

**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 1999 Shipment**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Public Health Practice Program Office
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by the U.S. Department of Health and Human Services.**

Report of the April 1999 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 6 and April 13, 1999 TLI Shipment Specimens

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

^aHuman immunodeficiency virus type 1

Figure 1. Primary classification of laboratories participating in the April 1999 shipment.

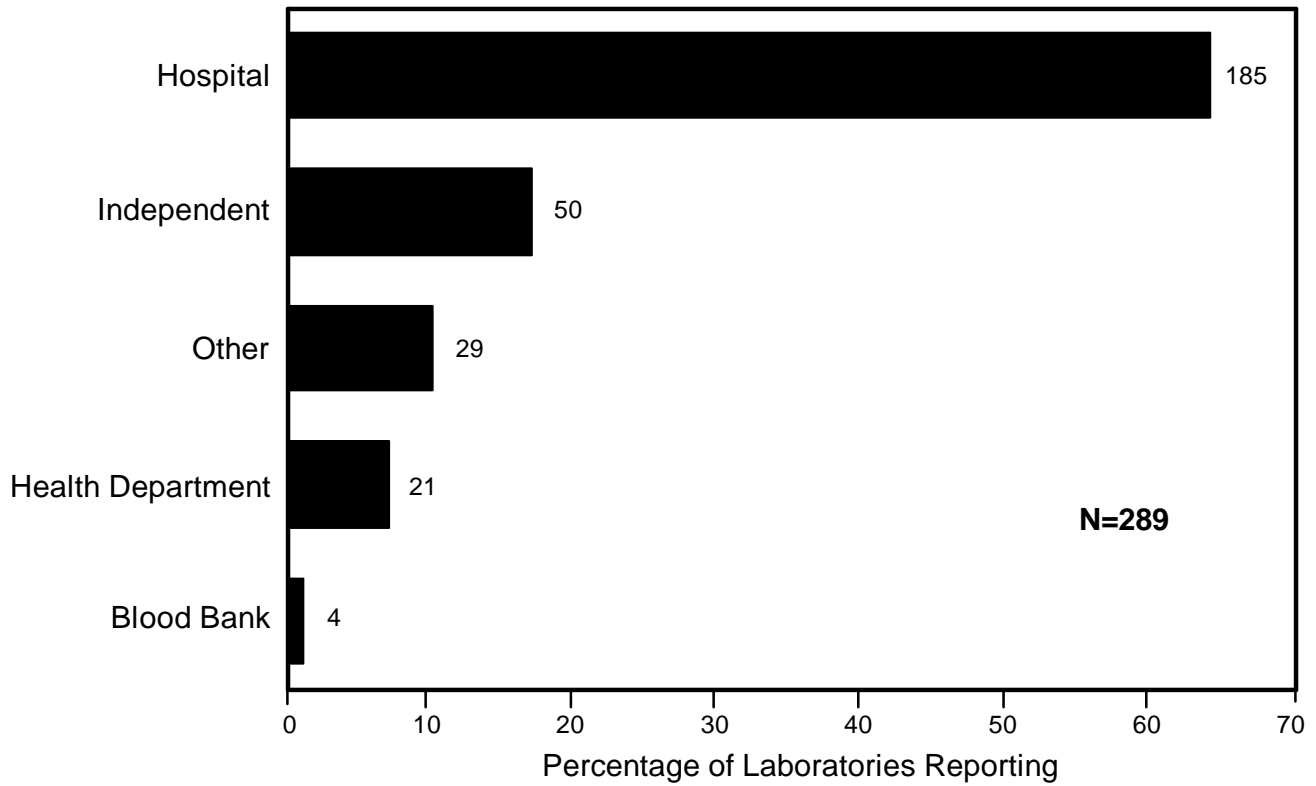


Figure 2. Methods used to prepare specimens for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the April 1999 shipment.

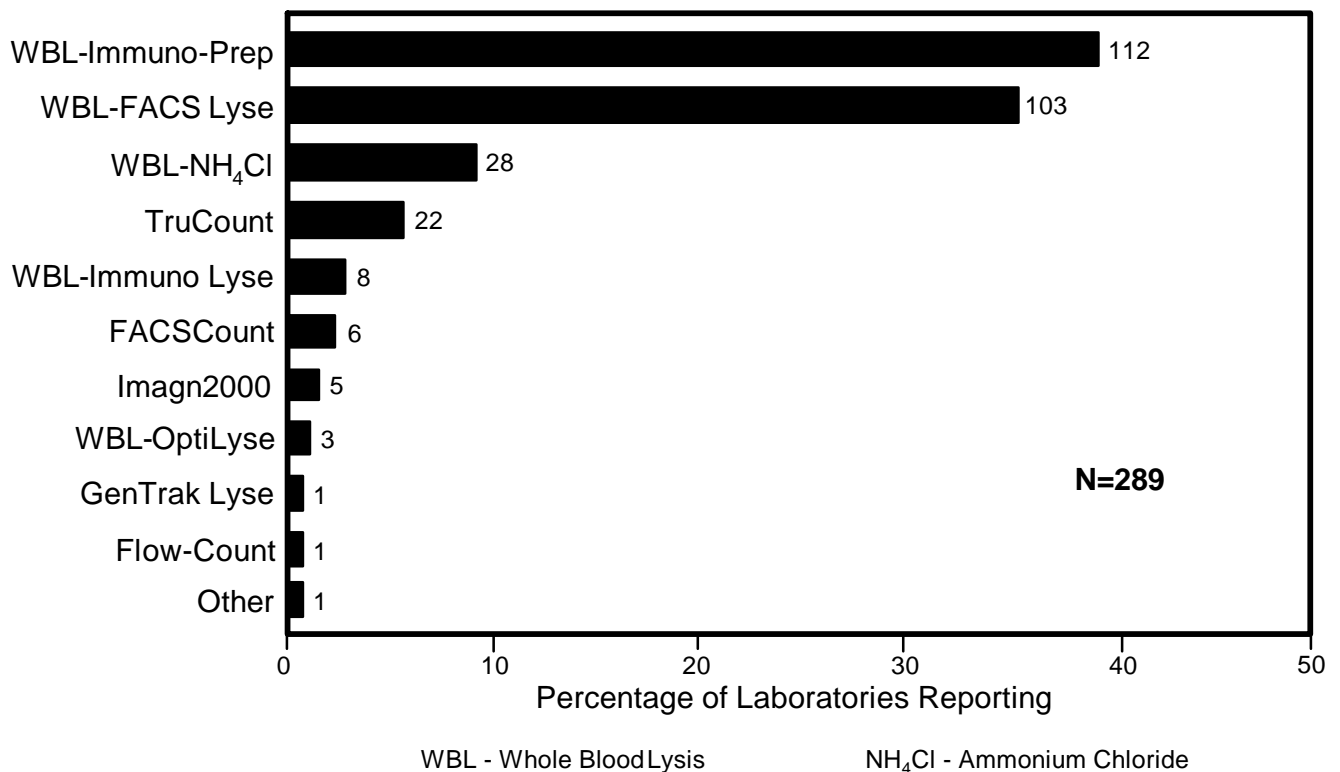


Figure 3. Methods used to fix specimens for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the April 1999 shipment.

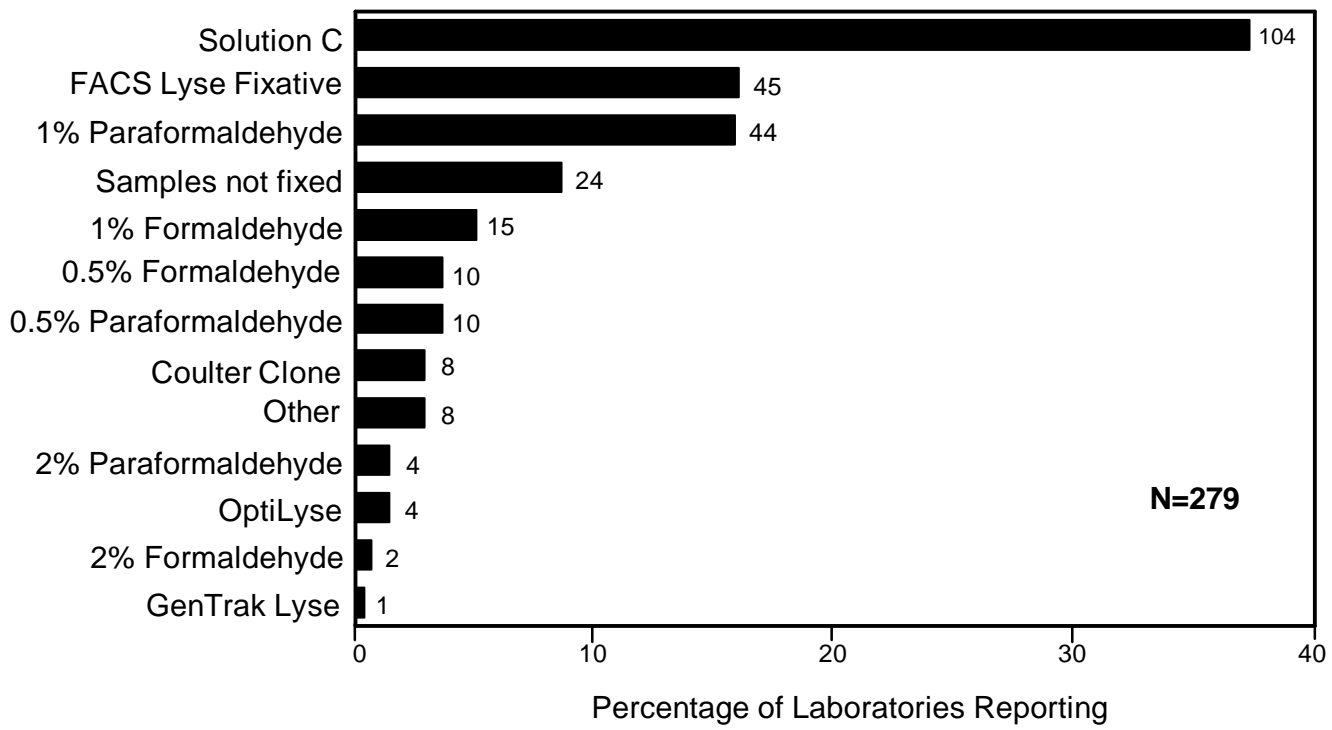


Figure 4. Types of flow cytometers used for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the April 1999 shipment.

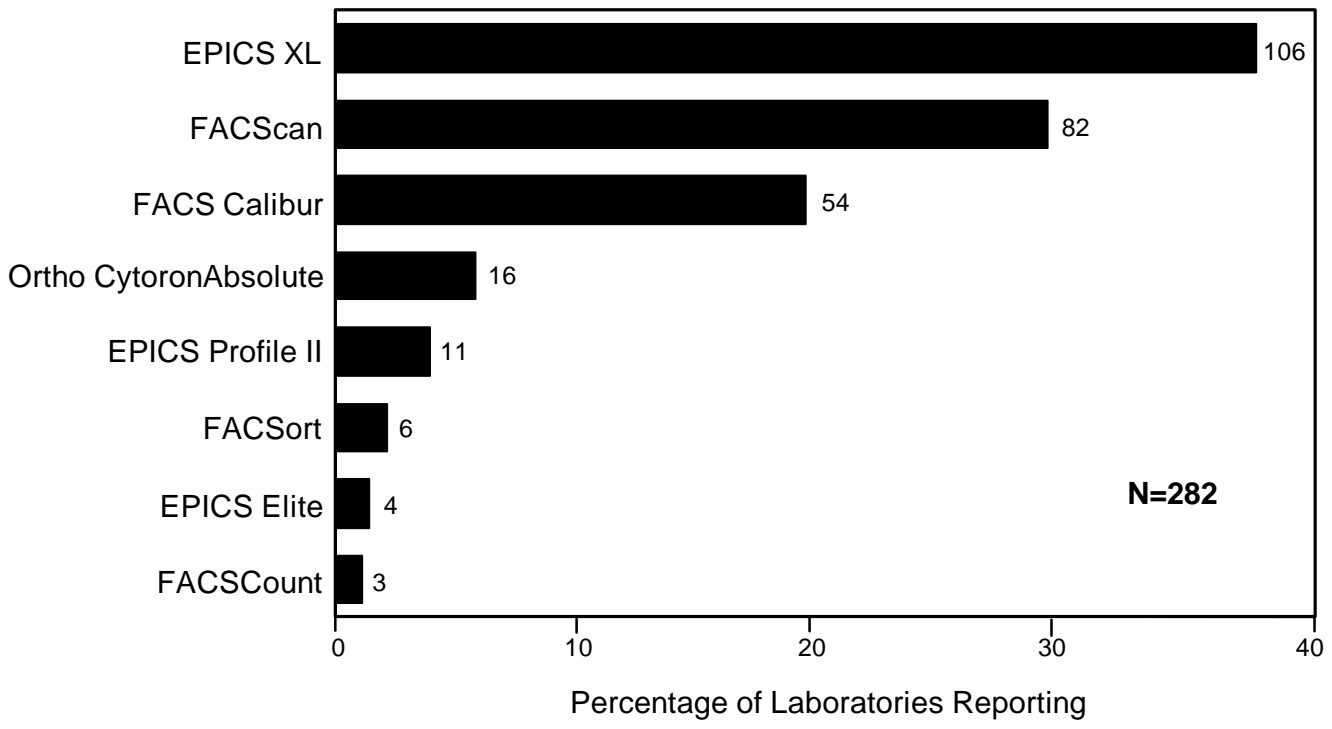
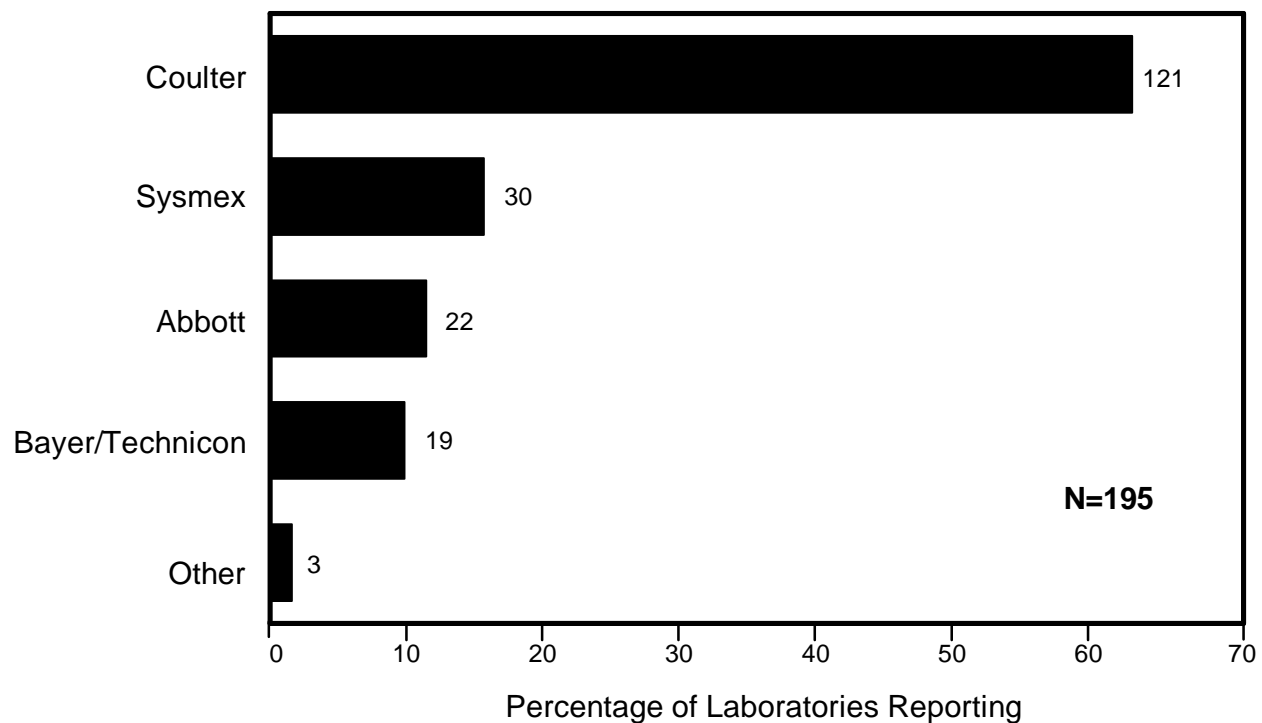


Figure 5. Types of hematology instruments used for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the April 1999 shipment.



Explanation of Results Table

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

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

Participant Laboratory Results for the April 1999 Shipment

Donor Number 1 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	1		
	92 - 100	71		
	< 92	3		
CD14	> 3	4		
	0 - 3	68		
	< 0	0		
CD4	> 49	2	> 1,534	3
	35 - 49	134	216 - 1,534	92
	< 35	3	< 216	3
CD8	> 40	0	> 1,343	2
	31 - 40	134	172 - 1,343	93
	< 31	4	< 172	2
CD19	> 18	0		
	6 - 18	108		
	< 6	3		
CD56+16	> 14	0		
	4 - 14	75		
	< 4	2		
CD3 Average	> 86	4		
	69 - 86	110		
	< 69	2		
CD56	0 - 11	25		
CD16	2 - 15	13		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 5,323	0
	2,943 - 5,323	82
	< 2,943	7
% Lymphs	> 88	0
	24 - 88	81
	< 24	3
Absolute Lymphs	> 3,845	1
	639 - 3,845	78
	< 639	2

Donor Number 2 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	91 - 100	67		
	< 91	5		
CD14	> 2	5		
	0 - 2	65		
	< 0	0		
CD4	> 49	5	> 997	2
	37 - 49	135	581 - 997	106
	< 37	1	< 581	4
CD8	> 19	4	> 387	4
	14 - 19	137	227 - 387	104
	< 14	0	< 227	4
CD19	> 37	2		
	24 - 37	114		
	< 24	4		
CD56+16	> 11	1		
	1 - 11	79		
	< 1	0		
CD3 Average	> 69	4		
	55 - 69	116		
	< 55	0		
CD56	1 - 5	31		
CD16	1 - 25	8		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 5,636	2
	4,689 - 5,636	93
	< 4,689	4
% Lymphs	> 42	3
	31 - 42	89
	< 31	7
Absolute Lymphs	> 2,209	3
	1,524 - 2,209	85
	< 1,524	5

Participant Laboratory Results for the April 1999 Shipment

Donor Number 3 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	94 - 100	76		
	< 94	4		
CD14	> 2	4		
	0 - 2	73		
	< 0	0		
CD4	> 49	4	> 807	5
	41 - 49	139	525 - 807	104
	< 41	4	< 525	2
CD8	> 31	4	> 513	5
	25 - 31	140	329 - 513	104
	< 25	2	< 329	2
CD19	> 12	1		
	9 - 12	110		
	< 9	4		
CD56+16	> 16	1		
	8 - 16	78		
	< 8	3		
CD3 Average	> 81	4		
	72 - 81	117		
	< 72	2		
CD56	1 - 12	26		
CD16	6 - 14	13		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 4,086	2
	3,429 - 4,086	88
	< 3,429	7
% Lymphs	> 46	6
	34 - 46	89
	< 34	2
Absolute Lymphs	> 1,718	5
	1,252 - 1,718	87
	< 1,252	2

Donor Number 4 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	92 - 100	82		
	< 92	4		
CD14	> 2	7		
	0 - 2	74		
	< 0	0		
CD4	> 47	0	> 877	8
	37 - 47	147	312 - 877	100
	< 37	4	< 312	0
CD8	> 43	6	> 740	9
	35 - 43	138	345 - 740	97
	< 35	5	< 345	2
CD19	> 14	1		
	9 - 14	105		
	< 9	4		
CD56+16	> 11	2		
	0 - 11	81		
	< 0	0		
CD3 Average	> 89	0		
	77 - 89	122		
	< 77	3		
CD56	1 - 6	20		
CD16	2 - 16	18		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 6,589	1
	5,526 - 6,589	85
	< 5,526	6
% Lymphs	> 32	6
	15 - 32	86
	< 15	0
Absolute Lymphs	> 1,968	6
	855 - 1,968	86
	< 855	0

Participant Laboratory Results for the April 1999 Shipment

Donor Number 5 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	93 - 100	76		
	< 93	4		
CD14	> 2	3		
	0 - 2	74		
	< 0	0		
CD4	> 10	2	> 143	6
	6 - 10	140	60 - 143	102
	< 6	3	< 60	2
CD8	> 79	5	> 1,201	7
	66 - 79	135	668 - 1,201	102
	< 66	4	< 668	1
CD19	> 8	1		
	2 - 8	112		
	< 2	0		
CD56+16	> 11	1		
	2 - 11	79		
	< 2	0		
CD3 Average	> 93	2		
	81 - 93	116		
	< 81	3		
CD56	2 - 5	26		
CD16	1 - 7	13		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 4,323	1
	3,514 - 4,323	88
	< 3,514	6
% Lymphs	> 42	7
	25 - 42	88
	< 25	0
Absolute Lymphs	> 1,626	7
	977 - 1,626	84
	< 977	1

Donor Number 6 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	90 - 100	77		
	< 90	2		
CD14	> 4	9		
	0 - 4	70		
	< 0	0		
CD4	> 46	8	> 640	4
	36 - 46	125	318 - 640	81
	< 36	2	< 318	3
CD8	> 46	1	> 624	0
	37 - 46	127	319 - 624	83
	< 37	7	< 319	5
CD19	> 10	2		
	3 - 10	101		
	< 3	2		
CD56+16	> 13	1		
	4 - 13	64		
	< 4	0		
CD3 Average	> 91	3		
	78 - 91	119		
	< 78	1		
CD56	1 - 9	22		
CD16	3 - 11	14		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 4,702	0
	3,370 - 4,702	70
	< 3,370	8
% Lymphs	> 41	6
	17 - 41	69
	< 17	1
Absolute Lymphs	> 1,479	0
	808 - 1,479	73
	< 808	3

Participant Laboratory Results for the April 1999 Shipment

Donor Number 7 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	89 - 100	53		
	< 89	3		
CD14	> 2	2		
	0 - 2	54		
	< 0	0		
CD4	> 38	2	> 464	7
	26 - 38	131	185 - 464	104
	< 26	7	< 185	1
CD8	> 48	3	> 574	7
	36 - 48	130	254 - 574	100
	< 36	5	< 254	1
CD19	> 23	0		
	9 - 23	104		
	< 9	2		
CD56+16	> 12	6		
	2 - 12	70		
	< 2	0		
CD3 Average	> 84	4		
	67 - 84	106		
	< 67	4		
CD56	1 - 5	26		
CD16	2 - 7	6		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 5,196	1
	3,457 - 5,196	80
	< 3,457	5
% Lymphs	> 32	6
	15 - 32	77
	< 15	1
Absolute Lymphs	> 1,472	4
	576 - 1,472	76
	< 576	4

Donor Number 8 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	92 - 100	68		
	< 92	1		
CD14	> 3	5		
	0 - 3	63		
	< 0	0		
CD4	> 46	6	> 916	7
	33 - 46	131	481 - 916	93
	< 33	1	< 481	2
CD8	> 26	3	> 520	6
	19 - 26	131	275 - 520	92
	< 19	3	< 275	2
CD19	> 18	0		
	13 - 18	100		
	< 13	6		
CD56+16	> 26	0		
	13 - 26	67		
	< 13	4		
CD3 Average	> 74	7		
	57 - 74	112		
	< 57	0		
CD56	1 - 20	24		
CD16	14 - 22	10		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 4,862	2
	3,948 - 4,862	73
	< 3,948	7
% Lymphs	> 50	8
	30 - 50	73
	< 30	1
Absolute Lymphs	> 2,136	5
	1,371 - 2,136	75
	< 1,371	2

Participant Laboratory Results for the April 1999 Shipment

Donor Number 9 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	94 - 100	67		
	< 94	2		
CD14	> 2	3		
	0 - 2	65		
	< 0	0		
CD4	> 44	8	> 1,521	6
	31 - 44	126	767 - 1,521	89
	< 31	1	< 767	3
CD8	> 35	7	> 1,216	6
	26 - 35	126	622 - 1,216	89
	< 26	1	< 622	1
CD19	> 18	1		
	9 - 18	96		
	< 9	6		
CD56+16	> 19	0		
	8 - 19	66		
	< 8	3		
CD3 Average	> 80	8		
	64 - 80	109		
	< 64	1		
CD56	1 - 14	24		
CD16	11 - 16	10		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 9,035	0
	7,256 - 9,035	76
	< 7,256	6
% Lymphs	> 48	6
	27 - 48	73
	< 27	1
Absolute Lymphs	> 3,559	7
	2,447 - 3,559	71
	< 2,447	2

Donor Number 10 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	93 - 100	66		
	< 93	3		
CD14	> 4	5		
	0 - 4	63		
	< 0	0		
CD4	> 12	0	> 291	8
	8 - 12	137	91 - 291	90
	< 8	0	< 91	1
CD8	> 75	3	> 1,953	6
	64 - 75	128	655 - 1,953	90
	< 64	5	< 655	1
CD19	> 10	2		
	3 - 10	101		
	< 3	2		
CD56+16	> 16	0		
	5 - 16	65		
	< 5	5		
CD3 Average	> 86	4		
	76 - 86	109		
	< 76	5		
CD56	2 - 15	24		
CD16	9 - 13	10		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 8,029	2
	6,512 - 8,029	75
	< 6,512	4
% Lymphs	> 39	7
	14 - 39	72
	< 14	0
Absolute Lymphs	> 2,809	7
	1,052 - 2,809	71
	< 1,052	1