

**Centers for Disease Control and Prevention
Model Performance Evaluation Program
T-Lymphocyte Immunophenotyping
(TLI)**

**Figures and Table Used for the Analysis
of Participant Laboratory Results
for the April 2000 Shipment**

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Report of the April 2000 T-Lymphocyte Immunophenotyping (TLI) Results Provided by Participant Laboratories in the Model Performance Evaluation Program, Centers for Disease Control and Prevention (CDC)

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**Centers for Disease Control and Prevention (CDC) - Model Performance Evaluation
Program
for T-Lymphocyte Immunophenotyping (TLI)**

Donor Identification for April 11 and April 18, 2000 TLI Shipment Specimens

Panel Letter	Participant Laboratory Vial Label	CDC Donor Number	Donor Information (HIV-1^a status)
A	A1, A4	02	HIV-1 Antibody-Positive
	A2	03	HIV-1 Antibody-Negative
	A3	01	HIV-1 Antibody-Negative
	A5	05	HIV-1 Antibody-Positive
B	B1	01	HIV-1 Antibody-Negative
	B2	03	HIV-1 Antibody-Negative
	B3	05	HIV-1 Antibody-Positive
	B4, B5	04	HIV-1 Antibody-Positive
C	C1, C5	07	HIV-1 Antibody-Positive
	C2	08	HIV-1 Antibody-Negative
	C3	10	HIV-1 Antibody-Positive
	C4	09	HIV-1 Antibody-Negative
D	D1	08	HIV-1 Antibody-Negative
	D2, D4	06	HIV-1 Antibody-Positive
	D3	09	HIV-1 Antibody-Negative
	D5	10	HIV-1 Antibody-Positive

^a Human immunodeficiency virus type 1

Figure 1. Primary classification of laboratories participating in the April 2000 shipment.

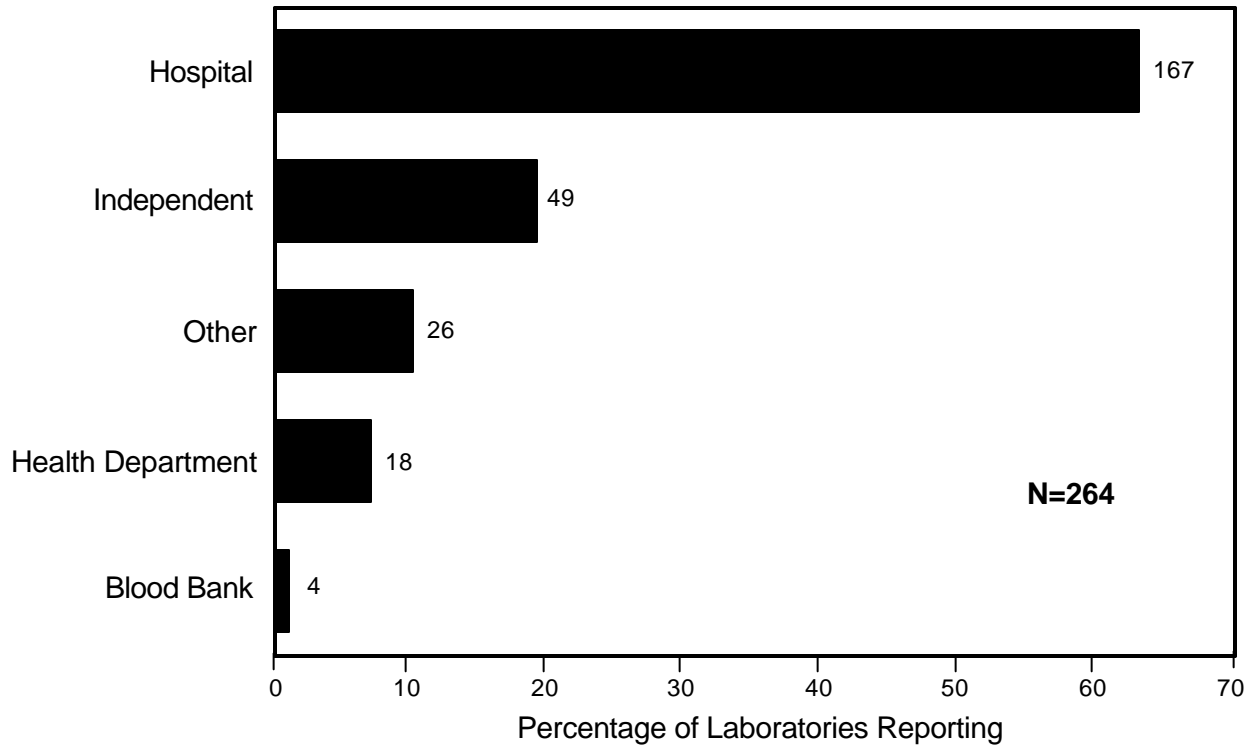


Figure 2. Methods used to prepare specimens for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the April 2000 shipment.

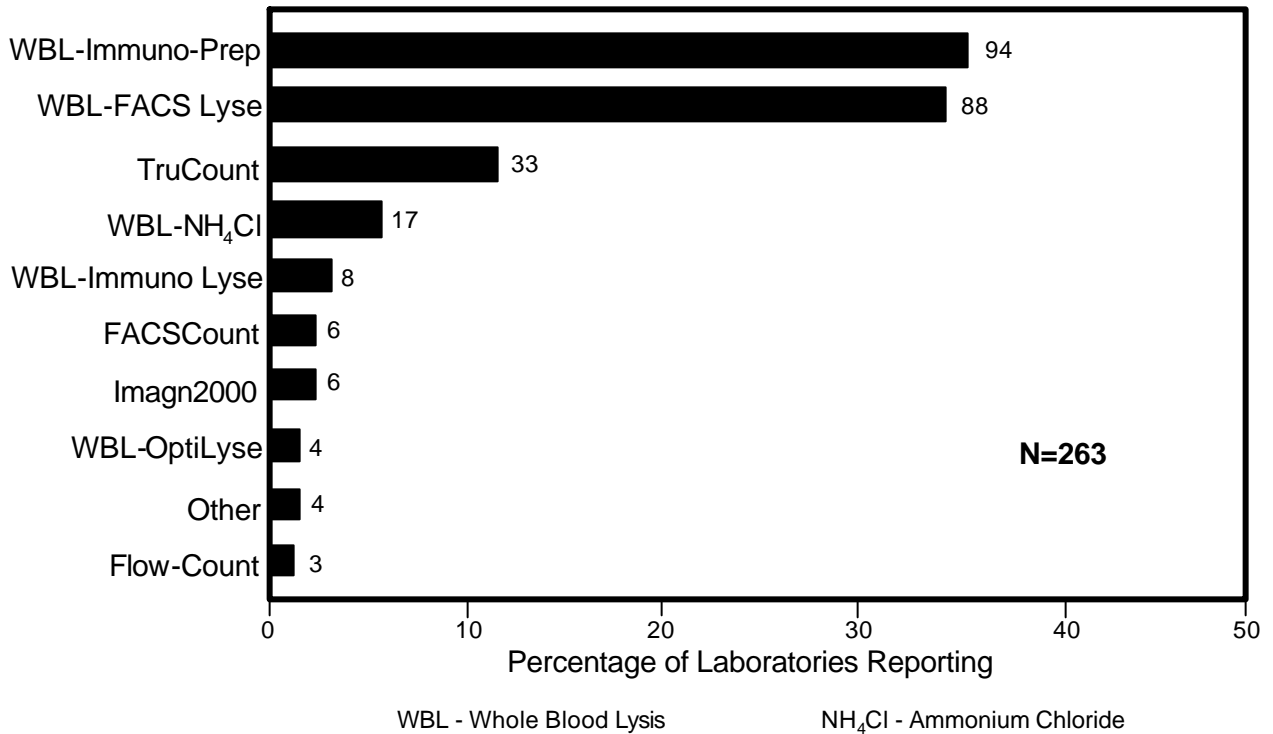


Figure 3. Methods used to fix specimens for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the April 2000 shipment.

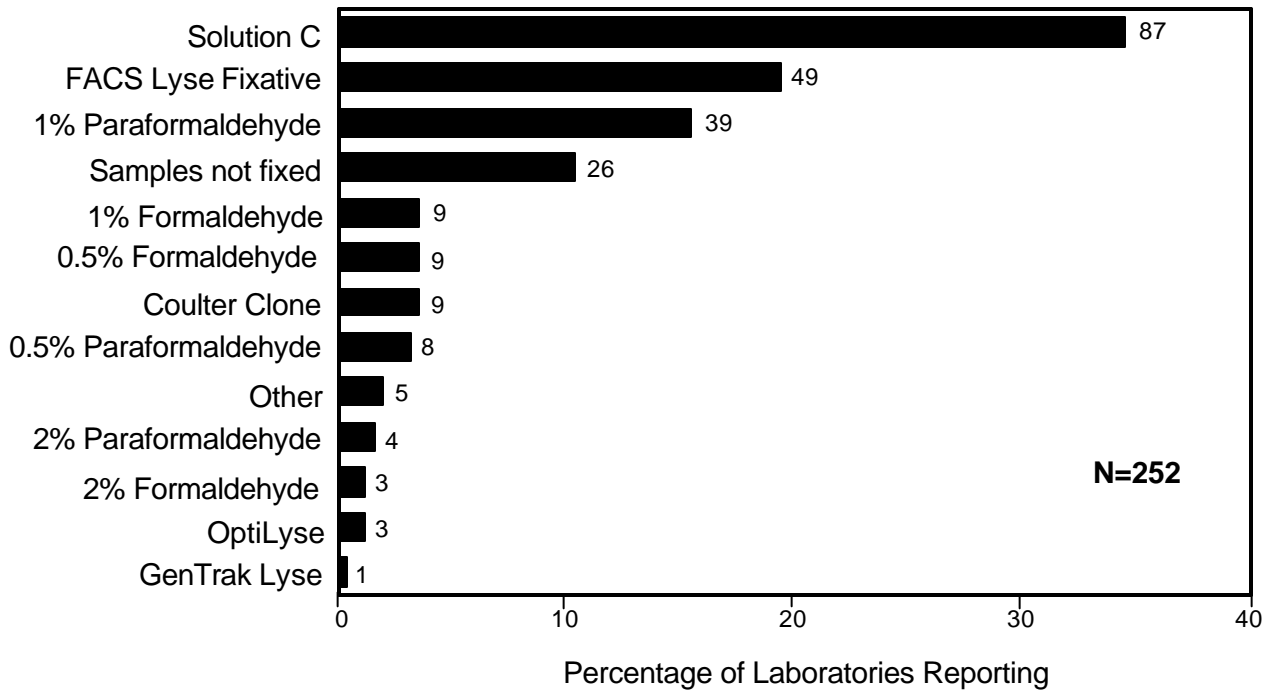


Figure 4. Types of flow cytometers used for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the April 2000 shipment.

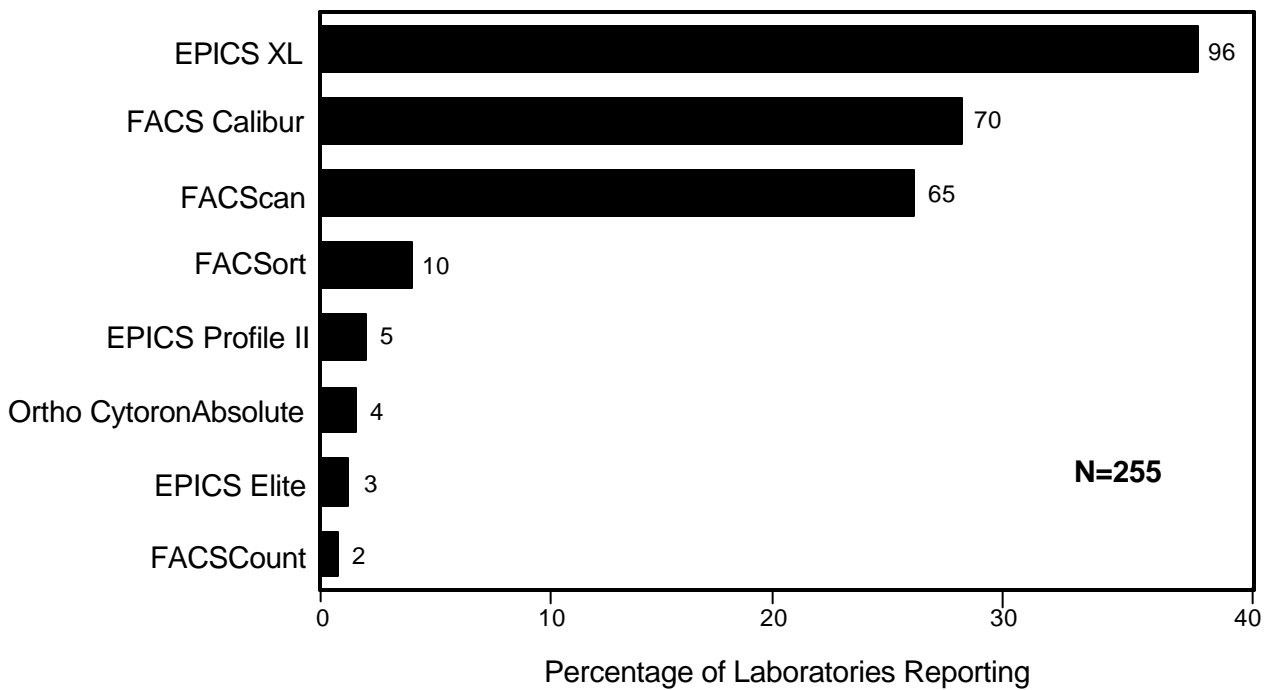
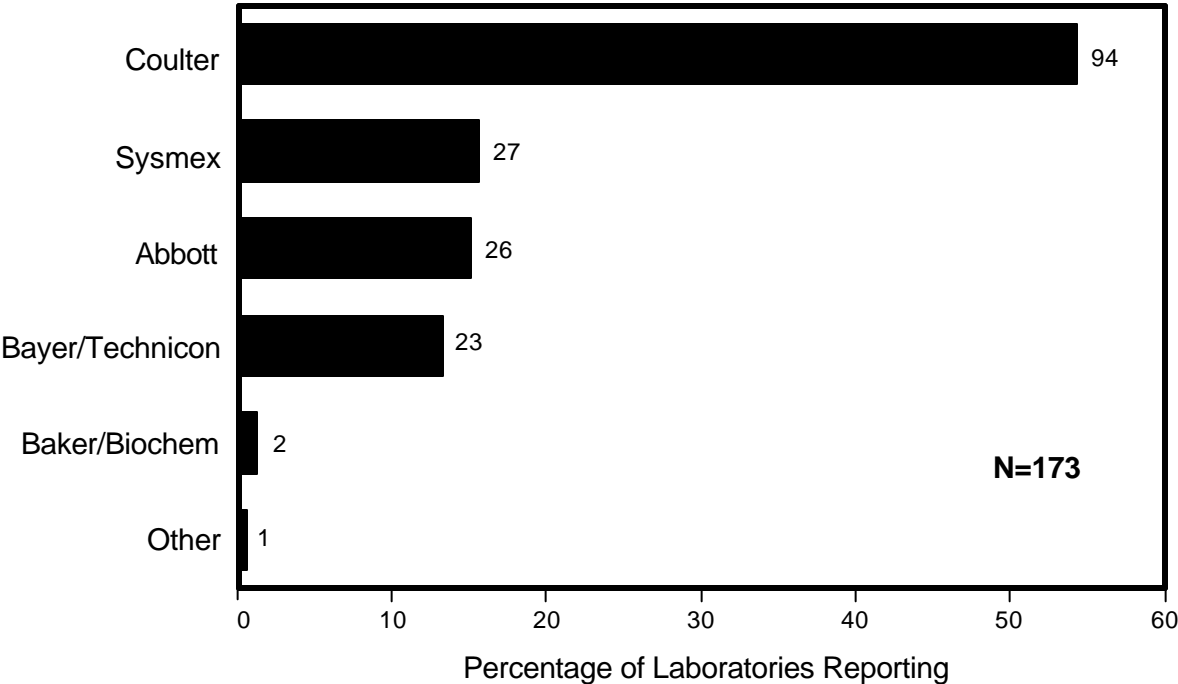


Figure 5. Types of hematology instruments used for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the April 2000 shipment.



Explanation of Results Table

In the following results table, please note the following terms:

Cell Marker	The cell surface marker of interest. All results for this surface marker are shown regardless of the monoclonal antibody combination used for their determination:
CD45 -	results from 2-color CD45/CD14
CD14 -	results from 2-color CD45/CD14
CD4 -	combined results from 2-color CD3/CD4; 3-color CD45/CD3/CD4, CD3/CD4/CD8; and 4-color CD45/CD3/CD4/CD8
CD8 -	combined results from 2-color CD3/CD8; 3-color CD45/CD3/CD8, CD3/CD4/CD8; and 4-color CD45/CD3/CD4/CD8
CD19 -	combined results from 2-color CD3/CD19; 3-color CD45/CD3/CD19, CD3/CD19/CD56, CD3/CD19/CD16, CD3/CD19/CD56+16; and 4-color CD45/CD3/CD19/CD56, CD45/CD3/CD19/CD56+16
CD56+16 -	combined results from 2-color CD3/CD56+16; 3-color CD45/CD3/CD56+16, CD3/CD19/CD56+16; and 4-color CD45/CD3/CD19/CD56+16
CD3 average	combined results from 2-color CD3 average; 3-color CD3 average; and 4-color CD3 average
CD56 -	results from 2-color CD3/CD56; 3-color CD45/CD14/CD56, CD3/CD19/CD56; and 4-color CD45/CD3/CD19/CD56
CD16 -	results from 2-color CD3/CD16 and 3-color CD3/CD19/CD16

Percentage Results

The 95% confidence ranges are shown along with the number of reported results within, above, and below the established confidence range (see accompanying written analysis for the method of establishing the confidence range). **Note:** Due to a limited number of reported results for CD56 and CD16, no 95% confidence range was established for these markers. The ranges shown are the maximum and minimum values reported for these cell markers.

Absolute Counts

The results within, above, and below the 95% confidence ranges for the specified cell-marker specific absolute count derived either by multi-platform (flow cytometer/hematology analyzer) or single-platform (single instrument or alternate technique) methods.

Hematology Results

The 95% confidence ranges, the number of results within, above, and below the confidence ranges are listed for the following hematology parameters: white blood cell count (WBC), percent lymphocytes, absolute lymphocyte count.

Participant Laboratory Results for the April 2000 Shipment

Donor Number 1 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	1		
	95 - 100	46		
	< 95	2		
CD14	> 1	2		
	0 - 1	45		
	< 0	0		
CD4	> 51	4	> 1,111	3
	45 - 51	114	791 - 1,111	94
	< 45	3	< 791	3
CD8	> 30	4	> 643	4
	24 - 30	116	417 - 643	94
	< 24	1	< 417	1
CD19	> 19	2		
	13 - 19	100		
	< 13	2		
CD56+16	> 7	4		
	3 - 7	71		
	< 3	1		
CD3 Average	> 81	4		
	75 - 81	101		
	< 75	1		
CD56	2 - 6	25		
CD16	3 - 5	10		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 6,082	3
	5,025 - 6,082	73
	< 5,025	4
% Lymphs	> 40	6
	31 - 40	73
	< 31	1
Absolute Lymphs	> 2,310	4
	1,666 - 2,310	72
	< 1,666	2

Donor Number 2 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	93 - 100	40		
	< 93	2		
CD14	> 2	2		
	0 - 2	38		
	< 0	0		
CD4	> 32	4	> 586	6
	26 - 32	117	274 - 586	100
	< 26	1	< 274	2
CD8	> 60	3	> 1,063	6
	51 - 60	115	555 - 1,063	97
	< 51	4	< 555	3
CD19	> 5	0		
	2 - 5	96		
	< 2	0		
CD56+16	> 12	1		
	5 - 12	85		
	< 5	0		
CD3 Average	> 91	3		
	83 - 91	102		
	< 83	3		
CD56	2 - 9	18		
CD16	6 - 8	4		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 8,204	3
	6,794 - 8,204	83
	< 6,794	0
% Lymphs	> 26	7
	14 - 26	78
	< 14	1
Absolute Lymphs	> 1,990	7
	1,020 - 1,990	72
	< 1,020	3

Participant Laboratory Results for the April 2000 Shipment

Donor Number 3 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	92 - 100	48		
	< 92	1		
CD14	> 2	2		
	0 - 2	45		
	< 0	0		
CD4	> 52	4	> 1,310	10
	43 - 52	111	647 - 1,310	89
	< 43	6	< 647	1
CD8	> 21	2	> 541	9
	17 - 21	116	245 - 541	89
	< 17	3	< 245	1
CD19	> 21	1		
	14 - 21	100		
	< 14	3		
CD56+16	> 16	4		
	8 - 16	70		
	< 8	2		
CD3 Average	> 74	3		
	63 - 74	100		
	< 63	3		
CD56	4 - 14	25		
CD16	9 - 15	10		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 9,800	2
	8,083 - 9,800	74
	< 8,083	3
% Lymphs	> 34	8
	14 - 34	71
	< 14	0
Absolute Lymphs	> 3,085	7
	1,226 - 3,085	68
	< 1,226	2

Donor Number 4 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	95 - 100	53		
	< 95	3		
CD14	> 3	0		
	0 - 3	54		
	< 0	0		
CD4	> 30	10	> 664	7
	23 - 30	107	394 - 664	85
	< 23	3	< 394	0
CD8	> 66	2	> 1,549	6
	57 - 66	115	931 - 1,549	86
	< 57	3	< 931	0
CD19	> 10	1		
	6 - 10	107		
	< 6	4		
CD56+16	> 5	2		
	1 - 5	64		
	< 1	0		
CD3 Average	> 92	2		
	83 - 92	98		
	< 83	4		
CD56	1 - 4	32		
CD16	2 - 4	16		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 6,177	2
	5,087 - 6,177	70
	< 5,087	2
% Lymphs	> 45	7
	29 - 45	67
	< 29	0
Absolute Lymphs	> 2,709	6
	1,498 - 2,709	68
	< 1,498	0

Participant Laboratory Results for the April 2000 Shipment

Donor Number 5 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	93 - 100	46		
	< 93	1		
CD14	> 3	2		
	0 - 3	43		
	< 0	0		
CD4	> 7	1	> 117	3
	4 - 7	118	38 - 117	96
	< 4	1	< 38	1
CD8	> 86	2	> 1,518	4
	76 - 86	117	933 - 1,518	91
	< 76	1	< 933	4
CD19	> 8	1		
	3 - 8	102		
	< 3	0		
CD56+16	> 8	3		
	1 - 8	72		
	< 1	0		
CD3 Average	> 95	1		
	85 - 95	101		
	< 85	3		
CD56	0 - 3	25		
CD16	2 - 5	10		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 5,094	2
	3,973 - 5,094	74
	< 3,973	4
% Lymphs	> 41	4
	27 - 41	72
	< 27	4
Absolute Lymphs	> 1,914	2
	1,140 - 1,914	72
	< 1,140	4

Donor Number 6 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	96 - 100	53		
	< 96	1		
CD14	> 2	3		
	0 - 2	51		
	< 0	0		
CD4	> 40	8	> 1,349	9
	34 - 40	133	858 - 1,349	98
	< 34	1	< 858	1
CD8	> 52	6	> 1,752	12
	44 - 52	133	1,091 - 1,752	92
	< 44	3	< 1,091	4
CD19	> 12	0		
	6 - 12	108		
	< 6	4		
CD56+16	> 7	4		
	3 - 7	78		
	< 3	0		
CD3 Average	> 88	0		
	81 - 88	110		
	< 81	0		
CD56	1 - 6	28		
CD16	2 - 6	8		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 10,387	3
	8,436 - 10,387	83
	< 8,436	4
% Lymphs	> 39	6
	25 - 39	82
	< 25	0
Absolute Lymphs	> 3,581	10
	2,356 - 3,581	76
	< 2,356	0

Participant Laboratory Results for the April 2000 Shipment

Donor Number 7 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	94 - 100	45		
	< 94	3		
CD14	> 4	5		
	0 - 4	43		
	< 0	0		
CD4	> 31	4	> 877	4
	20 - 31	124	467 - 877	82
	< 20	0	< 467	5
CD8	> 65	0	> 2,046	4
	53 - 65	123	1,068 - 2,046	79
	< 53	3	< 1,068	6
CD19	> 10	2		
	4 - 10	98		
	< 4	2		
CD56+16	> 6	2		
	2 - 6	72		
	< 2	4		
CD3 Average	> 92	0		
	83 - 92	102		
	< 83	6		
CD56	0 - 6	22		
CD16	4 - 12	6		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 9,290	0
	7,341 - 9,290	68
	< 7,341	5
% Lymphs	> 41	4
	24 - 41	69
	< 24	2
Absolute Lymphs	> 3,238	3
	2,038 - 3,238	67
	< 2,038	3

Donor Number 8 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	96 - 100	48		
	< 96	3		
CD14	> 9	2		
	0 - 9	49		
	< 0	0		
CD4	> 50	3	> 1,386	6
	41 - 50	130	847 - 1,386	90
	< 41	1	< 847	2
CD8	> 37	4	> 1,044	8
	31 - 37	125	614 - 1,044	86
	< 31	4	< 614	3
CD19	> 14	1		
	9 - 14	104		
	< 9	1		
CD56+16	> 5	2		
	2 - 5	75		
	< 2	2		
CD3 Average	> 87	3		
	81 - 87	103		
	< 81	2		
CD56	1 - 4	25		
CD16	1 - 14	7		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 8,775	4
	7,492 - 8,775	71
	< 7,492	5
% Lymphs	> 35	6
	25 - 35	73
	< 25	1
Absolute Lymphs	> 2,958	5
	1,902 - 2,958	72
	< 1,902	1

Participant Laboratory Results for the April 2000 Shipment

Donor Number 9 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	94 - 100	48		
	< 94	3		
CD14	> 9	2		
	0 - 9	49		
	< 0	0		
CD4	> 54	7	> 1,548	7
	46 - 54	124	959 - 1,548	88
	< 46	3	< 959	3
CD8	> 28	3	> 797	8
	23 - 28	125	476 - 797	88
	< 23	5	< 476	1
CD19	> 16	1		
	10 - 16	103		
	< 10	2		
CD56+16	> 12	0		
	6 - 12	78		
	< 6	1		
CD3 Average	> 82	4		
	73 - 82	103		
	< 73	1		
CD56	0 - 12	25		
CD16	5 - 21	7		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 8,743	1
	7,328 - 8,743	74
	< 7,328	5
% Lymphs	> 38	5
	24 - 38	75
	< 24	0
Absolute Lymphs	> 3,112	6
	1,880 - 3,112	72
	< 1,880	0

Donor Number 10 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	94 - 100	47		
	< 94	4		
CD14	> 12	2		
	0 - 12	49		
	< 0	0		
CD4	> 5	1	> 51	3
	2 - 5	133	19 - 51	91
	< 2	0	< 19	4
CD8	> 87	0	> 1,072	3
	73 - 87	128	620 - 1,072	88
	< 73	5	< 620	6
CD19	> 7	2		
	1 - 7	104		
	< 1	0		
CD56+16	> 12	1		
	6 - 12	75		
	< 6	3		
CD3 Average	> 91	2		
	83 - 91	102		
	< 83	4		
CD56	2 - 12	25		
CD16	4 - 12	7		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 2,331	0
	1,743 - 2,331	74
	< 1,743	6
% Lymphs	> 62	3
	43 - 62	72
	< 43	4
Absolute Lymphs	> 1,326	3
	831 - 1,326	71
	< 831	2