

Attachment 5 – FY16 Number of HCT/P Deviation Reports by Type of 361 HCT/P Establishment

Deviation Code	Cellular HCT/P	Tissue HCT/P	TOTAL	
Donor Eligibility			53	20.5%
DE0201	0	17	17	6.6%
DE0201A	0	15	15	5.8%
DE0201B	0	15	15	5.8%
DE0204	0	5	5	1.9%
DE0301	0	1	1	0.4%
Donor Screening			20	7.7%
DS0201	6	7	13	5.0%
DS0202	0	1	1	0.4%
DS0203	1	5	6	2.3%
Donor Testing			17	6.6%
DT0105	0	1	1	0.4%
DT0203	0	1	1	0.4%
DT0205	0	1	1	0.4%
DT0305B	0	4	4	1.5%
DT0306	0	7	7	2.7%
DT0307	0	2	2	0.8%
DT0401	1	0	1	0.4%
Environmental Control			0	0.0%
Equipment			1	0.4%
EQ0201	0	1	1	0.4%
Supplies and Reagents			8	3.1%
SR9901	4	0	4	1.5%
SR0101	1	3	4	1.5%
Recovery			10	3.9%
RE0101	7	3	10	3.9%
Processing and Processing Controls			88	34.0%
PC0101	55	6	61	23.6%
PC0101D	10	0	10	3.9%
PC0101E	5	0	5	1.9%
PC0101F	1	2	3	1.2%
PC0101G	1	0	1	0.4%
PC0101I	1	0	1	0.4%
PC0102	0	1	1	0.4%
PC0201	1	3	4	1.5%
PC0202	1	0	1	0.4%
PC0301	0	1	1	0.4%
Labeling Controls			0	0.0%
Storage			3	1.2%

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ST0201	2	0	2	0.8%
ST0401	0	1	1	0.4%
Receipt, Pre-Distribution, Shipment & Distribution			59	22.8%
SD0201	1	0	1	0.4%
SD0202	0	2	2	0.8%
SD0203	0	2	2	0.8%
SD0204	12	2	14	5.4%
SD0204A	2	0	2	0.8%
SD0204B	7	0	7	2.7%
SD0204C	3	0	3	1.2%
SD0204D	5	0	5	1.9%
SD0204E	1	0	1	0.4%
SD0204F	1	0	1	0.4%
SD0205	5	4	9	3.5%
SD0302	0	10	10	3.9%
SD0303	0	1	1	0.4%
SD0401	0	1	1	0.4%
Total	134	125	259	100%