M E M O R A N D U M DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

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DATE :

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

SUBJECT: ERROR AND ACCIDENT REPORTS – Annual Summary for FY2000

TO : Director, Division of Inspections and Surveillance (HFM-650)
Office of Compliance and Biologics Quality

Between October 1, 1999 and September 30, 2000, the Division of Inspections and Surveillance received 23,528 error and accident reports from biological product manufacturers. Blood and plasma establishments submitted 23,346 reports and non-blood manufacturers submitted 182 reports. There were 1401 (6.0%) 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, 644 (2.7%) 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.

Tables and charts are included that identify the types of errors and accidents submitted by blood and plasma establishments and by non-blood (allergenic, in-vitro diagnostic, therapeutic, derivative, and vaccine) manufacturers. Additional tables are included which identify, in more detail, the types of errors and accidents submitted by blood and plasma establishments included under the categories that represent the greatest percentage of reports received. 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 that CBER received the report.

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

| Reportable Errors/Accidents | | | Non-Reportable Errors/Accidents | | |
|---|---|---|---|---|---|
| Donor Suitability – 86.3% | | | Miscellaneous | | 48.1% |
| Post Donation Info | | 81.3% | Labeling | | 19.2% |
| Donor Screening | | 4.7% | Donor Suitability – 16.5% | | |
| Donor Deferral | 0.3% | | Donor Screening | 9.4% | |
| Storage and Distribution | | 6.6% | Post Donation Info | | 6.3% |
| Labeling | | 4.0% | Donor Deferral | 0.8% | |
| Product Testing – 1.7% | | | Storage and Distribution | | 14.3% |
| Routine Testing | | 1.4% | Collection | | 1.3% |
| Viral Testing | | 0.3% | Product Testing – 0.5% | | |
| Component Preparation | | 0.7% | Routine Testing | 0.3% | |
| Collection | | 0.6% | Viral Testing | | 0.2% |
| Miscellaneous | | 0.0% | Component Preparation | | 0.2% |

More specific summary charts are included 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 provided information of travelling to the United Kingdom for a cumulative of 6 months or more from 1980 to 1996. In most cases, this information was not solicited at the previous donations.

Of the 18,471 post donation information reports received, 16371 (88.6%) reports involved the donor providing the information at a subsequent donation, 1367 (7.4%) reports involved the donor calling back to the center within a few days of donating, and 733 (4.0%) reports involved a third party providing the information.

| INFORMATION RECEIVED BY: | LICENSED BLOOD BANKS | UNLICENSED BLOOD BANKS | PLASMA CENTERS | TOTAL | |
|---|---|---|---|---|---|
| SUBSEQUENT DONATION | 14120 | 14 | 2237 | 16371 | 88.6% |
| TELEPHONE CALL | 1347 | 3 | 17 | 1367 | 7.4% |
| THIRD PARTY | 382 | 1 | 350 | 733 | 4.0% |
| TOTAL | 15849 | 18 | 2604 | 18471 | 100.0% |

Of the 18,471 post donation information reports received, 16,654 (90.2%) 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. 1817 (9.8%) reports involved information in which the donor was not aware, such as post donation illness, cancer diagnosed post donation, or sex partner participated in high risk behavior or tested positive, etc.

| INFORMATION | LICENSED BLOOD BANKS | UNLICENSED BLOOD BANKS | PLASMA CENTERS | TOTAL | |
|---|---|---|---|---|---|
| AVAILABLE, NOT PROVIDED | 14118 | 14 | 2522 | 16654 | 90.2% |
| NOT KNOWN AT TIME OF DONATION | 1731 | 4 | 82 | 1817 | 9.8% |
| TOTAL | 15849 | 18 | 2604 | 18471 | 100.0% |

**ERROR AND ACCIDENT REPORTS**
**RECEIVED 10/1/99 - 9/30/00**

| | NUMBER OF REPORTING ESTABLISHMENTS | TOTAL REPORTS RECEIVED | POTENTIAL RECALLS | |
|---|---|---|---|---|
| **BLOOD/PLASMA MANUFACTURERS** | | | | |
| LICENSED BLOOD BANKS | 162* | 20196 | 1184 | 5.8% |
| UNLICENSED BLOOD BANKS | 52 | 125 | 11 | 8.8% |
| TRANSFUSION SERVICES | 19 | 53 | 2 | 3.8% |
| PLASMA CENTERS | 316 | 2972 | 179 | 6.0% |
| *SUB-TOTAL* | 549 | 23346 | 1376 | 5.9% |
| **NON-BLOOD MANUFACTURERS** | | | | |
| BLOOD DERIVATIVE MANUFACTURER | 15 | 34 | 3 | 8.8% |
| IN-VITRO DIAGNOSTIC MANUFACTURER | 11 | 38 | 7 | 18.4% |
| VACCINE MANUFACTURER | 8 | 21 | 4 | 19.0% |
| ALLERGENICS MANUFACTURER | 6 | 57 | 6 | 10.5% |
| THERAPEUTIC MANUFACTURER | 14 | 32 | 5 | 15.6% |
| *SUB-TOTAL* | 54 | 182 | 25 | 13.7% |
| TOTAL | **603** | **23528** | **1401** | **6.0%** |

*****Number of license holders; may be one establishment or multiple establishments operating under one license.

| | **Total Reports Received** | **Reportable** | **% Reportable** | **Non-Reportable** | **% Non-Reportable** |
|---|---|---|---|---|---|
| **BLOOD/PLASMA MANUFACTURERS** | | | | | |
| LICENSED BLOOD BANKS | 20196 | 19680 | 97.4% | 516 | 2.6% |
| UNLICENSED BLOOD BANKS | 125 | 109 | 87.2% | 16 | 12.8% |
| TRANSFUSION SERVICES | 53 | 36 | 67.9% | 17 | 32.1% |
| PLASMA CENTERS | 2972 | 2891 | 97.3% | 81 | 2.7% |
| *SUB-TOTAL* | 23346 | 22716 | 97.3% | 630 | 2.7% |
| **NON-BLOOD MANUFACTURERS** | | | | | |
| BLOOD DERIVATIVE MANUFACTURER | 34 | 31 | 91.2% | 3 | 8.8% |
| IN-VITRO DIAGNOSTIC MANUFACTURER | 38 | 35 | 92.1% | 3 | 7.9% |
| VACCINE MANUFACTURER | 21 | 20 | 95.2% | 1 | 4.8% |
| ALLERGENICS MANUFACTURER | 57 | 50 | 87.7% | 7 | 0.0% |
| THERAPEUTIC MANUFACTURER | 32 | 32 | 100.0% | 0 | 0.0% |
| *SUB-TOTAL* | 182 | 168 | 92.3% | 14 | 7.7% |
| TOTAL | **23528** | **22884** | **97.3%** | **644** | **2.7%** |

The following tables and pie charts show the type of errors and accidents reported by blood and plasma establishments:

TOTAL ERRORS AND ACCIDENTS

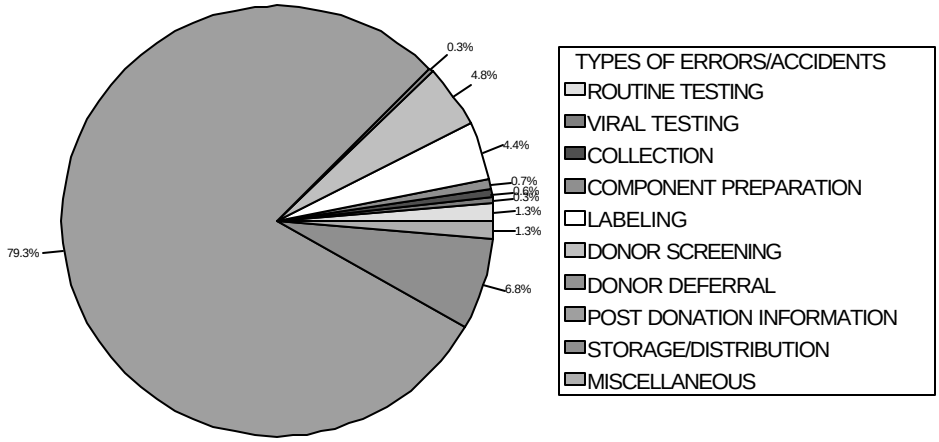
| TYPE OF ERROR/ACCIDENT | LICENSED BLOOD BANKS | UNLICENSED BLOOD BANKS | TRANSFUSION SERVICES | PLASMA CENTERS | TOTAL | |
|---|---|---|---|---|---|---|
| POST DONATION INFORMATION | 15888 | 19 | 0 | 2604 | 18511 | 79.3% |
| STORAGE/DISTRIBUTION | 1487 | 31 | 15 | 65 | 1598 | 6.8% |
| DONOR SCREENING | 925 | 8 | 0 | 196 | 1129 | 4.8% |
| LABELING | 986 | 29 | 4 | 10 | 1029 | 4.4% |
| ROUTINE TESTING | 285 | 11 | 16 | 0 | 312 | 1.3% |
| MISCELLANEOUS | 224 | 9 | 16 | 59 | 308 | 1.3% |
| COMPONENT PREPARATION | 162 | 2 | 2 | 0 | 166 | 0.7% |
| COLLECTION | 126 | 5 | 0 | 4 | 135 | 0.6% |
| VIRAL TESTING | 54 | 9 | 0 | 17 | 80 | 0.3% |
| DONOR DEFERRAL | 59 | 2 | 0 | 17 | 78 | 0.3% |
| *TOTAL* | 20196 | 125 | 53 | 2972 | 23346 | 100.0% |

POTENTIAL RECALLS

| TYPE OF ERROR/ACCIDENT | LICENSED BLOOD BANKS | UNLICENSED BLOOD BANKS | TRANSFUSION SERVICES | PLASMA CENTERS | TOTAL | |
|---|---|---|---|---|---|---|
| DONOR SCREENING | 498 | 2 | 0 | 95 | 595 | 43.2% |
| STORAGE/DISTRIBUTION | 212 | 3 | 1 | 40 | 256 | 18.6% |
| LABELING | 143 | 2 | 0 | 5 | 150 | 10.9% |
| COMPONENT PREPARATION | 115 | 0 | 1 | 0 | 116 | 8.4% |
| POST DONATION INFORMATION | 81 | 0 | 0 | 18 | 99 | 7.2% |
| COLLECTION | 72 | 0 | 0 | 4 | 76 | 5.5% |
| DONOR DEFERRAL | 44 | 1 | 0 | 14 | 59 | 4.3% |
| VIRAL TESTING | 16 | 3 | 0 | 3 | 22 | 1.6% |
| ROUTINE TESTING | 3 | 0 | 0 | 0 | 3 | 0.2% |
| MISCELLANEOUS | 0 | 0 | 0 | 0 | 0 | 0.0% |
| *TOTAL* | 1184 | 11 | 2 | 179 | 1376 | 100.0% |

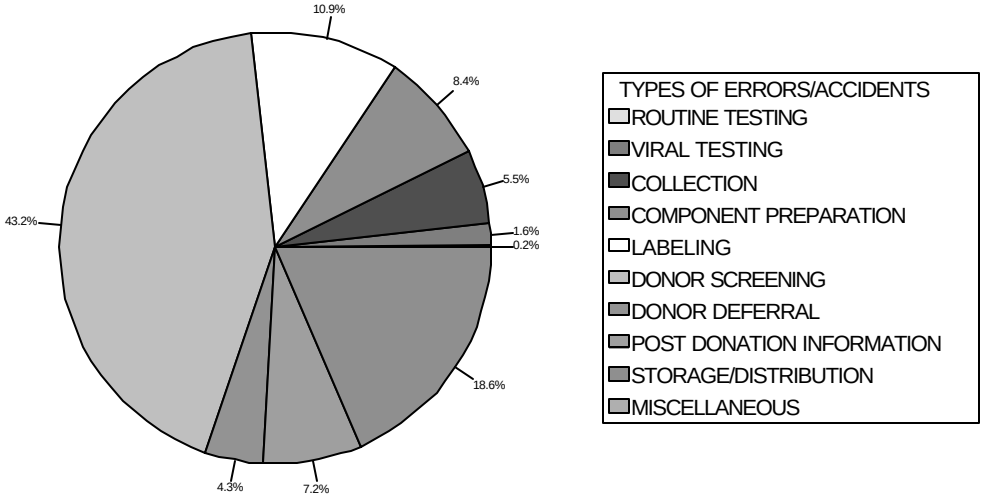
# ALL BLOOD AND PLASMA ESTABLISHMENTS FY-2000

## TOTAL REPORTS




*TOTAL REPORTS RECEIVED (10/1/99 - 9/30/00) = 23,346*

## POTENTIAL RECALLS




*POTENTIAL RECALLS = 1376*

# LICENSED BLOOD BANKS

## REPORTABLE ERRORS AND ACCIDENTS

| | QUARTER | | | | | |
|---|---|---|---|---|---|---|
| TYPE OF ERROR/ACCIDENT | FIRST | SECOND | THIRD | FOURTH | TOTAL | PERCENT |
| ROUTINE TESTING | 75 | 67 | 76 | 66 | 284 | 1.4% |
| VIRAL TESTING | 17 | 14 | 12 | 10 | 53 | 0.3% |
| COLLECTION | 35 | 23 | 35 | 25 | 118 | 0.6% |
| COMPONENT PREPARATION | 30 | 36 | 51 | 44 | 161 | 0.8% |
| LABELING | 197 | 237 | 236 | 198 | 868 | 4.4% |
| DONOR SCREENING | 202 | 262 | 226 | 200 | 890 | 4.5% |
| DONOR DEFERRAL | 13 | 7 | 16 | 18 | 54 | 0.3% |
| POST DONATION INFO | 2716 | 3184 | 5306 | 4643 | 15849 | 80.5% |
| STORAGE/DISTRIBUTION | 289 | 334 | 429 | 349 | 1401 | 7.1% |
| MISCELLANEOUS | 1 | 0 | 2 | 0 | 3 | 0.0% |
| TOTAL | 3575 | 4163 | 6389 | 5553 | 19680 | 100.0% |

## NON-REPORTABLE ERRORS AND ACCIDENTS

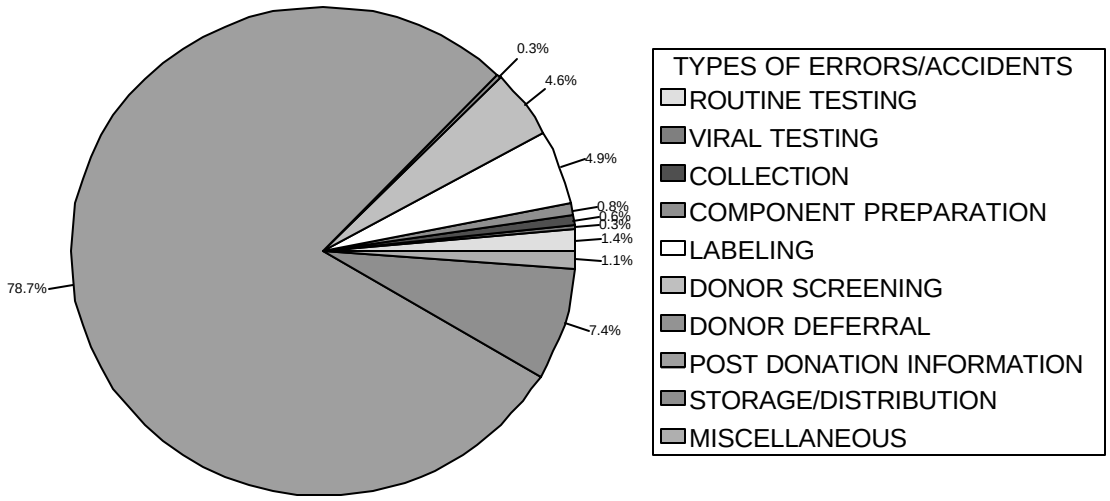
| | QUARTER | | | | | |
|---|---|---|---|---|---|---|
| TYPE OF ERROR/ACCIDENT | FIRST | SECOND | THIRD | FOURTH | TOTAL | PERCENT |
| ROUTINE TESTING | 2 | 0 | 0 | 0 | 2 | 0.4% |
| VIRAL TESTING | 0 | 0 | 1 | 0 | 1 | 0.2% |
| COLLECTION | 1 | 1 | 3 | 3 | 8 | 1.6% |
| COMPONENT PREPARATION | 0 | 0 | 1 | 0 | 1 | 0.2% |
| LABELING | 24 | 49 | 26 | 19 | 118 | 22.9% |
| DONOR SCREENING | 16 | 9 | 5 | 5 | 35 | 6.8% |
| DONOR DEFERRAL | 1 | 2 | 1 | 1 | 5 | 1.0% |
| POST DONATION INFO | 9 | 12 | 13 | 5 | 39 | 7.6% |
| STORAGE/DISTRIBUTION | 18 | 19 | 19 | 30 | 86 | 16.7% |
| MISCELLANEOUS | 45 | 64 | 70 | 42 | 221 | 42.8% |
| TOTAL | 116 | 156 | 139 | 105 | 516 | 100.0% |

## TOTAL ERRORS AND ACCIDENTS

| | QUARTER | | | | | |
|---|---|---|---|---|---|---|
| TOTAL | FIRST | SECOND | THIRD | FOURTH | TOTAL | PERCENT |
| ROUTINE TESTING | 77 | 66 | 76 | 66 | 285 | 1.4% |
| VIRAL TESTING | 17 | 14 | 13 | 10 | 54 | 0.3% |
| COLLECTION | 36 | 24 | 38 | 28 | 126 | 0.6% |
| COMPONENT PREPARATION | 30 | 36 | 52 | 44 | 162 | 0.8% |
| LABELING | 221 | 286 | 262 | 217 | 986 | 4.9% |
| DONOR SCREENING | 218 | 271 | 231 | 205 | 925 | 4.6% |
| DONOR DEFERRAL | 14 | 9 | 17 | 19 | 59 | 0.3% |
| POST DONATION INFO | 2725 | 3196 | 5319 | 4648 | 15888 | 78.7% |
| STORAGE/DISTRIBUTION | 307 | 353 | 448 | 379 | 1487 | 7.4% |
| MISCELLANEOUS | 46 | 64 | 72 | 42 | 224 | 1.1% |
| TOTAL | 3691 | 4319 | 6528 | 5658 | 20196 | 100.0% |

# FY-2000
# **Total Reports**

## LICENSED BLOOD ESTABLISHMENTS




*REPORTS RECEIVED (10/1/99 - 9/30/00) = 20,196*

# UNLICENSED BLOOD BANKS and TRANSFUSION SERVICES

## REPORTABLE ERRORS AND ACCIDENTS

| | QUARTER | | | | | |
|---|---|---|---|---|---|---|
| TYPE OF ERROR/ACCIDENT | FIRST | SECOND | THIRD | FOURTH | TOTAL | PERCENT |
| ROUTINE TESTING | 8 | 9 | 5 | 5 | 27 | 18.6% |
| VIRAL TESTING | 3 | 1 | 5 | 0 | 9 | 6.2% |
| COLLECTION | 3 | 1 | 1 | 0 | 5 | 3.4% |
| COMPONENT PREPARATION | 0 | 1 | 2 | 1 | 4 | 2.8% |
| LABELING | 5 | 8 | 4 | 13 | 30 | 20.7% |
| DONOR SCREENING | 0 | 0 | 2 | 5 | 7 | 4.8% |
| DONOR DEFERRAL | 1 | 1 | 0 | 0 | 2 | 1.4% |
| POST DONATION INFO | 3 | 1 | 5 | 9 | 18 | 12.4% |
| STORAGE/DISTRIBUTION | 7 | 13 | 11 | 12 | 43 | 29.7% |
| MISCELLANEOUS | 0 | 0 | 0 | 0 | 0 | 0.0% |
| TOTAL | 30 | 35 | 35 | 45 | 145 | 100.0% |

## NON-REPORTABLE ERRORS AND ACCIDENTS

| | QUARTER | | | | | |
|---|---|---|---|---|---|---|
| TYPE OF ERROR/ACCIDENT | FIRST | SECOND | THIRD | FOURTH | TOTAL | PERCENT |
| 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 | 1 | 0 | 1 | 3 | 9.1% |
| DONOR SCREENING | 1 | 0 | 0 | 0 | 1 | 3.0% |
| DONOR DEFERRAL | 0 | 0 | 0 | 0 | 0 | 0.0% |
| POST DONATION INFO | 0 | 0 | 0 | 1 | 1 | 3.0% |
| STORAGE/DISTRIBUTION | 0 | 1 | 2 | 0 | 3 | 9.1% |
| MISCELLANEOUS | 5 | 5 | 13 | 2 | 25 | 75.8% |
| TOTAL | 7 | 7 | 15 | 4 | 33 | 100.0% |

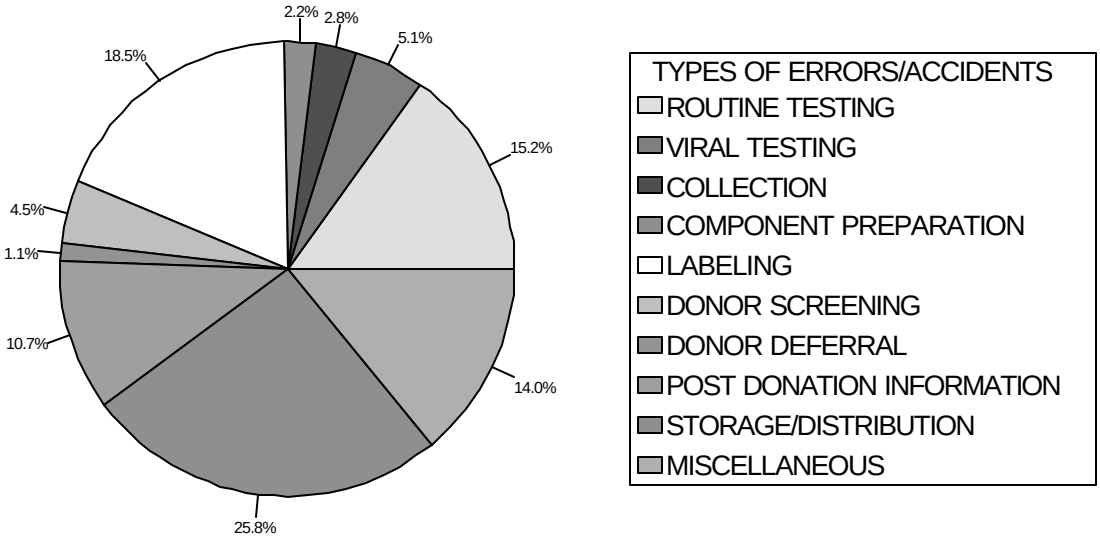
## TOTAL ERRORS AND ACCIDENTS

| | QUARTER | | | | | |
|---|---|---|---|---|---|---|
| TYPE OF ERROR/ACCIDENT | FIRST | SECOND | THIRD | FOURTH | TOTAL | PERCENT |
| ROUTINE TESTING | 8 | 9 | 5 | 5 | 27 | 15.2% |
| VIRAL TESTING | 3 | 1 | 5 | 0 | 9 | 5.1% |
| COLLECTION | 3 | 1 | 1 | 0 | 5 | 2.8% |
| COMPONENT PREPARATION | 0 | 1 | 2 | 1 | 4 | 2.2% |
| LABELING | 6 | 9 | 4 | 14 | 33 | 18.5% |
| DONOR SCREENING | 1 | 0 | 2 | 5 | 8 | 4.5% |
| DONOR DEFERRAL | 1 | 1 | 0 | 0 | 2 | 1.1% |
| POST DONATION INFO | 3 | 1 | 5 | 10 | 19 | 10.7% |
| STORAGE/DISTRIBUTION | 7 | 14 | 13 | 12 | 46 | 25.8% |
| MISCELLANEOUS | 5 | 5 | 13 | 2 | 25 | 14.0% |

| | | | | | | |
|---|---|---|---|---|---|---|
| TOTAL | 37 | 42 | 50 | 49 | 178 | 100.0% |

# FY-2000
# Total Reports

## UNLICENSED BLOOD ESTABLISHMENTS




*REPORTS RECEIVED (10/1/99 - 9/30/00) = 178*
*UNLICENSED BLOOD BANKS = 125; TRANSFUSION SERVICES = 53*

# PLASMA CENTERS

## REPORTABLE ERRORS AND ACCIDENTS

| | QUARTER | | | | | |
|---|---|---|---|---|---|---|
| TYPE OF ERROR/ACCIDENT | FIRST | SECOND | THIRD | FOURTH | TOTAL | PERCENT |
| ROUTINE TESTING | 0 | 0 | 0 | 0 | 0 | 0.0% |
| VIRAL TESTING | 2 | 0 | 4 | 11 | 17 | 0.6% |
| COLLECTION | 0 | 2 | 0 | 2 | 4 | 0.1% |
| COMPONENT PREPARATION | 0 | 0 | 0 | 0 | 0 | 0.0% |
| LABELING | 2 | 0 | 4 | 4 | 10 | 0.3% |
| DONOR SCREENING | 23 | 39 | 46 | 65 | 173 | 6.0% |
| DONOR DEFERRAL | 3 | 2 | 4 | 8 | 17 | 0.6% |
| POST DONATION INFO | 460 | 712 | 776 | 656 | 2604 | 90.1% |
| STORAGE/DISTRIBUTION | 10 | 25 | 15 | 14 | 64 | 2.2% |
| MISCELLANEOUS | 0 | 2 | 0 | 0 | 2 | 0.1% |
| TOTAL | 500 | 782 | 849 | 760 | 2891 | 100.0% |

## NON-REPORTABLE ERRORS AND ACCIDENTS

| | QUARTER | | | | | |
|---|---|---|---|---|---|---|
| TYPE OF ERROR/ACCIDENT | FIRST | SECOND | THIRD | FOURTH | TOTAL | PERCENT |
| ROUTINE TESTING | 0 | 0 | 0 | 0 | 0 | 0.0% |
| VIRAL TESTING | 0 | 0 | 0 | 0 | 0 | 0.0% |
| COLLECTION | 0 | 0 | 0 | 0 | 0 | 0.0% |
| COMPONENT PREPARATION | 0 | 0 | 0 | 0 | 0 | 0.0% |
| LABELING | 0 | 0 | 0 | 0 | 0 | 0.0% |
| DONOR SCREENING | 1 | 1 | 20 | 1 | 23 | 28.4% |
| DONOR DEFERRAL | 0 | 0 | 0 | 0 | 0 | 0.0% |
| POST DONATION INFO | 0 | 0 | 0 | 0 | 0 | 0.0% |
| STORAGE/DISTRIBUTION | 0 | 0 | 0 | 1 | 1 | 1.2% |
| MISCELLANEOUS | 8 | 9 | 19 | 21 | 57 | 70.4% |
| TOTAL | 9 | 10 | 39 | 23 | 81 | 100.0% |

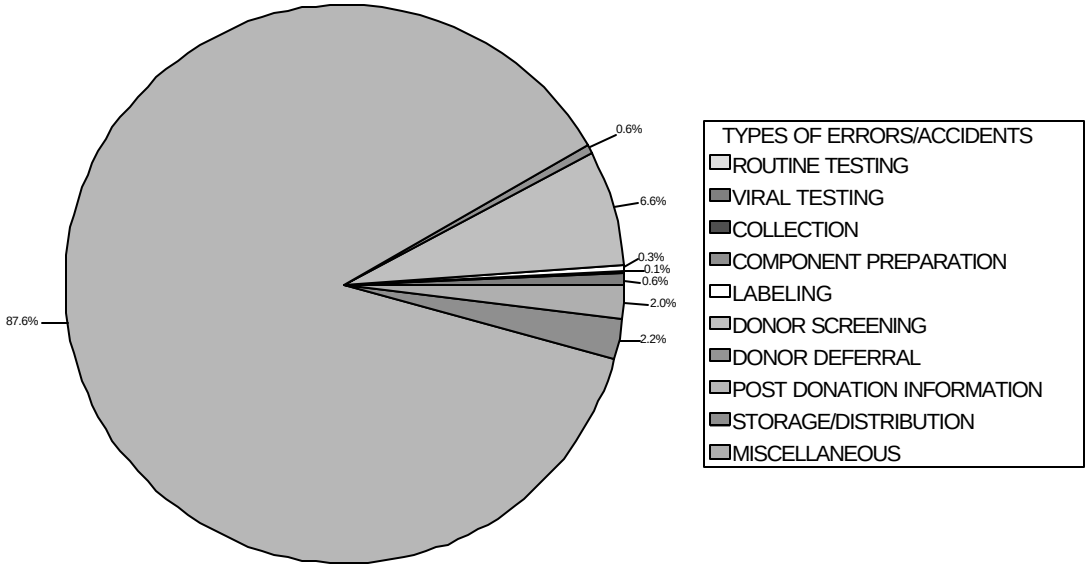
## TOTAL ERROR AND ACCIDENT REPORTS

| | QUARTER | | | | | |
|---|---|---|---|---|---|---|
| TYPE OF ERROR/ACCIDENT | FIRST | SECOND | THIRD | FOURTH | TOTAL | PERCENT |
| ROUTINE TESTING | 0 | 0 | 0 | 0 | 0 | 0.0% |
| VIRAL TESTING | 2 | 0 | 4 | 11 | 17 | 0.6% |
| COLLECTION | 0 | 2 | 0 | 2 | 4 | 0.1% |
| COMPONENT PREPARATION | 0 | 0 | 0 | 0 | 0 | 0.0% |
| LABELING | 2 | 0 | 4 | 4 | 10 | 0.3% |
| DONOR SCREENING | 24 | 40 | 66 | 66 | 196 | 6.6% |
| DONOR DEFERRAL | 3 | 2 | 4 | 8 | 17 | 0.6% |
| POST DONATION INFO | 460 | 712 | 776 | 656 | 2604 | 87.6% |
| STORAGE/DISTRIBUTION | 10 | 25 | 15 | 15 | 65 | 2.2% |
| MISCELLANEOUS | 8 | 11 | 19 | 21 | 59 | 2.0% |

| | | | | | | |
|---|---|---|---|---|---|---|
| TOTAL | 509 | 792 | 888 | 783 | 2972 | 100.0% |

# FY-2000
# Total Reports

## PLASMA CENTERS




*REPORTS RECEIVED (10/1/99 - 9/30/00) = 2972*

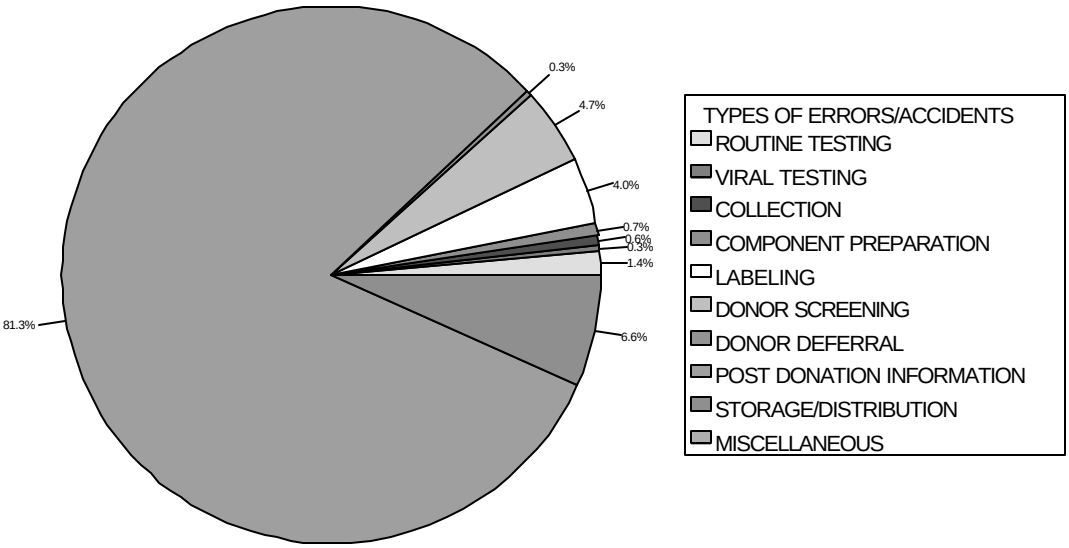
# REPORTABLE ERRORS AND ACCIDENTS

BLOOD AND PLASMAESTABLISHMENTS

| TYPE OF ERROR/ACCIDENT | LICENSED BLOOD BANKS | UNLICENSED BLOOD BANKS | TRANSFUSION SERVICES | PLASMA CENTERS | TOTAL | |
|---|---|---|---|---|---|---|
| POST DONATION INFORMATION | 15849 | 18 | 0 | 2604 | 18471 | 81.3% |
| STORAGE/DISTRIBUTION | 1401 | 29 | 14 | 64 | 1508 | 6.6% |
| DONOR SCREENING | 890 | 7 | 0 | 173 | 1070 | 4.7% |
| LABELING | 868 | 26 | 4 | 10 | 908 | 4.0% |
| ROUTINE TESTING | 283 | 11 | 16 | 0 | 310 | 1.4% |
| COMPONENT PREPARATION | 161 | 2 | 2 | 0 | 165 | 0.7% |
| COLLECTION | 118 | 5 | 0 | 4 | 127 | 0.6% |
| VIRAL TESTING | 53 | 9 | 0 | 17 | 79 | 0.3% |
| DONOR DEFERRAL | 54 | 2 | 0 | 17 | 73 | 0.3% |
| MISCELLANEOUS | 3 | 0 | 0 | 2 | 5 | 0.0% |
| *TOTAL* | 19680 | 109 | 36 | 2891 | 22716 | 100.0% |

# REPORTABLE ERRORS/ACCIDENTS

## FY2000




*TOTAL REPORTS RECEIVED (10/1/99 - 9/30/00) = 23,346*
*REPORTABLE ERRORS/ACCIDENTS = 22,716 (97.3%)*

Of the 22,716 reportable error and accident reports received from blood and plasma establishments, 18,471 (81.3%) reports involved post donation information. 15,867 (85.9%) reports were submitted by blood establishments and 2604 (14.1%) 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** | |
|---|---|---|---|---|---|---|
| Risk factors associated with CJD-lived in United Kingdom | 5181 | 32.7% | 175 | 6.7% | **5356** | **29.0%** |
| Travel to malaria endemic area or history of malaria | 2891 | 18.2% | 2 | 0.1% | **2893** | **15.7%** |
| Tattoo | 592 | 3.7% | 692 | 26.6% | **1284** | **7.0%** |
| History of cancer | 1214 | 7.7% | 12 | 0.5% | **1226** | **6.6%** |
| Post donation illness (not hepatitis, HIV, HTLV-I, STD, or cold/flu related) | 910 | 5.7% | 3 | 0.1% | **913** | **4.9%** |
| History of disease | 567 | 3.6% | 23 | 0.9% | **590** | **3.2%** |
| Body piercing | 170 | 1.1% | 385 | 14.8% | **555** | **3.0%** |
| Incarcerated | 21 | 0.1% | 444 | 17.1% | **465** | **2.5%** |
| IV drug use | 360 | 2.3% | 94 | 3.6% | **454** | **2.5%** |
| Male donor had sex with another man | 307 | 1.9% | 54 | 2.1% | **361** | **2.0%** |
| Received medication or antibiotics | 333 | 2.1% | 18 | 0.7% | **351** | **1.9%** |
| Sexual partner testing positive for HCV | 244 | 1.5% | 34 | 1.3% | **278** | **1.5%** |
| Sex with IV drug user | 211 | 1.3% | 22 | 0.8% | **233** | **1.3%** |
| History of hepatitis related risk-history of hepatitis not specified | 201 | 1.3% | 19 | 0.7% | **220** | **1.2%** |
| History of hepatitis related risk-history of jaundice | 202 | 1.3% | 2 | 0.1% | **204** | **1.1%** |
| Non-sexual exposure to Hepatitis C | 148 | 0.9% | 13 | 0.5% | **161** | **0.9%** |
| Risk factors associated with CJD-received insulin | 156 | 1.0% | 1 | 0.0% | **157** | **0.8%** |
| Ear piercing | 64 | 0.4% | 89 | 3.4% | **153** | **0.8%** |
| Non-IV drug use | 114 | 0.7% | 25 | 1.0% | **139** | **0.8%** |
| Received Proscar, Tegison or Accutane | 137 | 0.9% | 1 | 0.0% | **138** | **0.7%** |
| Multiple high risk behaviors | 114 | 0.7% | 18 | 0.7% | **132** | **0.7%** |
| Sex partner lived in or immigrated from an HIV Group O risk area | 118 | 0.7% | 7 | 0.3% | **125** | **0.7%** |
| High risk behavior-not specified | 62 | 0.4% | 54 | 2.1% | **116** | **0.6%** |
| Accidental needlestick | 112 | 0.7% | 1 | 0.0% | **113** | **0.6%** |
| TOTAL | 14429 | 90.9% | 2188 | 84.0% | **16617** | **90.0%** |

## POST DONATION INFORMATION REPORTS - TABLE 2

| POST DONATION INFORMATION RECEIVED | **BLOOD ESTABLISHMENTS** | | TOTAL | |
|---|---|---|---|---|
| Risk factors associated with CJD-lived in United Kingdom | **5181** | **32.7%** | 5356 | 29.0% |
| Travel to malaria endemic area or history of malaria | **2891** | **18.2%** | 2893 | 15.7% |
| History of cancer | **1214** | **7.7%** | 1226 | 6.6% |
| Post donation illness (not hepatitis, HIV, HTLV-I, STD, or cold/flu related) | **910** | **5.7%** | 913 | 4.9% |
| Tattoo | **592** | **3.7%** | 1284 | 7.0% |
| History of disease | **567** | **3.6%** | 590 | 3.2% |
| IV drug use | **360** | **2.3%** | 454 | 2.5% |
| Received medication or antibiotics | **333** | **2.1%** | 351 | 1.9% |
| Male donor had sex with another man | **307** | **1.9%** | 361 | 2.0% |
| Sexual partner testing positive for HCV | **244** | **1.5%** | 278 | 1.5% |
| Sex with IV drug user | **211** | **1.3%** | 233 | 1.3% |
| History of jaundice | **202** | **1.3%** | 204 | 1.1% |
| History of hepatitis, not specified | **201** | **1.3%** | 220 | 1.2% |
| Body piercing | **170** | **1.1%** | 555 | 3.0% |
| Risk factors associated with Creutzfeldt-Jakob Disease-received insulin | **156** | **1.0%** | 157 | 0.8% |
| Non-sexual exposure to Hepatitis C | **148** | **0.9%** | 161 | 0.9% |
| Received Proscar, Tegison or Accutane | **137** | **0.9%** | 138 | 0.7% |
| Sex partner lived in or immigrated from an HIV Group O risk area | **118** | **0.7%** | 125 | 0.7% |
| Non-IV drug use | **114** | **0.7%** | 139 | 0.8% |
| Multiple high risk behaviors | **114** | **0.7%** | 132 | 0.7% |
| Accidental needlestick | **112** | **0.7%** | 113 | 0.6% |
| TOTAL | **14282** | **90.0%** | 15883 | 86.0% |

## POST DONATION INFORMATION REPORTS - TABLE 3

| POST DONATION INFORMATION RECEIVED | **PLASMA CENTERS** | | TOTAL | |
|---|---|---|---|---|
| Tattoo | **692** | **26.6%** | 1284 | 7.0% |
| Incarcerated | **444** | **17.1%** | 465 | 2.5% |
| Body piercing | **385** | **14.8%** | 555 | 3.0% |
| Risk factors associated with CJD-lived in United Kingdom | **175** | **6.7%** | 5356 | 29.0% |
| Donor rejected at another center, reason not specified | **108** | **4.1%** | 109 | 0.6% |
| IV drug use | **94** | **3.6%** | 454 | 2.5% |
| Ear piercing | **89** | **3.4%** | 153 | 0.8% |
| Other high risk behavior-not specified | **54** | **2.1%** | 116 | 0.6% |
| Male donor had sex with another man | **54** | **2.1%** | 361 | 2.0% |
| Sexual partner testing positive for HIV | **42** | **1.6%** | 77 | 0.4% |
| Tattoo or ear piercing or body piercing, not specified | **37** | **1.4%** | 40 | 0.2% |
| Sexual partner testing positive for HCV | **34** | **1.3%** | 278 | 1.5% |
| Non-IV drug use | **25** | **1.0%** | 139 | 0.8% |
| Received vaccine or immune globulin | **23** | **0.9%** | 70 | 0.4% |
| History of disease | **23** | **0.9%** | 590 | 3.2% |
| Sex with IV drug user | **22** | **0.8%** | 233 | 1.3% |
| Sex partner engaged in high risk behavior | **21** | **0.8%** | 35 | 0.2% |
| History of hepatitis not specified | **19** | **0.7%** | 220 | 1.2% |

| | | | | |
|---|---|---|---|---|
| TOTAL | **2341** | **89.9%** | 10535 | 57.0% |

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** | |
|---|---|---|---|---|---|---|
| Risk factors associated with CJD-lived in United Kingdom | 5179 | 36.6% | 175 | 6.9% | **5354** | **32.1 %** |
| Travel to malarial endemic area | 2891 | 20.5% | 2 | 0.1% | **2893** | **17.4 %** |
| Tattoo | 592 | 4.2% | 692 | 27.4% | **1284** | **7.7%** |
| History of cancer | 764 | 5.4% | 7 | 0.3% | **771** | **4.6%** |
| History of disease/surgery | 550 | 3.9% | 22 | 0.9% | **572** | **3.4%** |
| Body piercing | 170 | 1.2% | 385 | 15.3% | **555** | **3.3%** |
| History of incarceration | 21 | 0.1% | 444 | 17.6% | **465** | **2.8%** |
| IV drug use | 359 | 2.5% | 94 | 3.7% | **453** | **2.7%** |
| Male to male sex | 306 | 2.2% | 54 | 2.1% | **360** | **2.2%** |
| Received medication or antibiotics | 333 | 2.4% | 18 | 0.7% | **351** | **2.1%** |
| Sex with an IV drug user | 205 | 1.5% | 20 | 0.8% | **225** | **1.4%** |
| History of hepatitis related risk-history of hepatitis not specified | 191 | 1.4% | 18 | 0.7% | **209** | **1.3%** |
| TOTAL | 11561 | 81.8% | 1931 | 76.6% | **13492** | **81.0 %** |

Table 2

| POST DONATION INFORMATION | **BLOOD ESTABLISHMENTS** | | TOTAL | |
|---|---|---|---|---|
| Risk factors associated with CJD-lived in United Kingdom | **5179** | **36.6%** | 5354 | 32.1% |
| Travel to malarial endemic area | **2891** | **20.5%** | 2893 | 17.4% |
| History of cancer | **764** | **5.4%** | 771 | 4.6% |
| Tattoo | **592** | **4.2%** | 1284 | 7.7% |
| History of disease/surgery | **550** | **3.9%** | 572 | 3.4% |
| IV drug use | **359** | **2.5%** | 453 | 2.7% |
| Received medication or antibiotics | **333** | **2.4%** | 351 | 2.1% |
| Male to male sex | **306** | **2.2%** | 360 | 2.2% |
| Sex with an IV drug user | **205** | **1.5%** | 225 | 1.4% |
| History of hepatitis related risk-history of jaundice | **202** | **1.4%** | 204 | 1.2% |
| TOTAL | **11381** | **80.5%** | 12467 | 74.9% |

Table 3

| POST DONATION INFORMATION | **PLASMA CENTERS** | | TOTAL | |
|---|---|---|---|---|
| Tattoo | **692** | **27.4%** | 1284 | 7.7% |
| History of incarceration | **444** | **17.6%** | 465 | 2.8% |

| | | | | |
|---|---|---|---|---|
| Body piercing | **385** | **15.3%** | 555 | 3.3% |
| Risk factors associated with CJD-lived in United Kingdom | **175** | **6.9%** | 5354 | 32.1% |
| IV drug use | **94** | **3.7%** | 453 | 2.7% |
| Ear piercing | **89** | **3.5%** | 153 | 0.9% |
| High risk behavior-donor rejected at another center | **85** | **3.4%** | 86 | 0.5% |
| Male to male sex | **54** | **2.1%** | 360 | 2.2% |
| TOTAL | **2018** | **80.0%** | 8710 | 52.3% |

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) | 903 | 52.0% | 3 | 3.7% | **906** | **49.9%** |
| Diagnosis of cancer, post donation | 450 | 25.9% | 5 | 6.1% | **455** | **25.0%** |
| Sex partner tests positive for HCV | 70 | 4.0% | 3 | 3.7% | **73** | **4.0%** |
| Exposure to Hepatitis A | 71 | 4.1% | | 0.0% | **71** | **3.9%** |
| TOTAL | 1494 | 86.1% | 82 | 100.0% | **1505** | **82.8%** |

Table 2

| POST DONATION INFORMATION | **BLOOD ESTABLISHMENTS** | | TOTAL | |
|---|---|---|---|---|
| Illness (not Aids or hepatitis related) | **903** | **52.0%** | 906 | 49.9% |
| Diagnosis of cancer, post donation | **450** | **25.9%** | 455 | 25.0% |
| Exposure to Hepatitis A | **71** | **4.1%** | 71 | 3.9% |
| TOTAL | **1424** | **82.1%** | 1432 | 78.8% |

Table 3

| POST DONATION INFORMATION | **PLASMA CENTERS** | | TOTAL | |
|---|---|---|---|---|
| High risk behavior-donor rejected at another center | **23** | **28.0%** | 23 | 1.3% |
| Sex partner tests positive for HIV | **16** | **19.5%** | 36 | 2.0% |
| Post donation illness - Hepatitis B | **5** | **6.1%** | 3 | 0.2% |
| Tested positive for HCV post donation | **5** | **6.1%** | 24 | 1.3% |
| History of cancer-diagnoses post donation | **5** | **6.1%** | 455 | 25.0% |
| Illness (not Aids or hepatitis related) | **3** | **3.7%** | 906 | 49.9% |
| Tested positive for anti-HIV post donation | **3** | **3.7%** | 9 | 0.5% |
| Sex partner tests positive for HCV | **3** | **3.7%** | 73 | 4.0% |
| High risk behavior-positive drug screen | **3** | **3.7%** | 3 | 0.2% |

| | | | | |
|---|---|---|---|---|
| TOTAL | **66** | **80.5%** | 1532 | 84.3% |

Of the 22,716 reportable error and accident reports received from blood and plasma establishments, 1508 (6.6%) reports involved storage and distribution. 1444 (95.8%) reports were submitted by blood establishments and 64 (4.2%) were submitted from plasma centers. The following 3 tables represent the type of storage and distribution errors and 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 | 712 | 49.3% | 1 | 1.6% | **713** | **47.3%** |
| Failure to quarantine unsuitable unit | 220 | 15.2% | 7 | 10.9% | **227** | **15.1%** |
| Shipped or stored at incorrect temperature | 222 | 15.4% | 1 | 1.6% | **223** | **14.8%** |
| Failure to quarantine unit due to medical history | 79 | 5.5% | 25 | 39.1% | **104** | **6.9%** |
| Failure to quarantine unit due to incorrect, incomplete, or positive testing | 73 | 5.1% | 15 | 23.4% | **88** | **5.8%** |
| Improper transfusion service practices | 62 | 4.3% | 0 | 0.0% | **62** | **4.1%** |
| Failure to quarantine unit due to testing not performed or documented | 43 | 3.0% | 14 | 21.9% | **57** | **3.8%** |
| Shipment of unlicensed product labeled with license number | 33 | 2.3% | 1 | 1.6% | **34** | **2.3%** |
| TOTAL | 1444 | 100.0% | 64 | 100.0% | **1508** | **100.0 %** |

STORAGE/DISTRIBUTION - TABLE 2

| STORAGE AND DISTRIBUTION ERRORS/ACCIDENTS | **BLOOD ESTABLISHMENTS** | | TOTAL | |
|---|---|---|---|---|
| Unsuitable product | **712** | **49.3%** | 713 | 47.3% |
| Shipped or stored at incorrect temperature | **222** | **15.4%** | 223 | 14.8% |
| Failure to quarantine unsuitable unit | **220** | **15.2%** | 227 | 15.1% |
| Failure to quarantine unit due to medical history | **79** | **5.5%** | 104 | 6.9% |
| Failure to quarantine unit due to incorrect, incomplete, or positive testing | **73** | **5.1%** | 88 | 5.8% |
| Improper transfusion service practices | **62** | **4.3%** | 62 | 4.1% |
| Failure to quarantine unit due to testing not performed or documented | **43** | **3.0%** | 57 | 3.8% |
| Shipment of unlicensed product labeled with license number | **33** | **2.3%** | 34 | 2.3% |
| TOTAL | **1444** | **100.0%** | 1508 | 100.0% |

STORAGE/DISTRIBUTION - TABLE 3

| STORAGE AND DISTRIBUTION ERRORS/ACCIDENTS | **PLASMA CENTERS** | | TOTAL | |
|---|---|---|---|---|
| Failure to quarantine unit due to medical history | **25** | **39.1%** | 104 | 6.9% |
| Failure to quarantine unit due to incorrect, incomplete, or positive testing | **15** | **23.4%** | 88 | 5.8% |
| Failure to quarantine unit due to testing not performed or documented | **14** | **21.9%** | 57 | 3.8% |
| Failure to quarantine unsuitable unit | **7** | **10.9%** | 227 | 15.1% |
| Unsuitable product | **1** | **1.6%** | 713 | 47.3% |

| | | | | |
|---|---|---|---|---|
| Shipped or stored at incorrect temperature | **1** | **1.6%** | 223 | 14.8% |
| Shipment of unlicensed product labeled with license number | **1** | **1.6%** | 34 | 2.3% |
| Improper transfusion service practices | **0** | **0.0%** | 62 | 4.1% |
| TOTAL | **64** | **100.0%** | 1508 | 100.0% |

## STORAGE/DISTRIBUTION - TABLE 2A

| STORAGE AND DISTRIBUTION ERRORS/ACCIDENTS (DETAILED) | **BLOOD ESTABLISHMENTS** | | TOTAL | |
|---|---|---|---|---|
| *Unsuitable product* | | | | |
| Broken/damaged unit | **382** | **26.5%** | 382 | 25.3% |
| Unit contained clots | **246** | **17.0%** | 246 | 16.3% |
| Shipped or stored at incorrect temperature | **222** | **15.4%** | 223 | 14.8% |
| *Failure to quarantine unsuitable unit* | | | | |
| Other[1] | **61** | **4.2%** | 68 | 4.5% |
| Outdated product | **36** | **2.5%** | 36 | 2.4% |
| Unit released prior to resolution of discrepancy | **26** | **1.8%** | 26 | 1.7% |
| Platelet count or platelet yield unacceptable | **25** | **1.7%** | 25 | 1.7% |
| *Failure to quarantine unit due to medical history* | | | | |
| Post donation illness | **33** | **2.3%** | 33 | 2.2% |
| Received medication or antibiotics | **13** | **0.9%** | 13 | 0.9% |
| *Failure to quarantine unit due to incorrect, incomplete, or positive testing for:* | | | | |
| Other reasons[2] | **30** | **2.1%** | 33 | 2.2% |
| Anti-HCV | **7** | **0.5%** | 13 | 0.9% |
| Anti-HBC | **6** | **0.4%** | 6 | 0.4% |
| *Improper transfusion service practice* | | | | |
| Improper ABO/Rh type selected for patient | **18** | **1.2%** | 18 | 1.2% |
| Product not irradiated as required | **17** | **1.2%** | 17 | 1.1% |
| Unit issued to wrong patient | **16** | **1.1%** | 16 | 1.1% |
| *Failure to quarantine unit due to testing not performed or documented for:* | | | | |
| Other reasons[3] | **27** | **1.9%** | 36 | 2.4% |
| Anti-HCV | **5** | **0.3%** | 5 | 0.3% |
| Antigen screen | **5** | **0.3%** | 5 | 0.3% |
| Interstate shipment of unlicensed product | **33** | **2.3%** | 34 | 2.3% |
| TOTAL | **1208** | **83.7%** | 1235 | 81.9% |

[1]- Includes arm inspection not documented; air contamination; unit released prior to QC testing

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

[3] - Includes DAT; NAT; all viral markers

## STORAGE/DISTRIBUTION - TABLE 3A

| STORAGE AND DISTRIBUTION ERRORS/ACCIDENTS (DETAILED) | **PLASMA CENTERS** | | TOTAL | |
|---|---|---|---|---|
| *Failure to quarantine unit due to medical history* | | | | |
| Received vaccine or immune globulin | **10** | **15.6%** | 11 | 0.7% |
| *Failure to quarantine unit due to incorrect, incomplete, or positive testing for*: | | | | |
| Anti-HCV | **6** | **9.4%** | 13 | 0.9% |
| ALT | **3** | **4.7%** | 8 | 0.5% |

| | | | | |
|---|---|---|---|---|
| Other reasons[1] | **3** | **4.7%** | 33 | 2.2% |
| *Failure to quarantine unit due to testing not performed or documented for:* | | | | |
| Other reasons[2] | **9** | **14.1%** | 36 | 2.4% |
| Syphilis | **5** | **7.8%** | 5 | 0.3% |
| TOTAL | **36** | **56.3%** | 106 | 7.0% |

[1, 2] - Includes all viral markers

Of the 22,716 reportable error and accident reports received from blood and plasma establishments, 1070 (4.7%) reports involved donor screening. 897 (83.8%) reports were submitted by blood establishments and 173 (16.2%) were submitted from plasma centers. The following 3 tables represent the type of donor screening errors and 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 SCREENINING - TABLE 1

| DONOR SCREENING ERRORS/ACCIDENTS | BLOOD ESTABLISHMENTS | | PLASMA CENTERS | | **TOTAL** | |
|---|---|---|---|---|---|---|
| Donor gave history which warranted deferral and was not deferred | 568 | 63.3% | 39 | 22.5% | **607** | **56.7%** |
| Donor record incomplete/incorrect/not reviewed | 175 | 19.5% | 71 | 41.0% | **246** | **23.0%** |
| Deferral screening not done, donor previously deferred | 80 | 8.9% | 34 | 19.7% | **114** | **10.7%** |
| Donor did not meet acceptance criteria | 40 | 4.5% | 24 | 13.9% | **64** | **6.0%** |
| Incorrect ID used during deferral search, donor previously deferred | 34 | 3.8% | 5 | 2.9% | **39** | **3.6%** |
| TOTAL | 897 | 100.0% | 173 | 100.0% | **1070** | **100.0%** |

DONOR SCREENING - TABLE 2

| DONOR SCREENING ERRORS/ACCIDENTS | **BLOOD ESTABLISHMENTS** | | TOTAL | |
|---|---|---|---|---|
| Donor gave history which warranted deferral and was not deferred | **568** | **63.3%** | 607 | 56.7% |
| Donor record incomplete/incorrect/not reviewed | **175** | **19.5%** | 246 | 23.0% |
| Deferral screening not done, donor previously deferred | **80** | **8.9%** | 114 | 10.7% |
| Donor did not meet acceptance criteria | **40** | **4.5%** | 64 | 6.0% |
| Incorrect ID used during deferral search, donor previously deferred | **34** | **3.8%** | 39 | 3.6% |
| TOTAL | **897** | **100.0%** | 1070 | 100.0% |

DONOR SCREENING - TABLE 3

| DONOR SCREENING ERRORS/ACCIDENTS | **PLASMA CENTERS** | | TOTAL | |
|---|---|---|---|---|
| Donor record incomplete/incorrect/not reviewed | **71** | **41.0%** | 246 | 23.0% |
| Donor gave history which warranted deferral and was not deferred | **39** | **22.5%** | 607 | 56.7% |
| Deferral screening not done, donor previously deferred | **34** | **19.7%** | 114 | 10.7% |
| Donor did not meet acceptance criteria | **24** | **13.9%** | 64 | 6.0% |
| Incorrect ID used during deferral search, donor previously deferred | **5** | **2.9%** | 39 | 3.6% |
| TOTAL | **173** | **100.0%** | 1070 | 100.0% |

## DONOR SCREENING - TABLE 2A

| DONOR SCREENING ERRORS/ACCIDENTS (DETAILED) | **BLOOD ESTABLISHMENTS** | | TOTAL | |
|---|---|---|---|---|
| *Donor gave history which warranted deferral and was not deferred* | | | | |
| Travel to malaria endemic area/history of malaria | **260** | **29.0%** | 260 | 24.3% |
| Received medication or antibiotics | **60** | **6.7%** | 63 | 5.9% |
| History of cancer | **44** | **4.9%** | 45 | 4.2% |
| History of disease/surgery | **41** | **4.6%** | 45 | 4.2% |
| *Donor record incomplete/incorrect/not reviewed* | | | | |
| Donor history questions | **131** | **14.6%** | 190 | 17.8% |
| Deferral screening not done, donor previously deferred due to | | | | |
| HIV reactivity | **36** | **4.0%** | 37 | 3.5% |
| History of hepatitis, not specified | **12** | **1.3%** | 13 | 1.2% |
| *Donor did not meet acceptance criteria* | | | | |
| Temperature unacceptable or not documented | **22** | **2.5%** | 34 | 3.2% |
| Hemoglobin <11.0g/dl, Hematocrit <33%, or Hgb/Hct not documented | **17** | **1.9%** | 17 | 1.6% |
| *Incorrect ID used during deferral search, donor previously deferred due to:* | | | | |
| HIV reactivity | **8** | **0.9%** | 8 | 0.7% |
| History of hepatitis, not specified | **3** | **0.3%** | 5 | 0.5% |
| Anti-HCV reactivity | **3** | **0.3%** | 4 | 0.4% |
| TOTAL | **637** | **71.0%** | 721 | 67.4% |

## DONOR SCREENING - TABLE 3A

| DONOR SCREENING ERRORS/ACCIDENTS (DETAILED) | **PLASMA CENTERS** | | TOTAL | |
|---|---|---|---|---|
| *Donor record incomplete/incorrect/not reviewed* | | | | |
| Donor history questions | **59** | **34.1%** | 190 | 17.8% |
| *Donor gave history which warranted deferral and was not deferred* | | | | |
| Received vaccine or immune globulin | **8** | **4.6%** | 13 | 1.2% |
| Received tattoo, earpiercing, needlestick, or transfusion | **5** | **2.9%** | 7 | 0.7% |
| *Deferral screening not done, donor previously deferred due to:* | | | | |
| Donor rejected at another center | **6** | **3.5%** | 7 | 0.7% |
| Incarcerated | **6** | **3.5%** | 6 | 0.6% |
| Anti-HCV reactivity | **3** | **1.7%** | 4 | 0.4% |
| ALT reactivity | **3** | **1.7%** | 4 | 0.4% |
| High risk behavior-not specified | **3** | **1.7%** | 4 | 0.4% |
| *Donor did not meet acceptance criteria* | | | | |
| Temperature unacceptable or not documented | **12** | **6.9%** | 34 | 3.2% |
| Medical review or physical not performed or inadequate | **10** | **5.8%** | 10 | 0.9% |

| | | | | |
|---|---|---|---|---|
| *Incorrect id used during deferral search, donor previously deferred due to:* | | | | |
| History of hepatitis, not specified | **2** | **1.2%** | 5 | 0.5% |
| TOTAL | **117** | **67.6%** | 284 | 26.5% |

Of the 22,716 reportable error and accident reports received from blood and plasma establishments, 908 (4.0%) reports involved labeling. 898 (98.9%) reports were submitted by blood establishments and 10 (1.1%) were submitted from plasma centers. The following 3 tables represent the type of labeling errors and accidents reported in order of prevalence.

LABELING - TABLE 1

| LABELING ERRORS/ACCIDENTS | BLOOD ESTABLISHMENTS | | PLASMA CENTERS | | **TOTAL** | |
|---|---|---|---|---|---|---|
| Extended expiration date | 176 | 19.6% | 0 | 0.0% | **176** | **19.4%** |
| Missing/incorrect label or tag-autologous labeling | 122 | 13.6% | 0 | 0.0% | **122** | **13.4%** |
| Incorrect ABO and/or Rh label or tag | 119 | 13.3% | 0 | 0.0% | **119** | **13.1%** |
| Missing/incorrect donor number | 105 | 11.7% | 2 | 20.0% | **107** | **11.8%** |
| Incorrect product label or tag | 51 | 5.7% | 5 | 50.0% | **56** | **6.2%** |
| Missing/incorrect label or tag | | | | | | |
| Antigen/antibody | 53 | 5.9% | 0 | 0.0% | **53** | **5.8%** |
| CMV | 45 | 5.0% | 0 | 0.0% | **45** | **5.0%** |
| Recipient number | 45 | 5.0% | 0 | 0.0% | **45** | **5.0%** |
| Biohazard/test status | 42 | 4.7% | 3 | 30.0% | **45** | **5.0%** |
| Irradiation | 32 | 3.6% | 0 | 0.0% | **32** | **3.5%** |
| Leukoreduction | 25 | 2.8% | 0 | 0.0% | **25** | **2.8%** |
| Platelet count | 24 | 2.7% | 0 | 0.0% | **24** | **2.6%** |
| Other[1] | 17 | 1.9% | 0 | 0.0% | **17** | **1.9%** |
| Anticoagulant | 13 | 1.4% | 0 | 0.0% | **13** | **1.4%** |
| HLA | 7 | 0.8% | 0 | 0.0% | **7** | **0.8%** |
| Crossmatch | 3 | 0.3% | 0 | 0.0% | **3** | **0.3%** |
| Unlicensed product labeled with license number | 18 | 2.0% | 0 | 0.0% | **18** | **2.0%** |
| Other | 1 | 0.1% | 0 | 0.0% | **1** | **0.1%** |
| TOTAL | 898 | 100.0% | 10 | 100.0% | **908** | **100.0 %** |

[1] - Includes volume

## LABELING - TABLE 2

| LABELING ERRORS/ACCIDENTS | **BLOOD ESTABLISHMENTS** | | TOTAL | |
|---|---|---|---|---|
| Extended expiration date | **176** | **19.6%** | 176 | 19.4% |
| Missing/incorrect label or tag-autologous labeling | **122** | **13.6%** | 122 | 13.4% |
| Incorrect ABO and/or Rh label or tag | **119** | **13.3%** | 119 | 13.1% |
| Missing/incorrect donor number | **105** | **11.7%** | 107 | 11.8% |
| Missing/incorrect label or tag- antigen/antibody | **53** | **5.9%** | 53 | 5.8% |
| Incorrect product label or tag | **51** | **5.7%** | 56 | 6.2% |
| Missing/incorrect label or tag | | | | |
| CMV | **45** | **5.0%** | 45 | 5.0% |
| Recipient number | **45** | **5.0%** | 45 | 5.0% |
| Biohazard/test status | **42** | **4.7%** | 45 | 5.0% |
| Irradiation | **32** | **3.6%** | 32 | 3.5% |
| Leukoreduction | **25** | **2.8%** | 25 | 2.8% |
| Platelet count | **24** | **2.7%** | 24 | 2.6% |
| Other[1] | **17** | **1.9%** | 17 | 1.9% |
| Anticoagulant | **13** | **1.4%** | 13 | 1.4% |
| HLA | **7** | **0.8%** | 7 | 0.8% |
| Crossmatch | **3** | **0.3%** | 3 | 0.3% |
| Unlicensed product labeled with license number | **18** | **2.0%** | 18 | 2.0% |
| Other | **1** | **0.1%** | 1 | 0.1% |
| TOTAL | **898** | **100.0%** | 908 | 100.0% |

[1] - Includes volume

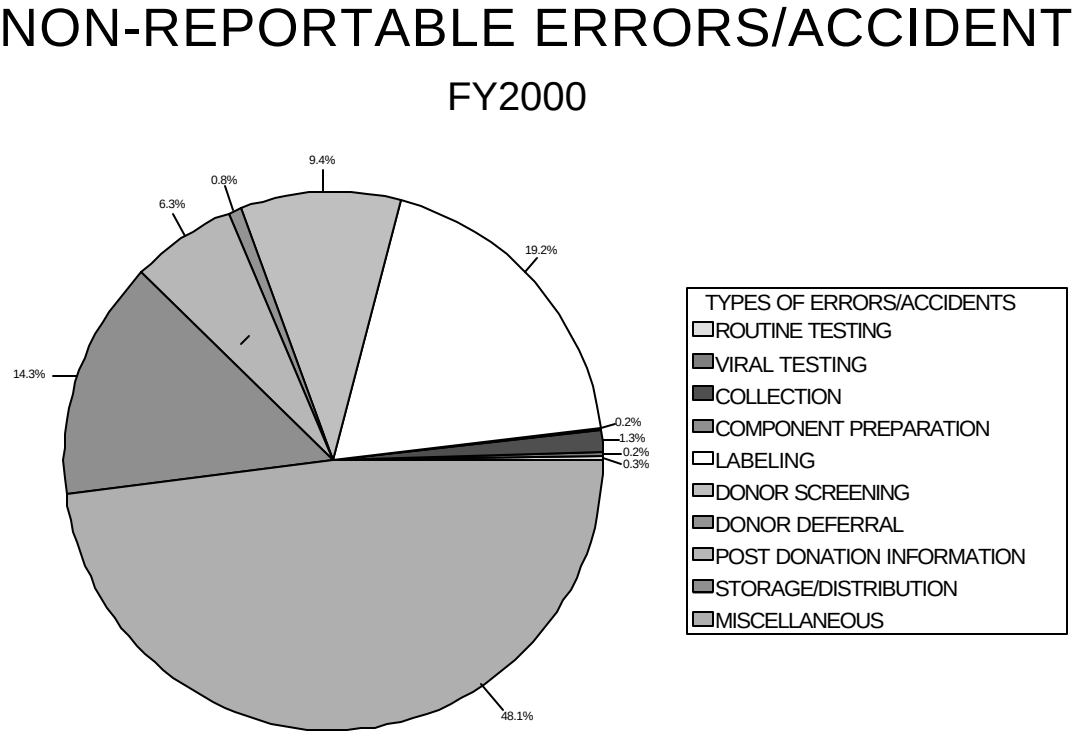
## LABELING - TABLE 3

| LABELING ERRORS/ACCIDENTS | **PLASMA CENTERS** | | TOTAL | |
|---|---|---|---|---|
| Incorrect product label or tag | **5** | **50.0%** | 56 | 6.2% |
| Missing/incorrect donor number | **3** | **30.0%** | 45 | 5.0% |
| Missing/incorrect label or tag-Biohazard/test status | **2** | **20.0%** | 107 | 11.8% |
| TOTAL | **10** | **100.0%** | 208 | 22.9% |

# NON-REPORTABLE ERRORS AND ACCIDENTS

BLOOD AND PLASMA MANUFACTURERS

| TYPE OF ERROR/ACCIDENT | LICENSED BLOOD BANKS | UNLICENSED BLOOD BANKS | TRANSFUSION SERVICES | PLASMA CENTERS | TOTAL | |
|---|---|---|---|---|---|---|
| MISCELLANEOUS | 221 | 9 | 16 | 57 | 303 | 48.1% |
| LABELING | 118 | 3 | 0 | 0 | 121 | 19.2% |
| STORAGE/DISTRIBUTION | 86 | 2 | 1 | 1 | 90 | 14.3% |
| DONOR SCREENING | 35 | 1 | 0 | 23 | 59 | 9.4% |
| POST DONATION INFORMATION | 39 | 1 | 0 | 0 | 40 | 6.3% |
| COLLECTION | 8 | 0 | 0 | 0 | 8 | 1.3% |
| DONOR DEFERRAL | 5 | 0 | 0 | 0 | 5 | 0.8% |
| ROUTINE TESTING | 2 | 0 | 0 | 0 | 2 | 0.3% |
| VIRAL TESTING | 1 | 0 | 0 | 0 | 1 | 0.2% |
| COMPONENT PREPARATION | 1 | 0 | 0 | 0 | 1 | 0.2% |
| *TOTAL* | 516 | 16 | 17 | 81 | 630 | 100.0% |




*TOTAL REPORTS RECEIVED (10/1/99 - 9/30/00) = 23,346*
*REPORTABLE ERRORS/ACCIDENTS = 630 (2.7%)*

Of the 630 non-reportable error and accident reports received from blood and plasma establishments, 303 (48.1%) reports were miscellaneous errors or accidents. 246 (81.2%) reports were submitted by blood establishments and 57 (18.8%) were submitted from plasma centers. The following table represents the type of miscellaneous errors and accidents reported in order of prevalence.

MISCELLANEOUS

| MISCELLANEOUS ERRORS/ACCIDENTS | BLOOD ESTABLISHMENTS | | PLASMA CENTERS | | **TOTAL** | |
|---|---|---|---|---|---|---|
| Recordkeeping error/accident (testing and labeling are acceptable) | 80 | 32.5% | 14 | 24.6% | **94** | **31.0%** |
| No products made available for distribution | 76 | 30.9% | 10 | 17.5% | **86** | **28.4%** |
| Records destroyed or lost/destruction records incomplete/final disposition unknown | 22 | 8.9% | 20 | 35.1% | **42** | **13.9%** |
| QC not performed or inadequate (other than viral marker, ABO/Rh) | 37 | 15.0% | 1 | 1.8% | **38** | **12.5%** |
| Notification/retrieval procedures not followed | 15 | 6.1% | 3 | 5.3% | **18** | **5.9%** |
| Emergency released unit not tested prior to release and found positive, labeled appropriately | 11 | 4.5% | 0 | 0.0% | **11** | **3.6%** |
| Lookback procedures not followed | 1 | 0.4% | 8 | 14.0% | **9** | **3.0%** |
| Recipient reaction | 4 | 1.6% | 0 | 0.0% | **4** | **1.3%** |
| Miscellaneous* | 0 | 0.0% | 1 | 1.8% | **1** | **0.3%** |
| TOTAL | 246 | 100.0% | 57 | 100.0% | **303** | **100.0 %** |

*Includes report not submitted in a timely manner

Of the 630 non-reportable error and accident reports received from blood and plasma establishments, 121 (19.2%) reports involved labeling. Blood establishments submitted all reports. The following table represents the type of labeling errors and accidents reported in order of prevalence.

LABELING

| LABELING ERRORS/ACCIDENTS | BLOOD ESTABLISHMENTS | | PLASMA CENTERS | | **TOTAL** | |
|---|---|---|---|---|---|---|
| Unit missing label for ABO &/or Rh, product or expiration date | 36 | 29.8% | 0 | 0.0% | **36** | **29.8%** |
| Unit labeled with missing/incorrect weight or volume; unit acceptable | 29 | 24.0% | 0 | 0.0% | **29** | **24.0%** |
| Unit labeled with shortened expiration date | 20 | 16.5% | 0 | 0.0% | **20** | **16.5%** |
| Directed unit, suitable for homologous use, labeled with incorrect name, SSN, or DOB | 16 | 13.2% | 0 | 0.0% | **16** | **13.2%** |
| Unit labeled with missing/incorrect facility identifiers; unit acceptable | 12 | 9.9% | 0 | 0.0% | **12** | **9.9%** |
| Miscellaneous* | 6 | 5.0% | 0 | 0.0% | **6** | **5.0%** |
| Unit labeled with missing/incorrect collection date; unit acceptable | 2 | 1.7% | 0 | 0.0% | **2** | **1.7%** |
| TOTAL | 121 | 100.0% | 0 | 0.0% | **121** | **100.0 %** |

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

Of the 630 non-reportable error and accident reports received from blood and plasma establishments, 90 (14.3%) reports involved storage and distribution. 89 (98.9%) reports were submitted by blood establishments and 1 (1.1%) were submitted from plasma centers. The following table represents the type of storage and distribution errors and accidents reported in order of prevalence.

STORAGE AND DISTRIBUTION

| STORAGE AND DISTRIBUTION ERROR/ACCIDENT | BLOOD ESTABLISHMENTS | | PLASMA CENTERS | | **TOTAL** | |
|---|---|---|---|---|---|---|
| Discrepancy between shipping form and shipment | 21 | 23.6% | 0 | 0.0% | **21** | **23.3%** |
| Irradiated unit requested, unit not irradiated, labeled appropriately | 16 | 18.0% | 0 | 0.0% | **16** | **17.8%** |
| Miscellaneous* | 14 | 15.7% | 0 | 0.0% | **14** | **15.6%** |
| Failure to quarantine unit after receiving information concerning post donation cold or flu symptoms | 9 | 10.1% | 0 | 0.0% | **9** | **10.0%** |
| Sterile weld inspection not documented | 8 | 9.0% | 0 | 0.0% | **8** | **8.9%** |
| Allogeneic unit issued instead of autologous | 8 | 9.0% | 0 | 0.0% | **8** | **8.9%** |
| Shipment to incorrect facility | 4 | 4.5% | 0 | 0.0% | **4** | **4.4%** |
| Distribution of units with no segments | 3 | 3.4% | 0 | 0.0% | **3** | **3.3%** |
| Unit lost or shipment never received | 2 | 2.2% | 1 | 100.0% | **3** | **3.3%** |
| Special antigen testing requested, unit not tested for special antigen, labeled appropriately | 3 | 3.4% | 0 | 0.0% | **3** | **3.3%** |
| Specific ABO/Rh type requested, incorrect ABO/Rh released, labeled appropriately | 1 | 1.1% | 0 | 0.0% | **1** | **1.1%** |
| Release of product other than that which was ordered, labeled appropriately | 0 | 0.0% | 0 | 0.0% | **0** | **0.0%** |
| TOTAL | 89 | 100.0% | 1 | 100.0% | **90** | **100.0 %** |

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

Of the 630 non-reportable error and accident reports received from blood and plasma establishments, 59 (9.4%) reports involved donor screening. 36 (61.0%) reports were submitted by blood establishments and 23 (39.0%) were submitted from plasma centers. The following table represents the type of donor screening errors and accidents reported in order of prevalence.

DONOR SCREENING

| DONOR SCREENING ERROR/ACCIDENT | BLOOD ESTABLISHMENTS | | PLASMA CENTERS | | **TOTAL** | |
|---|---|---|---|---|---|---|
| Donor did not meet acceptance criteria for time interval between donations (i.e., too short) | 20 | 55.6% | 2 | 8.7% | **22** | **37.3%** |
| Pheresis product quality not affected by low hematocrit | 0 | 0.0% | 15 | 65.2% | **15** | **25.4%** |
| Donor did not meet acceptance criteria for age | 7 | 19.4% | 1 | 4.3% | **8** | **13.6%** |
| Miscellaneous | 3 | 8.3% | 2 | 8.7% | **5** | **8.5%** |
| Unit collected from eligible donor but, donor deferral list not checked or checked with incorrect information | 3 | 8.3% | 0 | 0.0% | **3** | **5.1%** |
| Donor did not meet acceptance criteria for total protein or SPE | 0 | 0.0% | 3 | 13.0% | **3** | **5.1%** |
| Pheresis donor did not meet acceptance criteria for platelet count, product acceptable | 2 | 5.6% | 0 | 0.0% | **2** | **3.4%** |
| Donor did not meet acceptance criteria for blood pressure or pulse | 1 | 2.8% | 0 | 0.0% | **1** | **1.7%** |
| TOTAL | 36 | 100.0% | 23 | 100.0% | **59** | **100.0 %** |

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

ERROR AND ACCIDENT REPORTS
RECEIVED 10/1/99 - 9/30/00

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

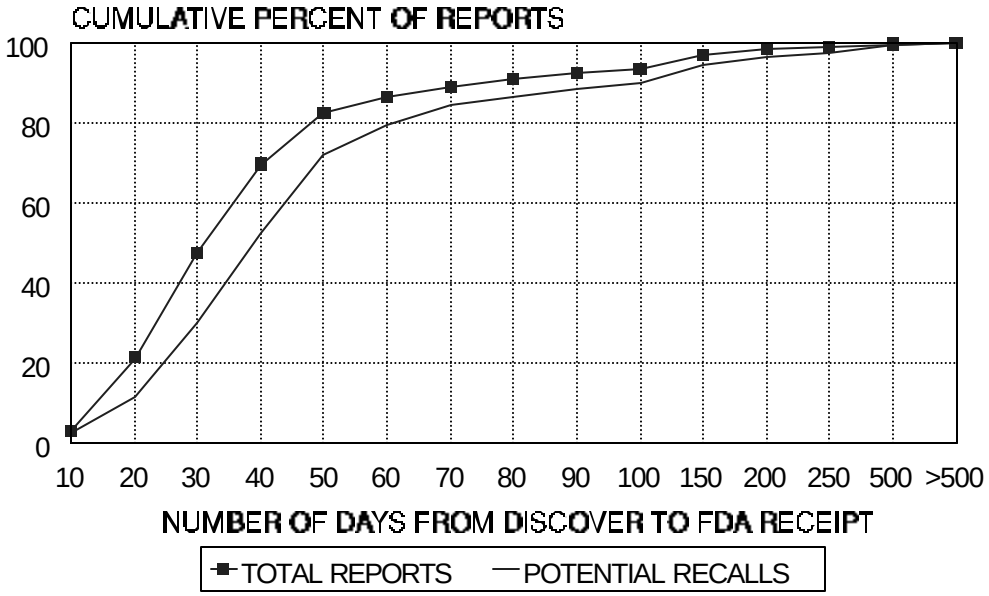
| CUMULATIVE PERCENT OF REPORTS | LICENSED (Days) | UNLICENSED (Days) | PLASMA (Days) | TOTAL( Days) |
|---|---|---|---|---|
| 10% | 15 | 9 | 14 | 15 |
| 25% | 21 | 19 | 23 | 21 |
| 50% | 30 | 37 | 39 | 31 |
| 75% | 41 | 90 | 67 | 44 |
| 90% | 63 | 223 | 131 | 74 |
| # REPORTS | 19680 | 145 | 2891 | 22716 |
| RANGE | 1-1648 | 1-1504 | 8-977 | 1-1648 |

# ERROR AND ACCIDENT REPORTS

## REPORTING TIME

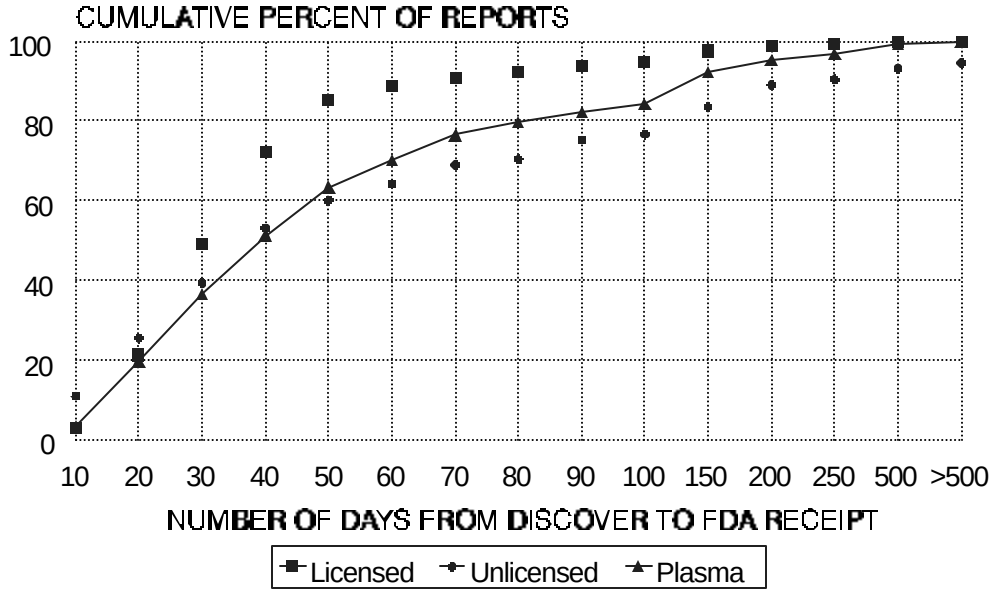
## ALL REPORTING BLOOD AND PLASMA ESTABLISHMENTS

*FY-2000*



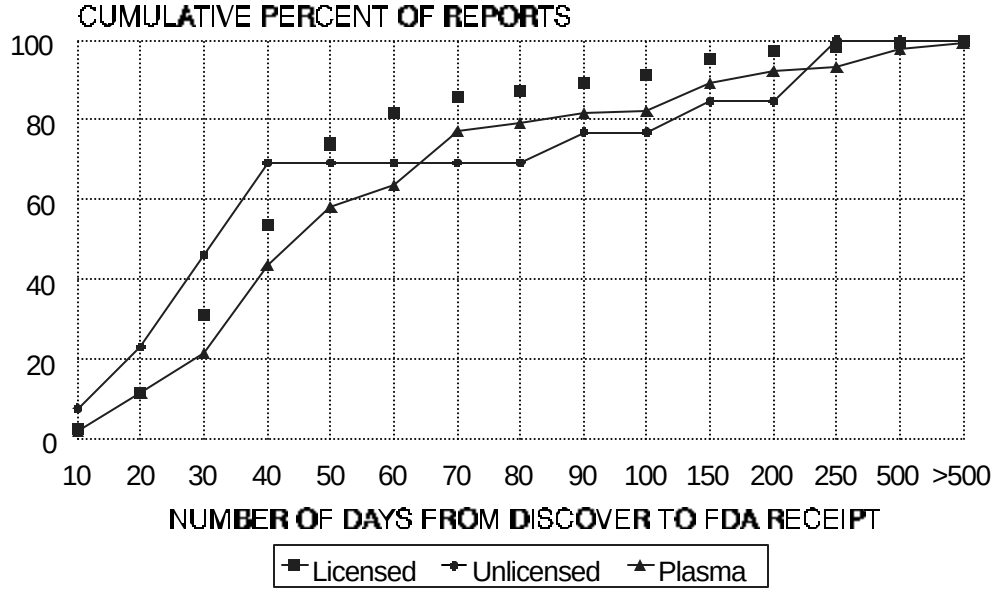

*TOTAL REPORTS = 22,716*
*POTENTIAL RECALLS = 1376*

# ERROR AND ACCIDENT REPORTS
## REPORTING TIME
## TOTAL REPORTS
## FY-2000




*TOTAL REPORTS = 22,716*
*LICENSED BLOOD EST.= 19,680; UNLICENSED BLOOD EST. = 145; PLASMA CENTERS = 2891*

# ERROR AND ACCIDENT REPORTS
## REPORTING TIME
## POTENTIAL RECALLS
## FY-2000




*TOTAL REPORTS = 1376*
*LICENSED BLOOD EST.= 1184; UNLICENSED BLOOD EST. = 13; PLASMA CENTERS = 179*

Reportable Errors and Accidents

| Error Code | Licensed Blood Banks | Unlicensed Blood Banks | Transfusion Services | Plasma Centers | Total | |
|---|---|---|---|---|---|---|
| **POST DONATION INFORMATION** | | | | | **18471** | **81.313%** |
| DD6301 | 907 | 3 | 0 | 3 | 913 | 4.019% |
| DD6302A | 2 | 1 | 0 | 0 | 3 | 0.013% |
| DD6302B | 12 | 0 | 0 | 5 | 17 | 0.075% |
| DD6302C | 26 | 0 | 0 | 4 | 30 | 0.132% |
| DD6303 | 2 | 0 | 0 | 0 | 2 | 0.009% |
| DD6303A | 10 | 0 | 0 | 2 | 12 | 0.053% |
| DD6303B | 20 | 0 | 0 | 5 | 25 | 0.110% |
| DD6303C | 15 | 0 | 0 | 0 | 15 | 0.066% |
| DD6304 | 1 | 0 | 0 | 1 | 2 | 0.009% |
| DD6304A | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DD6304B | 7 | 0 | 0 | 3 | 10 | 0.044% |
| DD6304C | 10 | 0 | 0 | 3 | 13 | 0.057% |
| DD6305B | 2 | 0 | 0 | 0 | 2 | 0.009% |
| DD6305C | 1 | 0 | 0 | 1 | 2 | 0.009% |
| DD6306 | 9 | 0 | 0 | 3 | 12 | 0.053% |
| DD6306A | 52 | 0 | 0 | 0 | 52 | 0.229% |
| DD6306B | 44 | 0 | 0 | 1 | 45 | 0.198% |
| DD6307 | 4 | 0 | 0 | 0 | 4 | 0.018% |
| DD6307A | 201 | 0 | 0 | 19 | 220 | 0.968% |
| DD6307B | 202 | 0 | 0 | 2 | 204 | 0.898% |
| DD6307C | 12 | 0 | 0 | 3 | 15 | 0.066% |
| DD6307D | 3 | 0 | 0 | 0 | 3 | 0.013% |
| DD6308 | 19 | 0 | 0 | 1 | 20 | 0.088% |
| DD6308A | 3 | 0 | 0 | 0 | 3 | 0.013% |
| DD6308C | 2 | 0 | 0 | 0 | 2 | 0.009% |
| DD6309 | 3 | 0 | 0 | 0 | 3 | 0.013% |
| DD6310 | 0 | 0 | 0 | 4 | 4 | 0.018% |
| DD6310A | 34 | 1 | 0 | 42 | 77 | 0.339% |
| DD6310B | 3 | 0 | 0 | 0 | 3 | 0.013% |
| DD6311 | 53 | 0 | 0 | 11 | 64 | 0.282% |
| DD6311A | 53 | 0 | 0 | 7 | 60 | 0.264% |
| DD6311B | 244 | 0 | 0 | 34 | 278 | 1.224% |
| DD6312 | 307 | 0 | 0 | 54 | 361 | 1.589% |
| DD6313 | 46 | 0 | 0 | 3 | 49 | 0.216% |
| DD6314 | 360 | 0 | 0 | 94 | 454 | 1.999% |
| DD6315 | 211 | 0 | 0 | 22 | 233 | 1.026% |
| DD6316 | 5 | 0 | 0 | 0 | 5 | 0.022% |
| DD6316A | 35 | 0 | 0 | 3 | 38 | 0.167% |
| DD6316B | 118 | 0 | 0 | 7 | 125 | 0.550% |
| DD6317 | 57 | 0 | 0 | 13 | 70 | 0.308% |
| DD6317A | 15 | 0 | 0 | 2 | 17 | 0.075% |
| DD6318 | 6 | 0 | 0 | 2 | 8 | 0.035% |

| Error Code | Licensed Blood Banks | Unlicensed Blood Banks | Transfusion Services | Plasma Centers | Total | |
|---|---|---|---|---|---|---|
| DD6318A | 592 | 0 | 0 | 692 | 1284 | 5.652% |
| DD6318B | 64 | 0 | 0 | 89 | 153 | 0.674% |
| DD6318C | 170 | 0 | 0 | 385 | 555 | 2.443% |
| DD6318D | 112 | 0 | 0 | 1 | 113 | 0.497% |
| DD6318E | 63 | 0 | 0 | 6 | 69 | 0.304% |
| DD6318F | 102 | 0 | 0 | 8 | 110 | 0.484% |
| DD6318G | 46 | 0 | 0 | 2 | 48 | 0.211% |
| DD6318H | 5 | 0 | 0 | 18 | 23 | 0.101% |
| DD6318I | 3 | 0 | 0 | 37 | 40 | 0.176% |
| DD6319 | 2 | 0 | 0 | 6 | 8 | 0.035% |
| DD6320 | 3 | 0 | 0 | 0 | 3 | 0.013% |
| DD6320A | 69 | 0 | 0 | 2 | 71 | 0.313% |
| DD6320B | 44 | 0 | 0 | 3 | 47 | 0.207% |
| DD6320C | 148 | 0 | 0 | 13 | 161 | 0.709% |
| DD6321 | 62 | 0 | 0 | 54 | 116 | 0.511% |
| DD6321A | 1 | 0 | 0 | 108 | 109 | 0.480% |
| DD6321B | 114 | 0 | 0 | 25 | 139 | 0.612% |
| DD6321C | 0 | 0 | 0 | 17 | 17 | 0.075% |
| DD6321D | 5 | 0 | 0 | 1 | 6 | 0.026% |
| DD6321E | 14 | 0 | 0 | 21 | 35 | 0.154% |
| DD6321F | 3 | 0 | 0 | 0 | 3 | 0.013% |
| DD6321G | 1 | 0 | 0 | 12 | 13 | 0.057% |
| DD6321H | 16 | 0 | 0 | 0 | 16 | 0.070% |
| DD6322 | 2886 | 5 | 0 | 2 | 2893 | 12.736% |
| DD6323 | 567 | 0 | 0 | 23 | 590 | 2.597% |
| DD6324 | 1212 | 2 | 0 | 12 | 1226 | 5.397% |
| DD6325 | 3 | 0 | 0 | 0 | 3 | 0.013% |
| DD6326 | 156 | 0 | 0 | 1 | 157 | 0.691% |
| DD6326A | 20 | 0 | 0 | 5 | 25 | 0.110% |
| DD6326B | 102 | 1 | 0 | 1 | 104 | 0.458% |
| DD6326C | 5179 | 2 | 0 | 175 | 5356 | 23.578% |
| DD6327 | 62 | 0 | 0 | 3 | 65 | 0.286% |
| DD6328 | 136 | 1 | 0 | 1 | 138 | 0.608% |
| DD6329 | 333 | 0 | 0 | 18 | 351 | 1.545% |
| DD6330 | 47 | 0 | 0 | 23 | 70 | 0.308% |
| DD6331 | 17 | 0 | 0 | 2 | 19 | 0.084% |
| DD6332 | 21 | 0 | 0 | 444 | 465 | 2.047% |
| DD6333 | 5 | 0 | 0 | 11 | 16 | 0.070% |
| DD6334 | 59 | 0 | 0 | 2 | 61 | 0.269% |
| DD6335 | 73 | 0 | 0 | 7 | 80 | 0.352% |
| DD6336 | 101 | 2 | 0 | 2 | 105 | 0.462% |
| DD6337 | 114 | 0 | 0 | 18 | 132 | 0.581% |
| **DONOR SCREENING** | | | | | **1070** | **4.710%** |
| DS5103 | 17 | 0 | 0 | 0 | 17 | 0.075% |
| DS5104 | 22 | 0 | 0 | 12 | 34 | 0.150% |
| DS5105 | 1 | 0 | 0 | 1 | 2 | 0.009% |

| Error Code | Licensed Blood Banks | Unlicensed Blood Banks | Transfusion Services | Plasma Centers | Total | |
|---|---|---|---|---|---|---|
| DS5106 | 0 | 0 | 0 | 10 | 10 | 0.044% |
| DS5109 | 0 | 0 | 0 | 1 | 1 | 0.004% |
| DS5200 | 14 | 0 | 0 | 4 | 18 | 0.079% |
| DS5201 | 10 | 0 | 0 | 4 | 14 | 0.062% |
| DS5202 | 11 | 0 | 0 | 2 | 13 | 0.057% |
| DS5203 | 129 | 2 | 0 | 59 | 190 | 0.836% |
| DS5205 | 9 | 0 | 0 | 2 | 11 | 0.048% |
| DS5300 | 4 | 0 | 0 | 0 | 4 | 0.018% |
| DS5301 | 36 | 0 | 0 | 1 | 37 | 0.163% |
| DS5302 | 3 | 0 | 0 | 0 | 3 | 0.013% |
| DS5302A | 12 | 0 | 0 | 1 | 13 | 0.057% |
| DS5302B | 2 | 0 | 0 | 0 | 2 | 0.009% |
| DS5302C | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5302D | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5303 | 4 | 0 | 0 | 0 | 4 | 0.018% |
| DS5304 | 1 | 0 | 0 | 3 | 4 | 0.018% |
| DS5306 | 1 | 0 | 0 | 3 | 4 | 0.018% |
| DS5307 | 2 | 0 | 0 | 1 | 3 | 0.013% |
| DS5308 | 0 | 0 | 0 | 1 | 1 | 0.004% |
| DS5311A | 1 | 0 | 0 | 1 | 2 | 0.009% |
| DS5314 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5318A | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5318B | 2 | 0 | 0 | 1 | 3 | 0.013% |
| DS5318C | 0 | 0 | 0 | 1 | 1 | 0.004% |
| DS5318F | 0 | 0 | 0 | 1 | 1 | 0.004% |
| DS5321 | 1 | 0 | 0 | 3 | 4 | 0.018% |
| DS5321A | 1 | 0 | 0 | 6 | 7 | 0.031% |
| DS5321B | 0 | 0 | 0 | 2 | 2 | 0.009% |
| DS5321C | 0 | 0 | 0 | 1 | 1 | 0.004% |
| DS5322 | 1 | 1 | 0 | 0 | 2 | 0.009% |
| DS5323 | 0 | 0 | 0 | 2 | 2 | 0.009% |
| DS5324 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5332 | 0 | 0 | 0 | 6 | 6 | 0.026% |
| DS5333 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5334 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5337 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5400 | 2 | 0 | 0 | 0 | 2 | 0.009% |
| DS5401 | 8 | 0 | 0 | 0 | 8 | 0.035% |
| DS5402A | 3 | 0 | 0 | 2 | 5 | 0.022% |
| DS5402C | 1 | 0 | 0 | 1 | 2 | 0.009% |
| DS5402D | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5403 | 2 | 0 | 0 | 0 | 2 | 0.009% |
| DS5404 | 3 | 0 | 0 | 1 | 4 | 0.018% |
| DS5405 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5406 | 2 | 0 | 0 | 0 | 2 | 0.009% |
| DS5407 | 1 | 0 | 0 | 0 | 1 | 0.004% |

| Error Code | Licensed Blood Banks | Unlicensed Blood Banks | Transfusion Services | Plasma Centers | Total | |
|---|---|---|---|---|---|---|
| DS5408 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5410A | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5411B | 0 | 0 | 0 | 1 | 1 | 0.004% |
| DS5412 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5414 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5415 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5417 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5418A | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5420A | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5421 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5432 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5501 | 4 | 1 | 0 | 0 | 5 | 0.022% |
| DS5502 | 2 | 0 | 0 | 0 | 2 | 0.009% |
| DS5502A | 9 | 0 | 0 | 0 | 9 | 0.040% |
| DS5502B | 33 | 0 | 0 | 0 | 33 | 0.145% |
| DS5502C | 7 | 0 | 0 | 1 | 8 | 0.035% |
| DS5502D | 9 | 0 | 0 | 0 | 9 | 0.040% |
| DS5507 | 0 | 0 | 0 | 4 | 4 | 0.018% |
| DS5508 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5510A | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5511 | 3 | 0 | 0 | 0 | 3 | 0.013% |
| DS5511A | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5511B | 5 | 0 | 0 | 0 | 5 | 0.022% |
| DS5512 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5514 | 2 | 0 | 0 | 0 | 2 | 0.009% |
| DS5515 | 0 | 1 | 0 | 0 | 1 | 0.004% |
| DS5516 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5516A | 6 | 0 | 0 | 0 | 6 | 0.026% |
| DS5516B | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5518A | 2 | 0 | 0 | 5 | 7 | 0.031% |
| DS5518B | 3 | 0 | 0 | 2 | 5 | 0.022% |
| DS5518C | 1 | 0 | 0 | 2 | 3 | 0.013% |
| DS5518D | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5518E | 2 | 0 | 0 | 0 | 2 | 0.009% |
| DS5518F | 10 | 0 | 0 | 0 | 10 | 0.044% |
| DS5518G | 2 | 0 | 0 | 0 | 2 | 0.009% |
| DS5520B | 2 | 0 | 0 | 0 | 2 | 0.009% |
| DS5520C | 2 | 0 | 0 | 0 | 2 | 0.009% |
| DS5521 | 0 | 0 | 0 | 3 | 3 | 0.013% |
| DS5521B | 1 | 0 | 0 | 1 | 2 | 0.009% |
| DS5522 | 259 | 1 | 0 | 0 | 260 | 1.145% |
| DS5523 | 41 | 0 | 0 | 4 | 45 | 0.198% |
| DS5524 | 44 | 0 | 0 | 1 | 45 | 0.198% |
| DS5526A | 2 | 0 | 0 | 1 | 3 | 0.013% |
| DS5526B | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5526C | 6 | 0 | 0 | 0 | 6 | 0.026% |

| Error Code | Licensed Blood Banks | Unlicensed Blood Banks | Transfusion Services | Plasma Centers | Total | |
|---|---|---|---|---|---|---|
| DS5527 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DS5528 | 9 | 0 | 0 | 0 | 9 | 0.040% |
| DS5529 | 60 | 0 | 0 | 3 | 63 | 0.277% |
| DS5530 | 5 | 0 | 0 | 8 | 13 | 0.057% |
| DS5533 | 0 | 0 | 0 | 4 | 4 | 0.018% |
| DS5534 | 10 | 0 | 0 | 0 | 10 | 0.044% |
| DS5535 | 12 | 0 | 0 | 0 | 12 | 0.053% |
| DS5536 | 2 | 1 | 0 | 0 | 3 | 0.013% |
| **DONOR DEFERRAL** | | | | | **73** | **0.321%** |
| DD6101 | 9 | 0 | 0 | 2 | 11 | 0.048% |
| DD6102C | 3 | 0 | 0 | 1 | 4 | 0.018% |
| DD6102D | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DD6103 | 1 | 1 | 0 | 0 | 2 | 0.009% |
| DD6104 | 7 | 0 | 0 | 1 | 8 | 0.035% |
| DD6106 | 1 | 0 | 0 | 1 | 2 | 0.009% |
| DD6107 | 6 | 0 | 0 | 0 | 6 | 0.026% |
| DD6111B | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DD6114 | 0 | 0 | 0 | 1 | 1 | 0.004% |
| DD6115 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DD6118A | 1 | 0 | 0 | 1 | 2 | 0.009% |
| DD6118C | 1 | 0 | 0 | 1 | 2 | 0.009% |
| DD6118G | 0 | 0 | 0 | 1 | 1 | 0.004% |
| DD6121A | 0 | 0 | 0 | 3 | 3 | 0.013% |
| DD6121B | 0 | 0 | 0 | 1 | 1 | 0.004% |
| DD6122 | 2 | 0 | 0 | 0 | 2 | 0.009% |
| DD6123 | 2 | 0 | 0 | 1 | 3 | 0.013% |
| DD6124 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DD6126C | 0 | 0 | 0 | 2 | 2 | 0.009% |
| DD6130 | 0 | 0 | 0 | 1 | 1 | 0.004% |
| DD6201 | 4 | 0 | 0 | 0 | 4 | 0.018% |
| DD6202C | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DD6203 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DD6204 | 3 | 1 | 0 | 0 | 4 | 0.018% |
| DD6205 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DD6206 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DD6207 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DD6220A | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DD6221A | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DD6223 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DD6226C | 1 | 0 | 0 | 0 | 1 | 0.004% |
| DD6232 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| **STORAGE AND DISTRIBUTION** | | | | | **1508** | **6.638%** |
| SD7101 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| SD7102A | 1 | 0 | 0 | 0 | 1 | 0.004% |
| SD7107 | 5 | 0 | 0 | 0 | 5 | 0.022% |
| SD7107A | 33 | 0 | 0 | 0 | 33 | 0.145% |

| Error Code | Licensed Blood Banks | Unlicensed Blood Banks | Transfusion Services | Plasma Centers | Total | |
|---|---|---|---|---|---|---|
| SD7110A | 0 | 0 | 0 | 1 | 1 | 0.004% |
| SD7111A | 0 | 0 | 0 | 1 | 1 | 0.004% |
| SD7111B | 1 | 0 | 0 | 1 | 2 | 0.009% |
| SD7116B | 1 | 0 | 0 | 0 | 1 | 0.004% |
| SD7118A | 1 | 0 | 0 | 2 | 3 | 0.013% |
| SD7118B | 1 | 0 | 0 | 1 | 2 | 0.009% |
| SD7118C | 0 | 0 | 0 | 1 | 1 | 0.004% |
| SD7118G | 1 | 0 | 0 | 0 | 1 | 0.004% |
| SD7120C | 0 | 0 | 0 | 2 | 2 | 0.009% |
| SD7121 | 1 | 0 | 0 | 1 | 2 | 0.009% |
| SD7121B | 1 | 0 | 0 | 0 | 1 | 0.004% |
| SD7121E | 0 | 0 | 0 | 1 | 1 | 0.004% |
| SD7122 | 5 | 0 | 0 | 0 | 5 | 0.022% |
| SD7123 | 5 | 0 | 0 | 0 | 5 | 0.022% |
| SD7124 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| SD7126C | 3 | 0 | 0 | 0 | 3 | 0.013% |
| SD7128 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| SD7129 | 13 | 0 | 0 | 0 | 13 | 0.057% |
| SD7130 | 1 | 0 | 0 | 10 | 11 | 0.048% |
| SD7131 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| SD7132 | 0 | 0 | 0 | 2 | 2 | 0.009% |
| SD7134 | 2 | 0 | 0 | 0 | 2 | 0.009% |
| SD7136 | 0 | 0 | 0 | 1 | 1 | 0.004% |
| SD7137 | 0 | 0 | 0 | 1 | 1 | 0.004% |
| SD7201 | 4 | 1 | 0 | 1 | 6 | 0.026% |
| SD7202 | 4 | 0 | 0 | 1 | 5 | 0.022% |
| SD7203 | 5 | 1 | 0 | 0 | 6 | 0.026% |
| SD7204 | 6 | 1 | 0 | 6 | 13 | 0.057% |
| SD7205 | 1 | 1 | 0 | 0 | 2 | 0.009% |
| SD7206 | 4 | 1 | 0 | 3 | 8 | 0.035% |
| SD7207 | 30 | 0 | 0 | 3 | 33 | 0.145% |
| SD7208 | 4 | 0 | 0 | 0 | 4 | 0.018% |
| SD7209 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| SD7210 | 3 | 0 | 1 | 1 | 5 | 0.022% |
| SD7212 | 4 | 1 | 0 | 0 | 5 | 0.022% |
| SD7302 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| SD7303 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| SD7304 | 5 | 0 | 0 | 0 | 5 | 0.022% |
| SD7307 | 25 | 1 | 1 | 9 | 36 | 0.158% |
| SD7308 | 2 | 0 | 0 | 0 | 2 | 0.009% |
| SD7310 | 2 | 0 | 0 | 0 | 2 | 0.009% |
| SD7311 | 4 | 1 | 0 | 0 | 5 | 0.022% |
| SD7312 | 0 | 0 | 0 | 5 | 5 | 0.022% |
| SD7400 | 60 | 0 | 1 | 7 | 68 | 0.299% |
| SD7401 | 32 | 3 | 1 | 0 | 36 | 0.158% |
| SD7402 | 1 | 0 | 0 | 0 | 1 | 0.004% |

| Error Code | Licensed Blood Banks | Unlicensed Blood Banks | Transfusion Services | Plasma Centers | Total | |
|---|---|---|---|---|---|---|
| SD7403A | 5 | 0 | 0 | 0 | 5 | 0.022% |
| SD7403B | 0 | 1 | 0 | 0 | 1 | 0.004% |
| SD7403C | 6 | 0 | 0 | 0 | 6 | 0.026% |
| SD7403D | 4 | 0 | 0 | 0 | 4 | 0.018% |
| SD7403E | 5 | 0 | 0 | 0 | 5 | 0.022% |
| SD7404 | 2 | 0 | 0 | 0 | 2 | 0.009% |
| SD7404A | 25 | 0 | 0 | 0 | 25 | 0.110% |
| SD7404B | 1 | 0 | 0 | 0 | 1 | 0.004% |
| SD7404C | 4 | 0 | 0 | 0 | 4 | 0.018% |
| SD7404D | 9 | 0 | 0 | 0 | 9 | 0.040% |
| SD7404E | 7 | 0 | 0 | 0 | 7 | 0.031% |
| SD7404F | 4 | 0 | 0 | 0 | 4 | 0.018% |
| SD7406 | 17 | 0 | 0 | 0 | 17 | 0.075% |
| SD7407 | 26 | 0 | 0 | 0 | 26 | 0.114% |
| SD7408 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| SD7409 | 2 | 0 | 0 | 0 | 2 | 0.009% |
| SD7410 | 3 | 0 | 0 | 0 | 3 | 0.013% |
| SD7500 | 11 | 0 | 0 | 1 | 12 | 0.053% |
| SD7501 | 245 | 0 | 1 | 0 | 246 | 1.083% |
| SD7502 | 73 | 0 | 0 | 0 | 73 | 0.321% |
| SD7503 | 382 | 0 | 0 | 0 | 382 | 1.682% |
| SD7600 | 220 | 1 | 1 | 1 | 223 | 0.982% |
| SD7700 | 32 | 1 | 0 | 1 | 34 | 0.150% |
| SD7800 | 3 | 0 | 0 | 0 | 3 | 0.013% |
| SD7801 | 11 | 4 | 2 | 0 | 17 | 0.075% |
| SD7802 | 11 | 4 | 1 | 0 | 16 | 0.070% |
| SD7803 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| SD7804 | 8 | 6 | 4 | 0 | 18 | 0.079% |
| SD7805 | 5 | 1 | 1 | 0 | 7 | 0.031% |
| **LABELING** | | | | | **908** | **3.997%** |
| LA4000 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| LA4101 | 113 | 6 | 0 | 0 | 119 | 0.524% |
| LA4102 | 47 | 3 | 1 | 5 | 56 | 0.247% |
| LA4103 | 165 | 10 | 1 | 0 | 176 | 0.775% |
| LA4201 | 122 | 0 | 0 | 0 | 122 | 0.537% |
| LA4202 | 44 | 1 | 0 | 0 | 45 | 0.198% |
| LA4203 | 53 | 0 | 0 | 0 | 53 | 0.233% |
| LA4204 | 29 | 3 | 0 | 0 | 32 | 0.141% |
| LA4205 | 24 | 0 | 0 | 0 | 24 | 0.106% |
| LA4206 | 3 | 0 | 0 | 0 | 3 | 0.013% |
| LA4207 | 15 | 1 | 1 | 0 | 17 | 0.075% |
| LA4208 | 13 | 0 | 0 | 0 | 13 | 0.057% |
| LA4209 | 103 | 1 | 1 | 2 | 107 | 0.471% |
| LA4210 | 45 | 0 | 0 | 0 | 45 | 0.198% |
| LA4211 | 41 | 1 | 0 | 3 | 45 | 0.198% |
| LA4212 | 25 | 0 | 0 | 0 | 25 | 0.110% |

| Error Code | Licensed Blood Banks | Unlicensed Blood Banks | Transfusion Services | Plasma Centers | Total | |
|---|---|---|---|---|---|---|
| LA4213 | 7 | 0 | 0 | 0 | 7 | 0.031% |
| LA4300 | 18 | 0 | 0 | 0 | 18 | 0.079% |
| **ROUTINE TESTING** | | | | | **310** | **1.365%** |
| RT1101 | 54 | 1 | 5 | 0 | 60 | 0.264% |
| RT1102 | 85 | 0 | 3 | 0 | 88 | 0.387% |
| RT1103 | 4 | 0 | 0 | 0 | 4 | 0.018% |
| RT1104 | 23 | 2 | 1 | 0 | 26 | 0.114% |
| RT1105 | 68 | 2 | 1 | 0 | 71 | 0.313% |
| RT1106 | 6 | 1 | 0 | 0 | 7 | 0.031% |
| RT1108 | 4 | 2 | 3 | 0 | 9 | 0.040% |
| RT1201 | 39 | 3 | 3 | 0 | 45 | 0.198% |
| **VIRAL TESTING** | | | | | **79** | **0.348%** |
| VT2000 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| VT2101 | 6 | 2 | 0 | 3 | 11 | 0.048% |
| VT2102 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| VT2104 | 2 | 0 | 0 | 3 | 5 | 0.022% |
| VT2105 | 6 | 3 | 0 | 3 | 12 | 0.053% |
| VT2106 | 10 | 0 | 0 | 2 | 12 | 0.053% |
| VT2107 | 4 | 1 | 0 | 0 | 5 | 0.022% |
| VT2108 | 0 | 1 | 0 | 0 | 1 | 0.004% |
| VT2109 | 4 | 0 | 0 | 0 | 4 | 0.018% |
| VT2110 | 4 | 0 | 0 | 1 | 5 | 0.022% |
| VT2111 | 8 | 2 | 0 | 5 | 15 | 0.066% |
| VT2112 | 7 | 0 | 0 | 0 | 7 | 0.031% |
| **COMPONENT PREPARATION** | | | | | **165** | **0.726%** |
| CP8100 | 1 | 1 | 0 | 0 | 2 | 0.009% |
| CP8200 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| CP8201 | 9 | 0 | 0 | 0 | 9 | 0.040% |
| CP8202 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| CP8300 | 5 | 0 | 0 | 0 | 5 | 0.022% |
| CP8301 | 16 | 0 | 0 | 0 | 16 | 0.070% |
| CP8302 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| CP8303 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| CP8304 | 10 | 0 | 0 | 0 | 10 | 0.044% |
| CP8400 | 3 | 0 | 0 | 0 | 3 | 0.013% |
| CP8401 | 4 | 0 | 0 | 0 | 4 | 0.018% |
| CP8402 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| CP8403 | 3 | 0 | 0 | 0 | 3 | 0.013% |
| CP8404 | 45 | 1 | 0 | 0 | 46 | 0.203% |
| CP8500 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| CP8501 | 9 | 0 | 0 | 0 | 9 | 0.040% |
| CP8502 | 2 | 0 | 0 | 0 | 2 | 0.009% |
| CP8503 | 3 | 0 | 0 | 0 | 3 | 0.013% |
| CP8504 | 17 | 0 | 0 | 0 | 17 | 0.075% |
| CP8600 | 17 | 0 | 2 | 0 | 19 | 0.084% |
| CP8700 | 9 | 0 | 0 | 0 | 9 | 0.040% |

| Error Code | Licensed Blood Banks | Unlicensed Blood Banks | Transfusion Services | Plasma Centers | Total | |
|---|---|---|---|---|---|---|
| CP8801 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| CP8802 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| **BLOOD COLLECTION** | | | | | **127** | **0.559%** |
| BC3100 | 3 | | 0 | 1 | 4 | 0.018% |
| BC3101 | 27 | 3 | 0 | | 30 | 0.132% |
| BC3102 | 20 | 0 | 0 | 3 | 23 | 0.101% |
| BC3103 | 15 | 0 | 0 | | 15 | 0.066% |
| BC3201 | 11 | 0 | 0 | 0 | 11 | 0.048% |
| BC3203 | 1 | 1 | 0 | 0 | 2 | 0.009% |
| BC3400 | 6 | 0 | 0 | 0 | 6 | 0.026% |
| BC3401 | 24 | 0 | 0 | 0 | 24 | 0.106% |
| BC3402 | 4 | 1 | 0 | 0 | 5 | 0.022% |
| BC3403 | 7 | 0 | 0 | 0 | 7 | 0.031% |
| **MISCELLANEOUS** | | | | | **5** | **0.022%** |
| MI9202 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| MI9501 | 0 | 0 | 0 | 1 | 1 | 0.004% |
| MI9502 | 0 | 0 | 0 | 1 | 1 | 0.004% |
| MI9503 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| MI9504 | 1 | 0 | 0 | 0 | 1 | 0.004% |
| *Total* | 19680 | 109 | 36 | 2891 | 22716 | 100.000% |

Non-Reportable Errors and Accidents

| ERROR CODE | Licensed Blood Banks | Unlicensed Blood Banks | Transfusion Services | Plasma Centers | Total | |
|---|---|---|---|---|---|---|
| **MISCELLANEOUS** | | | | | **303** | **48.10%** |
| MI1 | 20 | 2 | 0 | 20 | 42 | 6.67% |
| MI2 | 11 | 0 | 0 | 0 | 11 | 1.75% |
| MI3 | 80 | 0 | 0 | 14 | 94 | 14.92% |
| MI4 | 54 | 6 | 16 | 10 | 86 | 13.65% |
| MI6 | 3 | 1 | 0 | 0 | 4 | 0.63% |
| MI7 | 1 | 0 | 0 | 8 | 9 | 1.43% |
| MI8 | 15 | 0 | 0 | 3 | 18 | 2.86% |
| QC1 | 37 | 0 | 0 | 1 | 38 | 6.03% |
| Miscellaneous (MI5) | 0 | 0 | 0 | 1 | 1 | 0.16% |
| **LABELING** | | | | | **121** | **19.21%** |
| LA1 | 19 | 1 | 0 | 0 | 20 | 3.17% |
| LA2 | 34 | 2 | 0 | 0 | 36 | 5.71% |
| LA3 | 16 | 0 | 0 | 0 | 16 | 2.54% |
| LA4 | 29 | 0 | 0 | 0 | 29 | 4.60% |
| LA5 | 2 | 0 | 0 | 0 | 2 | 0.32% |
| LA6 | 12 | 0 | 0 | 0 | 12 | 1.90% |
| Miscellaneous (MI5) | 6 | 0 | 0 | 0 | 6 | 0.95% |
| **DONOR SCREENING** | | | | | **59** | **9.37%** |
| DS1 | 7 | 0 | 0 | 1 | 8 | 1.27% |
| DS3 | 1 | 0 | 0 | 0 | 1 | 0.16% |
| DS4 | 19 | 1 | 0 | 2 | 22 | 3.49% |
| DS6 | 3 | 0 | 0 | 0 | 3 | 0.48% |
| DS7 | 2 | 0 | 0 | 0 | 2 | 0.32% |
| DS8 | 0 | 0 | 0 | 3 | 3 | 0.48% |
| Miscellaneous (MI5) | 3 | 0 | 0 | 17 | 20 | 3.17% |
| **POST DONATION INFORMATION** | | | | | **40** | **6.35%** |
| DS5 | 37 | 1 | 0 | 0 | 38 | 6.03% |
| Miscellaneous (MI5) | 2 | 0 | 0 | 0 | 2 | 0.32% |
| **DONOR DEFERRAL** | | | | | **5** | **0.79%** |
| Miscellaneous (MI5) | 5 | 0 | 0 | 0 | 5 | 0.79% |
| **STORAGE AND DISTRIBUTION** | | | | | **90** | **14.29%** |
| DI1 | 21 | 0 | 0 | 0 | 21 | 3.33% |
| DI2 | 0 | 0 | 0 | 0 | 0 | 0.00% |
| DI3 | 4 | 0 | 0 | 0 | 4 | 0.63% |
| DI4 | 3 | 0 | 0 | 0 | 3 | 0.48% |
| DI5 | 2 | 0 | 0 | 1 | 3 | 0.48% |
| DI6 | 15 | 1 | 0 | 0 | 16 | 2.54% |
| DI8 | 3 | 0 | 0 | 0 | 3 | 0.48% |
| DI9 | 1 | 0 | 0 | 0 | 1 | 0.16% |
| DI10 | 9 | 0 | 0 | 0 | 9 | 1.43% |
| Miscellaneous (MI5) | 28 | 1 | 1 | 0 | 30 | 4.76% |
| **BLOOD COLLECTION** | | | | | **8** | **1.27%** |
| BC1 | 2 | 0 | 0 | 0 | 2 | 0.32% |
| BC2 | 1 | 0 | 0 | 0 | 1 | 0.16% |

| ERROR CODE | Licensed Blood Banks | Unlicensed Blood Banks | Transfusion Services | Plasma Centers | Total | |
|---|---|---|---|---|---|---|
| BC3 | 5 | 0 | 0 | 0 | 5 | 0.79% |
| **ROUTINE TESTING** | | | | | **2** | **0.32%** |
| LT1 | 1 | 0 | 0 | 0 | 1 | 0.16% |
| Miscellaneous (MI5) | 1 | 0 | 0 | 0 | 1 | 0.16% |
| **VIRAL TESTING** | | | | | **1** | **0.16%** |
| Miscellaneous (MI5) | 1 | 0 | 0 | 0 | 1 | 0.16% |
| COMPONENT PREPARATION | | | | | **1** | **0.16%** |
| Miscellaneous (MI5) | 1 | 0 | 0 | 0 | 1 | 0.16% |
| Total | 516 | 16 | 17 | 81 | 630 | 100.00% |

# NON-BLOOD MANUFACTURERS

## TOTAL REPORTS

| TYPE OF ERROR/ACCIDENT | DERIVATIVE | IN-VITRO DIAGNOSTIC | ALLERGENIC | THERAPUETIC | VACCINE | TOTAL REPORTS | |
|---|---|---|---|---|---|---|---|
| REAGENT PERFORMANCE | 0 | 4 | 0 | 0 | 0 | 4 | 2.2% |
| STERILITY COMPROMISED | 5 | 5 | 31 | 6 | 3 | 50 | 27.5% |
| LABELING | 2 | 17 | 13 | 4 | 2 | 38 | 20.9% |
| STORAGE/DISTRIBUTION | 6 | 3 | 1 | 3 | 2 | 15 | 8.2% |
| PROCESSING | 11 | 4 | 4 | 11 | 9 | 39 | 21.4% |
| MISCELLANEOUS | 7 | 2 | 1 | 8 | 4 | 22 | 12.1% |
| NOT REPORTABLE | 3 | 3 | 7 | 0 | 1 | 14 | 7.7% |
| TOTAL | 34 | 38 | 57 | 32 | 21 | 182 | 100.0% |

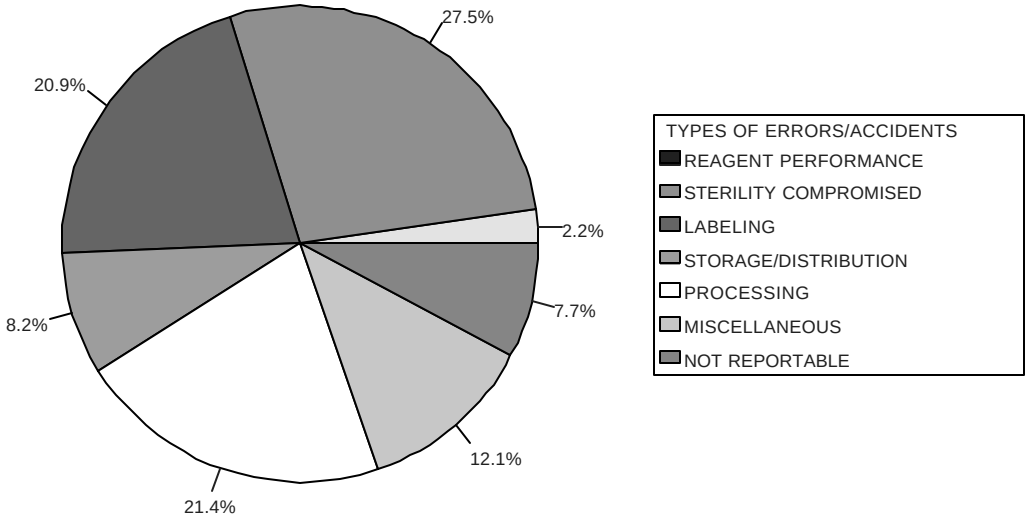
## POTENTIAL RECALLS

| TYPE OF ERROR/ACCIDENT | DERIVATIVE | IN-VITRO DIAGNOSTIC | ALLERGENIC | THERAPUETIC | VACCINE | POTENTIAL RECALL | |
|---|---|---|---|---|---|---|---|
| REAGENT PERFORMANCE | 0 | 3 | 0 | 0 | 0 | 3 | 12.0% |
| STERILITY COMPROMISED | 0 | 2 | 3 | 2 | 1 | 8 | 32.0% |
| LABELING | 0 | 2 | 2 | 0 | 1 | 5 | 20.0% |
| STORAGE/DISTRIBUTION | 1 | 0 | 0 | 0 | 1 | 2 | 8.0% |
| PROCESSING | 1 | 0 | 1 | 1 | 1 | 4 | 16.0% |
| MISCELLANEOUS | 1 | 0 | 0 | 2 | 0 | 3 | 12.0% |
| NOT REPORTABLE | 0 | 0 | 0 | 0 | 0 | 0 | 0.0% |
| TOTAL | 3 | 7 | 6 | 5 | 4 | 25 | 100.0% |

# ERROR AND ACCIDENT REPORTS

*NON-BLOOD MANUFACTURERS*

*FY2000*




*TOTAL REPORTS RECEIVED (10/1/99 - 9/30/00) = 182*

*REPORTABLE ERRORS/ACCIDENTS = 168; NON-REPORTA*

NON-BLOOD MANUFACTURERS

**DERIVATIVES**

| ERROR/ACCIDENT | #REPORTS |
|---|---|
| ***STERILITY COMPROMISED*** | ***5*** |
| Precipitate found in product | 2 |
| Possible mold contamination | 1 |
| Possible residual component | 2 |
| ***LABELING*** | ***2*** |
| Product label incorrect | 1 |
| Product label missing | 1 |
| ***STORAGE/DISTRIBUTION*** | ***6*** |
| Product released prior to CBER approval - expiration of CBE submission | 1 |
| Product released prior to validation of the lyophilization cycle | 1 |
| Product shipped or stored at incorrect temperature | 4 |
| ***PROCESSING*** | ***11*** |
| Source material unsuitable for processing | 3 |
| Lypholization cycle interrupted due to an earthquake that caused a power outage | 1 |
| Column effluent collected in flexible container rather than stainless steel tank | 1 |
| Out of specification volume of fill result | 1 |
| Product specification not met | 5 |
| ***MISCELLANEOUS*** | ***7*** |
| Glass defects | 1 |
| Water for Injection system was not sampled. | 1 |
| Product tested positive for HAV RNA during final container PCR testing, associated products released. | 1 |
| Evidence of surface change on stoppers of Normal Horse Serum packaged in the kit | 1 |
| Black particles found in WFI system | 1 |
| Stability testing failed | 1 |
| Decrease in potency | 1 |
| ***NON-REPORTABLE*** | ***3*** |
| Product labeled with missing/incorrect facility identifiers - product acceptable | 1 |
| Product not made available for distribution | 1 |
| Conflicting information on carton labels, container label correct | 1 |
| ***TOTAL*** | ***34*** |

NON-BLOOD MANUFACTURERS

## IN-VITRO DIAGNOSTICS

| ERROR/ACCIDENT | #REPORTS |
|---|---|
| ***REAGENT PERFORMANCE*** | ***4*** |
| Indicator Red Cells, used in Syphilis Test System, deteriorating | 1 |
| Product giving false positive results | 1 |
| A2 cells gave positive reaction when tested with Anti-A1 Lectin | 1 |
| B cells gave weak positive reactions | 1 |
| ***STERILITY COMPROMISED*** | ***5*** |
| Microbial contamination | 2 |
| Stoppers contaminated with endotoxin | 1 |
| Annual revalidation of aseptic dispensing exhibited an unacceptable number of contaminated units | 1 |
| Antimicrobial preservative effectiveness test may not have been performed | 1 |
| ***LABELING*** | ***17*** |
| Package insert incorrect | 9 |
| Product label incorrect | 2 |
| Lot number missing/incorrect and expiration date also missing | 4 |
| Lot number, expiration date and bar code missing | 1 |
| Insert contains information on the relationship between EU/ml and IU/ml that may be misinterpreted | 1 |
| ***PROCESSING*** | ***4*** |
| HEPA filtration system in filling area had 2 motors fail | 1 |
| Product specification not met – residual moisture | 2 |
| Inappropriate temperature | 1 |
| ***STORAGE/DISTRIBUTION*** | ***3*** |
| Product released prior to completion of required testing | 2 |
| Product shipped or stored at incorrect temperature | 1 |
| ***MISCELLANEOUS*** | ***2*** |
| Wrong vial replaced in the 11-cell panel, due to hemolysis. | 1 |
| Unacceptable results for linearity in the extended assay protocol | 1 |
| ***NON-REPORTABLE*** | ***3*** |
| Product not made available for distribution | 3 |
| ***TOTAL*** | ***38*** |

NON-BLOOD MANUFACTURERS

## ALLERGENICS

| ERROR/ACCIDENT | #REPORTS |
|---|---|
| ***STERILITY COMPROMISED*** | ***31*** |
| Loose seal resulted in a leaking vial | 1 |
| A piece of rubber from the stopper found in vial | 1 |
| Contents leaking out | 1 |
| Precipitate found in product | 28 |
| ***LABELING*** | ***13*** |
| Potency not on vial label | 2 |
| Product label incorrect | 1 |
| Lot number missing/incorrect | 1 |
| Concentration missing or incorrect | 1 |
| Expiration date extended or missing | 7 |
| Labeling did not list all ingredients | 1 |
| ***STORAGE/DISTRIBUTION*** | ***1*** |
| Sterility test cultures may not have been incubated appropriately before products released | 1 |
| ***PROCESSING*** | ***4*** |
| Computer calculation error for preparation of extract | 1 |
| Error in correcting calculation error resulted in concentration of 835 PNU/ml instead of 1000 PNU/ml | 1 |
| Formula change | 1 |
| PNU value incorrectly entered into the computer | 1 |
| ***MISCELLANEOUS*** | ***1*** |
| Stability data indicates increased potency over time | 1 |
| ***NON-REPORTABLE*** | ***7*** |
| Product labeled with missing/incorrect weight or volume; product acceptable | 1 |
| Illegible expiration date | 1 |
| Expiration date shortened | 2 |
| Product not made available for distribution | 1 |
| Discrepancy between shipping form and shipment | 1 |
| Release of product other than that which was ordered | 1 |
| ***TOTAL*** | ***57*** |

NON-BLOOD MANUFACTURERS

**THERAPEUTICS**

| ERROR/ACCIDENT | #REPORTS |
|---|---|
| ***STERILITY COMPROMISED*** | ***6*** |
| Bacterial contamination | 2 |
| Reovirus contamination diafiltered medium | 1 |
| Aspergillus flavus found in one roller bottle | 1 |
| Particles found in product | 2 |
| ***LABELING*** | ***4*** |
| Expiration date extended | 1 |
| Lot number incomplete | 1 |
| Concentration missing or incorrect | 1 |
| Label missing | 1 |
| ***STORAGE/DISTRIBUTION*** | ***3*** |
| Product released prior to completion of testing | 1 |
| Product shipped or stored at incorrect temperature | 2 |
| ***PROCESSING*** | ***11*** |
| Media fill failure | 1 |
| Rubber stoppers did not meet specifications | 1 |
| Product specification not met | 4 |
| BLA ELISA data was identical to that of a previously released lot | 1 |
| Purified water mixed into WFI distillate stream | 1 |
| Sanitization of the bulking gowning room and gowning room was not performed | 1 |
| Out of calibration situation involving the monitoring of solution levels in the processing tanks | 1 |
| Leaking ampule from punctures caused by the automatic feeder to the pouching equipment on the packaging line | 1 |
| ***MISCELLANEOUS*** | ***8*** |
| Stability testing failed | 4 |
| Lack of vacuum in vials | 1 |
| During stability study evaluation, the product demonstrated a new significant band for the SDS-PAGE test (gel electropheresis) | 1 |
| Low yield due to gel product adhering to walls of tank | 1 |
| Final product vial broke as being opened for cell implantation procedure | 1 |
| ***TOTAL*** | ***32*** |

NON-BLOOD MANUFACTURERS

## VACCINES

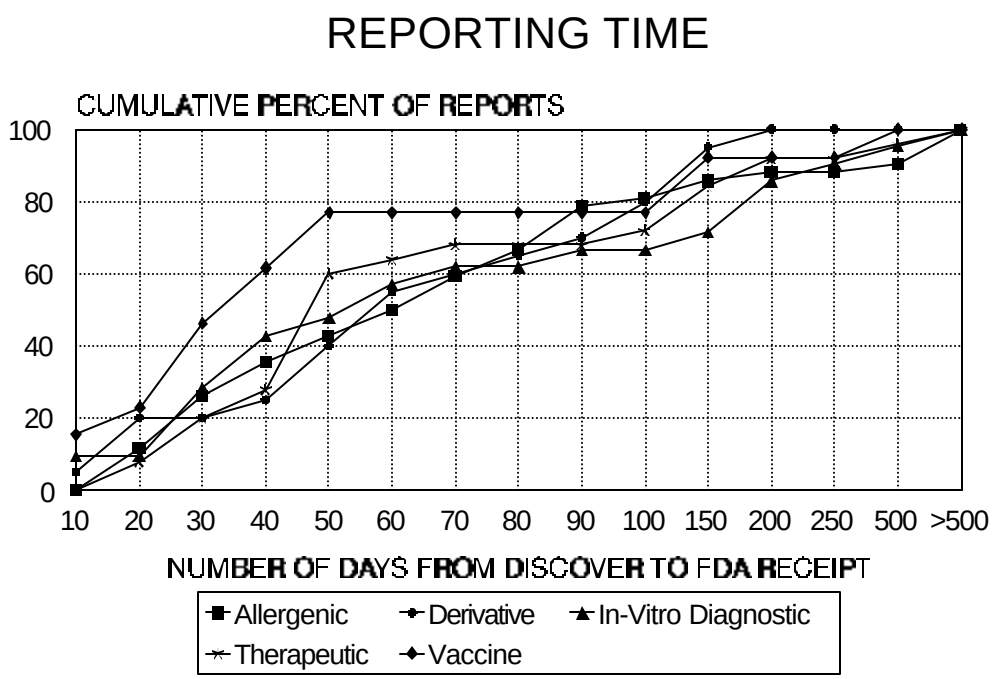
| ERROR/ACCIDENT | #REPORTS |
|---|---|
| ***STERILITY COMPROMISED*** | ***3*** |
| Bulk intermediate failed sterility test at 12-months | 1 |
| Sterility testing failed | 1 |
| Sterile media fill contaminated with fungi | 1 |
| ***LABELING*** | ***2*** |
| Expiration date extended | 2 |
| ***STORAGE/DISTRIBUTION*** | ***2*** |
| Product shipped or stored at incorrect temperature | 2 |
| ***PROCESSING*** | ***9*** |
| Appropriate testing was not performed | 1 |
| Product specification not met | 8 |
| ***MISCELLANEOUS*** | ***4*** |
| Stability testing failed | 2 |
| Decrease in potency | 1 |
| Stability potency assay not initiated within appropriate time | 1 |
| ***NON-REPORTABLE*** | ***1*** |
| Product not made available for distribution | 1 |
| ***TOTAL*** | ***21*** |

The following table and graph show the time periods in which CBER received the reports submitted by the non-blood manufacturers. The evaluation of timeliness is limited to only reports that met the threshold for reporting. In addition, reports that did not identify the date the error or accident was discovered are not included in the evaluation.

ERROR AND ACCIDENT REPORTS
RECEIVED 10/01/99 – 9/30/00

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

| CUMULATIVE PERCENT OF REPORTS | Derivative (Days) | In-Vitro Diagnostic (Days) | Allergenic (Days) | Therapeutic (Days) | Vaccine (Days) | TOTAL (Days) |
|---|---|---|---|---|---|---|
| 10% | 13 | 3 | 17 | 20 | 7 | 14 |
| 25% | 39 | 22 | 28 | 35 | 20 | 27 |
| 50% | 55 | 38 | 57 | 44 | 30 | 44 |
| 75% | 93 | 81 | 83 | 110 | 41 | 88 |
| 90% | 114 | 151 | 316 | 189 | 145 | 158 |
| # REPORTS | 20 | 21 | 42 | 25 | 13 | 121 |
| RANGE | 3-165 | 6-570 | 14-719 | 14-554 | 7-484 | 3-719 |
| *# Reports not evaluated* | *11* | *14* | *8* | *7* | *7* | *47* |




*REPORTS EVALUATED= 121*
*Allergenic = 42; Derivative = 20; In-Vitro Diagnostic = 21; Therapeutic = 25; Vaccine = 13*

## 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
- **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, or not reviewed
- **5200** - Other
- **5201** - Donor identification
- **5202** - Donor signature missing
- **5203** - Donor history questions
- **5205** - Arm inspection

**DS53** - Deferral screening not done, donor previously deferred due to:
- **5301** - HIV reactivity
- **5302** - Hepatitis related risk
  - A. history of hepatitis, not specified
  - B. history of jaundice
  - C. history of Hepatitis B or previous positive test
  - D. history of Hepatitis C or previous positive test
- **5303** - Anti-HBc reactivity
- **5304** - Anti-HCV reactivity
- **5305** - Anti-HTLV-I reactivity
  - A. history of HTLV I/II
- **5306** - ALT reactivity
- **5307** - Other reasons
- **5308** - Sexually transmitted disease, or positive STS
- **5309** - Sexual partner having sexually transmitted disease
- **5310** - Sexual partner testing positive for HIV/HTLV I/II
  - A. HIV
  - B. HTLV I/II
- **5311** - Sexual partner testing positive for Hepatitis marker
  - A. HBV
  - B. HCV
- **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
A. donor lived in or immigrated from an HIV Group O risk area
B. sex partner lived in or immigrated from an HIV Group O risk area
**5317** - Exchanged sex for drugs/money
A. sex partner
**5318** – Exposure to blood or body fluids
A. tattoo
B. ear piercing
C. body piercing
D. accidental needlestick
E. received transfusion or clotting factors
F. bone graft or transplant
G. blood exposure
H. multiple exposure
I. tattoo or ear piercing or body piercing
**5319** - Non-sexual exposure to HIV
**5320** - Non-sexual exposure to hepatitis
A. type not specified
B. Hepatitis B
C. Hepatitis C
**5321** – Other high risk behavior
A. donor rejected at another center
B. non-IV drug use
C. positive drug screen
D. rape
E. sex partner engaged in high risk behavior
F. sex partner used non-IV drugs
G. sex partner rejected at another center
H. sex partner received clotting factors
**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
A. brain surgery
B. family history
C. lived in United Kingdom (nvCJD)
**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
**5337** – Multiple high risk behaviors

**DS54** - Incorrect ID used during deferral search, donor previously deferred due to:
**5401** - HIV reactivity
**5402** – Hepatitis related risk
A. history of hepatitis, not specified
B. history of jaundice
C. history of Hepatitis B or previous positive test
D. history of Hepatitis C or previous positive test
**5403** - Anti-HBc reactivity
**5404** - Anti-HCV reactivity
**5405** - Anti-HTLV-I reactivity
A. history of HTLV I/II
**5406** - ALT reactivity
**5407** - Other reasons
**5408** - Sexually transmitted disease, or positive STS
**5409** - Sexual partner having sexually transmitted disease
**5410** - Sexual partner testing positive for HIV/HTLV I/II
A. HIV
B. HTLV I/II
**5411** - Sexual partner testing positive for Hepatitis marker
A. HBV
B. HCV
**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
A. donor lived in or immigrated from an HIV Group O risk area
B. sex partner lived in or immigrated from an HIV Group O risk area
**5417** - Exchanged sex for drugs/money
A. sex partner
**5418** – Exposure to blood or body fluids
A. tattoo
B. ear piercing
C. body piercing
D. accidental needlestick
E. received transfusion or clotting factors

F. bone graft or transplant
G. blood exposure
H. multiple exposure
I. tattoo or ear piercing or body piercing

**5419** - Non-sexual exposure to HIV
**5420** - Non-sexual exposure to hepatitis
A. type not specified
B. Hepatitis B
C. Hepatitis C
**5421** – Other high risk behavior
A. donor rejected at another center
B. non-IV drug use
C. positive drug screen
D. rape
E. sex partner engaged in high risk behavior
F. sex partner used non-IV drugs
G. sex partner rejected at another center
H. sex partner received clotting factors
**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
A. brain surgery
B. family history
C. lived in United Kingdom (nvCJD)
**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
**5437** – Multiple high risk behaviors

**DS55** - Donor gave history which warranted deferral and was not deferred
**5501** - AIDS related risk
**5502** - Hepatitis related risk
A. history of hepatitis, not specified
B. history of juandice
C. history of Hepatitis B or previous positive test

D. history of Hepatitis C or previous positive test

**5507** - Other reasons

**5508** - Sexually transmitted disease, or positive STS

**5509** - Sexual partner having sexually transmitted disease

**5510** - Sexual partner testing positive for HIV/HTLV I/II

A. HIV

B. HTLV I/II

**5511** - Sexual partner testing positive for Hepatitis marker

A. HBV

B. HCV

**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

A. donor lived in or immigrated from an HIV Group O risk area

B. sex partner lived in or immigrated from an HIV Group O risk area

**5517** - Exchanged sex for drugs/money

A. sex partner

**5518** – Exposure to blood or body fluids

A. tattoo

B. ear piercing

C. body piercing

D. accidental needlestick

E. received transfusion or clotting factors

F. bone graft or transplant

G. blood exposure

H. multiple exposure

I. tattoo or ear piercing or body piercing

**5519** - Non-sexual exposure to HIV

**5520** - Non-sexual exposure to hepatitis

A. type not specified

B. Hepatitis B

C. Hepatitis C

**5521** – Other high risk behavior

A. donor rejected at another center

B. non-IV drug use

C. positive drug screen

D. rape

E. sex partner engaged in high risk behavior

F. sex partner used non-IV drugs

G. sex partner rejected at another center

H. sex partner received clotting factors

**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
A. brain surgery
B. family history
C. lived in United Kingdom (nvCJD)
**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
**5537** - Multiple high risk behaviors

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

**6101** - HIV reactivity
**6102** – Hepatitis related risk
A. history of hepatitis, not specified
B. history of jaundice
C. history of Hepatitis B or previous positive test
D. history of Hepatitis C or previous positive test
**6103** - Anti-HBc reactivity
**6104** - Anti-HCV reactivity
**6105** - Anti-HTLV-I/II reactivity
**6106** - ALT reactivity
**6107** - Other reasons
**6108** - Sexually transmitted disease, or positive STS
**6109** - Sexual partner having sexually transmitted disease
**6110** - Sexual partner testing positive for HIV/HTLV I/II
A. HIV
B. HTLV I/II
**6111** - Sexual partner testing positive for Hepatitis marker
A. HBV
B. HCV
**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
A. donor lived in or immigrated from an HIV Group O risk area
B. sex partner lived in or immigrated from an HIV Group O risk area
**6117** - Exchanged sex for drugs/money
A. sex partner
**6118** – Exposure to blood or body fluids
A. tattoo
B. ear piercing
C. body piercing
D. accidental needlestick
E. received transfusion or clotting factors
F. bone graft or transplant
G. blood exposure
H. multiple exposure
I. tattoo or ear piercing or body piercing
**6119** - Non-sexual exposure to HIV
**6120** - Non-sexual exposure to hepatitis
A. type not specified
B. Hepatitis B
C. Hepatitis C
**6121** – Other high risk behavior
A. donor rejected at another center
B. non-IV drug use
C. positive drug screen
D. rape
E. sex partner engaged in high risk behavior
F. sex partner used non-IV drugs
G. sex partner rejected at another center
H. sex partner received clotting factor
**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
A. brain surgery
B. family history
C. lived in United Kingdom (nvCJD)
**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
**6137** - Multiple high risk behaviors

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

**6201** - HIV reactivity
**6202** – Hepatitis related risk
A. history of hepatitis, not specified
B. history of jaundice
C. history of Hepatitis B or previous positive test
D. history of Hepatitis C or previous positive test
**6203** - Anti-HBc reactivity
**6204** - Anti-HCV reactivity
**6205** - Anti-HTLV-I/II reactivity
A. history of HTLV I/II
**6206** - ALT reactivity
**6207** - Other reasons
**6208** - Sexually transmitted disease, or positive STS
**6209** - Sexual partner having sexually transmitted disease
**6210** - Sexual partner testing positive for HIV/HTLV I/II
A. HIV
B. HTLV I/II
**6211** - Sexual partner testing positive for Hepatitis marker
A. Hepatitis B
B. Hepatitis C
**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
A. donor lived in or immigrated from an HIV Group O risk area
B. sex partner lived in or immigrated from an HIV Group O risk area
**6217** - Exchanged sex for drugs/money
A. sex partner
**6218** – Exposure to blood or body fluids
A. tattoo

B. ear piercing
C. body piercing
D. accidental needlestick
E. received transfusion or clotting factors
F. bone graft or transplant
G. blood exposure
H. multiple exposure
I. tattoo or ear piercing or body piercing

**6219** - Non-sexual exposure to HIV
**6220** - Non-sexual exposure to hepatitis
A. type not specified
B. Hepatitis B
C. Hepatitis C
**6221** – Other high risk behavior
A. donor rejected at another center
B. non-IV drug use
C. positive drug screen
D. rape
E. sex partner engaged in high risk behavior
F. sex partner used non-IV drugs
G. sex partner rejected at another center
H. sex partner received clotting factors
**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
A. brain surgery
B. family history
C. lived in United Kingdom (nvCJD)
**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
**6237** - Multiple high risk behaviors

**DD63** - Post donation information
**6301** - Post donation illness (not hepatitis, HIV, HTLV-I, STD, or cold/flu related)

**6302** - Post donation information regarding Hepatitis B
- A. post donation diagnosis or symptoms
- B. tested positive post donation
- C. tested positive prior to donation

**6303** – Post donation information regarding Hepatitis C
- A. post donation diagnosis or symptoms
- B. tested positive post donation
- C. tested positive prior to donation

**6304** - Post donation information regarding HIV
- A. post donation diagnosis or symptoms
- B. tested positive post donation
- C. tested positive prior to donation

**6305** – Post donation information regarding HTLV I/II
- A. post donation diagnosis or symptoms
- B. tested positive post donation
- C. tested positive prior to donation

**6306** - Information not specifically related to high risk behavior
- A. donor does not want their blood used
- B. donated to be tested or called back for test results

**6307** – History of Hepatitis related risk
- A. history of hepatitis not specified
- B. history of jaundice
- C. history of hepatitis B
- D. history of hepatitis C

**6308** - Sexually transmitted disease
- A. post donation diagnosis or symptoms
- B. tested positive for syphilis post donation
- C. tested positive for syphilis prior to donation

**6309** - Sexual partner having sexually transmitted disease

**6310** - Sexual partner testing positive for HIV or HTLV I/II
- A. HIV
- B. HTLV I/II

**6311** - Sexual partner testing positive for Hepatitis marker
- A. HBV
- B. HCV

**6312** - Male donor had sex with another man

**6313**- Female had sex with a man who had sex with another man

**6314** - IV drug use

**6315** - Sex with IV drug user

**6316** - Travel/immigration - high risk area
- A. donor lived in or immigrated from an HIV Group O risk area
- B. sex partner lived in or immigrated from an HIV Group O risk area

**6317**- Exchanged sex for drugs or money

A. Sex partner

**6318**– Exposure to blood or body fluids
- A. tattoo
- B. ear piercing
- C. body piercing
- D. accidental needlestick
- E. received transfusion or clotting factors
- F. bone graft or transplant
- G. blood exposure
- H. multiple exposure
- I. tattoo or ear piercing or body piercing

**6319** - Non-sexual exposure to HIV

**6320** - Non-sexual exposure to hepatitis
- A. type not specified
- B. Hepatitis B
- C. Hepatitis C

**6321** – Other high risk behavior
- A. donor rejected at another center
- B. non-IV drug use
- C. positive drug screen
- D. rape
- E. sex partner engaged in high risk behavior
- F. sex partner used non-IV drugs
- G. sex partner rejected at another center
- H. sex partner received clotting factors

**6322** - Travel to malaria endemic area/history of malaria

**6323** - History of disease

**6324** - History of cancer

**6325** - History of Creutzfeldt-Jakob Disease

**6326** - Risk factors associated with Creutzfeldt-Jakob Disease
- A. brain surgery
- B. family history
- C. lived in United Kingdom (nvCJD)

**6327** - Received growth hormone

**6328** - Received Proscar, Tegison or Accutane

**6329** - Received medication or antibiotics

**6330** - Received vaccine or immune globulin

**6331** - Exposure to a disease

**6332** – Incarcerated

**6333** - Resided in a rehabilitation center or psychiatric hospital

**6334** - Received Methotrexate

**6335** - History of Hepatitis A

**6336** - Exposure to Hepatitis A

**6337** - Multiple high risk behaviors

**BC** - BLOOD COLLECTION
**BC3000** - Miscellaneous
**BC31** - Sterility compromised
**3100** - Other
**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** - Outdated anticoagulant
**BC33** - Donor/patient
**3301** - Wrong cell infusion - pheresis
**BC34** - Collection process
**3400** - Other
**3401** - Collection time extended, discrepant, or not documented; not discovered prior to component prep
**3402** – Overbleed; not discovered prior to component prep
**3403** – Collection status not documented or discrepant
**BC35** - Collection device
**3500** - Device defect

**CP** - COMPONENT PREPARATION
**CP8000** - Miscellaneous
**CP8100** - Components prepared more than 8 hours after collection
**CP8200** - Sterility compromised
**8200** - Other
**8201** - Bacterial contamination
**8202** - Air contamination
**CP8300** – Procedure for platelet component preparation not followed
**8300** - Other
**8301** - Collected from donor who took aspirin within 72 hours of donation
**8302** - Resting time requirements not met
**8303** - Platelets not agitated
**8304** - Platelet count or platelet yield not acceptable or platelet count not performed on product
**CP8400** - Procedure for component preparation not followed
**8400** - Other
**8401** - Processed at incorrect centrifuge setting
**8402** - Expired reagents used
**8403** - Freezing time requirements not met or not documented

**8404** - Prepared at incorrect temperature or held at incorrect temperature during component prep

**CP8500** - Component prepared from unacceptable whole blood unit

**8500** - Other

**8501** - Overweight

**8502** - Underweight

**8503** - Collected at unacceptable or undocumented temperature

**8504** - Extended or difficult collection

**CP8600** – Procedure for leukoreduction not followed

**CP8700** – Procedure for irradiation not followed

**CP8800** - Unacceptable component

**8800** - Other

**8801** - Overweight

**8802** - Underweight

**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

**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/II

**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
**4208** - Anticoagulant
**4209** - Donor number
**4210** - Recipient number or name
**4211** – Biohazard or test status
**4212** - Leukoreduced
**4213** - HLA
**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** – Hepatitis related risk
A. history of hepatitis, not specified
B. history of jaundice
C. history of Hepatitis B or previous positive test
D. history of Hepatitis C or previous positive test
**7103** - Previous Anti-HBc reactivity
**7104** - Previous Anti-HCV reactivity
**7105** - Previous Anti-HTLV-I reactivity
A. history of HTLV I/II
**7106** - Previous ALT reactivity
**7107** - Other reasons
A. post donation illness
**7108** - Sexually transmitted disease, or positive STS

**7109** - Sexual partner having sexually transmitted disease
**7110** - Sexual partner testing positive for HIV/HTLV I/II
A. HIV
B. HTLV I/II
**7111** - Sexual partner testing positive for Hepatitis marker
A. HBV
B. HCV
**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
A. donor lived in or immigrated from an HIV Group O risk area
B. sex partner lived in or immigrated from an HIV Group O risk area
**7117** - Exchanged sex for drugs/money
A. sex partner
**7118** – Exposure to blood or body fluids
A. tattoo
B. ear piercing
C. body piercing
D. accidental needlestick
E. received transfusion or clotting factors
F. bone graft or transplant
G. blood exposure
H. multiple exposure
I. tattoo or ear piercing or body piercing
**7119** - Non-sexual exposure to HIV
**7120** - Non-sexual exposure to hepatitis
A. type not specified
B. Hepatitis B
C. Hepatitis C
**7121** – Other high risk behavior
A. donor rejected at another center
B. non-IV drug use
C. positive drug screen
D. rape
E. sex partner engaged in high risk behavior
F. sex partner used non-IV drugs
G. sex partner rejected at another center
H. sex partner received clotting factors
**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
A. brain surgery
B. family history
C. lived in United Kingdom (nvCJD)
**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
**7137** - Multiple high risk behaviors

**SD72** - Failure to quarantine unit due to incorrect, incomplete, or positive testing for:
**7201** – HIV
**7202** - HBsAg
**7203** - Anti-HBc
**7204** - Anti-HCV
**7205** - Anti-HTLV-I
**7206** - ALT
**7207** - Other reasons
**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** - HIV
**7302** - HBsAg
**7303** - Anti-HBc
**7304** - Anti-HCV
**7305** - Anti-HTLV-I
**7306** - ALT
**7307** - Other reasons
**7308** - ABO
**7309** - Rh
**7310** - Antibody screen
**7311** - Antigen screen
**7312** – Syphilis

**SD74** – Failure to quarantine unit due to:

**7400** - Other
**7401** - Outdated product
**7402** - Autologous unit not meeting homologous criteria
**7403** - Product QC unacceptable or not documented
A. platelet
B. pH
C. hematocrit
D. WBC
E. RBC recovery
**7404** – Product specification not met
A. platelet count or platelet yield
B. pH
C. hematocrit
D. WBC count
E. RBC recovery
F. volume
**7405** - Instrument QC or validation unacceptable or not documented
A. viral marker testing
B. ABO/Rh testing
**7406** - Collection time extended, discrepant or not documented
**7407** - Unit released prior to resolution of discrepancy
**7408** - Associated product contained clots
**7409** – Overweight component
**7410** – Underweight component

**SD75** - Unsuitable product
**7500** - Other
**7501** - Unit contained clots or would not flow through filter
**7502** – Unit or segment hemolyzed
**7503** – Broken or damaged unit

**SD7600** – Shipped or stored at incorrect temperature
**SD7700** - Shipment of unlicensed product labeled with license number
**SD7800** - Improper transfusion service practices
**7800** - Miscellaneous
**7801** – Product not irradiation as required
**7802** - Unit issued to wrong patient
**7803** - Improper product selected for patient
**7804** - Improper ABO or Rh type selected for patient
**7805** - Product not leukoreduced as required

**MI** - Miscellaneous
**MI90** - Miscellaneous
**9000** - Miscellaneous
**MI92** - Donor implicated in transfusion associated disease

**9201** - HIV
**9202** - Hepatitis
**9203** - Other

**MI9500** - Lookback; subsequent unit tested
**9500** – other
**9501** - HIV antibody positive
**9502** - HBsAg positive
**9503** - HCV positive
**9504** - HTLV-I positive
**9505** - HIV antigen positive

## 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

## NON-REPORTABLE ERRORS/ACCIDENTS

**Donor Suitability - DS**

DS1 - Donor did not meet acceptance criteria for age
DS2 - Donor did not meet acceptance criteria for Hemoglobin/Hematocrit (Hgb>=11.0g/dl, Hct>=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 or volume; unit acceptable
LA5 - Unit labeled with missing/incorrect collection date; unit acceptable
LA6 - Unit labeled with missing/incorrect facility identifiers - unit acceptable

**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

DI10 - Failure to quarantine unit after receiving information concerning post donation cold or flu symptoms

**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 - product quality not affected

MI6 - Recipient reaction

MI7 - Lookback procedures not followed

MI8 - Notification/retrieval procedures not followed

**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