Biological Product and HCT/P Deviation Reports

Annual Summary for Fiscal Year 2022

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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) described in 21 CFR 1271.10 and regulated by FDA solely under section 361 of the Public Health Service Act and 21 CFR Part 1271 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 related to the prevention of communicable disease transmission or HCT/P contamination [21 CFR 1271.350(b)]. 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 Biological Product Deviation Guidances & Rules | FDA. 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 after Fiscal Year 2021 (FY21). A guidance document for deviation reporting for 361 HCT/Ps (Ref. 3) is available at 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 | FDA.

This annual summary report provides an overview of the reports submitted during the fiscal year encompassing October 1, 2021, through September 30, 2022 (FY22), 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 FY22 to FY21, whereas Tables 1 through 4 below also include comparative data for FY20. Previous summary reports are available at Biological Product Deviation Reports Annual Summaries | FDA. 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 15,010 reports submitted during FY22, 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 FY22 (15,010) increased 3% compared to FY21 (14,556). The total number of reporting establishments increased from 2,152 in FY21 to 2,276 in FY22. Compared to FY21, there were 105 more blood and Source Plasma establishments, 14 more manufacturers of licensed biological products other than blood and blood components, and five more 361 HCT/P manufacturer reporting in FY22.

Table 1 - Total Deviation Reports FY20 – FY22

Establishment Type	Number of Reporting Establishments			Total Reports Submitted			*Potential* Recalls		
	FY20	FY21	FY22	FY20	FY21	FY22	FY20	FY21	FY22
Blood/Source Plasma Manufacturers									
Licensed Blood Establishments	200 (78*)	193 (70*)	188(72*)	9,769	6,234	6,131	396	456	422
Unlicensed Blood Establishments[1]	348	340	328	2,890	2,589	2,429	6	10	13
Transfusion Services[2]	671	701	722	1,785	1,832	1,875	0	0	0
Source Plasma Establishments	761 (23*)	774 (15*)	875(17*)	15,678	3,166	3,848	120	0	0
Sub-Total	*1,980*	*2,008*	*2,113*	*30,122*	*13,821*	*14,283*	*522*	*466*	*435*
Licensed Non-Blood Manufacturers									
Allergenic	8 (8*)	6 (6*)	4(4*)	100	85	81	1	0	0
Blood Derivative	28 (23*)	24 (18*)	27(18*)	117	91	92	1	1	1
In Vitro Diagnostic	10 (10*)	9 (9*)	14(13*)	110	91	87	2	1	1
Vaccine	19 (17*)	16 (14*)	25(23*)	255	233	201	0	1	2
Gene Therapy Products	3 (3*)	3(3*)	4(4*)	5	8	18	0	0	0
351 HCT/P	6 (4*)	6 (4*)	4(3*)	28	21	25	0	0	0
Sub-Total	*74 (65*)*	*64 (54*)*	*78(65*)*	*615*	*529*	*504*	*4*	*3*	*4*
361 HCT/P Manufacturers									
Cellular HCT/P	47	46	44	130	136	134	0	0	0
Tissue HCT/P	32	34	41	62	70	89	15	11	27
Sub-Total	*79*	*80*	*85*	*192*	*206*	*223*	*15*	*11*	*27*
Total	**2,133**	**2,152**	**2,276**	**30,929**	**14,556**	**15,010**	**541**	**480**	**466**

[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 FY22 and 462 more reports in FY22 compared to FY21 (Table 1). 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 43%, unlicensed registered blood establishments submitted 17%, transfusion services submitted 13%, and Source Plasma establishments submitted 27% of the total blood and Source Plasma reports in FY22. Compared to FY21, licensed blood establishments submitted 103 fewer reports (1.7% decrease), unlicensed registered blood establishments submitted 160 fewer reports (6.2% decrease), transfusion services submitted 43 more reports (2.3% increase), and Source Plasma establishments submitted 682 more reports (21.5% increase) in FY22.

Table 2 - Blood and Source Plasma Establishments

Licensed Blood Establishments

Manufacturing System	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
QC & Distribution	1,823	18.7%	2,018	32.4%	2,328	38.0%
Blood Collection	1,118	11.4%	1,898	30.4%	1,785	29.1%
Donor Screening	1,586	16.2%	1,549	24.8%	1,118	18.2%
Labeling	290	3.0%	334	5.4%	326	5.3%
Routine Testing	263	2.7%	205	3.3%	230	3.8%
Component Preparation	217	2.2%	158	2.5%	230	3.8%
Transfusion-Transmitted Infection Testing	44	0.5%	47	0.8%	86	1.4%
Donor Deferral	17	0.2%	25	0.4%	28	0.5%
Post Donation Information	4,411	45.1%	0	0%	0	0%
Total	**9,769**	100%	**6,234**	100%	**6,131**	100%

Unlicensed Blood Establishments

Manufacturing System	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
QC & Distribution	1,663	57.5%	1,598	61.7%	1,463	60.2%
Labeling	542	18.8 %	489	18.9%	467	19.2%
Routine Testing	460	15.9%	392	15.1%	426	17.5%
Component Preparation	61	2.1%	75	2.9%	54	2.2%
Donor Screening	21	0.7%	10	0.4%	6	0.2%
Blood Collection	3	0.1%	3	0.1%	6	0.2%
Transfusion-Transmitted Infection Testing	30	1.0%	22	0.8%	5	0.2%
Donor Deferral	0	0.0%	0	0.0%	2	0.1%
Post Donation Information	110	3.8%	0	0.0%	0	0.0%
Total	**2,890**	100%	**2,589**	100%	**2,429**	100%

Transfusion Services

Manufacturing System	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
QC & Distribution	1,002	56.1%	995	54.3%	1,018	54.3%
Routine Testing	472	26.5%	528	28.8%	535	28.5%
Labeling	305	17.1%	303	16.5%	313	16.7%
Component Preparation	5	0.3%	3	0.2%	7	0.4%
Transfusion-Transmitted Infection Testing*	1	0.1%	3	0.2%	2	0.1%
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	**1,785**	100%	**1,832**	100%	**1,875**	100%

**Bacterial detection testing*

Source Plasma Establishments

Manufacturing System	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
QC & Distribution	3,173	20.3%	2,785	88.0%	3,433	89.2%
Donor Screening	540	3.4%	352	11.1%	395	10.3%
Blood Collection	45	0.3%	20	0.6%	11	0.3%
Donor Deferral	8	0.1%	8	0.3%	5	0.1%
Transfusion-Transmitted Infection Testing	2	<0.1%	0	0.0%	4	0.1%
Component Preparation	3	<0.1%	1	<0.1%	0	0.0%
Labeling	3	<0.1%	0	0.0%	0	0.0%
Routine Testing	0	0.0%	0	0.0%	0	0.0%
Post Donation Information	11,904	75.9%	0	0.0%	0	0.0%
Total	**15,678**	100%	**3,166**	100%	**3,848**	100%

Manufacturers of licensed non-blood products submitted 3% of the total reports in FY22 and 25 fewer reports in FY22 compared to FY21 (Table 1). 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 18%, in-vitro diagnostic manufacturers submitted 17%, vaccine manufacturers submitted 40%, gene therapy product manufacturers submitted 4%, and licensed HCT/P manufacturers (351 HCT/Ps) submitted 5%, of the total licensed non-blood reports in FY22. Compared to FY21, allergenic manufacturers submitted four fewer reports, plasma derivative manufacturers submitted one more report, in-vitro diagnostic manufacturers submitted four fewer reports, vaccine manufacturers submitted 32 fewer reports, gene therapy product manufacturers submitted 10 more reports, and licensed HCT/P manufacturers submitted four more reports in FY22.

Table 3 - Licensed Non-Blood Manufacturers

Allergenic Manufacturers

Manufacturing System	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
Product Specifications	93	93.0%	78	91.8%	78	96.3%
Labeling	5	5.0%	3	3.5%	2	2.5%
Testing	1	1.0%	0	0.0%	1	1.2%
Quality Control & Distribution	1	1.0%	1	1.2%	0	0.0%
Process Controls	0	0.0%	1	1.2%	0	0.0%
Incoming Material	0	0.0%	2	2.4%	0	0.0%
Total	**100**	100%	**85**	100%	**81**	100%

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Blood Derivatives Manufacturers

Manufacturing System	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
Product Specifications	34	29.1%	33	36.2%	32	34.8%
Process Controls	13	11.1%	16	17.6%	20	21.7%
Quality Control & Distribution	24	20.5%	23	25.3%	19	20.7%
Testing	19	16.2%	6	6.6%	10	10.9%
Labeling	13	11.1%	8	8.8%	8	8.7%
Incoming Material	14	12.0%	5	5.5%	3	3.3%
Total	**117**	100%	**91**	100%	**92**	100%

In-Vitro Diagnostic Manufacturers

Manufacturing System	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
Quality Control & Distribution	23	20.9%	26	28.6%	30	34.5%
Product Specifications	54	49.1%	46	50.6%	24	27.6%
Labeling	24	21.8%	11	12.1%	17	19.5%
Testing	4	3.6%	2	2.2%	7	8.0%
Incoming Material	0	0.0%	5	5.5%	7	8.0%
Process Controls	5	4.6%	1	1.1%	2	2.3%
Total	**110**	100%	**91**	100 %	**87**	100%

Vaccine Manufacturers

Manufacturing System	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
Product Specifications	128	50.2%	125	53.6%	86	42.8%
Quality Control & Distribution	70	27.5%	61	26.2%	43	21.4%
Process Controls	23	9.0%	15	6.4%	27	13.4%
Incoming Material	9	3.5%	9	3.9%	25	12.4%
Labeling	15	5.9%	11	4.7%	12	6.0%
Testing	10	3.9%	12	5.2%	8	4.0%
Total	**255**	100%	**233**	100%	**201**	100%

Gene Therapy Product Manufactures

Manufacturing System	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
Product Specifications	0	0%	1	12.5%	6	33.3%
Testing	3	60.0%	0	0%	5	27.8%
Incoming Material	1	20.0%	2	25.0%	3	16.7%
Quality Control & Distribution	0	0%	0	0%	2	11.1%
Labeling	0	0%	2	25.0%	1	5.6%
Process Controls	1	20.0%	3	37.5%	1	5.6%
Total	**5**	100%	**8**	100%	**18**	100%

Licensed HCT/P Manufacturers (351 HCT/Ps)

Manufacturing System	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
Labeling	16	57.1%	9	42.9%	20	80.0%
Product Specifications	7	25.0%	6	28.6%	2	8.0%
Process Controls	0	0%	0	0%	2	8.0%
Incoming Material	0	0%	2	9.5%	1	4.0%
Quality Control & Distribution	0	0%	2	9.5%	0	0.0%
Testing	5	17.9%	2	9.5%	0	0.0%
Total	**28**	100%	**21**	100%	**25**	100%

Manufacturers of 361 HCT/Ps submitted 1% of the total reports in FY22 and 17 more reports in FY22 compared to FY21 (Table 1). 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 60% and manufacturers of tissue 361 HCT/Ps submitted 40% of the total 361 HCT/P deviation reports in FY22. Compared to FY21, manufacturers of cellular 361 HCT/Ps submitted two fewer reports and manufacturers of tissue 361 HCT/Ps submitted 19 more reports in FY22.

Table 4 - 361 HCT/P Manufacturers

Cellular 361 HCT/P Manufacturers

Manufacturing System	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
Receipt, Pre-Distribution, Shipment & Distribution	109	83.8%	102	75.0%	91	67.9%
Processing & Processing Controls	11	8.4%	16	11.8%	24	17.9%
Storage	0	0%	3	2.2%	6	4.5%
Supplies and Reagents	3	2.3%	5	3.7%	5	3.7%
Facilities	0	0.0%	1	0.7%	3	2.2%
Donor Screening	0	0%	2	1.5%	2	1.5%
Recovery	4	3.1%	3	2.2%	1	0.7%
Environmental Control	0	0%	2	1.5%	1	0.7%
Equipment	1	0.8%	0	0.0%	1	0.7%
Donor Testing	1	0.8%	1	0.7%	0	0.0%
Donor Eligibility	1	0.8%	1	0.7%	0	0.0%
Labeling Controls	0	0%	0	0.0%	0	0.0%
Total	**130**	100%	**136**	100%	**134**	100%

Tissue 361 HCT/Ps Manufacturers

Manufacturing System	FY20 (#)	FY20 (%)	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
Donor Eligibility	14	22.6%	20	28.6%	37	41.6%
Receipt, Pre-Distribution, Shipment & Distribution	20	32.2%	22	31.4%	18	20.2%
Donor Testing	8	12.9%	8	11.4%	11	12.4%
Processing & Processing Controls	4	6.5%	5	7.2%	11	12.4%
Donor Screening	9	14.5%	8	11.4%	7	7.9%
Recovery	2	3.2%	3	4.3%	2	2.2%
Labeling Controls	0	0%	2	2.9%	1	1.1%
Supplies and Reagents	4	6.5%	1	1.4%	1	1.1%
Storage	0	0%	0	0.0%	1	1.1%
Environmental Control	0	0%	0	0%	0	0.0%
Equipment	1	1.6%	1	1.4%	0	0.0%
Facilities	0	0.0%	0	0.0%	0	0.0%
Total	**62**	100%	**70**	100%	**89**	100%

In FY22, 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.

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 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 | FDA

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 FY22 by each type of blood and Source Plasma establishment compared to reports submitted in FY21. 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 6,131 reports submitted by licensed blood establishments in FY22 (Table 2), 2,328 reports (38.0%) involved quality control and distribution deviations or unexpected events (Table 5). The number of these reports increased 15% compared to FY21, which is an increase of 310 reports. There were 129 more reports submitted in FY22 compared to FY21 involving distributed units collected from a donor who subsequently tested confirmed positive for a relevant transfusion-transmitted infection. There were 240 more reports submitted in FY22 compared to FY21 involving a positive bacterial detection test result. *Cutibacterium acnes* was identified as the organism in 351 (64%) of the 547 reports regarding bacterial testing submitted in FY22.

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

QC & Distribution (QC)	FY21 (#)	FY21 (% of QC)	FY22 (#)	FY22 (% of QC)
Total QC Reports	**2,018**	**-**	**2,328**	**-**
Distribution of a unit collected from a donor who subsequently tested confirmed positive for a relevant transfusion transmitted disease	***841***	***41.7%***	***970***	***41.7%***
Babesia	258	12.8%	379	16.3%
HCV	245	12.1%	218	9.4%
HBV	203	10.1%	212	9.1%
Anti-HBc	115	5.7%	99	4.3%
West Nile Virus	53	2.6%	92	4.0%
HIV	57	2.8%	56	2.4%
Chagas	19	0.9%	8	0.3%
Distribution of product that did not meet specifications	***553***	***27.4%***	***514***	***22.1%***
Product QC unacceptable, not performed, not documented, or incomplete	278	13.8%	276	11.9%
White Blood Cell count	122	6.0%	129	5.5%
RBC recovery	30	1.5%	29	1.2%
Platelet count	46	2.3%	28	1.2%
Product in which specification, other than QC, was not met	68	3.4%	48	2.1%
Outdated product	28	1.4%	43	1.8%
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or documented	35	1.7%	42	1.8%
Product identified as unsuitable due to positive testing; event discovered subsequent to distribution	***311***	***15.4%***	***551***	***23.7%***
Bacterial testing	308	15.3%	547	23.5%
Shipping and storage	***201***	***10.0%***	***198***	***8.5%***

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

Of the 6,131 reports submitted by licensed blood establishments in FY22 (Table 2), 1,785 reports (29.1%) involved blood collection deviations or unexpected events (Table 6)**.** The number of these reports decreased 6% compared to FY21, which is a decrease of 113 reports. The number of reports involving clots or fibrin discovered in a product decreased 5%. There was a 4% decrease in reports of clots or fibrin discovered in frozen products after thawing (FY21-1,412; FY22-1,359).

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

Blood Collection (BC)	FY21 (#)	FY21 (% of BC)	FY22 (#)	FY22 (% of BC)
Total BC Reports	**1,898**	**-**	**1,785**	**-**
Collection process	***1,726***	***90.9%***	***1,618***	***90.6%***
Product contained clots or fibrin, not discovered prior to distribution	1,629	85.8%	1543	86.4%
Product hemolyzed, not discovered prior to distribution	79	4.2%	60	3.4%
Sterility compromised	***64***	***3.4%***	***67***	***3.8%***
Bacterial contamination	49	2.6%	30	1.7%
Collection bag	***104***	***5.5%***	***97***	***5.4%***
Potential collection set defect	101	5.3%	97	5.4%

Of the 6,131 reports submitted by licensed blood establishments in FY22 (Table 2), 1,118 reports (18.2%) involved donor screening deviations or unexpected events (Table 7). The number of these reports decreased 28% compared to FY21, which is a decrease of 431 reports. There were 422 fewer reports submitted in FY22 compared to FY21 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)	FY21 (#)	FY21 (% of DS)	FY22 (#)	FY22 (% of DS)
Total DS Reports	**1,549**	**-**	**1,118**	**-**
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***1,374***	***88.7%***	***942***	***84.3%***
Donor not previously deferred	1,276	82.4%	854	76.4%
Donor previously deferred due to history	48	3.1%	47	4.2%
Donor previously deferred due to testing	50	3.2%	41	3.7%
Donor record incomplete or incorrect	***139***	***9.0%***	***112***	10.0%
Donor history questions	105	6.8%	97	8.7%
Incorrect gender specific question asked, or incorrect answer documented	77	5.0%	81	7.2%
Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked	***28***	***1.8%***	***49***	***4.4%***
Travel to or resided in malaria endemic area/history of malaria	9	0.6%	19	1.7%
Received antibiotics or medication which may adversely affect the product	5	0.3%	19	1.7%
Donor did not meet eligibility criteria	***8***	***0.5%***	***11***	***1.0%***

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

Of the 2,429 reports submitted by unlicensed registered blood establishments in FY22 (Table 2), 1,463 reports (60.2%) involved quality control and distribution deviations or unexpected events (Table 8). The number of these reports decreased 8.4% compared to FY21, which is a decrease of 135 reports.

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

QC & Distribution (QC)	FY21 (#)	FY21 (% of QC)	FY22 (#)	FY22 (% of QC)
Total QC Reports Received	**1,598**	**-**	**1,463**	**-**
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***1,405***	***87.9%***	***1,267***	***86.6%***
Visual inspection not performed, not documented, or inadequate, includes product not documented or incorrectly documented as issued in the computer	619	38.7%	616	42.1%
Product not irradiated as required	157	9.8%	167	11.4%
Improper product selected for patient	185	11.6%	147	10.0%
Improper ABO or Rh type selected for patient	109	6.8%	131	9.0%
Procedure for issuing not performed or documented in accordance with specifications	107	6.7%	63	4.3%
Distribution of product that did not meet specifications	***127***	***7.9%***	***142***	***9.7%***
Product in which specification, other than QC, was not met	27	1.7%	43	2.9%
Product in which instrument QC, calibration, or validation unacceptable, incomplete or not documented	36	2.3%	41	2.8%
Outdated product	26	1.6%	25	1.7%
Shipping and storage	***52***	***3.3%***	***32***	***2.2%***
No documentation that product was stored at appropriate temperature	11	0.7%	11	0.8%
Product was reissued without a record of proper temperature maintenance	26	1.6%	9	0.6%

Of the 2,429 reports submitted by unlicensed registered blood establishments in FY22 (Table 2), 467 reports (19.2%) involved labeling deviations or unexpected events (Table 9). The number of these reports decreased 4.5% compared to FY21, which is a decrease of 22 reports.

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

Labeling (LA)	FY21 (#)	FY21 (% of LA)	FY22 (#)	FY22 (% of LA)
Total LA Reports Received	**489**	**-**	**467**	**-**
Crossmatch tag, tie tag, to transfusion record incorrect or missing information	***307***	***62.8%***	***296***	***63.4%***
Recipient identification incorrect or missing	107	21.9%	123	26.3%
Crossmatch tag, tie tag, or transfusion record incorrect or missing or attached to incorrect unit	47	9.6%	56	12.0%
Expiration date or time extended or missing	34	7.0%	21	4.5%
Compatibility information incorrect or missing	32	6.5%	20	4.3%
Unit or pool number incorrect or missing	24	4.9%	15	3.2%
Product type or code incorrect or missing	19	3.9%	12	2.6%
Product volume incorrect or missing	23	4.7%	6	1.3%
Labels applied to blood unit incorrect or missing information	***182***	***37.2%***	***171***	***36.6%***
Expiration date or time extended or missing	79	16.2%	89	19.1%
Irradiation status incorrect or missing	20	4.1%	22	4.7%
Product type or code incorrect or missing	36	7.4%	14	3.0%
Combination of incorrect or missing information	15	3.1%	11	2.4%

Of the 2,429 reports submitted by unlicensed registered blood establishments in FY22 (Table 2), 426 reports (17.5%) involved routine testing deviations or unexpected events (Table 10). The number of these reports increased 9% compared to FY21, which was an increase of 34 reports.

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

Routine Testing (RT)	FY21 (#)	FY21 (% of RT)	FY22 (#)	FY22 (% of RT)
Total RT Reports	**392**	**-**	**426**	**-**
Testing performed, interpreted, or documented incorrectly; not performed; incompletely performed; or not documented	***348***	***88.8%***	***380***	***89.2%***
Compatibility	94	24.0%	106	24.9%
Antigen typing	88	22.4%	91	21.4%
Antibody screening or identification	79	20.2%	79	18.5%
ABO and/or Rh	58	14.8%	70	16.4%
Sample (used for testing) identification	***44***	***11.2%***	***46***	***10.8%***
Sample used for testing was incorrectly or incompletely labeled	25	6.4%	27	6.3%
Unsuitable sample used for testing (e.g., too old)	12	3.1%	12	2.8%
Incorrect sample tested	6	1.5%	7	1.6%

3. Most Frequent BPD Reports Submitted by Transfusion Services

Of the 1,875 reports submitted by transfusion services in FY22 (Table 2), 1,018 reports (54.3%) involved quality control and distribution deviations or unexpected events (Table 11). The number of these reports increased 2% compared to FY21, which was an increase of 23 reports.

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

QC & Distribution (QC)	FY21 (#)	FY21 (% of QC)	FY22 (#)	FY22 (% of QC)
Total QC Reports Received	**995**	**-**	**1,018**	**-**
Distribution procedures not performed in accordance with blood bank transfusion service's specifications	***868***	***87.2%***	***913***	***89.8%***
Visual inspection not performed, not documented, or inadequate, includes product not documented or incorrectly documented as issued in the computer	408	41.0%	442	43.5%
Product not irradiated as required	111	11.2%	105	10.3%
Improper product selected for patient	116	11.7%	92	9.0%
Improper ABO or Rh type selected for patient	82	8.2%	87	8.6%
Procedure for issuing not performed or documented in accordance with specifications	55	5.5%	72	7.1%
Distribution of product that did not meet specifications	***91***	***9.1%***	***71***	***7.0%***
Outdated product	51	5.1%	29	2.9%
Product in which instrument QC, calibration, or validation was unacceptable, incomplete, not performed or not documented	26	2.6%	29	2.9%
Shipping and storage	***32***	***3.2%***	***27***	***2.7%***
No documentation that product was stored at appropriate temperature	10	1.0%	14	1.4%
Product was reissued without a record of proper temperature maintenance	7	0.7%	6	0.6%
Product stored at incorrect temperature	12	1.2%	5	0.5%

Of the 1,875 reports submitted by transfusion services in FY22 (Table 2), 535 reports (28.5%) involved routine testing deviations or unexpected events (Table 12). Compared to FY21, there were seven more reports submitted in FY22 involving routine testing.

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

Routine Testing (RT)	FY21 (#)	FY21 (% of RT)	FY22 (#)	FY22 (% of RT)
Total RT Reports Received	**528**	**-**	**535**	**-**
Testing performed, interpreted, or documented incorrectly; not performed; incompletely performed; or not documented	***480***	***90.9%***	***479***	***89.5%***
Compatibility	124	23.5%	135	25.2%
Antigen typing	114	21.6%	121	22.6%
Antibody screening or identification	97	18.4%	103	19.3%
ABO and/or Rh typing	104	19.7%	83	15.5%
Sample (used for testing) identification	***48***	***9.1%***	***56***	***10.5%***
Sample used for testing was incorrectly or incompletely labeled	32	6.1%	45	8.4%
Unsuitable sample used for testing	10	1.9%	6	1.1%
Incorrect sample tested	6	1.1%	5	0.9%

Of the 1,875 reports submitted by transfusion services in FY22 (Table 2), 313 reports (16.7%) involved labeling deviations or unexpected events (Table 13). Compared to FY21, there were 10 more reports submitted in FY22 involving labeling.

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

Labeling (LA)	FY21 (#)	FY21 (% of LA)	FY22 (#)	FY22 (% of LA)
Total LA Reports Received	**303**	**-**	**313**	**-**
Crossmatch tag, tie tag or transfusion record incorrect or missing information	***225***	***74.3%***	***236***	***75.4%***
Recipient identification incorrect or missing	93	30.7%	117	37.4%
Crossmatch tag, tie tag, or transfusion record missing or attached to incorrect unit	29	9.6%	35	11.2%
Combination of incorrect or missing information	11	3.6%	16	5.1%
Product type or code incorrect or missing	15	5.0%	12	3.8%
Expiration date or time extended or missing	12	4.0%	12	3.8%
Antigen incorrect or missing	11	3.6%	11	3.5%
Unit or pool number incorrect or missing	12	4.0%	9	2.9%
Labels applied to blood unit incorrect or missing information	***78***	***25.7%***	***77***	***24.6%***
Expiration date or time extended or missing	36	11.9%	41	13.1%
Combination of incorrect or missing information	12	4.0%	10	3.2%
Product type or code incorrect or missing	15	5.0%	9	2.9%

4. Most Frequent BPD Reports Submitted by Source Plasma Establishments

Of the 3,848 reports submitted by Source Plasma establishments in FY22 (Table 2), 3,433 reports (89.2%) involved quality control and distribution deviations or unexpected events (Table 14). The number of these reports increased 23% compared to FY21, which was an increase of 648 reports. The number of reports related to a donor subsequently testing positive for HCV or HBV increased from 1,377 and 672 in FY21 to 1,540 and 1,089 in FY22 respectively.

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

QC & Distribution (QC)	FY21 (#)	FY21 (% of QC)	FY22 (#)	FY22 (% of QC)
Total QC Reports Received	**2,785**	**-**	**3,433**	**-**
Distribution of a unit collected from a donor who subsequently tested confirmed positive for a relevant transfusion transmitted disease	***2,587***	***92.9%***	***3,259***	***94.9%***
HCV	1,377	49.4%	1,540	44.9%
HBV	672	24.1%	1,089	31.7%
HIV	534	19.2%	620	18.1%
Distribution of product that did not meet specifications	***234***	***8.4%***	***153***	***4.5%***
Product identified as unsuitable due to a collection deviation or unexpected event	76	2.7%	59	1.7%
Product identified as unsuitable due to a donor screening deviation or unexpected event	23	0.8%	33	1.0%
Product identified as unsuitable due to a transfusion-transmitted infection testing deviation or unexpected event	25	0.9%	31	0.9%
Unit tested positive for Syphilis	2	0.1%	15	0.4%
Donor subsequently tested positive for Syphilis	0	0.0%	9	0.3%
Donor subsequently tested positive for HIV/HBV or HCV	23	0.8%	3	0.1%
Failure to quarantine unit due to medical history	***57***	***2.0%***	***20***	***0.6%***

Of the 3,848 reports submitted by Source Plasma establishments in FY22 (Table 2), 395 reports (10.3%) involved donor screening deviations or unexpected events (Table 15). The number of these reports increased 12% compared to FY21, which was an increase of 43 reports. There were 48 more reports submitted in FY22 compared to FY21 involving a donor providing history which warranted deferral or follow up and was not deferred. The same number of reports were submitted in FY22 compared to FY21 involving donor history questions incorrect or incomplete (124). However, there were 16 more reports related to donor comprehension and 17 fewer reports involving the incorrect gender specific questions asked.

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

Donor Screening (DS)	FY21 (#)	FY21 (% of DS)	FY22 (#)	FY22 (% of DS)
Total DS Reports Received	**352**	**-**	**395**	**-**
Donor gave history which warranted deferral or follow up and was not deferred or follow up questions were not asked	***140***	***39.8%***	***188***	***47.6%***
Unacceptable address	87	24.7%	115	29.1%
Unreliable donor	2	0.6%	17	4.3%
Donor received tattoo and/or piercing	17	4.8%	9	2.3%
Donor record incomplete or incorrect	***146***	***41.5%***	***163***	***41.3%***
Donor history questions	124	35.2%	124	31.4%
Donor comprehension	68	19.3%	84	21.3%
Incorrect gender specific question asked or incorrect answer	54	15.3%	37	9.4%
Donor identification	17	4.8%	39	9.9%
Deferral screening not done or incorrectly performed, including incorrect ID used during search	***27***	***7.7%***	***36***	***9.1%***
Donor not previously deferred	18	5.1%	22	5.6%
Donor previously deferred due to history	9	2.6%	14	3.5%
Donor did not meet eligibility criteria	***39***	***11.1%***	***8***	***2.0%***
Medical history interview or physical assessment not performed or inadequate	20	5.7%	7	1.8%

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 FY22 by each type of licensed non-blood manufacturer compared to reports submitted in FY21. 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 81 reports submitted by allergenic manufacturers in FY22 (Table 3), 96% of the reports were related to product specifications (Table 16).

Table 16 - Most Frequent BPD Reports Submitted by Allergenic Manufacturers

Allergenic Manufacturers	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
Total Reports	**85**	-	**81**	-
Product Specifications	***78***	***91.8%***	***78***	***96.3%***
Product specification not met; contains precipitate	77	***90.6%***	74	***91.4%***

Of the 92 reports submitted by plasma derivative manufacturers in FY22 (Table 3), 35% of the reports were related to product specifications and 21% 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	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
Total Reports	**91**	-	**92**	-
Product Specifications	***33***	***36.2%***	***32***	***34.8%***
Stability testing failed	15	16.5%	11	12.0%
Potency	3	3.3%	5	5.4%
Appearance	3	3.3%	3	3.3%
Product specification not met	10	11.0%	7	7.6%
Appearance	7	7.7%	4	4.3%
Component packaged with final product did not meet specifications	8	8.8%	14	15.2%
Broken/cracked vial	4	4.4%	11	12.0%
Contains precipitate/particle	4	4.4%	2	2.2%
Quality Control and Distribution	***23***	***25.3%***	***19***	***20.7%***
Packing; Broken or cracked vial/syringe	15	16.5%	11	12.0%

Of the 87 reports submitted by in-vitro diagnostic manufacturers in FY22 (Table 3), 31% of the reports were related to quality control and distribution and 25% of the reports were related to product specification. The number of reports involving unexpected reactions in testing decreased from 27 in FY21 to six in FY22 (Table 18).

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

In-Vitro Diagnostic Manufacturers	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
Total Reports	**91**	-	**87**	-
Quality Control and Distribution	***26***	***28.6%***	***30***	***30.9%***
Packing	21	23.1%	22	22.7%
Product Specifications	***46***	***50.5%***	***24***	***24.7%***
Product specification not met; Container closure not secure or damaged	12	13.2%	11	11.3%
Product specification not met; Unexpected positive, negative, or weak reactions in testing	27	29.7%	6	6.2%
Labeling	***11***	***12.1%***	***17***	***17.5%***
Package insert	2	2.2%	6	6.2%
Multiple information	2	2.2%	6	6.2%
Product label	4	4.4%	3	3.1%

Of the 201 reports submitted by vaccine manufacturers in FY22 (Table 3), 43% of the reports were related to product specifications and 21% of the reports were related to quality control and distribution (Table 19). There were 41 fewer reports submitted in FY22 compared to FY21 involving product specification not met.

Table 19 - Most Frequent BPD Reports Submitted by Vaccine Manufacturers

Vaccine Manufacturers	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
Total Reports	**233**	-	**201**	-
Product Specifications	***125***	***53.6%***	***86***	***42.8%***
Product specification not met	116	49.8%	75	37.3%
Container closure not secure or damaged	60	25.8%	37	18.4%
Appearance	51	21.9%	36	17.9%
Quality Control and Distribution	***61***	***26.2%***	***43***	***21.4%***
Packing; Broken or cracked vial/syringe	55	23.6%	41	20.4%
Process Controls	15	***6.4%***	27	13.4%
Process/Procedure	9	3.9%	19	9.5%

In FY21, some of the gene therapy products and 351 HCT/Ps were incorrectly characterized. The information provided in the charts below for FY21 has been updated with the correct characterizations.

Of the 18 reports submitted by gene therapy manufacturers in FY22 (Table 3), 33% of the reports were related to product specification (Table 20).

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

Licensed Gene Therapy Manufacturers	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
Total Reports	**8**	-	**18**	-
Product Specifications	**1**	**12.5%**	**6**	**33.3%**
Product specification not met; Container closure not secure or damaged	0	0.0%	3	16.7%
Testing	***0***	***0.0%***	***5***	***27.8%***
Stability; Not performed or not documented	0	0.0%	3	16.7%
Incoming Material	**2**	**25.0%**	**3**	**16.7%**
Quality Control & Distribution	**0**	**0.0%**	**2**	**11.1%**
Labeling	**2**	**25.0%**	**1**	**5.6%**
Process Controls	**3**	**37.5%**	**1**	**5.6%**

Of the 25 reports submitted by licensed HCT/P manufacturers (351 HCT/Ps) in FY22 (Table 3), 80% 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)	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
Total Reports	**21**	-	**25**	-
Labeling	***9***	***42.9%***	***20***	***80.0%***
Product label; incorrect/illegible; recipient identification	9	42.9%	18	72.0%
Product Specifications	***6***	***28.9%***	***2***	***8.0%***
Product specification not met; contaminated with microorganism	3	1.5%	1	4.0%
Product specification not met; Container closure not secure or damaged	3	1.5%	1	4.0%
Incoming Material	***2***	***0.1%***	***1***	***4.0%***

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

Tables 22 and 23 highlight the most frequent reports submitted in FY22 by each type of 361 HCT/P manufacturer compared to reports submitted in FY21. 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 134 reports submitted by cellular 361 HCT/P manufacturers in FY22 (Table 4), 68% of the reports involved receipt, pre-distribution, shipment and distribution and 18% 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	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
Total Reports	**136**	-	**134**	-
Receipt, Pre-Distribution, Shipment & Distribution	***102***	***75.0%***	***91***	***67.9%***
Inappropriate distribution; Contaminated or potentially contaminated HCT/P	100	73.5%	89	66.4%
Processing & Processing Controls	***16***	***11.8%***	***24***	***17.9%***
Processing; HCT/P contaminated, potentially contaminated, or cross-contaminated during processing	11	8.1%	17	12.7%
In-process controls; Not followed	5	3.7%	7	5.2%

Of the 89 reports submitted by tissue 361 HCT/P manufacturers in FY22 (Table 4), 20% of the reports involved receipt, pre-distribution, shipment and distribution and 42% 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	FY21 (#)	FY21 (%)	FY22 (#)	FY22 (%)
Total Reports	**70**	-	**89**	-
Receipt, Pre-Distribution, Shipment & Distribution	***22***	***31.4%***	***18***	***20.2%***
Distributed without review of required records	4	5.7%	6	6.7%
Inappropriate distribution; Contaminated or potentially contaminated HCT/P	16	22.9%	4	4.5%
Donor Eligibility	***20***	***28.6%***	***37***	***41.6%***
Ineligible donor accepted; Risk factors for, or clinical evidence of infection due to RCDAD	18	25.7%	12	13.5%
Final autopsy results received post distribution	11	15.7%	4	4.5%
Donor Testing	***8***	11.4%	***11***	***12.4%***
Unacceptable specimen tested; Donor incorrectly or not evaluated for plasma dilution	5	7.1%	8	9.0%
Inappropriate test or test laboratory used; Laboratory performing tests not CLIA certified	0	0.0%	1	1.1%
Donor Screening	***8***	***11.4%***	***7***	***7.9%***
Donor screening not performed or performed incorrectly	8	11.4%	7	7.9%
Donor medical history interview	5	7.1%	6	6.7%
Medical record review	3	4.3%	1	1.1%