

**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 October 1999 Shipment**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Report of the October 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 October 12 and October 19, 1999 TLI Shipment Specimens

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

^aHuman immunodeficiency virus type 1

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

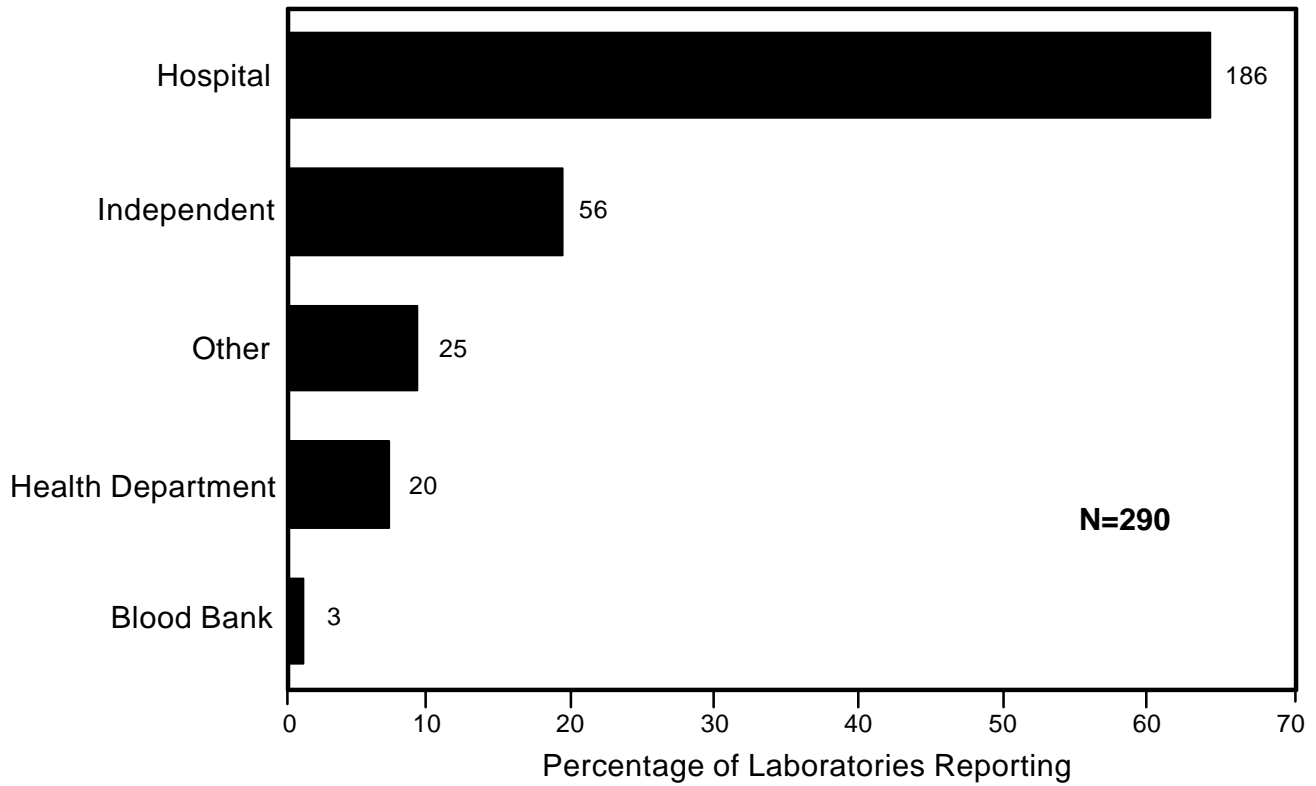


Figure 2. Methods used to prepare specimens for T-lymphocyte immunophenotyping reported by participant laboratories to CDC for the October 1999 shipment.

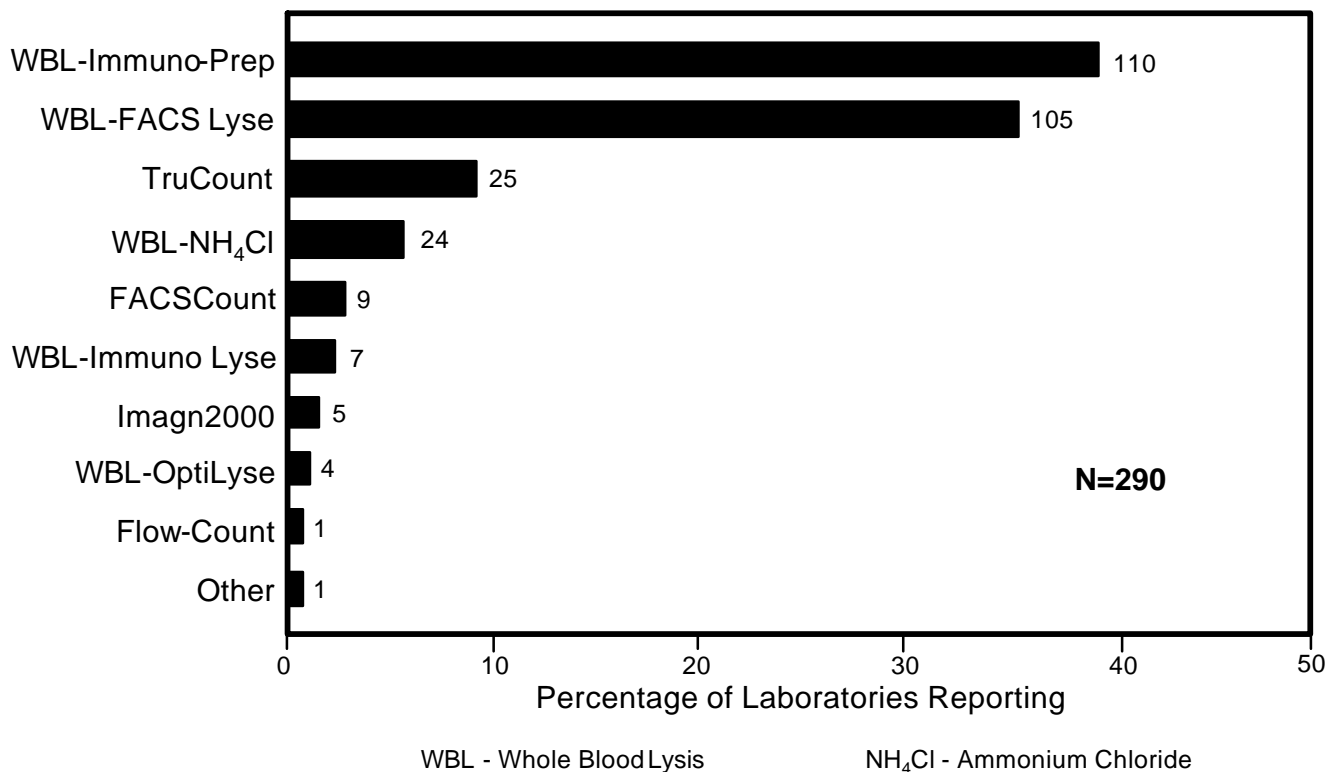


Figure 3. Methods used to fix specimens for T-lymphocyte immunophenotyping reported by participant laboratories to CDC for the October 1999 shipment.

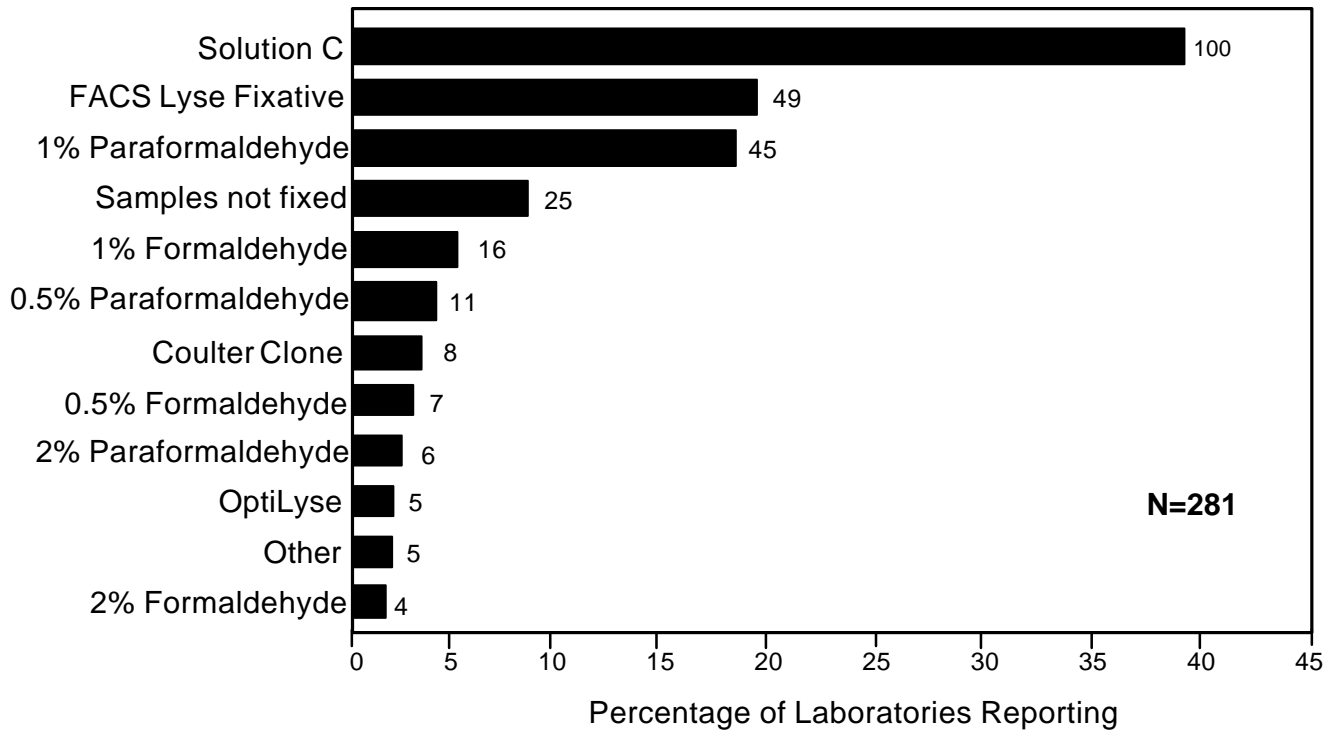


Figure 4. Types of flowcytometers used for T-lymphocyte immunophenotyping reported by participant laboratories to CDC for the October 1999 shipment.

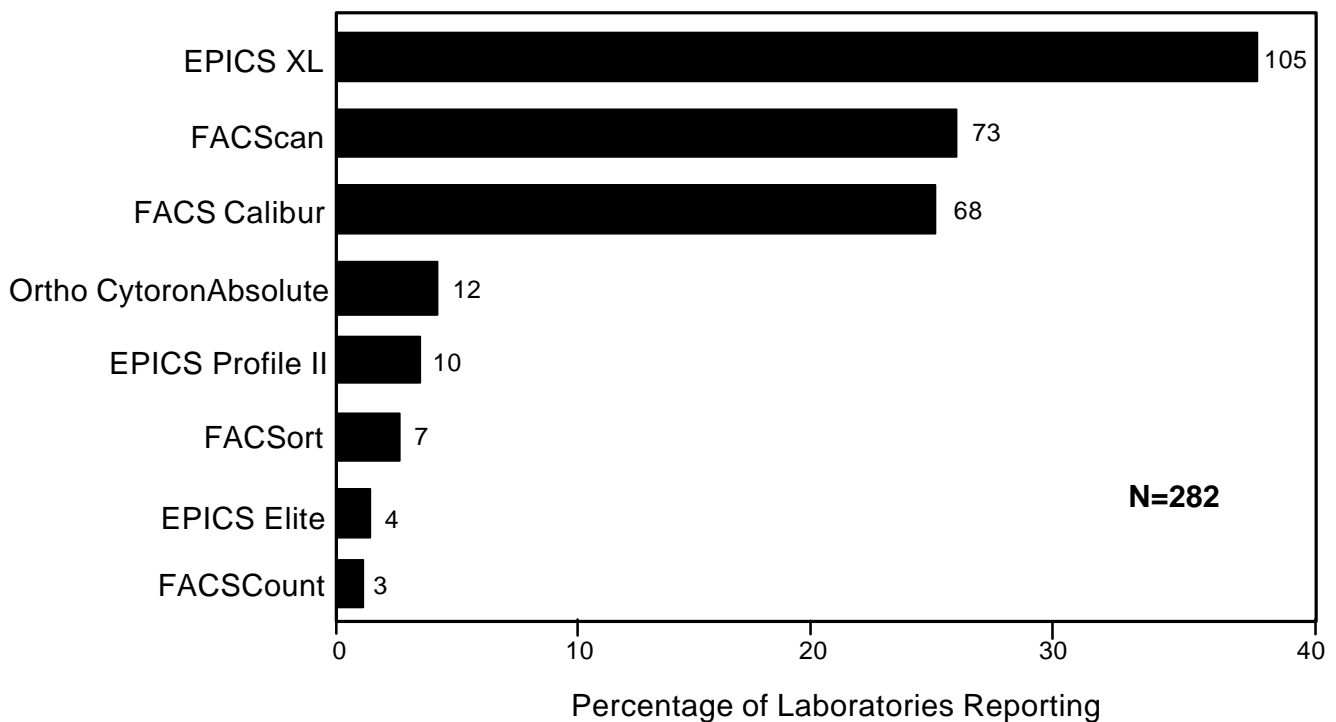
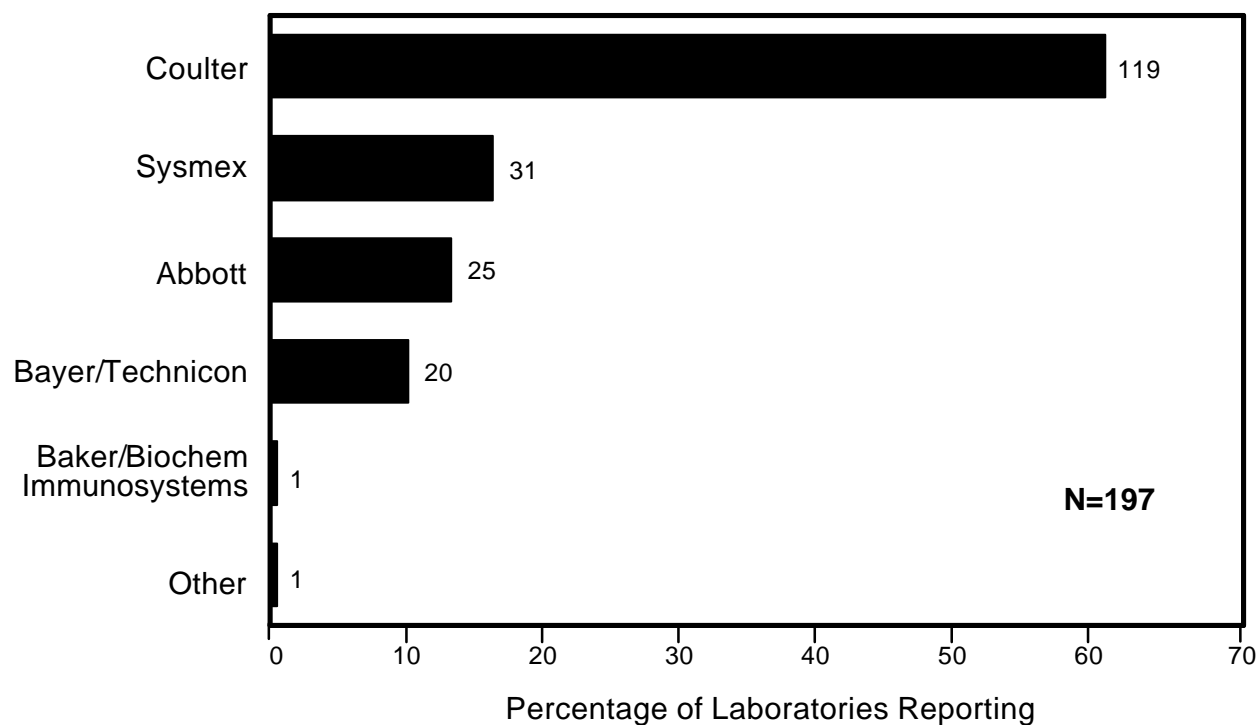


Figure 5. Types of hematology instruments used for T-lymphocyte immunophenotyping reported by participant laboratories to CDC for the October 1999 shipment.



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 October 1999 Shipment

Donor Number 1 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	94 - 100	68		
	< 94	2		
CD14	> 5	3		
	0 - 5	67		
	< 0	0		
CD4	> 51	6	> 1,119	8
	40 - 51	140	701 - 1,119	95
	< 40	1	< 701	2
CD8	> 39	0	> 895	7
	32 - 39	142	509 - 895	97
	< 32	3	< 509	1
CD19	> 12	6		
	9 - 12	106		
	< 9	6		
CD56+16	> 5	1		
	1 - 5	84		
	< 1	0		
CD3 Average	> 89	4		
	82 - 89	120		
	< 82	3		
CD56	1 - 86	22		
CD16	1 - 7	11		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 7,519	5
	6,168 - 7,519	88
	< 6,168	1
% Lymphs	> 36	6
	22 - 36	88
	< 22	0
Absolute Lymphs	> 2,549	7
	1,436 - 2,549	84
	< 1,436	2

Donor Number 2 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	95 - 100	79		
	< 95	3		
CD14	> 1	3		
	0 - 1	79		
	< 0	0		
CD4	> 55	3	> 1,729	11
	47 - 55	141	767 - 1,729	90
	< 47	3	< 767	0
CD8	> 36	2	> 1,116	9
	28 - 36	141	469 - 1,116	91
	< 28	2	< 469	1
CD19	> 16	1		
	7 - 16	113		
	< 7	3		
CD56+16	> 8	4		
	3 - 8	85		
	< 3	0		
CD3 Average	> 88	3		
	78 - 88	123		
	< 78	4		
CD56	1 - 84	22		
CD16	3 - 12	10		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 6,597	4
	5,417 - 6,597	88
	< 5,417	4
% Lymphs	> 56	11
	27 - 56	85
	< 27	0
Absolute Lymphs	> 3,542	9
	1,347 - 3,542	85
	< 1,347	2

Participant Laboratory Results for the October 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	66		
	< 94	3		
CD14	> 6	3		
	0 - 6	66		
	< 0	0		
CD4	> 54	8	> 1,490	6
	41 - 54	137	916 - 1,490	98
	< 41	2	< 916	2
CD8	> 30	4	> 869	7
	24 - 30	137	513 - 869	99
	< 24	4	< 513	0
CD19	> 14	2		
	9 - 14	109		
	< 9	7		
CD56+16	> 15	0		
	7 - 15	81		
	< 7	4		
CD3 Average	> 83	9		
	71 - 83	117		
	< 71	1		
CD56	3 - 78	22		
CD16	3 - 15	11		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 9,172	4
	7,715 - 9,172	88
	< 7,715	3
% Lymphs	> 37	6
	23 - 37	89
	< 23	0
Absolute Lymphs	> 3,119	6
	1,930 - 3,119	85
	< 1,930	3

Donor Number 4 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	93 - 100	57		
	< 93	1		
CD14	> 5	6		
	0 - 5	51		
	< 0	0		
CD4	> 38	8	> 657	7
	30 - 38	136	443 - 657	98
	< 30	2	< 443	3
CD8	> 46	6	> 819	6
	39 - 46	134	544 - 819	101
	< 39	4	< 544	1
CD19	> 10	2		
	6 - 10	114		
	< 6	2		
CD56+16	> 18	1		
	7 - 18	73		
	< 7	6		
CD3 Average	> 86	4		
	71 - 86	118		
	< 71	2		
CD56	4 - 13	22		
CD16	1 - 13	12		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 4,080	6
	3,462 - 4,080	86
	< 3,462	0
% Lymphs	> 50	6
	36 - 50	86
	< 36	0
Absolute Lymphs	> 1,899	6
	1,329 - 1,899	84
	< 1,329	0

Participant Laboratory Results for the October 1999 Shipment

Donor Number 5 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	89 - 100	67		
	< 89	3		
CD14	> 7	3		
	0 - 7	66		
	< 0	0		
CD4	> 9	0	> 86	5
	5 - 9	146	39 - 86	98
	< 5	1	< 39	2
CD8	> 81	4	> 834	7
	67 - 81	137	460 - 834	97
	< 67	4	< 460	1
CD19	> 9	0		
	2 - 9	116		
	< 2	2		
CD56+16	> 13	1		
	5 - 13	81		
	< 5	3		
CD3 Average	> 90	4		
	77 - 90	120		
	< 77	4		
CD56	3 - 81	22		
CD16	2 - 12	11		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 2,518	3
	1,947 - 2,518	89
	< 1,947	2
% Lymphs	> 49	7
	31 - 49	87
	< 31	0
Absolute Lymphs	> 1,122	5
	645 - 1,122	86
	< 645	2

Donor Number 6 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	94 - 100	64		
	< 94	2		
CD14	> 1	4		
	0 - 1	58		
	< 0	0		
CD4	> 48	4	> 901	3
	39 - 48	120	584 - 901	93
	< 39	0	< 584	4
CD8	> 39	6	> 758	4
	33 - 39	115	495 - 758	91
	< 33	3	< 495	3
CD19	> 15	0		
	7 - 15	97		
	< 7	4		
CD56+16	> 10	2		
	3 - 10	65		
	< 3	0		
CD3 Average	> 88	6		
	76 - 88	100		
	< 76	2		
CD56	2 - 6	28		
CD16	4 - 8	12		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 4,450	3
	3,819 - 4,450	69
	< 3,819	4
% Lymphs	> 51	4
	33 - 51	70
	< 33	4
Absolute Lymphs	> 2,045	3
	1,456 - 2,045	67
	< 1,456	4

Participant Laboratory Results for the October 1999 Shipment

Donor Number 7 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	93 - 100	67		
	< 93	1		
CD14	> 2	0		
	0 - 2	66		
	< 0	0		
CD4	> 47	6	> 1,321	9
	38 - 47	134	864 - 1,321	96
	< 38	3	< 864	2
CD8	> 40	1	> 1,109	5
	32 - 40	139	696 - 1,109	99
	< 32	3	< 696	3
CD19	> 11	1		
	7 - 11	109		
	< 7	5		
CD56+16	> 5	0		
	1 - 5	85		
	< 1	0		
CD3 Average	> 91	5		
	85 - 91	118		
	< 85	4		
CD56	1 - 10	32		
CD16	2 - 5	8		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 7,579	4
	4,228 - 7,579	81
	< 4,228	4
% Lymphs	> 53	8
	32 - 53	78
	< 32	1
Absolute Lymphs	> 3,198	8
	1,955 - 3,198	75
	< 1,955	0

Donor Number 8 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	93 - 100	65		
	< 93	1		
CD14	> 2	2		
	0 - 2	61		
	< 0	0		
CD4	> 50	3	> 1,099	5
	41 - 50	129	698 - 1,099	98
	< 41	3	< 698	2
CD8	> 30	6	> 658	6
	23 - 30	129	408 - 658	97
	< 23	0	< 408	1
CD19	> 18	2		
	12 - 18	102		
	< 12	5		
CD56+16	> 10	0		
	5 - 10	75		
	< 5	2		
CD3 Average	> 81	4		
	73 - 81	113		
	< 73	2		
CD56	2 - 15	30		
CD16	4 - 7	10		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 7,561	2
	4,743 - 7,561	80
	< 4,743	2
% Lymphs	> 39	6
	25 - 39	77
	< 25	1
Absolute Lymphs	> 2,465	6
	1,583 - 2,465	73
	< 1,583	1

Participant Laboratory Results for the October 1999 Shipment

Donor Number 9 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	92 - 100	62		
	< 92	2		
CD14	> 2	4		
	0 - 2	57		
	< 0	0		
CD4	> 55	7	> 1,925	10
	44 - 55	122	426 - 1,925	90
	< 44	1	< 426	0
CD8	> 23	0	> 688	10
	18 - 23	127	230 - 688	89
	< 18	3	< 230	0
CD19	> 21	0		
	13 - 21	99		
	< 13	6		
CD56+16	> 14	1		
	5 - 14	70		
	< 5	4		
CD3 Average	> 78	9		
	67 - 78	104		
	< 67	2		
CD56	1 - 13	28		
CD16	3 - 10	9		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 10,809	2
	6,739 - 10,809	75
	< 6,739	2
% Lymphs	> 43	9
	10 - 43	70
	< 10	0
Absolute Lymphs	> 4,166	8
	746 - 4,166	68
	< 746	0

Donor Number 10 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	94 - 100	66		
	< 94	1		
CD14	> 1	2		
	0 - 1	62		
	< 0	0		
CD4	> 11	0	> 336	6
	7 - 11	134	195 - 336	94
	< 7	0	< 195	1
CD8	> 72	2	> 2,300	2
	61 - 72	129	1,604 - 2,300	95
	< 61	3	< 1,604	3
CD19	> 21	1		
	10 - 21	103		
	< 10	4		
CD56+16	> 8	3		
	2 - 8	73		
	< 2	0		
CD3 Average	> 82	2		
	72 - 82	112		
	< 72	4		
CD56	1 - 5	30		
CD16	2 - 9	10		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 8,509	2
	5,532 - 8,509	79
	< 5,532	2
% Lymphs	> 48	5
	35 - 48	76
	< 35	2
Absolute Lymphs	> 3,435	2
	2,493 - 3,435	73
	< 2,493	4