

**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 2000 Shipment**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Centers for Disease Control and Prevention  
Public Health Practice Program Office  
Division of Laboratory Systems  
Atlanta, Georgia 30341-3717**



Use of trade names is for identification only and does not constitute endorsement  
by the U.S. Department of Health and Human Services.

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

---

---

The production of this report was coordinated in CDC by:

Public Health Practice Program Office.....Edward L. Baker, M.D., M.P.H., Director  
Division of Laboratory Systems..... Robert Martin, Dr.P.H., Director  
Thomas L. Hearn, Ph.D., Deputy Director

The material in this report was developed and prepared by:

Model Performance Evaluation Program (MPEP).....William O. Schalla, M.S., Chief  
MPEP TLI Performance Evaluation.....G. David Cross, M.S.,  
TLI Project Coordinator

---

---

Information about this report should be addressed to the Model Performance Evaluation  
Program by calling (770) 488-8091 or (770) 488-8098.

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

**Donor Identification for October 10 and October 17, 2000 TLI Shipment Specimens**

<b>Panel Letter</b>	<b>Participant Laboratory Vial Label</b>	<b>CDC Donor Number</b>	<b>Donor Information (HIV-1<sup>a</sup> status)</b>
A	A1	04	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, B4	05	HIV-1 Antibody-Positive
	B2	04	HIV-1 Antibody-Positive
	B3	03	HIV-1 Antibody-Negative
	B5	01	HIV-1 Antibody-Negative
C	C1	08	HIV-1 Antibody-Negative
	C2	09	HIV-1 Antibody-Negative
	C3, C4	06	HIV-1 Antibody-Positive
	C5	10	HIV-1 Antibody-Positive
D	D1	10	HIV-1 Antibody-Positive
	D2, D5	07	HIV-1 Antibody-Positive
	D3	09	HIV-1 Antibody-Negative
	D4	08	HIV-1 Antibody-Negative

<sup>a</sup> Human immunodeficiency virus type 1

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

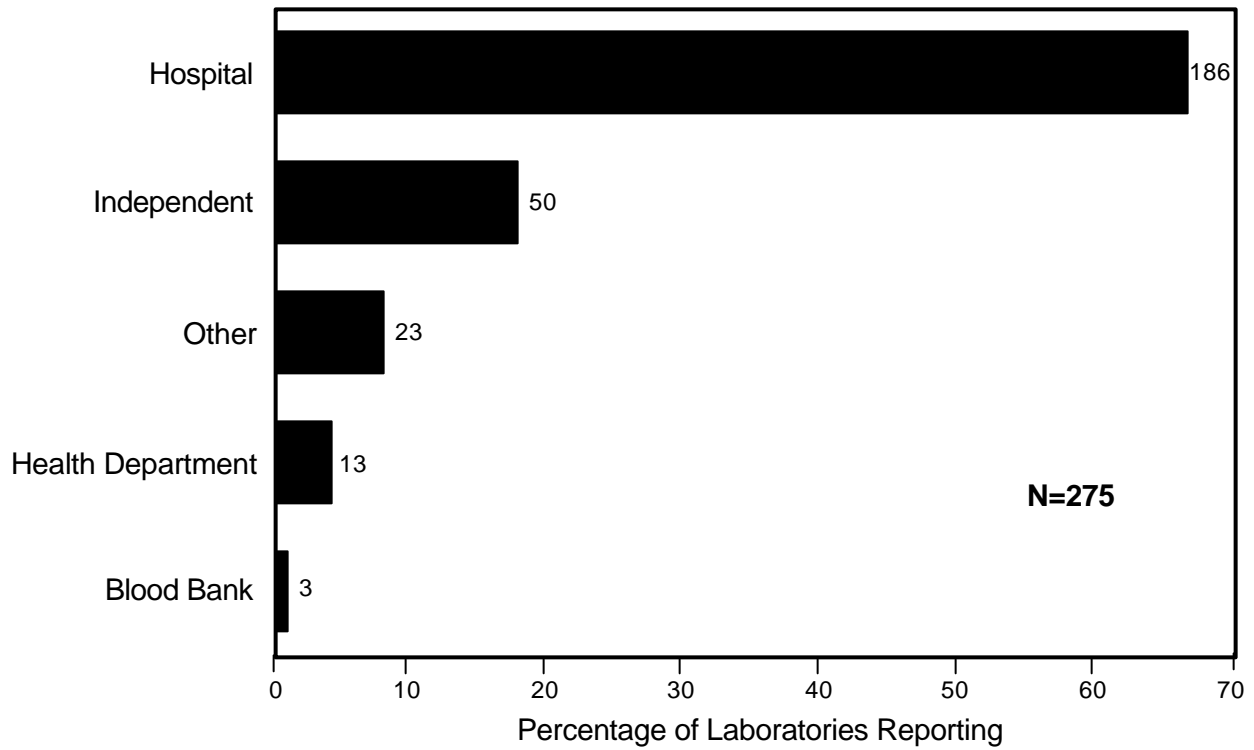


Figure 2. Methods used to prepare specimens for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the October 2000 shipment.

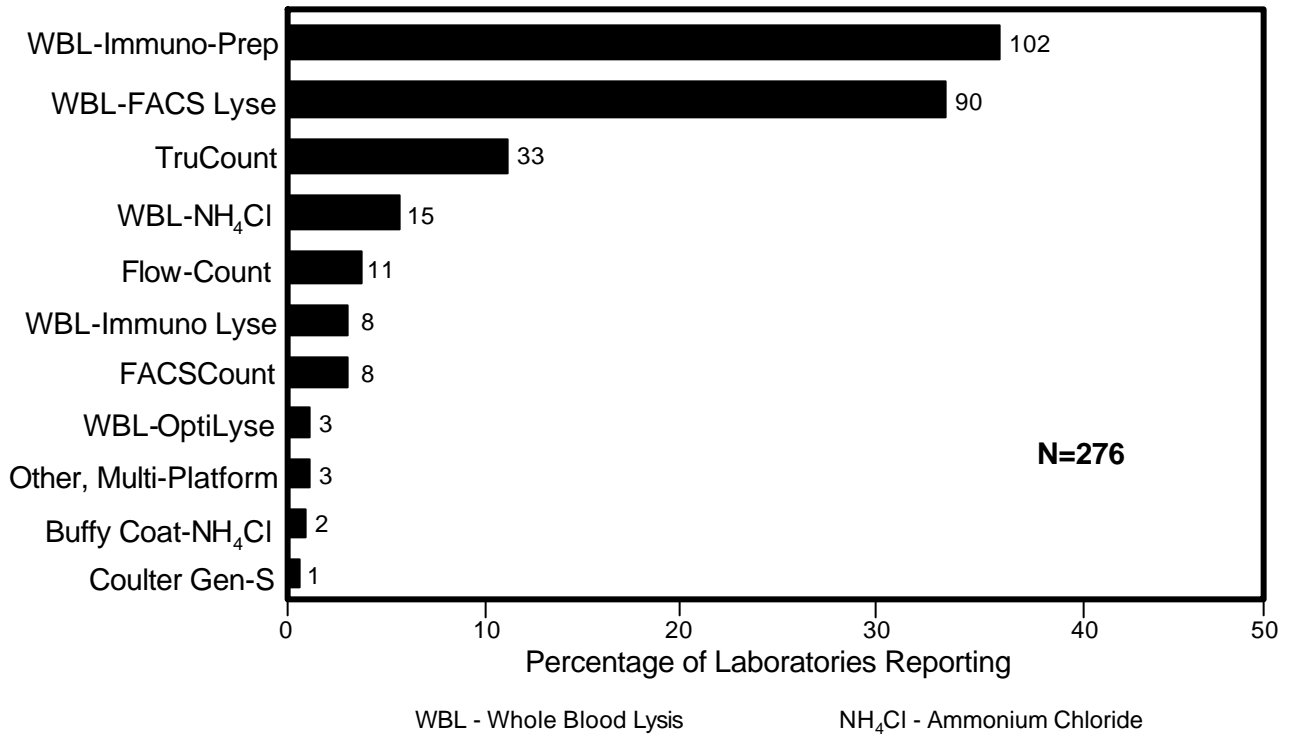


Figure 3. Methods used to fix specimens for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the October 2000 shipment.

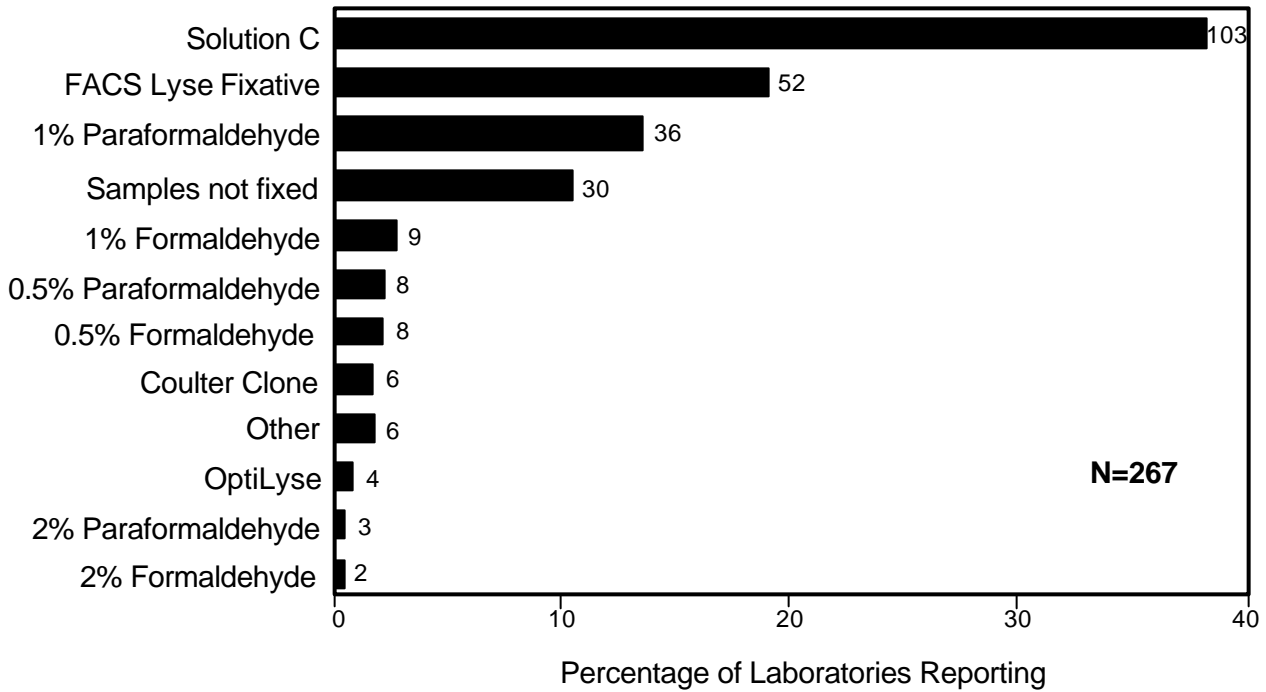


Figure 4. Types of flow cytometers used for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the October 2000 shipment.

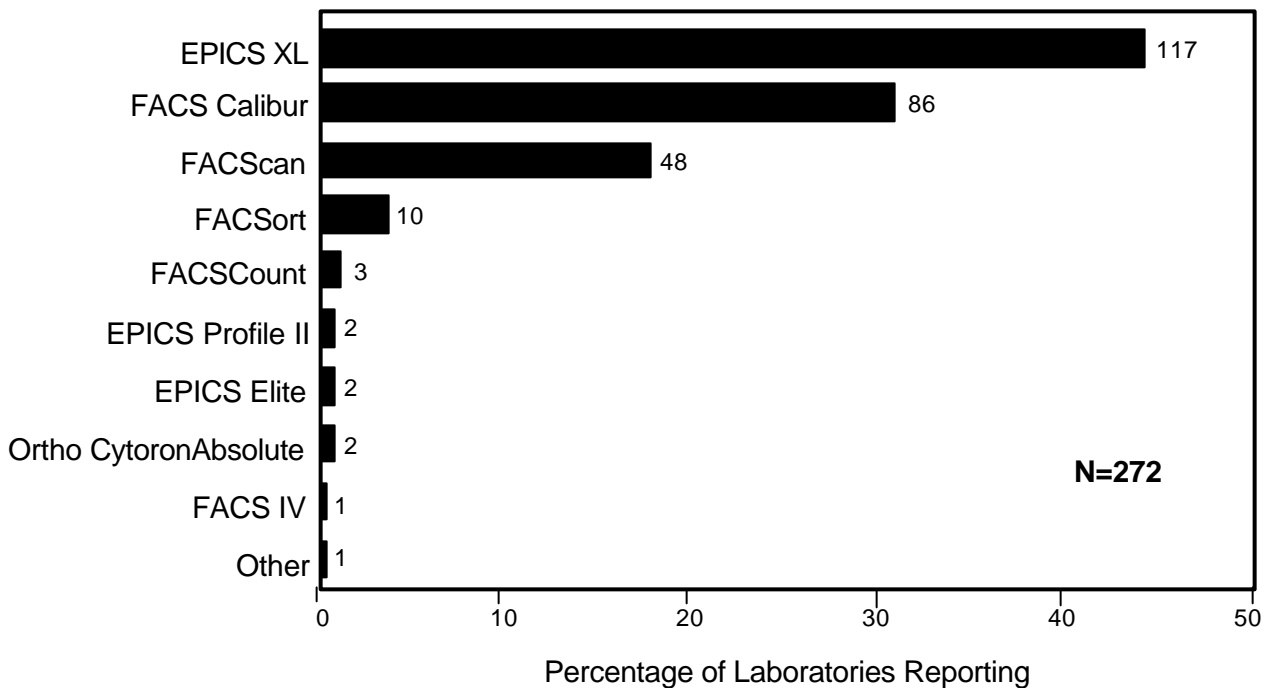
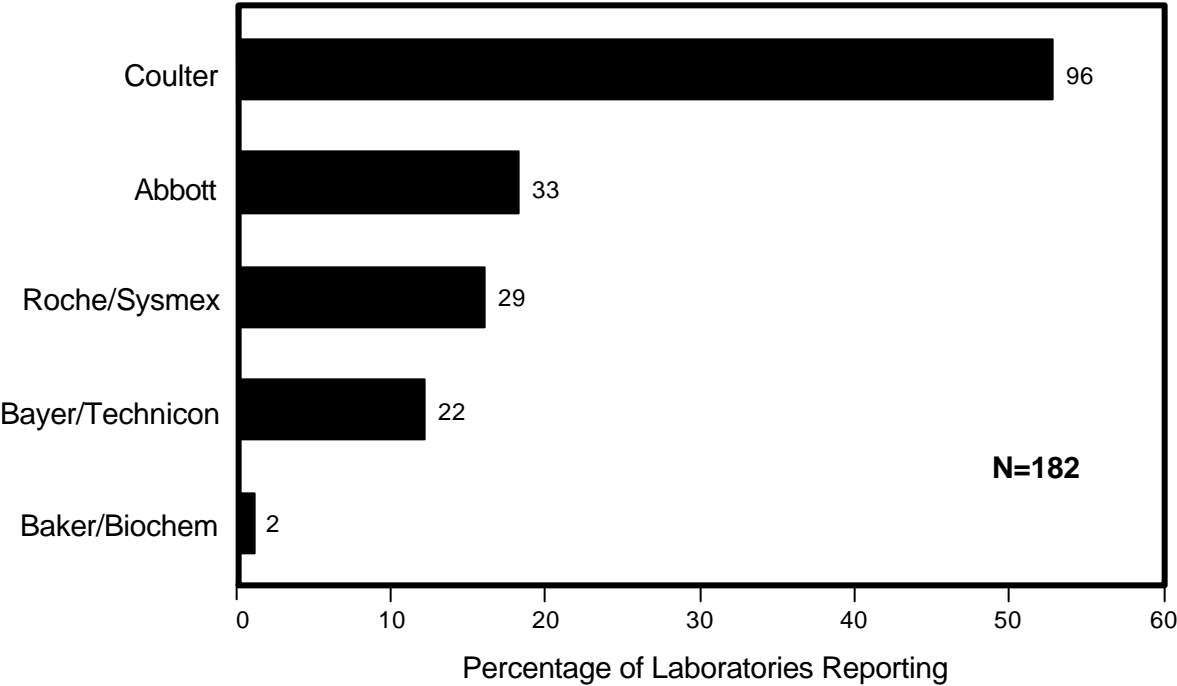


Figure 5. Types of hematology instruments used for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the October 2000 shipment.



## Explanation of Results Table

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

<b>Cell Marker</b>	<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>
<b>Percentage Results</b>	<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). <b>Note:</b> 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>
<b>Absolute Counts</b>	<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>
<b>Hematology Results</b>	<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 2000 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	2		
CD14	> 2	1		
	0 - 2	37		
	< 0	0		
CD4	> 53	4	> 1,163	6
	45 - 53	124	726 - 1,163	96
	< 45	3	< 726	3
CD8	> 29	4	> 638	7
	23 - 29	123	370 - 638	95
	< 23	4	< 370	2
CD19	> 17	2		
	12 - 17	97		
	< 12	8		
CD56+16	> 8	1		
	4 - 8	65		
	< 4	3		
CD3 Average	> 83	3		
	75 - 83	111		
	< 75	3		
CD56	1 - 7	33		
CD16	4 - 6	4		

### Hematology Results

Hematology Parameter	Range	No.
WBC	> 7,620	1
	6,497 - 7,620	77
	< 6,497	3
% Lymphs	> 33	5
	22 - 33	74
	< 22	2
Absolute Lymphs	> 2,328	4
	1,523 - 2,328	75
	< 1,523	2

## Donor Number 2 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	96 - 100	42		
	< 96	2		
CD14	> 2	2		
	0 - 2	40		
	< 0	0		
CD4	> 39	4	> 950	7
	34 - 39	119	630 - 950	92
	< 34	3	< 630	3
CD8	> 56	5	> 1,323	5
	46 - 56	117	884 - 1,323	93
	< 46	4	< 884	4
CD19	> 11	2		
	6 - 11	99		
	< 6	5		
CD56+16	> 10	4		
	5 - 10	68		
	< 5	4		
CD3 Average	> 86	5		
	80 - 86	110		
	< 80	1		
CD56	3 - 9	22		
CD16	6 - 8	4		

### Hematology Results

Hematology Parameter	Range	No.
WBC	> 7,524	0
	5,947 - 7,524	71
	< 5,947	5
% Lymphs	> 38	7
	27 - 38	67
	< 27	2
Absolute Lymphs	> 2,706	7
	1,732 - 2,706	66
	< 1,732	3



## Participant Laboratory Results for the October 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	40		
	< 92	0		
CD14	> 2	1		
	0 - 2	38		
	< 0	0		
CD4	> 53	4	> 1,435	11
	46 - 53	123	685 - 1,435	92
	< 46	3	< 685	1
CD8	> 21	5	> 573	9
	16 - 21	120	237 - 573	94
	< 16	5	< 237	0
CD19	> 21	2		
	15 - 21	101		
	< 15	3		
CD56+16	> 14	3		
	5 - 14	64		
	< 5	2		
CD3 Average	> 75	4		
	67 - 75	109		
	< 67	4		
CD56	1 - 10	33		
CD16	6 - 10	4		

#### Hematology Results

Hematology Parameter	Range	No.
WBC	> 8,249	3
	6,939 - 8,249	74
	< 6,939	4
% Lymphs	> 37	8
	20 - 37	72
	< 20	1
Absolute Lymphs	> 2,879	8
	1,494 - 2,879	72
	< 1,494	1

### Donor Number 4 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	91 - 100	39		
	< 91	1		
CD14	> 1	2		
	0 - 1	37		
	< 0	0		
CD4	> 3	1	> 34	8
	0 - 3	130	2 - 34	96
	< 0	0	< 2	1
CD8	> 88	2	> 1,132	3
	74 - 88	124	574 - 1,132	96
	< 74	5	< 574	5
CD19	> 6	1		
	1 - 6	105		
	< 1	1		
CD56+16	> 8	3		
	4 - 8	66		
	< 4	0		
CD3 Average	> 93	1		
	83 - 93	112		
	< 83	4		
CD56	1 - 7	33		
CD16	4 - 6	4		

#### Hematology Results

Hematology Parameter	Range	No.
WBC	> 2,616	1
	1,765 - 2,616	76
	< 1,765	4
% Lymphs	> 62	3
	37 - 62	75
	< 37	3
Absolute Lymphs	> 1,372	2
	792 - 1,372	75
	< 792	4

# Participant Laboratory Results for the October 2000 Shipment

## Donor Number 5 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	94 - 100	34		
	< 94	2		
CD14	> 1	1		
	0 - 1	35		
	< 0	0		
CD4	> 42	2	> 1,395	1
	33 - 42	125	755 - 1,395	101
	< 33	9	< 755	6
CD8	> 56	5	> 1,732	5
	44 - 56	130	1,174 - 1,732	98
	< 44	1	< 1,174	3
CD19	> 8	1		
	3 - 8	103		
	< 3	3		
CD56+16	> 6	2		
	1 - 6	60		
	< 1	0		
CD3 Average	> 94	1		
	87 - 94	114		
	< 87	3		
CD56	1 - 5	44		
CD16	3 - 5	4		

### Hematology Results

Hematology Parameter	Range	No.
WBC	> 7,740	0
	5,827 - 7,740	77
	< 5,827	9
% Lymphs	> 49	1
	39 - 49	83
	< 39	2
Absolute Lymphs	> 3,456	1
	2,397 - 3,456	80
	< 2,397	5

## Donor Number 6 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	95 - 100	44		
	< 95	0		
CD14	> 2	4		
	0 - 2	38		
	< 0	0		
CD4	> 28	3	> 613	2
	22 - 28	136	377 - 613	96
	< 22	1	< 377	4
CD8	> 65	4	> 1,405	3
	55 - 65	130	975 - 1,405	92
	< 55	6	< 975	7
CD19	> 10	1		
	6 - 10	106		
	< 6	2		
CD56+16	> 9	0		
	3 - 9	54		
	< 3	0		
CD3 Average	> 88	3		
	80 - 88	111		
	< 80	4		
CD56	0 - 7	40		
CD16	4 - 9	12		

### Hematology Results

Hematology Parameter	Range	No.
WBC	> 5,136	1
	4,132 - 5,136	74
	< 4,132	7
% Lymphs	> 48	3
	38 - 48	75
	< 38	2
Absolute Lymphs	> 2,281	1
	1,673 - 2,281	76
	< 1,673	3

# Participant Laboratory Results for the October 2000 Shipment

## Donor Number 7 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	93 - 100	50		
	< 93	2		
CD14	> 3	4		
	0 - 3	47		
	< 0	0		
CD4	> 28	4	> 737	3
	17 - 28	132	360 - 737	101
	< 17	3	< 360	3
CD8	> 71	5	> 2,080	4
	58 - 71	128	1,075 - 2,080	97
	< 58	4	< 1,075	4
CD19	> 10	0		
	4 - 10	119		
	< 4	0		
CD56+16	> 5	2		
	1 - 5	93		
	< 1	0		
CD3 Average	> 92	1		
	87 - 92	111		
	< 87	1		
CD56	0 - 4	30		
CD16	2 - 6	6		

### Hematology Results

Hematology Parameter	Range	No.
WBC	> 8,459	1
	4,723 - 8,459	80
	< 4,723	4
% Lymphs	> 46	3
	30 - 46	80
	< 30	2
Absolute Lymphs	> 3,158	5
	1,759 - 3,158	77
	< 1,759	1

## Donor Number 8 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	95 - 100	46		
	< 95	2		
CD14	> 2	4		
	0 - 2	42		
	< 0	0		
CD4	> 61	7	> 2,240	8
	51 - 61	130	1,472 - 2,240	94
	< 51	1	< 1,472	1
CD8	> 26	5	> 1,186	4
	19 - 26	130	370 - 1,186	98
	< 19	2	< 370	0
CD19	> 17	2		
	12 - 17	106		
	< 12	5		
CD56+16	> 7	1		
	3 - 7	71		
	< 3	2		
CD3 Average	> 84	5		
	76 - 84	108		
	< 76	1		
CD56	0 - 10	34		
CD16	4 - 6	9		

### Hematology Results

Hematology Parameter	Range	No.
WBC	> 9,165	0
	7,450 - 9,165	79
	< 7,450	4
% Lymphs	> 46	5
	35 - 46	76
	< 35	1
Absolute Lymphs	> 3,939	4
	2,815 - 3,939	74
	< 2,815	3

## Participant Laboratory Results for the October 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	0		
CD14	> 2	3		
	0 - 2	43		
	< 0	0		
CD4	> 50	3	> 1,271	5
	44 - 50	134	942 - 1,271	97
	< 44	2	< 942	2
CD8	> 34	1	> 855	3
	28 - 34	135	591 - 855	98
	< 28	2	< 591	2
CD19	> 16	2		
	12 - 16	105		
	< 12	7		
CD56+16	> 5	0		
	2 - 5	73		
	< 2	1		
CD3 Average	> 85	4		
	79 - 85	110		
	< 79	1		
CD56	0 - 8	35		
CD16	2 - 4	9		

#### Hematology Results

Hematology Parameter	Range	No.
WBC	> 7,041	2
	5,967 - 7,041	77
	< 5,967	4
% Lymphs	> 41	5
	31 - 41	77
	< 31	0
Absolute Lymphs	> 2,644	3
	2,032 - 2,644	76
	< 2,032	2

### Donor Number 10 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	93 - 100	45		
	< 93	3		
CD14	> 2	3		
	0 - 2	44		
	< 0	0		
CD4	> 8	3	> 82	5
	0 - 8	136	37 - 82	98
	< 0	0	< 37	2
CD8	> 75	3	> 1,482	6
	61 - 75	131	868 - 1,482	97
	< 61	4	< 868	1
CD19	> 17	0		
	7 - 17	113		
	< 7	1		
CD56+16	> 17	0		
	7 - 17	72		
	< 7	3		
CD3 Average	> 82	4		
	70 - 82	110		
	< 70	1		
CD56	1 - 17	34		
CD16	5 - 12	9		

#### Hematology Results

Hematology Parameter	Range	No.
WBC	> 4,936	2
	3,815 - 4,936	78
	< 3,815	4
% Lymphs	> 48	5
	32 - 48	76
	< 32	2
Absolute Lymphs	> 2,177	4
	1,316 - 2,177	77
	< 1,316	1