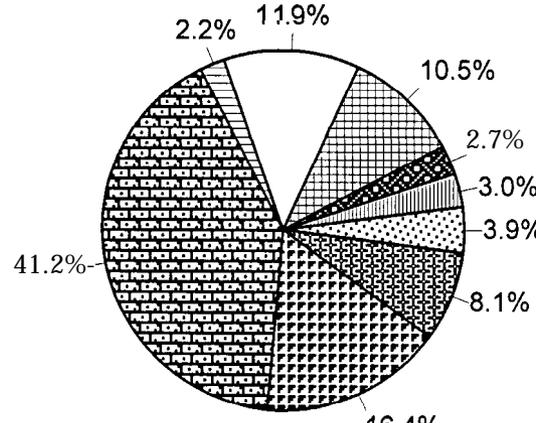
FY-93



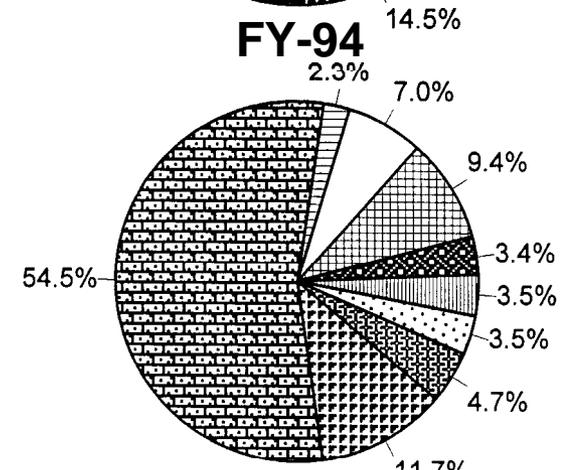
FY-94



FY-95



FY-96



FY-97

TYPES OF ERRORS/ACCIDENTS:

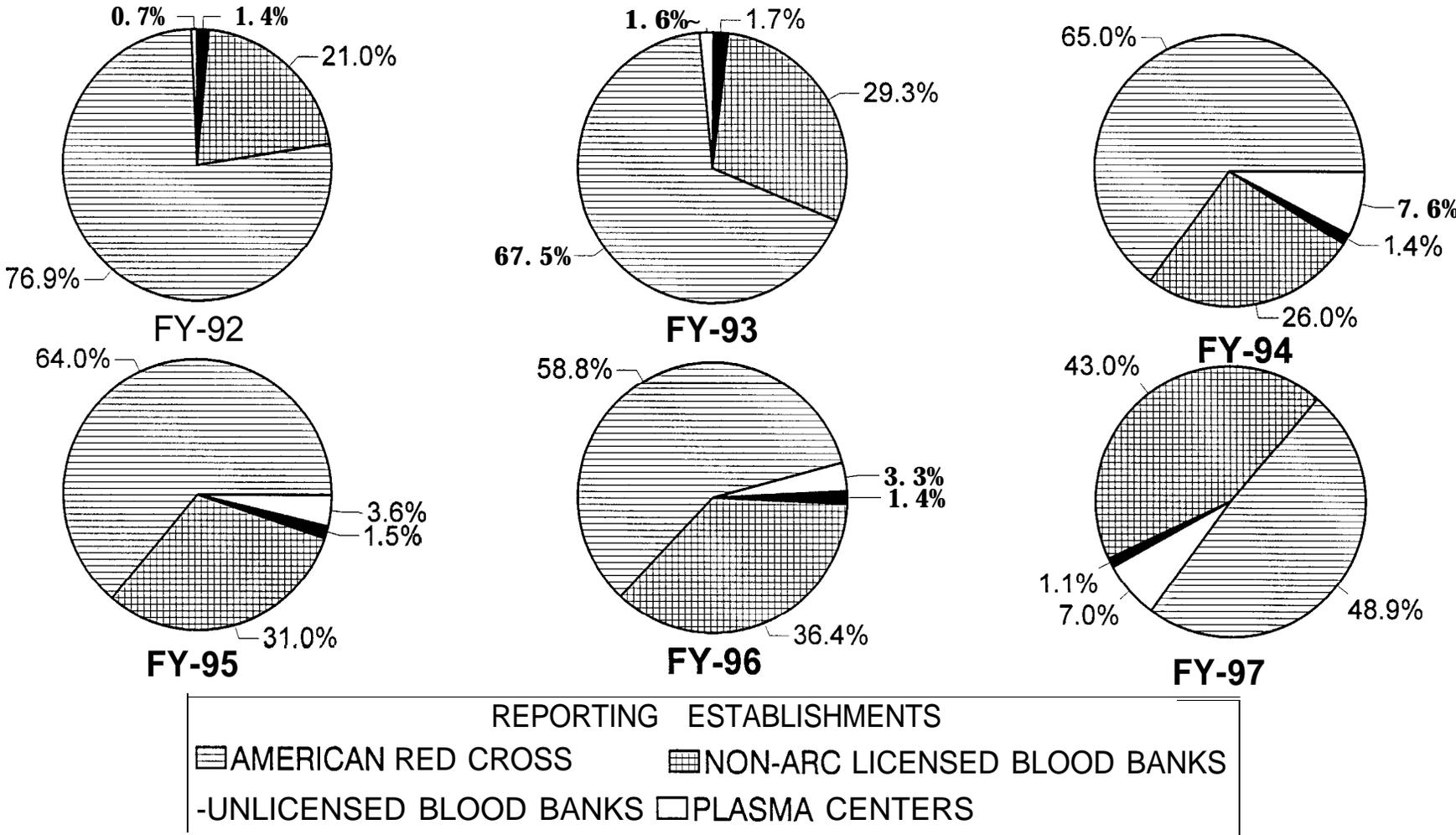
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-
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REPORTS RECEIVED 10/1/91 - 9/30/97

FY-92 = 10,456; FY-93 = 8,991; FY-94 = 11,298; FY-95 = 12,923; FY-96 = 14,034; FY-97 = 12,421

ERROR AND ACCIDENT REPORTS

ALL REPORTING BLOOD ESTABLISHMENTS

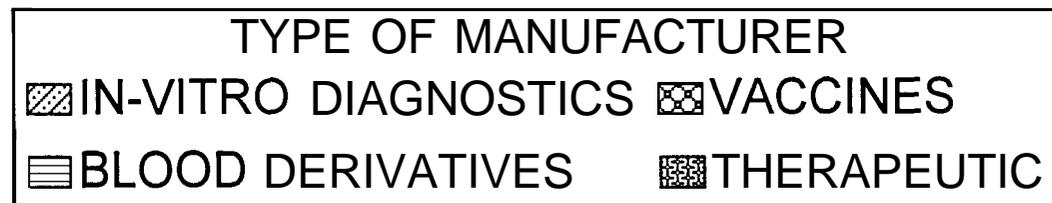
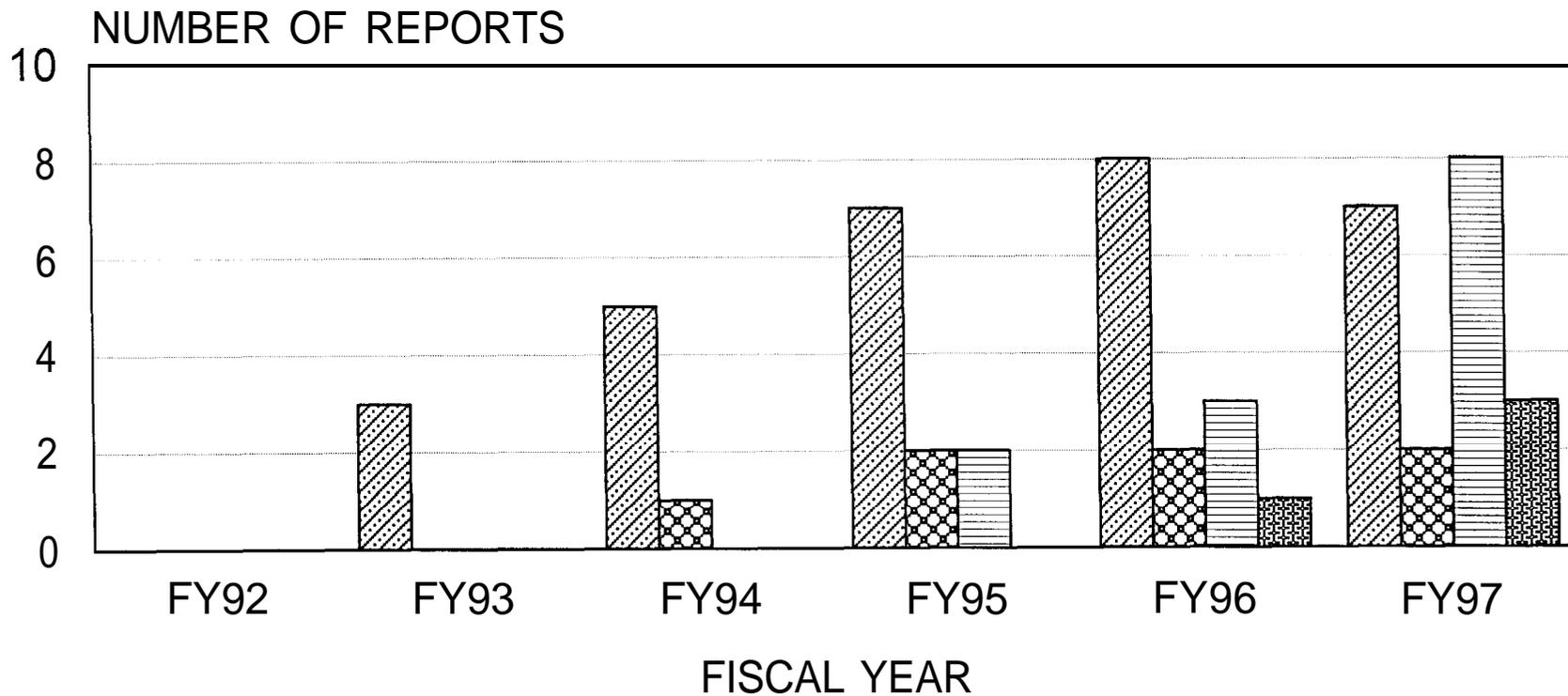


REPORTS RECEIVED 10/1/91 - 9/30/97

FY-92 = 70,456; FY-93 = 8,988; FY-94 = 17,292; FY-95 = 72,923; FY-96 = 74,034; FY-97 = 12,421

ERROR AND ACCIDENT REPORTS

ALL REPORTING NON-BLOOD ESTABLISHMENTS



REPORTS RECEIVED 10/1/91 - 9/30/97

FY-92 = 0; FY-93 = 3; FY-94 = 6; FY-95 = 11; FY-96 = 20, FY-97 = 20

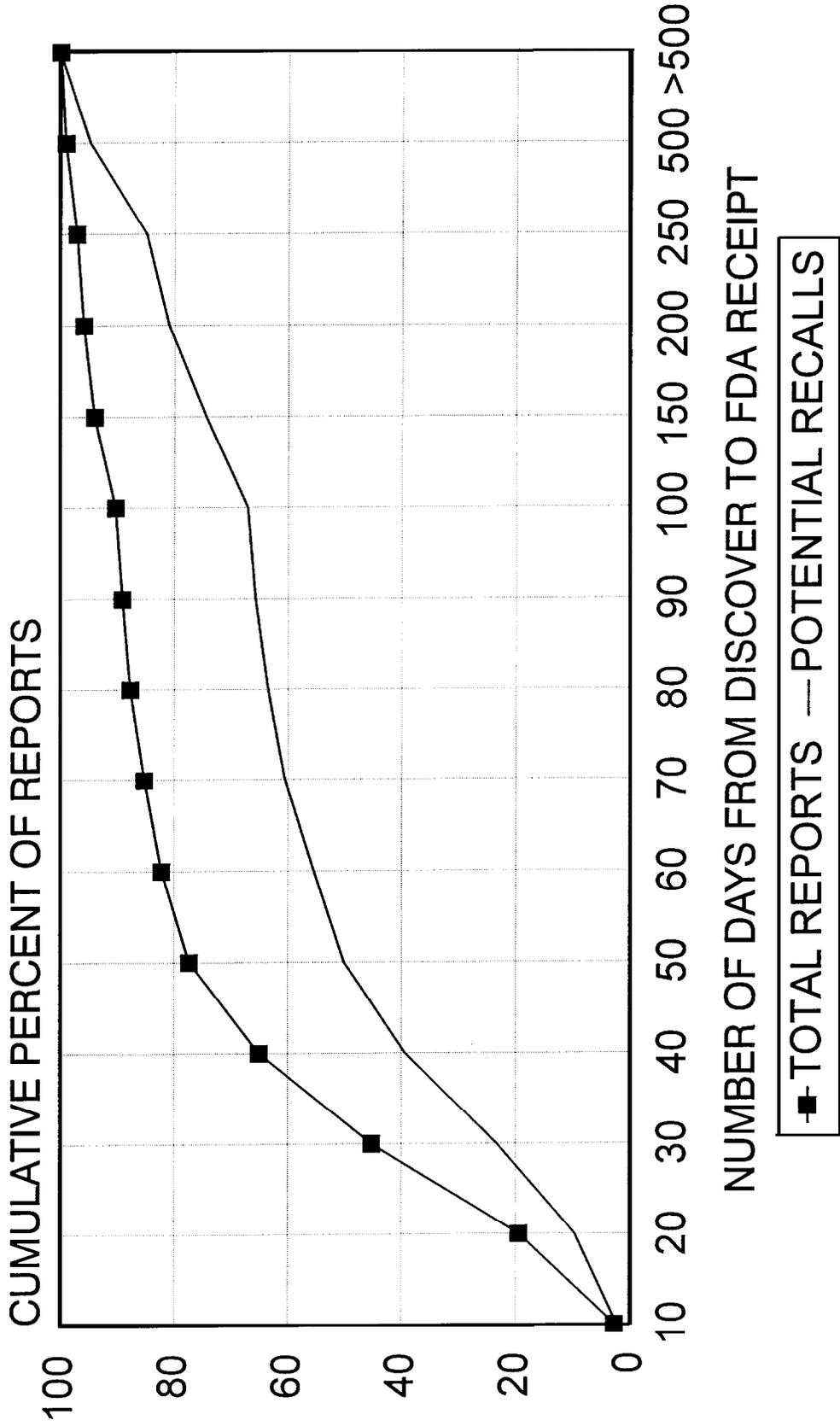
The following table and graphs show the time periods in which the reports were received by CBER. The evaluation of timeliness is limited to only reports that met the threshold for reporting.

**ERROR AND ACCIDENT REPORTS
RECEIVED 10/1/96 - 9/30/97**

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

CUMULATIVE PERCENT OF REPORTS	ARC (DAYS)	NON-ARC LICENSED (DAYS)	UNLICENSED (DAYS)	PLASMA (DAYS)	TOTAL (DAYS)
10%	16	17	8	12	16
25%	21	25	13	18	22
50%	29	42	25	35	32
75%	37	81	47	74	48
90%	46	183	90	118	98
# REPORTS	5566	4545	121	843	11093
RANGE	2-2342	3-2427	3-879	4-668	2-2427

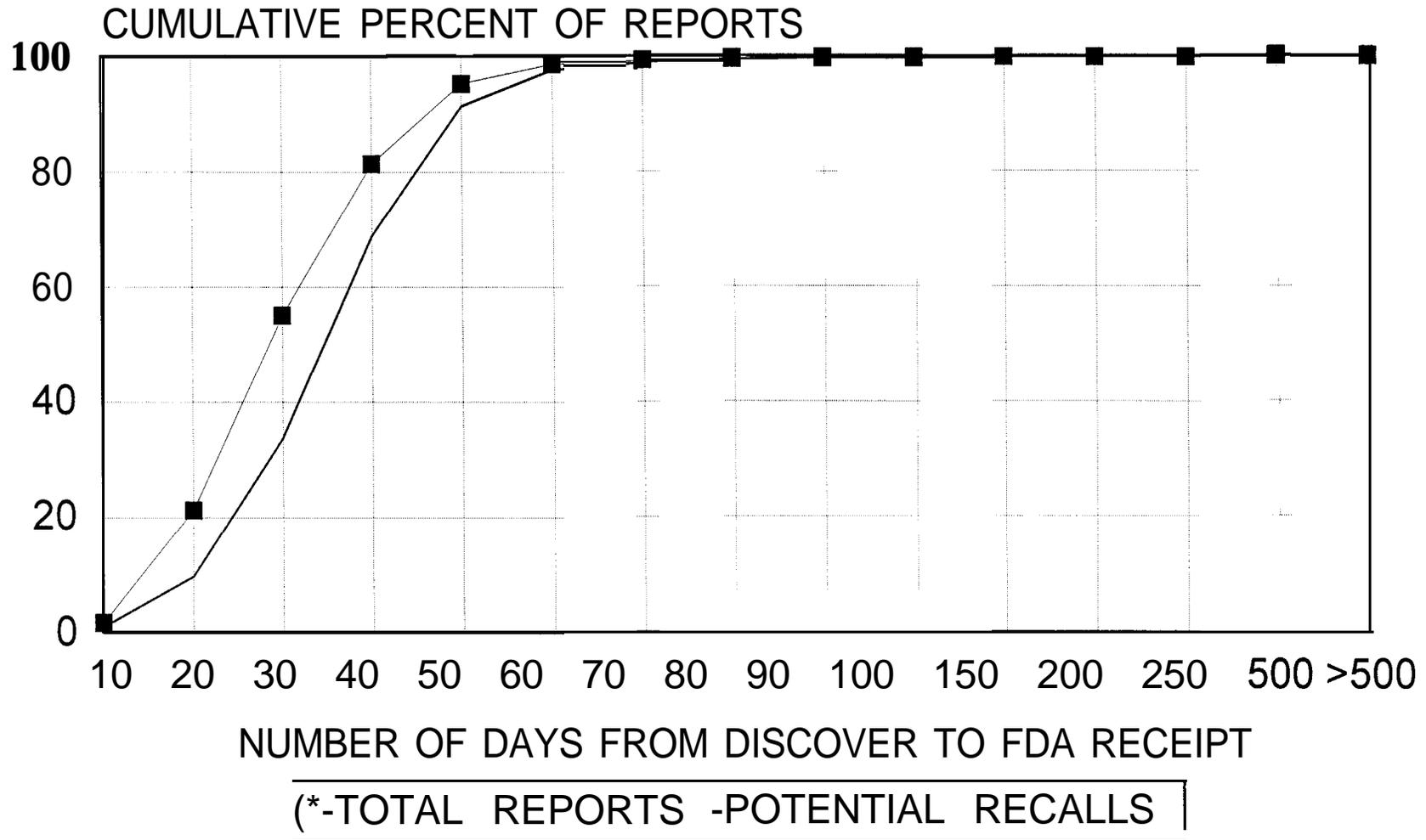
ERROR AND ACCIDENT REPORTS REPORTING TIME ALL REPORTING BLOOD ESTABLISHMENTS FY97



TOTAL REPORTS = 11,093
POTENTIAL RECALLS = 1478

ERROR AND ACCIDENT REPORTS

REPORTING TIME AMERICAN RED CROSS FY97



TOTAL REPORTS = 5566

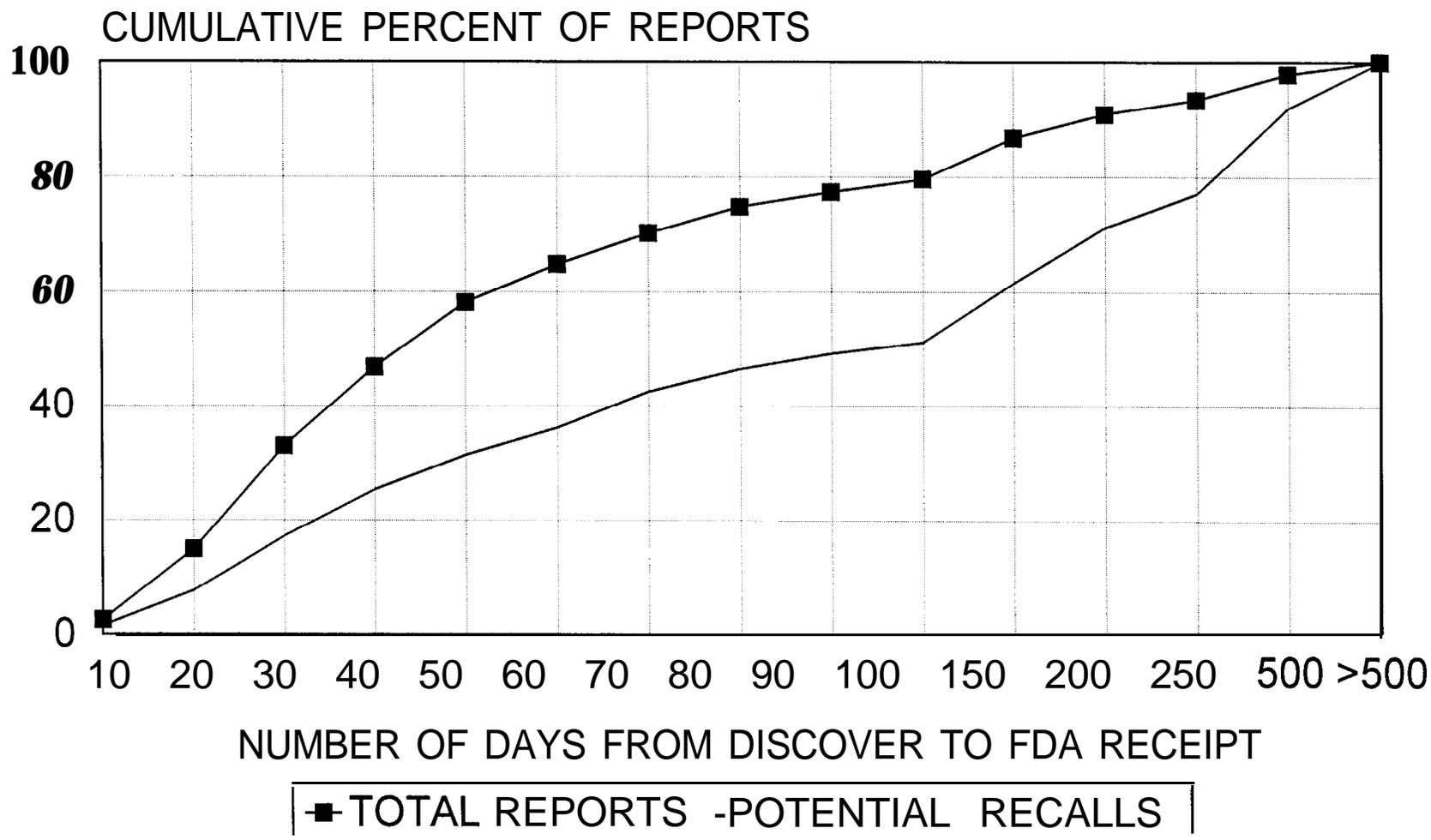
POTENTIAL RECALLS = 476

ERROR AND ACCIDENT REPORTS

REPORTING TIME

NON-ARC LICENSED BLOOD BANKS

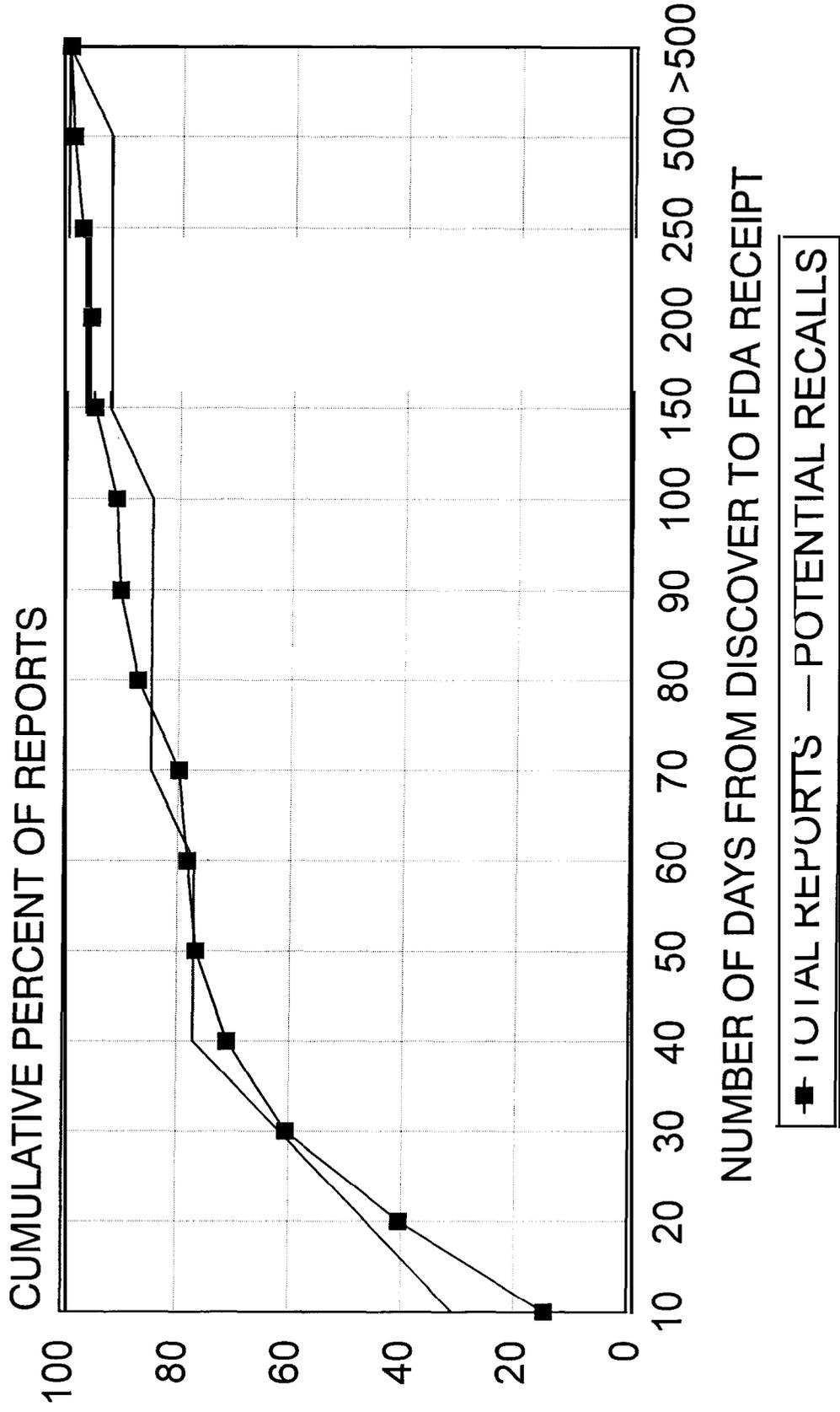
FY97



TOTAL REPORTS = 4545

POTENTIAL RECALLS = 949

ERROR AND ACCIDENT REPORTS REPORTING TIME ≤ UNLICENSED BLOOD BANKS FY97



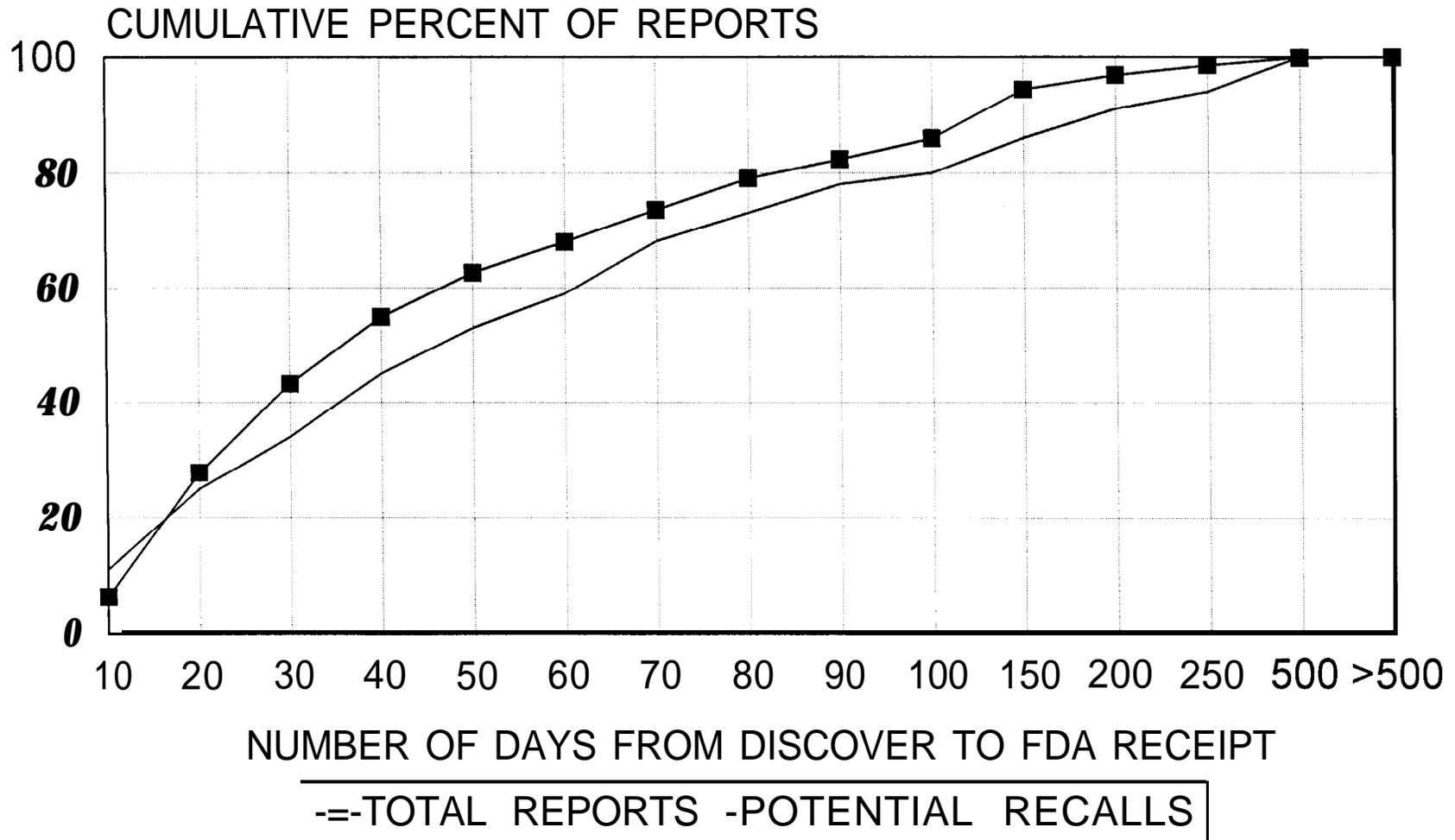
TOTAL REPORTS = 121
POTENTIAL RECALLS = 13

ERROR AND ACCIDENT REPORTS

REPORTING TIME

PLASMA CENTERS

FY97



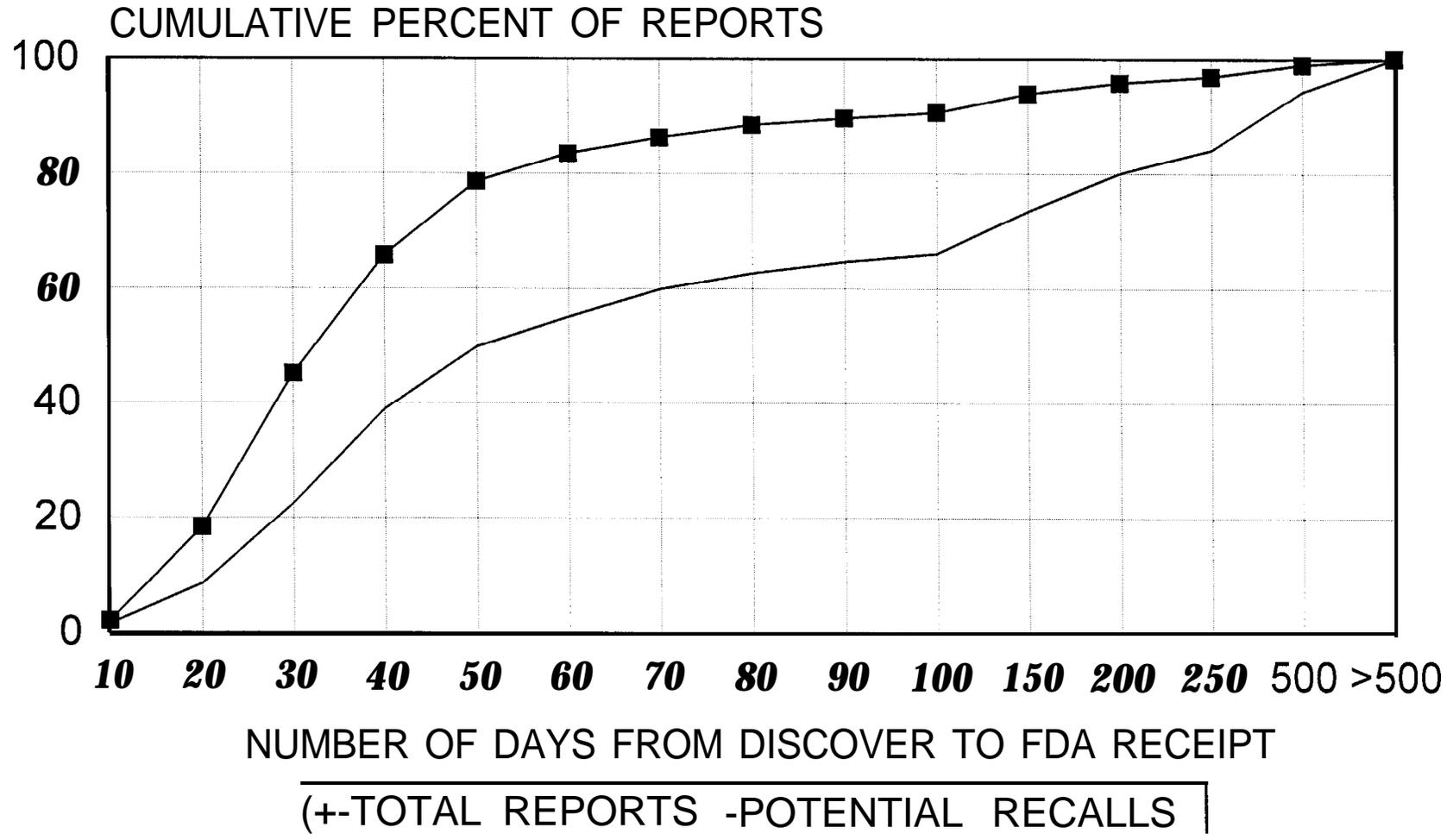
TOTAL REPORTS = 843
 POTENTIAL RECALLS = 13

ERROR AND ACCIDENT REPORTS

REPORTING TIME

ALL LICENSED BLOOD BANKS

FY97



TOTAL REPORTS = 10,111
 POTENTIAL RECALLS = 1378

FY-97

DS/DD - DONOR SUITABILITY

DS - Donor Screening

DS5000 - Miscellaneous (see remarks)

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)

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)

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)

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 (see remarks)

5317 - Exchanged sex for drugs/money

5318 - Received tattoo, ear-piercing, 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 (see remarks)

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)
- 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 (see remarks)
- 5417 - Exchanged sex for drugs/money
- 5418 - Received tattoo, ear-piercing, 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 (see remarks)
- 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)
- 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 (see remarks)
- 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 (see remarks)
- 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 (see remarks)

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)
- 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 (see remarks)
- 6117 - Exchanged sex for drugs/money
- 6118 - Received tattoo, ear-piercing, 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 (see remarks)
- 6127 - Received growth hormone
- 6128 - Received Proscar, Tegison or Accutane
- 6129 - Received medication or antibiotics
- 6130 - Received vaccine or immune globulin
- 6131 - Exposure to a disease
- 6132 - Incarcerated
- 6133 - Resided in a rehabilitation center or psychiatric hospital
- 6134 - Received Methotrexate
- 6135 - History of Hepatitis A
- 6136 - Exposure to Hepatitis A

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

- 6201 - HIV reactivity
- 6202 - HBsAg reactivity or history of hepatitis
- 6203 - Anti-HBc reactivity
- 6204 - Anti-HCV reactivity
- 6205 - Anti-HTLV-I reactivity
- 6206 - ALT reactivity
- 6207 - Other reasons (see remarks)
- 6208 - Sexually transmitted disease, or positive STS
- 6209 - Sexual partner having sexually transmitted disease
- 6210 - Sexual partner testing positive for HIV
- 6211 - Sexual partner testing positive for Hepatitis marker
- 6212 - Male donor had sex with another man
- 6213 - Female had sex with a man who has had sex with another man
- 6214 - IV drug use
- 6215 - Sex with IV drug user
- 6216 - Travel/immigration - high risk area (see remarks)
- 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 (see remarks)
- 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)
- 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 (see remarks)
- 6317 - Exchanged sex for drugs/money
- 6318 - Received tattoo, ear-piercing, 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 (comment if diagnosed post donation)
- 6325 - History of Creutzfeldt-Jakob Disease
- 6326 - Risk factors associated with Creutzfeldt-Jakob Disease (see remarks)
- 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)
- BC31 - Sterility compromised
 - 3100 - Other (see remarks)
 - 3101 - Bacterial contamination (see remarks)
 - 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)

3401 - Collection time extended, discrepant, or not documented

3402 - Overbleed

BC35 - Collection device

3500 - Device defect (see remarks)

CP - COMPONENT PREPARATION

CP8000 - Miscellaneous

CP8100 - Components prepared more than 8 hours after collection

CP8200 - Additive not added or added inappropriately

CP8300 - Sterility compromised

8301 - Other (see remarks)

8302 - Bacterial contamination (see remarks)

8303 - Air contamination

CP8400 - Incorrect/inappropriate preparation of platelets

8400 - Other (see remarks)

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)

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

RTNT - LABORATORY TESTING

RT - ROUTINE TESTING

RT1000 - Miscellaneous (see remarks)

RT11 - Incorrectly tested for:

1101 - ABO

1102 - Rh

1103 - ABO & Rh

1104 - Antibody screening

1105 - Antigen typing

1106 - Other (see remarks)

1107 - Platelet count

1108 - Compatibility

RT12 - Sample identification

1201 - Incorrect sample tested/sample misidentified

VT - VIRAL TESTING

VT2000 - Miscellaneous (see remarks)

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 (see remarks)
- 2 112 - Cytomegalovirus

LA - Labeling

LA4000 - Miscellaneous (see remarks)

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)
- 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 (see remarks)

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)
- 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 (see remarks)
- 7117 - Exchanged sex for drugs/money
- 7118 - Received tattoo, ear-piercing, 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 (see remarks)
- 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)
 - 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)
 - 7308 - ABO
 - 7309 - Rh
 - 7310 - Antibody screen
 - 7311 - Antigen screen

- 7312 - Syphilis
- SD74 - Inappropriate release
 - 7400 - Other (see remarks)
 - 7401 - Outdated product
 - 7402 - Autologous unit not meeting homologous criteria
- SD75 - Unsuitable product
 - 7500 - Other (see remarks)
 - 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
 - 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 (see remarks)
 - 9000 - Miscellaneous
- MI92 - Donor implicated in transfusion associated disease
 - 9201** - HIV
 - 9202 - Hepatitis
 - 9203 - Other (see remarks)
- 9500 - Lookback; subsequent unit tested
 - 9501 - HIV antibody positive
 - 9502 - HBsAg positive
 - 9503 - HCV positive
 - 9504 - HTLV-I positive
 - 9505 - HIV antigen positive

NB - Non-Blood Products**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 (see remarks)
- 2020 - Bacterial contamination

NB30 - Labeling

- 3010 - Other (see remarks)
- 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 (see remarks)
- 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 (see remarks)
- 5020 - Stability testing

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 { 606.15 1 (e), 606.12 1 (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 (see remarks)
- 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 (DAT)
- LT2 - Testing not routinely performed, unit tested positive for Bilirubin
- LT3 - Testing not routinely performed, unit tested positive for Sickle Cell
- LT4 - Retrospective testing - repeat reactive; unit suitable at time of distribution
- LT5 - Retrospective testing - initial reactive; unit suitable at time of distribution

ERROR CODE	ARC	LICENSED BLOOD BANKS	REGISTERED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	Total	
DONOR SCREENING						720	6.5%
DS5103	13	3	0	0	0	16	0.14%
DS5104	5	18	0	0	0	23	0.21%
DS5105	1	0	0	0	1	2	0.02%
DS5107	0	1	0	0	0	1	0.01%
DS5109	0	0	0	0	1	1	0.01%
DS5200	9	4	0	0	0	13	0.12%
DS5201	4	4	0	0	1	9	0.08%
DS5202	0	10	0	0	0	10	0.09%
DS5203	17	34	0	0	3	54	0.49%
DS5204	10	36	0	0	0	46	0.42%
DS5301	36	1	0	0	1	38	0.34%
DS5302	4	1	0	0	5	10	0.09%
DS5303	1	3	0	0	0	4	0.04%
DS5304	1	0	0	0	4	5	0.05%
DS5305	0	1	0	0	0	1	0.01%
DS5306	0	1	0	0	0	1	0.01%
DS5307	1	5	1	0	14	21	0.19%
DS5308	0	1	0	0	0	1	0.01%
DS5310	0	0	0	0	1	1	0.01%
DS5318	1	4	0	0	2	7	0.06%
DS5320	0	0	0	0	1	1	0.01%
DS5321	0	0	0	0	1	1	0.01%
DS5322	0	3	0	0	0	3	0.03%
DS5323	3	0	0	0	0	3	0.03%
DS5324	0	1	0	0	0	1	0.01%
DS5329	0	2	0	0	0	2	0.02%
DS5332	0	1	0	0	0	1	0.01%
DS5335	1	0	0	0	0	1	0.01%
DS5401	4	7	0	0	1	12	0.11%
DS5402	4	2	0	0	2	8	0.07%
DS5403	0	2	0	0	0	2	0.02%
DS5404	4	2	0	0	2	8	0.07%
DS5405	1	0	0	0	0	1	0.01%
DS5406	0	2	0	0	1	3	0.03%
DS5407	0	2	1	0	1	4	0.04%
DS5408	0	1	0	0	1	2	0.02%
DS5412	0	1	0	0	0	1	0.01%
DS5414	2	2	0	0	0	4	0.04%
DS5418	0	6	0	0	0	6	0.05%
DS5422	1	2	0	0	0	3	0.03%
DS5423	0	1	0	0	0	1	0.01%
DS5501	0	1	0	0	0	1	0.01%
DS5502	11	8	0	0	2	21	0.19%
DS5507	0	1	0	0	0	1	0.01%
DS5508	0	1	0	0	0	1	0.01%
DS5509	0	1	0	0	0	1	0.01%
DS5511	5	1	0	0	0	6	0.05%
DS5512	0	1	0	0	0	1	0.01%

ERROR CODE	ARC	LICENSED BLOOD BANKS	REGISTERED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	Total	
DS5514	0	1	0	0	0	1	0.01%
DS5515	0	1	0	0	0	1	0.01%
DS5516	0	3	0	0	0	3	0.03%
DS5518	6	19	1	0	2	28	0.25%
DS5520	3	0	0	0	0	3	0.03%
DS5521	0	3	0	0	2	5	0.05%
DS5522	67	75	1	0	0	143	1.29%
DS5523	12	17	0	0	0	29	0.26%
DS5524	19	34	0	0	1	54	0.49%
DS5526	7	2	0	0	3	12	0.11%
DS5527	0	1	0	0	0	1	0.01%
DS5528	7	4	0	0	0	11	0.10%
DS5529	18	21	0	0	1	40	0.36%
DS5530	4	0	0	0	0	4	0.04%
DS5534	8	1	0	0	0	9	0.08%
DS5535	1	6	1	0	2	10	0.09%
DS5536	0	2	0	0	0	2	0.02%
DONOR DEFERRAL						176	1.6%
DD6101	15	73	0	0	2	90	0.81%
DD6102	3	8	0	0	0	11	0.10%
DD6103	2	14	0	0	0	16	0.14%
DD6104	4	5	0	0	3	12	0.11%
DD6105	0	2	1	0	0	3	0.03%
DD6106	0	0	0	0	1	1	0.01%
DD6107	0	2	0	0	1	3	0.03%
DD6108	0	2	0	0	0	2	0.02%
DD6114	0	0	0	0	1	1	0.01%
DD6118	1	3	0	0	1	5	0.05%
DD6122	2	0	0	0	0	2	0.02%
DD6124	2	1	0	0	0	3	0.03%
DD6126	0	0	1	0	0	1	0.01%
DD6129	0	1	0	0	0	1	0.01%
DD6132	0	0	0	0	1	1	0.01%
DD6201	11	0	0	0	0	11	0.10%
DD6202	0	2	0	0	0	2	0.02%
DD6203	0	2	0	0	0	2	0.02%
DD6204	0	5	0	0	0	5	0.05%
DD6207	0	1	0	0	0	1	0.01%
DD6211	1	0	0	0	0	1	0.01%
DD6223	1	0	0	0	0	1	0.01%
DD6224	1	0	0	0	0	1	0.01%
POST DONATION INFORMATION						6658	60.1%
DD6301	35	12	1	0	0	48	0.43%
DD6303	501	279	4	0	2	786	7.10%
DD6304	29	22	1	0	8	60	0.54%
DD6305	12	7	0	0	4	23	0.21%
DD6306	7	6	1	0	7	21	0.19%
DD6307	133	74	2	0	22	231	2.09%
DD6308	17	11	0	0	3	31	0.28%
DD6309	1	2	0	0	1	4	0.04%

ERROR CODE	ARC	LICENSED BLOOD BANKS	REGISTERED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	Total	
DD6310	23	15	0	0	27	65	0.59%
DD6311	102	77	3	0	18	200	1.81%
DD6312	156	53	2	0	28	239	2.16%
DD6313	30	12	0	0	2	44	0.40%
DD6314	181	157	2	0	80	420	3.79%
DD6315	97	55	1	0	20	173	1.56%
DD6316	24	39	0	0	17	80	0.72%
DD6317	28	23	0	0	13	64	0.58%
DD6318	659	299	7	0	131	1096	9.90%
DD6319	6	1	0	0	0	7	0.06%
DD6320	69	49	0	0	5	123	1.11%
DD6321	45	77	1	0	87	210	1.90%
DD6322	360	484	4	0	2	850	7.67%
DD6323	185	153	2	0	5	345	3.11%
DD6324	347	229	5	0	6	587	5.30%
DD6325	2	2	0	0	0	4	0.04%
DD6326	148	89	0	0	2	239	2.16%
DD6327	19	19	0	0	1	39	0.35%
DD6328	76	35	0	0	0	111	1.00%
DD6329	88	41	0	0	3	132	1.19%
DD6330	32	19	0	0	1	52	0.47%
DD6331	10	3	0	0	2	15	0.14%
DD6332	12	10	1	0	150	173	1.56%
DD6333	10	1	0	0	3	14	0.13%
DD6334	6	0	0	0	0	6	0.05%
DD6335	26	35	1	0	7	69	0.62%
DD6336	68	27	0	0	2	97	0.88%
COLLECTION						93	0.8%
BC3000	2	0	0	0	0	2	0.02%
BC3100	3	1	1	0	1	6	0.05%
BC3101	21	12	4	0	0	37	0.33%
BC3102	10	5	0	0	0	15	0.14%
BC3103	0	3	0	0	0	3	0.03%
BC3201	0	2	0	0	0	2	0.02%
BC3202	2	0	0	0	0	2	0.02%
BC3203	1	1	0	0	0	2	0.02%
BC3303	0	0	0	0	1	1	0.01%
BC3400	0	1	0	0	0	1	0.01%
BC3401	3	4	0	0	0	7	0.06%
BC3402	8	3	0	0	0	11	0.10%
BC3500	1	3	0	0	0	4	0.04%
COMPONENT PREPARATION						252	2.3%
CP8100	0	2	0	0	0	2	0.02%
CP8200	9	5	0	0	0	14	0.13%
CP8301	1	0	0	0	0	1	0.01%
CP8302	6	5	0	0	0	11	0.10%
CP8303	1	4	0	0	0	5	0.05%
CP8400	15	10	0	0	0	25	0.23%
CP8401	15	13	0	0	0	28	0.25%
CP8402	2	11	0	0	0	13	0.12%

ERROR CODE	ARC	LICENSED BLOOD BANKS	REGISTERED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	Total	
CP8403	0	2	0	0	0	2	0.02%
CP8404	3	1	0	0	0	4	0.04%
CP8405	1	2	0	0	0	3	0.03%
CP8406	6	4	0	0	0	10	0.09%
CP8407	34	14	0	0	0	48	0.43%
CP8500	20	22	0	0	0	42	0.38%
CP8502	2	12	0	0	0	14	0.13%
CP8503	1	3	0	0	0	4	0.04%
CP8504	0	1	0	0	0	1	0.01%
CP8600	1	0	0	0	0	1	0.01%
CP8700	15	7	1	1	0	24	0.22%
ROUTINE TESTING						427	3.9%
RT1101	32	50	2	0	0	84	0.76%
RT1102	90	74	5	0	0	169	1.53%
RT1103	0	3	0	0	0	3	0.03%
RT1104	20	32	0	1	0	53	0.48%
RT1105	45	17	0	0	0	62	0.56%
RT1106	3	2	0	0	0	5	0.05%
RT1107	1	0	0	0	0	1	0.01%
RT1108	4	2	0	0	0	6	0.05%
RT1201	15	18	8	1	2	44	0.40%
VIRAL TESTING						413	3.7%
VT2101	5	64	1	0	1	71	0.64%
VT2102	4	35	0	0	0	39	0.35%
VT2104	2	9	0	0	0	11	0.10%
VT2105	1	4	0	0	3	8	0.07%
VT2106	7	12	0	0	0	19	0.17%
VT2107	4	12	2	0	0	18	0.16%
VT2108	2	202	0	0	0	204	1.84%
VT2109	1	7	1	0	0	9	0.08%
VT2110	3	9	0	0	1	13	0.12%
VT2111	2	7	1	0	1	11	0.10%
VT2112	9	1	0	0	0	10	0.09%
LABELING						947	8.6%
LA4101	27	63	6	0	0	96	0.87%
LA4102	49	39	2	0	0	90	0.81%
LA4103	28	128	1	3	1	161	1.45%
LA4201	209	93	0	0	0	302	2.73%
LA4202	27	33	0	0	0	60	0.54%
LA4203	35	23	0	0	0	58	0.52%
LA4204	2	11	0	1	0	14	0.13%
LA4205	2	2	0	0	0	4	0.04%
LA4206	3	7	0	0	0	10	0.09%
LA4207	6	7	0	0	0	13	0.12%
LA4208	1	4	0	0	1	6	0.05%
LA4209	39	30	1	0	1	71	0.64%
LA4210	3	0	0	0	0	3	0.03%
LA4211	26	10	0	0	0	36	0.33%
LA4300	11	12	0	0	0	23	0.21%

ERROR CODE	ARC	LICENSED BLOOD BANKS	REGISTERED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	Total	
STORAGE/DISTRIBUTION						1353	12.2%
SD7000	0	1	0	0	0	1	0.01%
SD7101	1	2	0	0	2	5	0.05%
SD7102	1	0	0	0	0	1	0.01%
SD7103	0	1	0	0	0	1	0.01%
SD7104	0	0	0	0	1	1	0.01%
SD7106	0	1	0	0	1	2	0.02%
SD7107	28	35	1	0	2	66	0.60%
SD7108	1	0	0	0	1	2	0.02%
SD7111	0	0	0	0	2	2	0.02%
SD7112	0	2	0	0	0	2	0.02%
SD7115	1	1	0	0	0	2	0.02%
SD7118	2	1	0	0	7	10	0.09%
SD7120	1	0	0	0	0	1	0.01%
SD7121	0	1	0	0	0	1	0.01%
SD7122	1	3	0	0	0	4	0.04%
SD7124	1	1	0	0	0	2	0.02%
SD7125	1	0	0	0	0	1	0.01%
SD7128	0	1	0	0	0	1	0.01%
SD7129	2	2	0	0	1	5	0.05%
SD7130	0	3	0	0	0	3	0.03%
SD7132	0	1	0	0	4	5	0.05%
SD7135	0	1	0	0	0	1	0.01%
SD7201	0	5	2	0	0	7	0.06%
SD7202	1	7	0	0	1	9	0.08%
SD7203	0	10	3	0	0	13	0.12%
SD7204	0	4	2	0	12	18	0.16%
SD7205	0	1	0	0	0	1	0.01%
SD7206	1	2	0	0	6	9	0.08%
SD7207	7	8	0	0	1	16	0.14%
SD7208	4	2	0	0	0	6	0.05%
SD7210	10	3	1	0	0	14	0.13%
SD7211	0	1	0	0	0	1	0.01%
SD7212	2	2	0	0	1	5	0.05%
SD7301	1	5	1	0	6	13	0.12%
SD7302	1	2	0	0	0	3	0.03%
SD7303	0	4	0	0	0	4	0.04%
SD7304	1	1	0	0	0	2	0.02%
SD7305	0	4	0	0	0	4	0.04%
SD7306	0	1	0	0	1	2	0.02%
SD7307	6	10	2	0	16	34	0.31%
SD7308	1	3	0	0	0	4	0.04%
SD7309	1	0	0	0	0	1	0.01%
SD7310	3	1	0	0	0	4	0.04%
SD7311	1	1	0	0	0	2	0.02%
SD7312	0	6	1	0	8	15	0.14%
SD7400	14	6	0	1	0	21	0.19%
SD7401	11	22	4	0	0	37	0.33%
SD7402	1	1	0	0	0	2	0.02%
SD7500	33	13	0	0	0	46	0.42%

ERROR CODE	ARC	LICENSED BLOOD BANKS	REGISTERED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	Total	
SD7501	376	147	1	0	0	524	4.73%
SD7502	91	23	0	0	0	114	1.03%
SD7503	42	2	0	0	0	44	0.40%
SD7600	119	59	0	1	3	182	1.64%
SD7700	14	16	0	0	2	32	0.29%
SD7800	2	3	2	0	0	7	0.06%
SD7801	0	3	1	1	0	5	0.05%
SD7802	0	7	3	1	0	11	0.10%
SD7803	0	5	1	0	0	6	0.05%
SD7804	2	10	2	2	0	16	0.14%
MISCELLANEOUS						37	0.3%
MI9000	0	1	0	0	0	1	0.01%
MI9501	0	1	0	0	5	6	0.05%
MI9502	0	1	0	0	2	3	0.03%
MI9503	2	3	0	0	18	23	0.21%
MI9504	0	1	0	0	0	1	0.01%
MI9505	0	0	0	0	3	3	0.03%
Total	5566	4545	108	13	844	11076	100.00%

Non-Reportable Errors and Accidents

ERROR CODES	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
DONOR SCREENING						148	11.0%
DS1	14	5	0	0	2	21	1.56%
DS2	1	1	0	0	0	2	0.15%
DS3	9	10	0	0	0	19	1.41%
DS4	23	59	2	0	0	84	6.25%
DS6	3	2	0	0	0	5	0.37%
DS8	0	0	0	0	3	3	0.22%
miscellaneous	3	11	0	0	0	14	1.04%
DONOR DEFERRAL						105	7.8%
miscellaneous	0	104	0	0	1	105	7.81%
POST DONATION INFORMATION						106	7.9%
DS5	31	62	0	0	0	93	6.91%
miscellaneous	6	1	0	0	6	13	0.97%
COLLECTION						73	5.4%
BC1	5	1	0	0	0	6	0.45%
BC3	59	4	0	0	1	64	4.76%
miscellaneous	3	0	0	0	0	3	0.22%
COMPONENT PREPARATION						4	0.3%
miscellaneous	0	3	1	0	0	4	0.30%
ROUTINE TESTING						4	0.3%
LT1	2	0	0	0	0	2	0.15%
miscellaneous	0	2	0	0	0	2	0.15%
VIRAL TESTING						27	2.0%
LT4	0	3	0	0	0	3	0.22%
LT5	0	17	0	0	0	17	1.26%
miscellaneous	2	5	0	0	0	7	0.52%
LABELING						222	16.5%
LA1	8	40	1	0	0	49	3.64%
LA2	27	40	1	0	0	68	5.06%
LA3	19	11	0	0	0	30	2.23%
LA4	32	30	0	0	0	62	4.61%
miscellaneous	5	8	0	0	0	13	0.97%
STORAGE/DISTRIBUTION						104	7.7%
DI1	18	19	0	0	0	37	2.75%
DI3	4	11	0	0	0	15	1.12%
DI4	0	1	0	0	0	1	0.07%
DI5	1	0	0	0	0	1	0.07%
DI6	10	20	1	0	0	31	2.30%
DI7	6	1	0	0	0	7	0.52%
DI8	0	1	0	0	0	1	0.07%
miscellaneous	5	6	0	0	0	11	0.82%

ERROR CODES	ARC	LICENSED BLOOD BANKS	UNLICENSED BLOOD BANKS	TRANSFUSION SERVICES	PLASMA CENTERS	TOTAL	
MISCELLANEOUS						552	41.0%
MI1	42	45	1	0	1	89	6.62%
MI2	7	3	0	0	0	10	0.74%
MI3	47	43	3	0	2	95	7.06%
MI4	33	208	2	0	11	254	18.88%
MI5	22	4	1	0	0	27	2.01%
MI6	16	1	0	0	0	17	1.26%
QC1	40	18	2	0	0	60	4.46%
TOTAL	503	798	17	0	27	1345	100.0%