Biological Product and HCT/P Deviation Reports

Annual Summary for Fiscal Year 2021

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I. Summary

FDA requires reporting of certain deviations and unexpected events in manufacturing in accordance with 21 CFR 600.14, 606.171 or 1271.350(b). The following manufacturers, who had control over the product when an event associated with manufacturing (deviation or unexpected event) occurred, are required to submit Biological Product Deviation (BPD) reports to the Center for Biologics Evaluation and Research (CBER), if the safety, purity, or potency of a distributed product may be affected:

- Manufacturers of licensed biological products other than blood and blood components (licensed non-blood) who hold the biological product license [21 CFR 600.14];
- Licensed manufacturers of blood and blood components, including Source Plasma [21 CFR 606.171];
- Unlicensed registered blood establishments [21 CFR 606.171]; and
- Transfusion services [21 CFR 606.171].

In addition, manufacturers of nonreproductive Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) regulated by FDA solely under section 361 of the Public Health Service Act and 21 CFR Part 1271 [21 CFR 1271.350(b)] are required to submit HCT/P deviation reports to CBER, if the deviation or unexpected event involving a distributed product is related to a Core Current Good Tissue Practice requirement [21 CFR 1271.150(b)] and to the prevention of communicable disease transmission or HCT/P contamination. Hereafter, to improve the readability of this annual summary report, these products are collectively referred to as "361 HCT/Ps" rather than "nonreproductive HCT/Ps".

Detailed information concerning deviation reporting, including guidance documents on BPD reporting for blood and Source Plasma establishments (Ref. 1) and licensed manufacturers of biological products other than blood and blood components (Ref. 2), is available at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviation-guidances-rules. The guidance document for blood and Source Plasma establishments was updated in March 2020 and explains that we do not consider post donation information (PDI) events to require BPD reports. As a result, there were no PDI events reported in Fiscal Year 2021 (FY21). A guidance document for deviation reporting for 361 HCT/Ps (Ref. 3) is available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deviation-reporting-human-cells-tissues-and-cellular-and-tissue-based-products-regulated-solely.

This annual summary report provides an overview of the reports submitted during the fiscal year encompassing October 1, 2020, through September 30, 2021, including detailed information regarding the number and types of deviation reports. Each firm responsible for reporting biological product and HCT/P deviations should use this information in evaluating their own deviation management program. We provide combined data submitted over the last three fiscal years to compare data and highlight changes. However, based on the limited data, we may not be able to determine the reason for changes to the number of reports submitted compared to the previous fiscal year.

Detailed information for blood and Source Plasma establishments can be found in Appendix 1; detailed information for licensed non-blood establishments can be found in Appendix 2; and detailed information for 361 HCT/P establishments can be found in Appendix 3. These appendices provide data to compare FY21 to fiscal year 2020 (FY20), whereas Tables 1 through 4 below also include comparative data for fiscal year 2019 (FY19). Previous summary reports are available at https://www.fda.gov/vaccines-blood-biologics/report-problem-center-biologics-evaluation-research/biological-product-deviation-reports-annual-summaries. Our system does not collect the necessary denominator data to calculate genuine rates when evaluating possible trends.

Table 1 shows the number of reports submitted and the number of establishments who submitted reports each fiscal year for the past three years for each type of establishment. Although there were more than 14,556 reports submitted during FY21, this summary excludes data for deviation reports that did not meet the reporting requirements. We notified the reporter when a report was not required.

The total number of reports submitted in FY21 (14,556) decreased 52.9% compared to FY20 (30,929). There was a decrease in reporting due to the implementation of the BPD guidance (Ref. 1) eliminating reporting of post donation information. In FY20, there were 16,425 post donation information reports submitted between October 2019 and March 2020, prior to the implementation of the BPD guidance.

The total number of reporting establishments increased from 2,133 in FY20 to 2,152 in FY21. Compared to FY20, there were 28 more blood and Source Plasma establishments, four fewer manufacturers of licensed biological products other than blood and blood components, and one more 361 HCT/P manufacturer reporting in FY21.

Table 1 - Total Deviation Reports FY19 – FY21

Establishment Type	Number of Reporting Establishments			Total Reports Submitted			*Potential* Recalls		
	FY19	FY20	FY21	FY19	FY20	FY21	FY19	FY20	FY21
Blood/Source Plasma Manufacturers									
Licensed Blood Establishments	222 (86*)	200 (78*)	193 (70*)	15,826	9,769	6,234	449	396	456
Unlicensed Blood Establishments[1]	359	348	340	3,159	2,890	2,589	14	6	10
Transfusion Services[2]	691	671	701	1,909	1,785	1,832	0	0	0
Source Plasma Establishments	713 (21*)	761 (23*)	774 (15*)	27,550	15,678	3,166	269	120	0
Sub-Total	*1,985*	*1,980*	*2,008*	*48,444*	*30,122*	*13,821*	*732*	*522*	*466*
Licensed Non-Blood Manufacturers									
Allergenic	6 (6*)	8 (8*)	6 (6*)	88	100	85	0	1	0
Blood Derivative	24 (19*)	28 (23*)	24 (18*)	119	117	91	5	1	1
In Vitro Diagnostic	9 (8*)	10 (10*)	9 (9*)	93	110	91	1	2	1
Vaccine	18 (15*)	19 (17*)	16 (14*)	193	255	233	1	0	1
Gene Therapy Products	3 (3*)	1 (1*)	0	3	1	0	0	0	0
351 HCT/P	11 (9*)	8 (6*)	9 (7*)	50	32	29	0	0	0
Sub-Total	*71 (60*)*	*74 (65*)*	*64 (54*)*	*546*	*615*	*529*	*7*	*4*	*3*
361 HCT/P Manufacturers									
Cellular HCT/P	50	47	46	143	130	136	0	0	0
Tissue HCT/P	53	32	34	115	62	70	22	15	11
Sub-Total	*103*	*79*	*80*	*258*	*192*	*206*	*22*	*15*	*11*
Total	**2,159**	**2,133**	**2,152**	**49,248**	**30,929**	**14,556**	**761**	**541**	**480**

[1]Unlicensed Blood Establishments – unlicensed blood establishments that perform manufacturing of blood and blood components are required to register with FDA.
[2]Transfusion Services – blood banks that perform limited blood and blood component manufacturing (e.g., pooling, thawing, compatibility testing), may or may not register with FDA.
*Number of license holders; one or more establishments operate under one biologics license.

Blood and Source Plasma establishments submitted 95% of the total reports in FY21 and 16,301 fewer reports in FY21 compared to FY20. The decrease was mostly due to the elimination of reporting PDI. Table 2 shows the number of reports submitted each fiscal year for the past three years by each type of establishments. Licensed blood establishments submitted 45%, unlicensed registered blood establishments submitted 19%, transfusion services submitted 13%, and Source Plasma establishments submitted 23% of the total blood and Source Plasma reports in FY21. Compared to FY20, licensed blood establishments submitted 3,535 fewer reports (36% decrease), unlicensed registered blood establishments submitted 301 fewer reports (10% decrease), transfusion services submitted 47 more reports (3% increase), and Source Plasma establishments submitted 12,512 fewer reports (80% decrease) in FY21.

Table 2 - Blood and Source Plasma Establishments

Licensed Blood Establishments

Manufacturing System	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
QC & Distribution	1,696	10.7%	1,823	18.7%	2,018	32.4%
Blood Collection	868	5.5%	1,118	11.4%	1,898	30.4%
Donor Screening	1,210	7.6%	1,586	16.2%	1,549	24.8%
Labeling	292	1.8%	290	3.0%	334	5.4%
Routine Testing	234	1.5%	263	2.7%	205	3.3%
Component Preparation	106	0.7%	217	2.2%	158	2.5%
Transfusion-Transmitted Infection Testing	49	0.3%	44	0.5%	47	0.8%
Donor Deferral	13	0.1%	17	0.2%	25	0.4%
Post Donation Information	11,358	71.8%	4,411	45.1%	0	0%
Total	**15,826**	100%	**9,769**	100%	**6,234**	100%

Unlicensed Blood Establishments

Manufacturing System	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
QC & Distribution	1,747	55.3%	1,663	57.5%	1,598	61.7%
Labeling	625	19.8%	542	18.8%	489	18.9%
Routine Testing	442	14.0%	460	15.9%	392	15.1%
Component Preparation	74	2.3%	61	2.1%	75	2.9%
Transfusion-Transmitted Infection Testing	54	1.7%	30	1.1%	22	0.9%
Donor Screening	24	0.8%	21	0.7%	10	0.4%
Blood Collection	8	0.3%	3	0.1%	3	0.1%
Donor Deferral	1	<0.0%	0	0.0%	0	0.0%
Post Donation Information	184	5.8%	110	3.8%	0	0.0%
Total	**3,159**	100%	**2,890**	100%	**2,589**	100%

Transfusion Services

Manufacturing System	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
QC & Distribution	980	51.3%	1,002	56.1%	995	54.3%
Routine Testing	566	29.6%	472	26.5%	528	28.8%
Labeling	357	18.7%	305	17.1%	303	16.5%
Component Preparation	3	0.2%	5	0.3%	3	0.2%
Transfusion-Transmitted Infection Testing*	3	0.2%	1	0.1%	3	0.2%
Donor Screening	NA	NA	NA	NA	NA	NA
Blood Collection	NA	NA	NA	NA	NA	NA
Donor Deferral	NA	NA	NA	NA	NA	NA
Post Donation Information	NA	NA	NA	NA	NA	NA
Total	**1,909**	100%	**1,785**	100%	**1,832**	100.0%

**Bacterial detection testing*

Source Plasma Establishments

Manufacturing System	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
QC & Distribution	3,587	13.0%	3,173	20.3%	2,785	88.0%
Donor Screening	343	1.2%	540	3.4%	352	11.1%
Blood Collection	29	0.1%	45	0.3%	20	0.6%
Donor Deferral	41	0.2%	8	0.1%	8	0.3%
Component Preparation	1	<0.1%	3	<0.1%	1	<0.1%
Labeling	4	<0.1%	3	<0.1%	0	0.0%
Transfusion-Transmitted Infection Testing	1	<0.1%	2	<0.1%	0	0.0%
Routine Testing	0	0.0%	0	0.0%	0	0.0%
Post Donation Information	23,544	85.5%	11,904	75.9%	0	0.0%
Total	**27,550**	100%	**15,678**	100%	**3,166**	100%

Manufacturers of licensed non-blood products submitted 4% of the total reports in FY21 and 86 fewer reports in FY21 compared to FY20. Table 3 shows the number of reports submitted each fiscal year for the past three years each type of manufacturer. Allergenic manufacturers submitted 16%, plasma derivative manufacturers submitted 17%, in-vitro diagnostic manufacturers submitted 17%, vaccine manufacturers submitted 44%, and licensed HCT/P manufacturers (351 HCT/Ps) submitted 5% of the total licensed non-blood reports in FY21. Compared to FY20, allergenic manufacturers submitted 15 fewer reports, plasma derivative manufacturers submitted 26 fewer reports, in-vitro diagnostic manufacturers submitted 19 fewer reports, vaccine manufacturers submitted 22 fewer reports, gene therapy product manufacturers did not submit any reports in FY21, and licensed HCT/P manufacturers submitted three fewer reports.

Table 3 - Licensed Non-Blood Manufacturers

Allergenic Manufacturers

Manufacturing System	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
Product Specifications	85	96.6%	93	93.0%	78	91.8%
Labeling	2	2.3%	5	5.0%	3	3.5%
Incoming Material	0	0.0%	0	0.0%	2	2.4%
Quality Control & Distribution	0	0.0%	1	1.0%	1	1.2%
Process Controls	1	1.1%	0	0.0%	1	1.2%
Testing	0	0.0%	1	1.0%	0	0.0%
Total	**88**	100%	**100**	100%	**85**	100%

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Blood Derivatives Manufacturers

Manufacturing System	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
Product Specifications	54	45.4%	34	29.1%	33	36.2%
Quality Control & Distribution	22	18.5%	24	20.5%	23	25.3%
Process Controls	6	5.0%	13	11.1%	16	17.6%
Labeling	13	10.9%	13	11.1%	8	8.8%
Testing	14	11.8%	19	16.2%	6	6.6%
Incoming Material	10	8.4%	14	12.0%	5	5.5%
Total	**119**	100%	**117**	100%	**91**	100%

In-Vitro Diagnostic Manufacturers

Manufacturing System	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
Product Specifications	49	52.7%	54	49.1%	46	50.6%
Quality Control & Distribution	24	25.8%	23	20.9%	26	28.6%
Labeling	15	16.1%	24	21.8%	11	12.1%
Incoming Material	0	0.0%	0	0.0%	5	5.5%
Testing	4	4.3%	4	3.6%	2	2.2%
Process Controls	1	1.1%	5	4.6%	1	1.1%
Total	**93**	100%	**110**	100%	**91**	100 %

Vaccine Manufacturers

Manufacturing System	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
Product Specifications	83	43.0%	128	50.2%	125	53.6%
Quality Control & Distribution	49	25.4%	70	27.5%	61	26.2%
Process Controls	24	12.4%	23	9.0%	15	6.4%
Labeling	12	6.2%	15	5.9%	11	4.7%
Testing	21	10.9%	10	3.9%	12	5.2%
Incoming Material	4	2.1%	9	3.5%	9	3.9%
Total	**193**	100%	**255**	100%	**233**	100%

Gene Therapy Product Manufactures

Manufacturing System	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
Testing	1	33.3%	1	100%	0	0%
Product Specifications	2	66.7%	0	0%	0	0%
Labeling	0	0%	0	0%	0	0%
Quality Control & Distribution	0	0%	0	0%	0	0%
Incoming Material	0	0%	0	0%	0	0%
Process Controls	0	0%	0	0%	0	0%
Total	**3**	100%	**1**	100%	**0**	0%

Licensed HCT/P Manufacturers (351 HCT/Ps)

Manufacturing System	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
Labeling	18	36.0%	16	50.0%	11	37.9%
Product Specifications	20	40.0%	7	21.9%	7	24.1%
Process Controls	4	8.0%	1	3.1%	3	10.3%
Incoming Material	2	4.0%	1	3.1%	4	13.8%
Quality Control & Distribution	4	8.0%	0	0%	2	6.9%
Testing	1	2.0%	7	21.9%	2	6.9%
Receipt, Pre-Distribution Shipment, Distribution	1	2.0%	0	0%	0	0.0%
Total	**50**	100%	**32**	100%	**29**	100%

Manufacturers of 361 HCT/Ps submitted 1% of the total reports in FY21 and 14 more reports in FY21 compared to FY20. Table 4 shows the number of reports submitted each fiscal year for the past three years by 361 HCT/P manufacturers, with the data displayed separately for cellular 361 HCT/P manufacturers (e.g., hematopoietic stem/progenitor cells) and tissue 361 HCT/P manufacturers (e.g., skin, musculoskeletal, cornea). Manufacturers of cellular 361 HCT/Ps submitted 66% and manufacturers of tissue 361 HCT/Ps submitted 34% of the total 361 HCT/P deviation reports in FY21. Compared to FY20, manufacturers of cellular 361 HCT/Ps submitted six more reports and manufacturers of tissue 361 HCT/Ps submitted eight more reports in FY21.

Table 4 - 361 HCT/P Manufacturers

Cellular 361 HCT/P Manufacturers

Manufacturing System	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
Receipt, Pre-Distribution, Shipment & Distribution	119	83.2%	109	83.8%	102	75.0%
Processing & Processing Controls	11	7.7%	11	8.4%	16	11.8%
Supplies and Reagents	3	2.1%	3	2.3%	5	3.7%
Recovery	0	0%	4	3.1%	3	2.2%
Storage	0	0%	0	0%	3	2.2%
Donor Screening	6	4.2%	0	0%	2	1.5%
Environmental Control	1	0.7%	0	0%	2	1.5%
Donor Testing	2	1.4%	1	0.8%	1	0.7%
Donor Eligibility	1	0.7%	1	0.8%	1	0.7%
Facilities	0	0.0%	0	0.0%	1	0.7%
Equipment	0	0%	1	0.8%	0	0.0%
Labeling Controls	0	0%	0	0%	0	0.0%
Total	**143**	100%	**130**	100%	**136**	100%

Tissue 361 HCT/Ps Manufacturers

Manufacturing System	FY19 (#)	FY19 (%)	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
Receipt, Pre-Distribution, Shipment & Distribution	30	26.1%	20	32.2%	22	31.4%
Donor Eligibility	22	19.1%	14	22.6%	20	28.6%
Donor Screening	8	7.0%	9	14.5%	8	11.4%
Donor Testing	7	6.1%	8	12.9%	8	11.4%
Processing & Processing Controls	12	10.4%	4	6.5%	5	7.2%
Recovery	31	27.0%	2	3.2%	3	4.3%
Labeling Controls	2	1.7%	0	0%	2	2.9%
Supplies and Reagents	1	0.9%	4	6.5%	1	1.4%
Environmental Control	0	0%	0	0%	0	0%
Equipment	2	1.7%	1	1.6%	1	1.4%
Storage	0	0%	0	0%	0	0.0%
Facilities	0	0.0%	0	0.0%	0	0.0%
Total	**115**	100%	**62**	100%	**70**	100%

In FY21, there were no changes to the HCT/P Deviation Codes. There were minor changes in the Non-Blood BPD Codes and Blood BPD Codes to clarify reportable events. However, as discussed above, the BPD reporting guidance issued March 2020 eliminated the reporting of post donation information, which decreased the number of total reports submitted by blood and Source Plasma establishments by 54%.

You may submit questions concerning this summary to:

U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

You may also contact us by email at bp_deviations@fda.hhs.gov or hctp_deviations@fda.hhs.gov.

II. References

1. Guidance for Industry - Biological Product Deviation Reporting for Blood and Plasma Establishments March 2020 https://www.fda.gov/media/70694/download
2. Guidance for Industry - Biological Product Deviation Reporting for Licensed Manufacturers of Biological Products Other than Blood and Blood Components October 2006 https://www.fda.gov/media/76309/download
3. Guidance for Industry - Deviation Reporting for Human Cells, Tissues, and Cellular and Tissue-Based Products Regulated Solely Under Section 361 of the Public Health Service Act and 21 CFR Part 1271 September 2017 https://www.fda.gov/regulatory-information/search-fda-guidance-documents/deviation-reporting-human-cells-tissues-and-cellular-and-tissue-based-products-regulated-solely

III. Appendices

1. BPD Reports Submitted by Blood and Source Plasma Establishments
2. BPD Reports Submitted by Licensed Non-Blood Manufacturers
3. HCT/P Reports Submitted by 361 HCT/P Manufacturers

Appendix 1. BPD Reports Submitted by Blood and Source Plasma Establishments

Tables 5 through 15 highlight the most frequent reports submitted in FY21 by each type of blood and Source Plasma establishment compared to reports submitted in FY20. Not all reports submitted are represented in these tables and therefore the numbers of reports listed do not add up to the total reports listed in the table.

1. Most Frequent BPD Reports Submitted by Licensed Blood Establishments[1]

Of the 6,234 reports submitted by licensed blood establishments in FY21 (Table 2), 2,018 reports (32.4%) involved quality control and distribution deviations or unexpected events (Table 5). The number of these reports increased 11% compared to FY20, which is an increase of 195 reports. There were 295 more reports submitted in FY21 compared to FY20 involving distributed units collected from a donor who subsequently tested confirmed positive for a relevant transfusion-transmitted infection. There were 167 fewer reports submitted in FY21 compared to FY20 involving a positive bacterial detection test result. *Cutibacterium acnes* was identified as the organism in 175 (57%) of the 308 reports regarding bacterial testing submitted in FY21.

Table 5 - Most Frequent BPD Reports - Quality Control & Distribution from Licensed Blood Establishments

QC & Distribution (QC)	FY20 (#)	FY20 (% of QC)	FY21 (#)	FY21 (% of QC)
Total QC Reports	**1,823**	**-**	**2,018**	**-**
Distribution of a unit collected from a donor who subsequently tested confirmed positive for a relevant transfusion transmitted disease	***546***	***30.0%***	***841***	***41.7%***
Babesia	69	3.8%	258	12.8%
HCV	196	10.8%	245	12.1%
HBV	135	7.4%	203	10.1%
Anti-HBc	46	2.5%	115	5.7%
HIV	67	3.7%	57	2.8%
West Nile Virus	29	1.6%	53	2.6%
Chagas	46	2.5%	19	0.9%
Distribution of product that did not meet specifications	***500***	***27.4%***	***553***	***27.4%***
Product QC unacceptable, not performed, not documented, or incomplete	271	14.9%	278	13.8%
White Blood Cell count	128	7.0%	122	6.0%
Platelet count	28	1.5%	46	2.3%
RBC recovery	33	1.8%	30	1.5%
Product in which specification, other than QC, was not met	48	2.6%	68	3.4%
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or documented	40	2.2%	35	1.7%
Outdated product	36	2.0%	28	1.4%
Product identified as unsuitable due to positive testing; event discovered subsequent to distribution	***479***	***26.3%***	***311***	***15.4%***
Bacterial testing	473	25.9%	308	15.3%
Shipping and storage	***165***	***9.1%***	***201***	***10.0%***

[1] Licensed blood establishments do not include Source Plasma establishments, for the purpose of this summary.

Of the 6,234 reports submitted by licensed blood establishments in FY21 (Table 2), 1,898 reports (30.4%) involved blood collection deviations or unexpected events (Table 6)**.** The number of these reports increased 70% compared to FY20, which is an increase of 780 reports. The number of reports involving clots or fibrin discovered in a product increased 77%. There was a 42% increase in reports of clots or fibrin discovered in frozen products after thawing (FY20-818; FY21-1,412)

Table 6 - Most Frequent BPD Reports – Blood Collection from Licensed Blood Establishments

Blood Collection (BC)	FY20 (#)	FY20 (% of BC)	FY21 (#)	FY21 (% of BC)
Total BC Reports	***1,118***	**-**	**1,898**	**-**
Collection process	***984***	***88.0%***	***1,726***	***90.9%***
Product contained clots or fibrin, not discovered prior to distribution	918	82.1%	1,629	85.8%
Product hemolyzed, not discovered prior to distribution	53	4.7%	79	4.2%
Sterility compromised	***72***	***6.4%***	***64***	***3.4%***
Bacterial contamination	57	5.1%	49	2.6%
Collection bag	***60***	***5.4%***	***104***	***5.5%***
Potential collection set defect	59	5.3%	101	5.3%

Of the 6,234 reports submitted by licensed blood establishments in FY21 (Table 2), 1,549 reports (24.8%) involved donor screening deviations or unexpected events (Table 7). The number of these reports decreased 2% compared to FY20, which is a decrease of 37 reports. There were seven fewer reports submitted in FY21 compared to FY20 involving deferral screening not performed or performed incorrectly prior to product distribution, but the donor was not previously deferred.

Table 7 - Most Frequent BPD Reports - Donor Screening from Licensed Blood Establishments

Donor Screening (DS)	FY20 (#)	FY20 (% of DS)	FY21 (#)	FY21 (% of DS)
Total DS Reports	**1,586**	**-**	**1,549**	**-**
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***1,383***	***87.2%***	***1,374***	***88.7%***
Donor not previously deferred	1,283	80.9%	1,276	82.4%
Donor previously deferred due to history	53	3.3%	50	3.2%
Donor previously deferred due to testing	47	3.0%	48	3.1%
Donor record incomplete or incorrect	***120***	***7.6%***	***139***	***9.0%***
Donor history questions	113	7.1%	105	6.8%
Incorrect gender specific question asked, or incorrect answer documented	96	6.1%	77	5.0%
Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked	***72***	***4.5%***	***28***	***1.8%***
Travel to or resided in malaria endemic area/history of malaria	38	2.4%	9	0.6%
Risk factors associated with Creutzfeldt-Jakob Disease (vCJD) - travel	16	1.0%	2	0.1%
Donor did not meet eligibility criteria	***11***	***0.7%***	***8***	***0.5%***

2. Most Frequent BPD Reports Submitted by Unlicensed Registered Blood Establishments

Of the 2,589 reports submitted by unlicensed registered blood establishments in FY21 (Table 2), 1,598 reports (61.7%) involved quality control and distribution deviations or unexpected events (Table 8). The number of these reports decreased 4% compared to FY20, which is a decrease of 65 reports.

Table 8 - Most Frequent BPD Reports - Quality Control & Distribution from Unlicensed Registered Blood Establishments

QC & Distribution (QC)	FY20 (#)	FY20 (% of QC)	FY21 (#)	FY21 (% of QC)
Total QC Reports	**1,663**	**-**	**1,598**	**-**
Distribution procedure not performed in accordance with blood bank transfusion service's specifications	***1,486***	***89.4%***	***1,405***	***87.9%***
Visual inspection not performed, not documented, or inadequate, includes product not documented or incorrectly documented as issued in the computer	655	39.4%	619	38.7%
Improper product selected for patient	194	11.7%	185	11.6%
Product not irradiated as required	191	11.5%	157	9.8%
Improper ABO or Rh type selected for patient	117	7.0%	109	6.8%
Procedure for issuing not performed or documented in accordance with specifications	120	7.2%	107	6.7%
Distribution of product that did not meet specifications	***108***	***6.5%***	***127***	***7.9%***
Product in which instrument QC, calibration, or validation unacceptable, incomplete or not documented	32	1.9%	36	2.3%
Product in which specification, other than QC, was not met	22	1.3%	27	1.7%
Outdated product	25	1.5%	26	1.6%
Shipping and storage	***57***	***3.4%***	***52***	***3.3%***
Product was reissued without a record of proper temperature maintenance	20	1.2%	26	1.6%

Of the 2,589 reports submitted by unlicensed registered blood establishments in FY21 (Table 2), 489 reports (18.9%) involved labeling deviations or unexpected events (Table 9). The number of these reports decreased 9.8% compared to FY20, which is a decrease of 53 reports.

Table 9 - Most Frequent BPD Reports – Labeling from Unlicensed Registered Blood Establishments

Labeling (LA)	FY20 (#)	FY20 (% of LA)	FY21 (#)	FY21 (% of LA)
Total LA Reports	**542**	**-**	**489**	**-**
Crossmatch tag, tie tag, or transfusion record incorrect or missing information	***355***	***65.5%***	***307***	***62.8%***
Recipient identification incorrect or missing	163	30.1%	107	21.9%
Crossmatch tag, tie tag, or transfusion record missing or attached to incorrect unit	54	10.0%	47	9.6%
Expiration date or time extended or missing	38	7.0%	34	7.0%
Compatibility information incorrect or missing	8	1.5%	32	6.5%
Unit or pool number incorrect or missing	19	3.5%	24	4.9%
Product volume incorrect or missing	15	2.8%	23	4.7%
Product type or code incorrect or missing	19	3.5%	19	3.9%
Labels applied to blood unit incorrect or missing information	***187***	***34.5%***	***182***	***37.2%***
Expiration date or time extended or missing	101	18.6%	79	16.2%
Product type or code incorrect or missing	19	3.5%	36	7.4%
Irradiation status incorrect or missing	25	4.6%	20	4.1%
Combination of incorrect or missing information	8	1.5%	15	3.1%

Of the 2,589 reports submitted by unlicensed registered blood establishments in FY21 (Table 2), 392 reports (15.1%) involved routine testing deviations or unexpected events (Table 10). The number of these reports decreased 14.8% compared to FY20, which was a decrease of 68 reports. There were 94 fewer reports submitted in FY21 compared to FY20 involving ABO/Rh testing.

Table 10 - Most Frequent BPD Reports - Routine Testing from Unlicensed Registered Blood Establishments

Routine Testing (RT)	FY20 (#)	FY20 (% of RT)	FY21 (#)	FY21 (% of RT)
Total RT Reports	**460**	**-**	**392**	**-**
Testing performed, interpreted, or documented incorrectly; not performed; incompletely performed; or not documented	***423***	***92.0%***	***348***	***88.8%***
Compatibility	88	19.1%	94	24.0%
Antigen typing	72	15.7%	88	22.4%
Antibody screening or identification	91	19.8%	79	20.2%
ABO and/or Rh	152	33.0%	58	14.8%
Sample (used for testing) identification	***37***	***8.0%***	***44***	***11.2%***
Sample used for testing was incorrectly or incompletely labeled	26	5.7%	25	6.4%
Unsuitable sample used for testing (e.g., too old)	7	1.5%	12	3.1%
Incorrect sample tested	4	0.9%	6	1.5%

3. Most Frequent BPD Reports Submitted by Transfusion Services

Of the 1,832 reports submitted by transfusion services in FY21 (Table 2), 995 reports (54.3%) involved quality control and distribution deviations or unexpected events (Table 11). The number of these reports decreased 0.7% compared to FY20, which was a decrease of seven reports.

Table 11 - Most Frequent BPD Reports - Quality Control & Distribution from Transfusion Services

QC & Distribution (QC)	FY20 (#)	FY20 (% of QC)	FY21 (#)	FY21 (% of QC)
Total QC Reports	**1,002**	**-**	**995**	**-**
Distribution procedure not performed in accordance with blood bank transfusion service's specifications	***889***	***88.7%***	***868***	***87.2%***
Visual inspection not performed, not documented, or inadequate, includes product not documented or incorrectly documented as issued in the computer	384	38.4%	408	41.0%
Product not irradiated as required	125	12.5%	111	11.2%
Improper product selected for patient	113	11.3%	116	11.7%
Procedure for issuing not performed or documented in accordance with specifications	100	10.0%	55	5.5%
Improper ABO or Rh type selected for patient	62	6.2%	82	8.2%
Distribution of product that did not meet specifications	***71***	***7.1%***	***91***	***9.1%***
Outdated product	25	2.5%	51	5.1%
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or not documented	31	3.1%	26	2.6%
Shipping and storage	***41***	***4.1%***	***32***	***3.2%***
No documentation that product was stored at appropriate temperature	21	2.1%	10	1.0%
Product stored at incorrect temperature	11	1.1%	12	1.2%
Product was reissued without a record of proper temperature maintenance	7	0.7%	7	0.7%

Of the 1,832 reports submitted by transfusion services in FY21 (Table 2), 528 reports (28.8%) involved routine testing deviations or unexpected events (Table 12). The number of these reports increased 11.9% compared to FY20, which was an increase of 56 reports.

Table 12 - Most Frequent BPD Reports - Routine Testing from Transfusion Services

Routine Testing (RT)	FY20 (#)	FY20 (% of RT)	FY21 (#)	FY21 (% of RT)
Total RT Reports	**472**	**-**	**528**	**-**
Testing performed, interpreted, or documented incorrectly; not performed; incompletely performed; or not documented	***424***	***89.8%***	***480***	***90.9%***
Antigen typing	113	23.9%	114	21.6%
Compatibility	105	22.2%	124	23.5%
ABO and/or Rh typing	77	16.3%	104	19.7%
Antibody screening or identification	94	19.9%	97	18.4%
Sample (used for testing) identification	***48***	***10.2%***	***48***	***9.1%***
Sample used for testing was incorrectly or incompletely labeled	31	6.6%	32	6.1%
Unsuitable sample used for testing (e.g., too old)	8	1.7%	10	1.9%
Incorrect sample tested	9	1.9%	6	1.1%

Of the 1,832 reports submitted by transfusion services in FY21 (Table 2), 303 reports (16.5%) involved labeling deviations or unexpected events (Table 13). Compared to FY20, there were two fewer reports submitted in FY21 involving labeling and 12 fewer reports submitted involving labeling of the crossmatch tag, tie tag, or transfusion record.

Table 13 - Most Frequent BPD Reports - Labeling from Transfusion Services

Labeling (LA)	FY20 (#)	FY20 (% of LA)	FY20 (#)	FY20 (% of LA)
Total LA Reports	**305**	**-**	**303**	**-**
Crossmatch tag, tie tag or transfusion record incorrect or missing information	***237***	***77.7%***	***225***	***74.3%***
Recipient identification incorrect or missing	97	31.8%	93	30.7%
Crossmatch tag, tie tag, or transfusion record missing or attached to incorrect unit	34	11.1%	29	9.6%
Product type or code incorrect or missing	12	3.9%	15	5.0%
Expiration date or time extended or missing	17	5.6%	12	4.0%
Unit or pool number incorrect or missing	15	4.9%	12	4.0%
Combination of incorrect or missing information	14	4.6%	11	3.6%
Compatibility information incorrect or missing	13	4.3%	11	3.6%
Antigen incorrect or missing	9	3.0%	11	3.6%
Antibody incorrect or missing	5	1.6%	11	3.6%
Labels applied to blood unit incorrect or missing information	***68***	***22.3%***	***78***	***25.7%***
Expiration date or time extended or missing	39	12.8%	36	11.9%
Combination of incorrect or missing information	11	3.6%	12	4.0%
Product type or code incorrect or missing	8	2.6%	15	5.0%

4. Most Frequent BPD Reports Submitted by Source Plasma Establishments

Of the 3,166 reports submitted by Source Plasma establishments in FY21 (Table 2), 2,785 reports (88%) involved quality control and distribution deviations or unexpected events (Table 14)**.** The number of these reports decreased 12% compared to FY20, which was a decrease of 388 reports. The number of reports related to a donor subsequently testing positive for HCV or HBV decreased from 1,510 and 1,055 in FY20 to 1,377 and 672 in FY21 respectively.

Table 14 - Most Frequent BPD Reports - Quality Control & Distribution from Source Plasma Establishments

QC & Distribution (QC)	FY20 (#)	FY20 (% of QC)	FY20 (#)	FY20 (% of QC)
Total QC Reports	**3,173**	**-**	**2,785**	**-**
Distribution of a unit collected from a donor who subsequently tested confirmed positive for a relevant transfusion transmitted disease	***3,072***	***96.8%***	***2,587***	***92.9%***
HCV	1,510	47.6%	1,377	49.4%
HBV	1,055	33.2%	672	24.1%
HIV	494	15.6%	534	19.2%
Distribution of product that did not meet specifications	***56***	***1.8%***	***234***	***8.4%***
Product identified as unsuitable due to a collection deviation or unexpected event	18	0.6%	76	2.7%
Product identified as unsuitable due to a transfusion-transmitted infection testing deviation or unexpected event	2	0.1%	25	0.9%
Product identified as unsuitable due to a donor screening deviation or unexpected event	31	1.0%	23	0.8%
Failure to quarantine unit due to medical history	***35***	***1.1%***	***57***	***2.0%***
Post donation illness	15	0.5%	14	0.5%
Behavior/history unknown	0	0.0%	10	0.4%
Intimate contact with risk for a relevant transfusion-transmitted infection - sex partner to a reactive donor	8	0.3%	8	0.3%
Donor received tattoo and/or piercing	9	0.3%	7	0.3%

Of the 3,166 reports submitted by Source Plasma establishments in FY21 (Table 2), 352 reports (11.1%) involved donor screening deviations or unexpected events (Table 15). The number of these reports decreased 34.8% compared to FY20, which was a decrease of 188 reports. There were 143 fewer reports submitted in FY21 compared to FY20 involving donor history questions incorrect or incomplete, with most reports related to incorrect gender specific questions. There were 36 more reports submitted in FY21 compared to FY20 involving a donor providing history which warranted deferral or follow up and was not deferred. There were 77 fewer reports submitted in FY21 compared to FY20 involving deferral screening not performed or performed incorrectly prior to product distribution, but the donor was not previously deferred.

Table 15 - Most Frequent BPD Reports - Donor Screening from Source Plasma Establishments

Donor Screening (DS)	FY20 (#)	FY20 (% of DS)	FY21 (#)	FY21 (% of DS)
Total DS Reports	**540**	**-**	**352**	**-**
Donor record incomplete or incorrect	***298***	***55.2%***	***146***	***41.5%***
Donor history questions	267	49.4%	124	35.2%
Incorrect gender specific question asked or incorrect answer	184	34.1%	54	15.3%
Donor comprehension	66	12.2%	68	19.3%
Donor identification	31	5.7%	17	4.8%
Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked	***104***	***19.3%***	***140***	***39.8%***
Other (unacceptable address)	51	9.4%	87	24.7%
Donor received tattoo and/or piercing	33	6.1%	17	4.8%
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***101***	***18.7%***	***27***	***7.7%***
Donor not previously deferred	95	17.6%	18	5.1%
Donor previously deferred due to history	6	1.1%	9	2.6%
Donor did not meet eligibility criteria	***37***	***10.8%***	***39***	***11.1%***
Medical history interview or physical assessment not performed or inadequate	35	6.5%	20	5.7%
Temperature unacceptable or not documented	1	0.2%	18	5.1%

Appendix 2. BPD Reports Submitted by Licensed Manufacturers of Biological Products Other Than Blood and Blood Components (Licensed Non-Blood)

Tables 16 through 21 highlight the most frequent reports submitted in FY21 by each type of licensed non-blood manufacturer compared to reports submitted in FY20. Not all reports submitted are represented in these tables and therefore the numbers of reports listed do not add up to the total reports listed in the table.

Of the 85 reports submitted by allergenic manufacturers in FY21 (Table 3), 92% of the reports were related to product specifications (Table 16).

Table 16 - Most Frequent BPD Reports Submitted by Allergenic Manufacturers

Allergenic Manufacturers	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
Total Reports	**100**	-	**85**	-
Product Specifications	***93***	***93.0%***	***78***	***91.8%***
Product specification not met; contains precipitate	86	***86.0%***	77	***90.6%***

Of the 91 reports submitted by plasma derivative manufacturers in FY21 (Table 3), 36% of the reports were related to product specifications and 25% of the reports were related to quality control and distribution (Table 17).

Table 17 - Most Frequent BPD Reports Submitted by Plasma Derivative Manufacturers

Plasma Derivative Manufacturers	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
Total Reports	**117**	-	**91**	-
Product Specifications	***34***	***29.1%***	***33***	***36.2%***
Stability testing failed	12	10.3%	15	16.5%
Appearance	5	4.3%	3	3.3%
Potency	3	2.6%	3	3.3%
Product specification not met	8	6.8%	10	11.0%
Appearance	5	4.3%	7	7.7%
Component packaged with final product did not meet specifications	13	11.1%	8	8.8%
Broken/cracked vial	6	5.1%	4	4.4%
Contains precipitate/particle	6	5.1%	4	4.4%
Quality Control and Distribution	***24***	***20.5%***	***23***	***25.3%***
Packing; Broken or cracked vial/syringe	21	17.9%	15	16.5%

Of the 91 reports submitted by in-vitro diagnostic manufacturers in FY21 (Table 3), 51% of the reports were related to product specifications and 29% of the reports were related to quality control and distribution. The number of reports involving labeling decreased from 24 in FY20 to 11 in FY21 (Table 18).

Table 18 - Most Frequent BPD Reports Submitted by In-Vitro Diagnostic Manufacturers

In-Vitro Diagnostic Manufacturers	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
Total Reports	**110**	-	**91**	-
Product Specifications	***54***	***49.1%***	***46***	***50.6%***
Product specification not met; Unexpected positive, negative, or weak reactions in testing	36	32.7%	27	29.7%
Product specification not met; Container closure not secure or damaged	11	10.0%	12	13.2%
Quality Control and Distribution	***23***	***20.9%***	***26***	***28.6%***
Packing	15	13.6%	21	23.1%
Labeling	***24***	***21.8%***	***11***	***12.1%***
Package insert	7	6.4%	2	2.2%
Product label	5	4.5%	4	4.4%
Multiple information	5	4.5%	2	2.2%

Of the 233 reports submitted by vaccine manufacturers in FY21 (Table 3), 54% of the reports were related to product specifications and 26% of the reports were related to quality control and distribution (Table 19).

Table 19 - Most Frequent BPD Reports Submitted by Vaccine Manufacturers

Vaccine Manufacturers	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
Total Reports	**255**	-	**233**	-
Product Specifications	***128***	***50.2%***	***125***	***53.6%***
Product specification not met	121	47.5%	116	49.8%
Container closure not secure or damaged	56	22.0%	60	25.8%
Appearance	52	20.4%	51	21.9%
Quality Control and Distribution	***70***	***27.5%***	***61***	***26.2%***
Packing; Broken or cracked vial/syringe	67	26.3%	55	23.6%

There were no reports submitted by gene therapy manufacturers in FY21 (Table 3).

Table 20 - Most Frequent BPD Reports Submitted by Gene Therapy Manufacturers

Licensed Gene Therapy Manufacturers	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
Total Reports	**1**	-	**0**	-
Testing	***1***	***100%***	***0***	***0%***

Of the 29 reports submitted by licensed HCT/P manufacturers (351 HCT/Ps) in FY21 (Table 3), 38% of the reports were related to labeling (Table 21).

Table 21 - Most Frequent BPD Reports Submitted by Licensed HCT/P Manufacturers (351 HCT/Ps)

Licensed HCT/P Manufacturers (351 HCT/Ps)	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
Total Reports	**32**	-	**29**	-
Labeling	***16***	***50.0%***	***11***	***37.9%***
Product label; incorrect/illegible; recipient identification	16	50.0%	9	31.0%
Product Specifications	***7***	***21.9%***	***7***	***24.1%***
Product specification not met; contaminated with microorganism	5	15.6%	3	10.3%
Product specification not met; Container closure not secure or damaged	2	6.3%	3	10.3%
Incoming Material	***1***	***3.1%***	***4***	***13.8%***
Source/raw material does not meet specifications; Testing Deviation	0	0.0%	2	6.9%

Appendix 3. HCT/P Deviation Reports Submitted by Manufacturers of 361 HCT/Ps

Tables 22 and 23 highlight the most frequent reports submitted in FY21 by each type of 361 HCT/P manufacturer compared to reports submitted in FY20. Not all reports submitted are represented in these tables and therefore the numbers of reports listed do not add up to the total reports listed in the table.

Of the 136 reports submitted by cellular 361 HCT/P manufacturers in FY21 (Table 4), 75% of the reports involved receipt, pre-distribution, shipment and distribution and 12% of the reports involved processing and process controls (Table 22).

Table 22 - Most Frequent HCT/P Deviation Reports Submitted by Cellular 361 HCT/Ps Manufacturers

Cellular 361 HCT/Ps Manufacturers	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
Total Reports	**130**	-	**136**	-
Receipt, Pre-Distribution, Shipment & Distribution	***109***	***83.8%***	***102***	***75.0%***
Inappropriate distribution; Contaminated or potentially contaminated HCT/P	103	79.2%	100	73.5%
Processing & Processing Controls	***11***	***8.5%***	***16***	***11.8%***
Processing; HCT/P contaminated, potentially contaminated, or cross-contaminated during processing	7	5.4%	11	8.1%
In-process controls; Not followed	4	3.1%	5	3.7%

Of the 70 reports submitted by tissue 361 HCT/P manufacturers in FY21 (Table 4), 31% of the reports involved receipt, pre-distribution, shipment and distribution and 29% of the reports involved donor eligibility (Table 23).

Table 23 - Most Frequent HCT/P Deviation Reports Submitted by Tissue 361 HCT/Ps Manufacturers

Tissue 361 HCT/Ps Manufacturers	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)
Total Reports	**62**		**70**	
Receipt, Pre-Distribution, Shipment & Distribution	***20***	***32.3%***	***22***	***31.4%***
Inappropriate distribution; Contaminated or potentially contaminated HCT/P	13	21.0%	16	22.9%
Donor Eligibility	***14***	***22.6%***	***20***	***28.6%***
Ineligible donor accepted; Risk factors for, or clinical evidence of infection due to RCDAD	13	21.0%	18	25.7%
Final autopsy results received post distribution	6	9.7%	7	10.0%
Donor Screening	***9***	***14.5%***	***8***	***11.4%***
Donor screening not performed or performed incorrectly	9	14.5%	8	11.4%
Donor medical history interview	6	9.7%	5	7.1%
Medical record review	2	3.2%	3	4.3%
Donor Testing	***2***	3.2%	***8***	11.4%
Unacceptable specimen tested; Donor incorrectly or not evaluated for plasma dilution	6	9.7%	5	7.1%
Inappropriate test or test laboratory used; Required test used was not licensed, approved, or cleared	0	0.0%	2	2.9%
Testing not performed or documented when required, for: Treponema pallidum	0	0.0%	1	1.4%