

**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 2001 Shipment**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Report of the April 2001 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 2001 TLI Shipment Specimens

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

^a Human immunodeficiency virus type 1

Figure 1. Primary classification of laboratories participating in the April 2001 shipment.

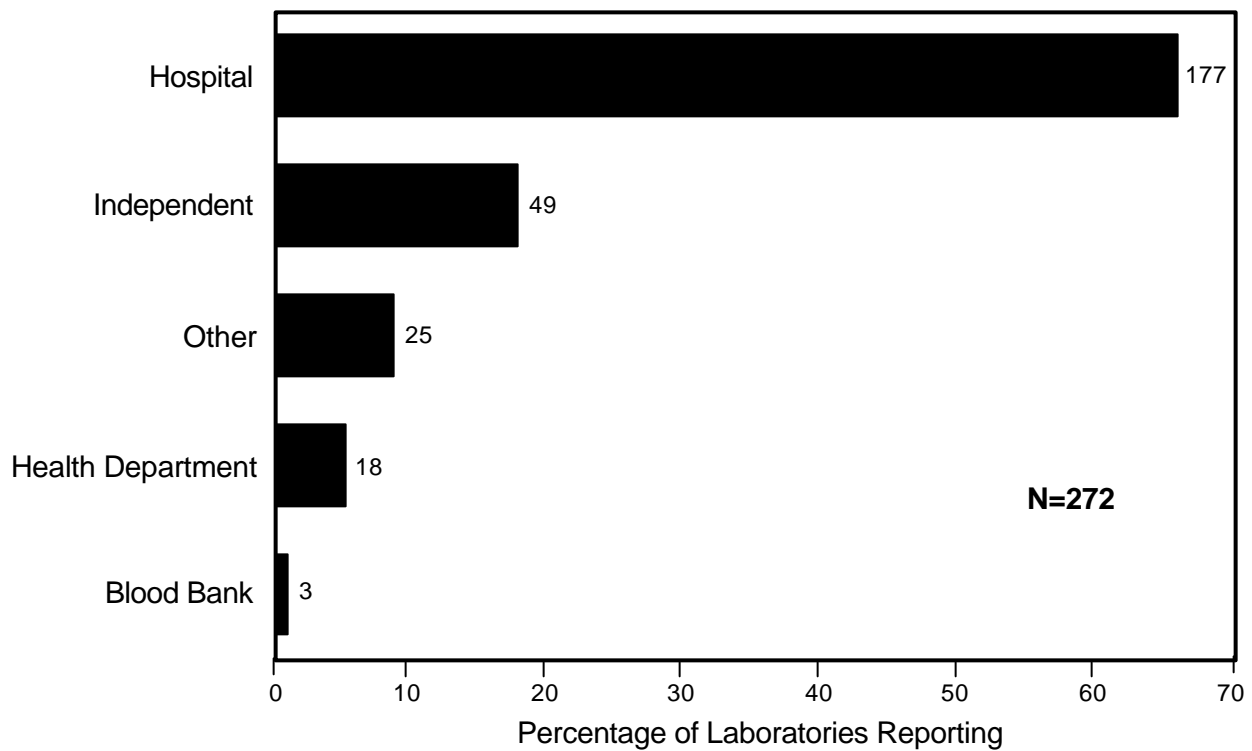


Figure 2. Methods used to prepare specimens for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the April 2001 shipment.

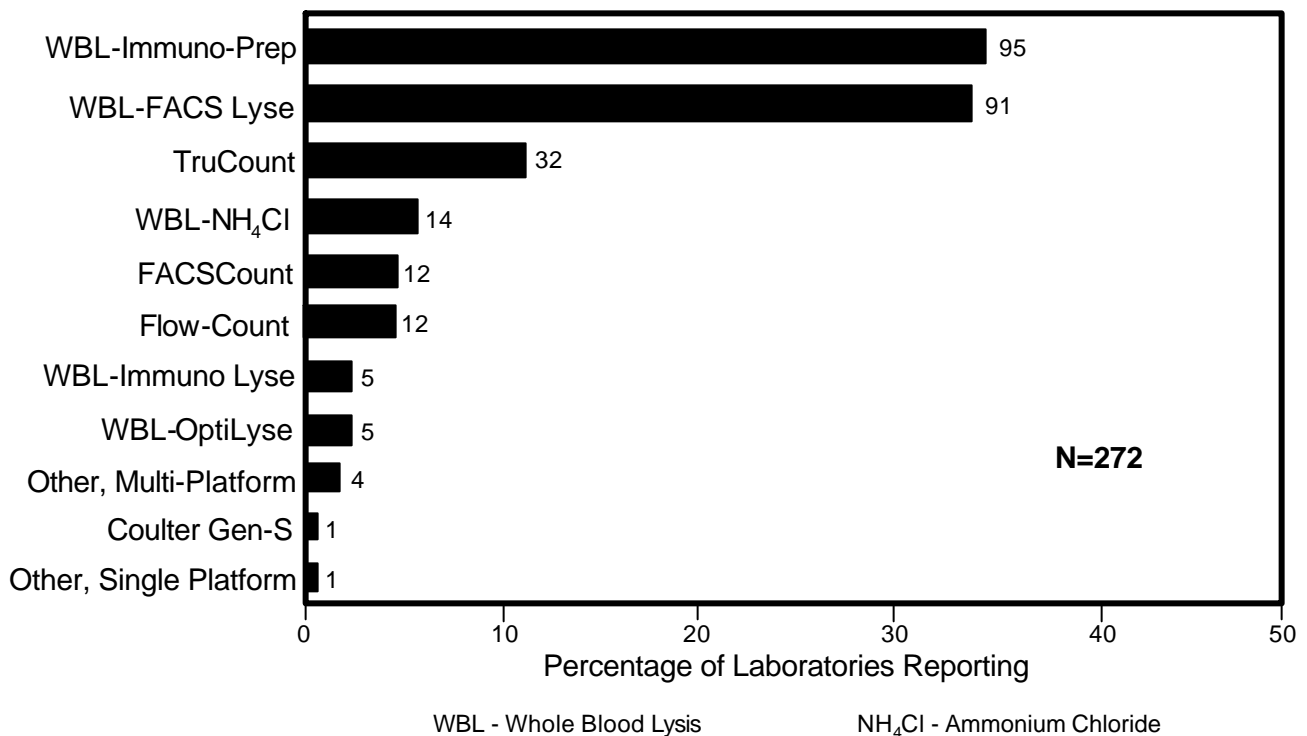


Figure 3. Methods used to fix specimens for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the April 2001 shipment.

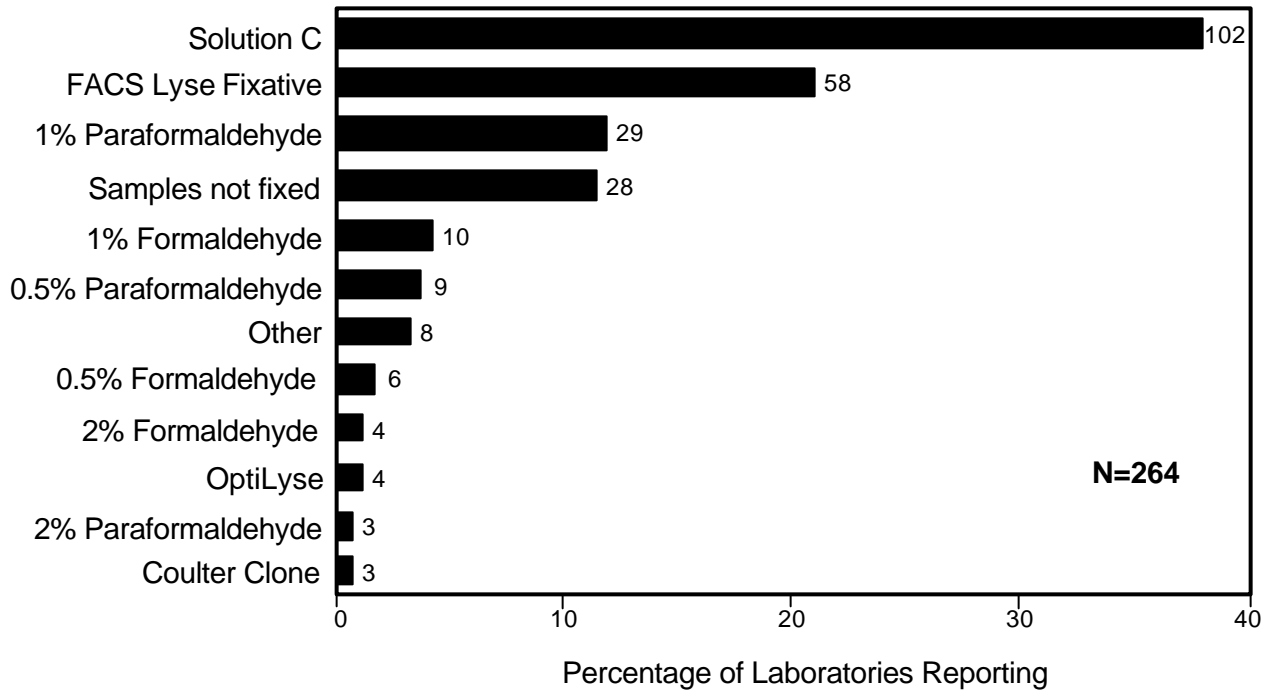


Figure 4. Types of flow cytometers used for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the April 2001 shipment.

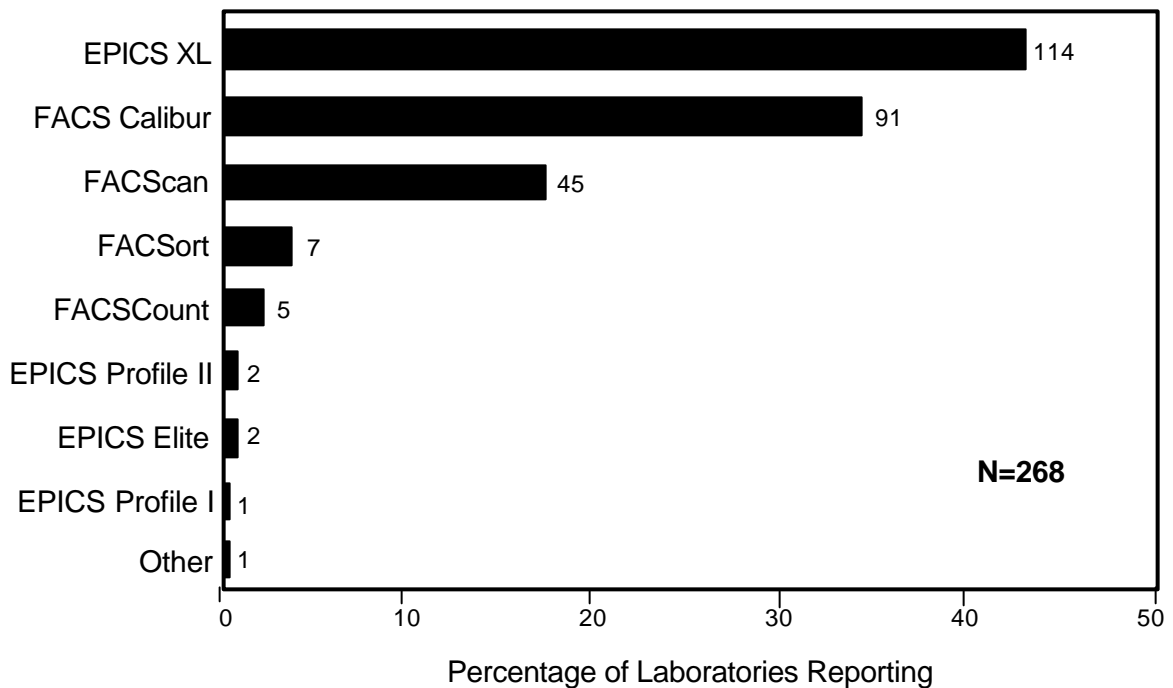
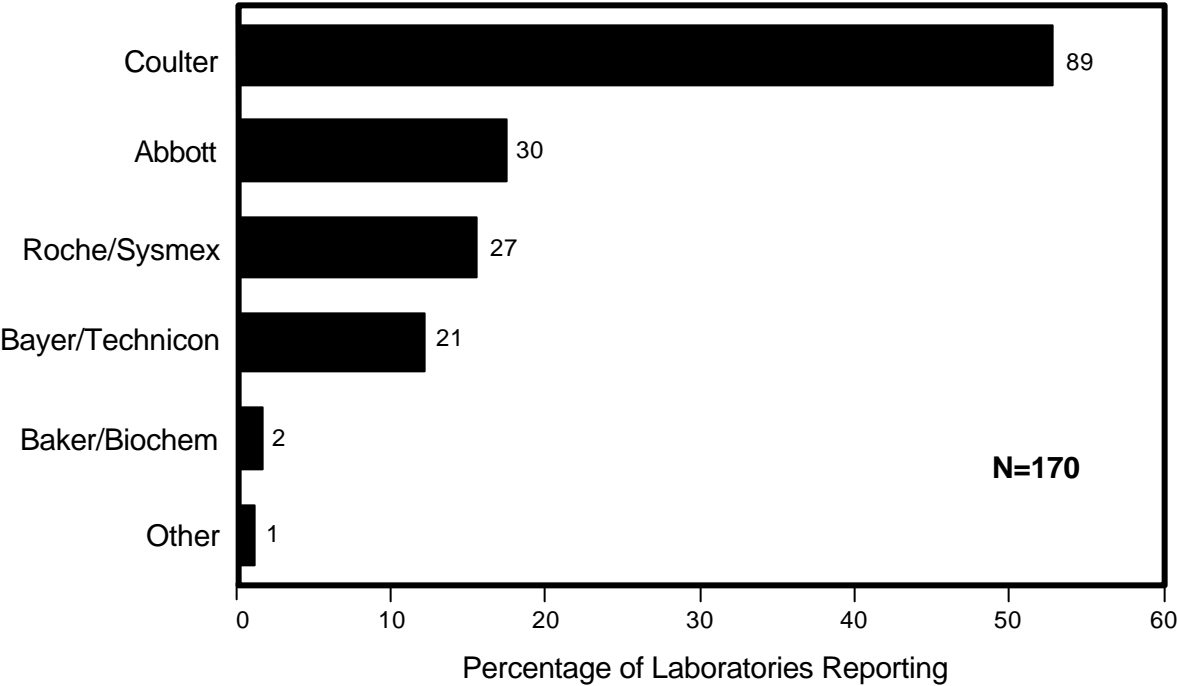


Figure 5. Types of hematology instruments used for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the April 2001 shipment.



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
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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 2001 Shipment

Donor Number 1 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	94 - 100	38		
	< 94	1		
CD14	> 2	0		
	0 - 2	38		
	< 0	0		
CD4	> 49	2	> 1,670	6
	38 - 49	117	967 - 1,670	90
	< 38	5	< 967	2
CD8	> 31	3	> 1,089	5
	25 - 31	117	627 - 1,089	91
	< 25	3	< 627	2
CD19	> 25	3		
	16 - 25	95		
	< 16	5		
CD56+16	> 6	3		
	3 - 6	64		
	< 3	0		
CD3 Average	> 79	4		
	70 - 79	100		
	< 70	4		
CD56	1 - 20	33		
CD16	4 - 6	5		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 11,188	0
	9,681 - 11,188	74
	< 9,681	4
% Lymphs	> 35	5
	23 - 35	71
	< 23	1
Absolute Lymphs	> 3,849	5
	2,311 - 3,849	69
	< 2,311	2

Donor Number 2 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	93 - 100	39		
	< 93	1		
CD14	> 2	0		
	0 - 2	38		
	< 0	0		
CD4	> 33	2	> 989	7
	26 - 33	119	607 - 989	94
	< 26	3	< 607	5
CD8	> 59	7	> 1,754	3
	50 - 59	115	1,242 - 1,754	98
	< 50	2	< 1,242	5
CD19	> 15	0		
	5 - 15	103		
	< 5	1		
CD56+16	> 10	2		
	3 - 10	68		
	< 3	0		
CD3 Average	> 89	2		
	77 - 89	107		
	< 77	1		
CD56	1 - 7	22		
CD16	5 - 8	4		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 5,941	0
	4,829 - 5,941	71
	< 4,829	7
% Lymphs	> 58	3
	47 - 58	72
	< 47	1
Absolute Lymphs	> 3,246	2
	2,326 - 3,246	68
	< 2,326	4

Participant Laboratory Results for the April 2001 Shipment

Donor Number 3 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	91 - 100	39		
	< 91	0		
CD14	> 3	0		
	0 - 3	38		
	< 0	0		
CD4	> 54	2	> 1,533	6
	45 - 54	112	759 - 1,533	91
	< 45	10	< 759	1
CD8	> 21	1	> 589	6
	16 - 21	118	268 - 589	89
	< 16	4	< 268	3
CD19	> 24	4		
	17 - 24	95		
	< 17	4		
CD56+16	> 11	3		
	5 - 11	62		
	< 5	2		
CD3 Average	> 74	1		
	65 - 74	101		
	< 65	6		
CD56	2 - 21	33		
CD16	7 - 12	5		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 11,194	1
	9,534 - 11,194	73
	< 9,534	4
% Lymphs	> 31	4
	16 - 31	73
	< 16	0
Absolute Lymphs	> 3,180	5
	1,679 - 3,180	70
	< 1,679	1

Donor Number 4 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	90 - 100	40		
	< 90	0		
CD14	> 2	1		
	0 - 2	38		
	< 0	0		
CD4	> 4	5	> 50	5
	0 - 4	120	0 - 50	94
	< 0	0	< 0	0
CD8	> 85	4	> 1,135	2
	74 - 85	116	757 - 1,135	92
	< 74	4	< 757	5
CD19	> 5	3		
	1 - 5	100		
	< 1	1		
CD56+16	> 13	3		
	5 - 13	63		
	< 5	1		
CD3 Average	> 92	1		
	81 - 92	105		
	< 81	3		
CD56	4 - 12	33		
CD16	5 - 10	5		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 2,477	1
	1,996 - 2,477	74
	< 1,996	3
% Lymphs	> 62	2
	47 - 62	72
	< 47	3
Absolute Lymphs	> 1,433	1
	1,006 - 1,433	71
	< 1,006	4

Participant Laboratory Results for the April 2001 Shipment

Donor Number 5 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	94 - 100	40		
	< 94	0		
CD14	> 2	2		
	0 - 2	38		
	< 0	0		
CD4	> 40	4	> 1,127	9
	31 - 40	118	676 - 1,127	83
	< 31	4	< 676	0
CD8	> 59	0	> 1,623	7
	45 - 59	115	998 - 1,623	85
	< 45	9	< 998	0
CD19	> 9	4		
	3 - 9	100		
	< 3	1		
CD56+16	> 13	1		
	6 - 13	63		
	< 6	0		
CD3 Average	> 88	2		
	79 - 88	102		
	< 79	4		
CD56	1 - 10	44		
CD16	9 - 15	6		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 6,766	0
	5,829 - 6,766	75
	< 5,829	3
% Lymphs	> 52	7
	30 - 52	71
	< 30	0
Absolute Lymphs	> 3,212	7
	1,934 - 3,212	71
	< 1,934	0

Donor Number 6 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	96 - 100	46		
	< 96	2		
CD14	> 1	4		
	0 - 1	42		
	< 0	0		
CD4	> 40	4	> 1,634	7
	31 - 40	132	1,007 - 1,634	112
	< 31	0	< 1,007	1
CD8	> 49	5	> 2,015	7
	41 - 49	129	1,339 - 2,015	107
	< 41	0	< 1,339	6
CD19	> 18	1		
	8 - 18	109		
	< 8	2		
CD56+16	> 6	3		
	1 - 6	69		
	< 1	0		
CD3 Average	> 88	2		
	78 - 88	116		
	< 78	2		
CD56	0 - 3	34		
CD16	2 - 3	8		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 8,129	2
	6,239 - 8,129	92
	< 6,239	4
% Lymphs	> 64	7
	42 - 64	89
	< 42	2
Absolute Lymphs	> 4,397	4
	3,064 - 4,397	90
	< 3,064	4

Participant Laboratory Results for the April 2001 Shipment

Donor Number 7 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	91 - 100	37		
	< 91	3		
CD14	> 2	1		
	0 - 2	35		
	< 0	0		
CD4	> 49	5	> 756	8
	41 - 49	133	345 - 756	88
	< 41	3	< 345	3
CD8	> 33	6	> 528	9
	28 - 33	132	225 - 528	86
	< 28	3	< 225	0
CD19	> 14	1		
	9 - 14	102		
	< 9	4		
CD56+16	> 15	1		
	5 - 15	72		
	< 5	0		
CD3 Average	> 83	3		
	72 - 83	117		
	< 72	3		
CD56	5 - 9	26		
CD16	5 - 12	6		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 6,461	4
	4,507 - 6,461	63
	< 4,507	2
% Lymphs	> 31	4
	15 - 31	65
	< 15	0
Absolute Lymphs	> 1,716	7
	809 - 1,716	61
	< 809	1

Donor Number 8 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	96 - 100	43		
	< 96	1		
CD14	> 2	1		
	0 - 2	40		
	< 0	0		
CD4	> 56	8	> 1,543	6
	48 - 56	127	913 - 1,543	100
	< 48	3	< 913	3
CD8	> 23	5	> 663	6
	19 - 23	132	345 - 663	99
	< 19	0	< 345	2
CD19	> 15	2		
	10 - 15	104		
	< 10	3		
CD56+16	> 12	2		
	6 - 12	69		
	< 6	1		
CD3 Average	> 81	5		
	74 - 81	115		
	< 74	1		
CD56	0 - 8	30		
CD16	3 - 9	7		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 6,771	2
	5,598 - 6,771	75
	< 5,598	6
% Lymphs	> 50	7
	28 - 50	74
	< 28	2
Absolute Lymphs	> 3,067	5
	1,786 - 3,067	76
	< 1,786	2

Participant Laboratory Results for the April 2001 Shipment

Donor Number 9 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	94 - 100	42		
	< 94	2		
CD14	> 3	2		
	0 - 3	39		
	< 0	0		
CD4	> 51	3	> 1,143	3
	44 - 51	130	746 - 1,143	103
	< 44	5	< 746	3
CD8	> 31	7	> 704	6
	25 - 31	129	408 - 704	99
	< 25	1	< 408	2
CD19	> 17	3		
	12 - 17	101		
	< 12	5		
CD56+16	> 8	2		
	3 - 8	69		
	< 3	1		
CD3 Average	> 82	2		
	76 - 82	115		
	< 76	4		
CD56	1 - 8	30		
CD16	2 - 5	7		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 5,912	2
	4,783 - 5,912	78
	< 4,783	3
% Lymphs	> 46	3
	30 - 46	79
	< 30	1
Absolute Lymphs	> 2,387	5
	1,618 - 2,387	76
	< 1,618	2

Donor Number 10 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	92 - 100	40		
	< 92	2		
CD14	> 3	2		
	0 - 3	38		
	< 0	0		
CD4	> 3	8	> 41	9
	1 - 3	129	8 - 41	99
	< 1	0	< 8	0
CD8	> 71	6	> 930	5
	45 - 71	130	394 - 930	97
	< 45	0	< 394	4
CD19	> 36	1		
	11 - 36	103		
	< 11	4		
CD56+16	> 14	4		
	0 - 14	67		
	< 0	0		
CD3 Average	> 82	4		
	55 - 82	115		
	< 55	1		
CD56	1 - 7	30		
CD16	2 - 7	7		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 6,182	1
	1,973 - 6,182	75
	< 1,973	7
% Lymphs	> 39	4
	20 - 39	78
	< 20	1
Absolute Lymphs	> 1,767	3
	606 - 1,767	75
	< 606	5