

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

*Figures and Tables Used for the Analysis of  
Participant Laboratory Results for the  
September 1995 Shipment*

***U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES***

*Public Health Service*

*Centers for Disease Control and Prevention*

*Public Health Practice Program Office*

*Division of Laboratory Systems*

*Atlanta, Georgia 30333*

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

**Centers for Disease Control and Prevention (CDC) - Model Performance Evaluation Program  
for T-Lymphocyte Immunophenotyping (TLI)  
Donor Specimen Identification for September 12, 1995 TLI Shipment Specimens**

<b>Panel Letter</b>	<b>Participant Lab Vial Label</b>	<b>CDC Donor Number</b>	<b>Donor Information (HIV-1<sup>a</sup> status and CD4<sup>+</sup> cell count)</b>
A	A1, A5	01	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\geq$ 500
	A2	08	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\leq$ 200
	A3	12	HIV-1 Antibody-Negative
	A4	13	HIV-1 Antibody-Negative
B	B1	09	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\leq$ 200
	B2	13	HIV-1 Antibody-Negative
	B3, B4	02	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\geq$ 500
	B5	14	HIV-1 Antibody-Negative
C	C1, C2	03	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\geq$ 500
	C3	15	HIV-1 Antibody-Negative
	C4	12	HIV-1 Antibody-Negative
	C5	10	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\leq$ 200
D	D1	12	HIV-1 Antibody-Negative
	D2, D4	04	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\geq$ 500
	D3	08	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\leq$ 200
	D5	13	HIV-1 Antibody-Negative
E	E1	13	HIV-1 Antibody-Negative
	E2	15	HIV-1 Antibody-Negative
	E3	09	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\leq$ 200
	E4, E5	05	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\geq$ 500
F	F1	14	HIV-1 Antibody-Negative
	F2, F3	06	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\geq$ 500
	F4	10	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\leq$ 200
	F5	12	HIV-1 Antibody-Negative
G	G1	14	HIV-1 Antibody-Negative
	G2, G4	07	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\geq$ 500
	G3	15	HIV-1 Antibody-Negative
	G5	11	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\leq$ 200

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

**Centers for Disease Control and Prevention (CDC) - Model Performance Evaluation Program  
for T-Lymphocyte Immunophenotyping (TLI)  
Donor Specimen Identification for September 19, 1995 TLI Shipment Specimens**

<b>Panel Letter</b>	<b>Participant Lab Vial Label</b>	<b>CDC Donor Number</b>	<b>Donor Information (HIV-1<sup>a</sup> status and CD4<sup>+</sup> cell count)</b>
H	H1	24	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count ≤ 200
	H2	29	HIV-1 Antibody-Negative
	H3, H5	17	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count ≥ 500
	H4	28	HIV-1 Antibody-Negative
I	I1, I4	18	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count ≥ 500
	I2	27	HIV-1 Antibody-Negative
	I3	25	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count ≤ 200
	I5	30	HIV-1 Antibody-Negative
J	J1	23	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count > 200 but < 500
	J2	28	HIV-1 Antibody-Negative
	J3, J5	19	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count ≥ 500
	J4	27	HIV-1 Antibody-Negative
K	K1, K5	20	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count ≥ 500
	K2	24	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count ≤ 200
	K3	29	HIV-1 Antibody-Negative
	K4	28	HIV-1 Antibody-Negative
L	L1	25	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count ≤ 200
	L2, L5	21	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count ≥ 500
	L3	27	HIV-1 Antibody-Negative
	L4	30	HIV-1 Antibody-Negative
M	M1	23	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count > 200 but < 500
	M2	27	HIV-1 Antibody-Negative
	M3, M5	16	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count ≥ 500
	M4	28	HIV-1 Antibody-Negative
N	N1, N4	22	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count ≥ 500
	N2	26	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count > 200 but < 500
	N3	29	HIV-1 Antibody-Negative
	N5	30	HIV-1 Antibody-Negative

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

**Centers for Disease Control and Prevention (CDC) - Model Performance Evaluation Program  
for T-Lymphocyte Immunophenotyping (TLI)  
Donor Specimen Identification for September 26, 1995 TLI Shipment Specimens**

<b>Panel Letter</b>	<b>Participant Lab Vial Label</b>	<b>CDC Donor Number</b>	<b>Donor Information (HIV-1<sup>a</sup> status and CD4<sup>+</sup> cell count)</b>
O	O1	44	HIV-1 Antibody-Negative
	O2, O3	33	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\geq$ 500
	O4	42	HIV-1 Antibody-Negative
	O5	40	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\leq$ 200
P	P1, P3	34	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\geq$ 500
	P2	43	HIV-1 Antibody-Negative
	P4	38	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\leq$ 200
	P5	42	HIV-1 Antibody-Negative
Q	Q1	39	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\leq$ 200
	Q2, Q4	35	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\geq$ 500
	Q3	45	HIV-1 Antibody-Negative
	Q5	43	HIV-1 Antibody-Negative
R	R1, R5	36	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\geq$ 500
	R2	40	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\leq$ 200
	R3	42	HIV-1 Antibody-Negative
	R4	45	HIV-1 Antibody-Negative
S	S1, S5	31	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\geq$ 500
	S2	42	HIV-1 Antibody-Negative
	S3	43	HIV-1 Antibody-Negative
	S4	38	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\leq$ 200
T	T1	43	HIV-1 Antibody-Negative
	T2	39	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\leq$ 200
	T3, T4	32	HIV-1 Antibody-Positive, CD4 <sup>+</sup> count $\geq$ 500
	T5	44	HIV-1 Antibody-Negative

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

Figure 1. Methods used to prepare specimens for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the September 1995 shipment.

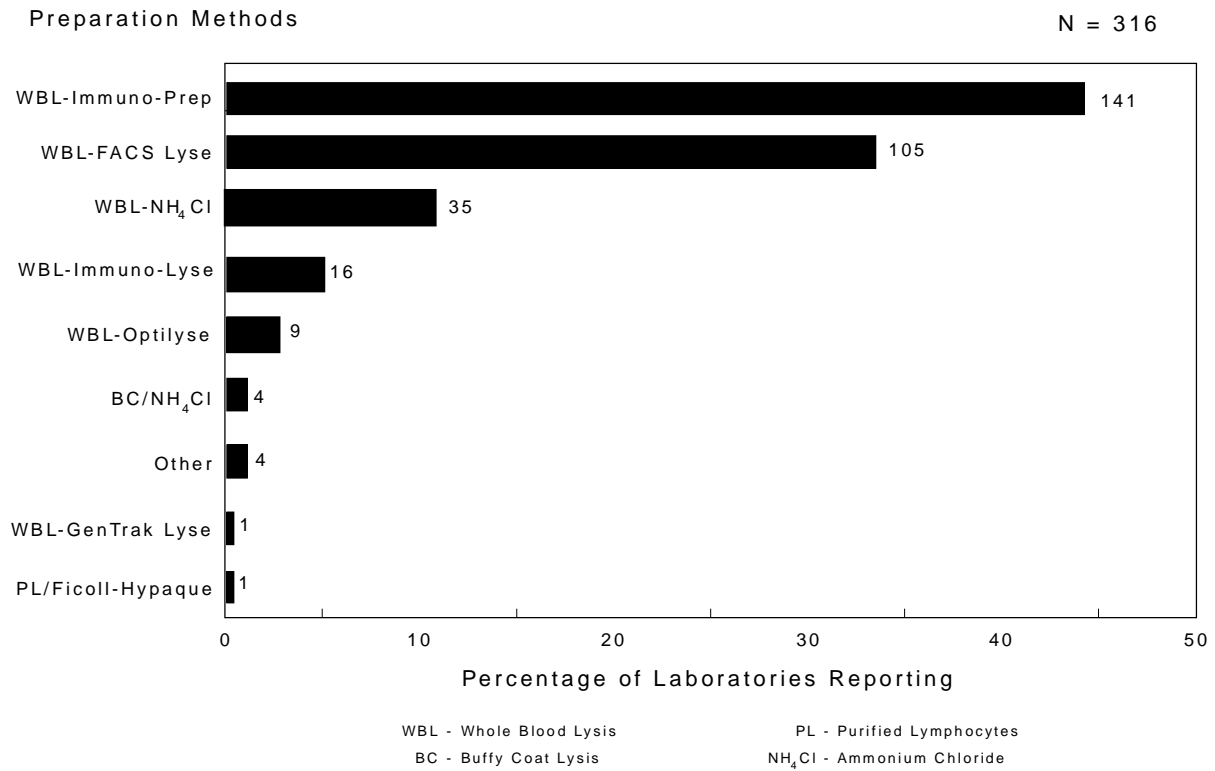


Figure 2. Methods used to fix specimens for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the September 1995 shipment.

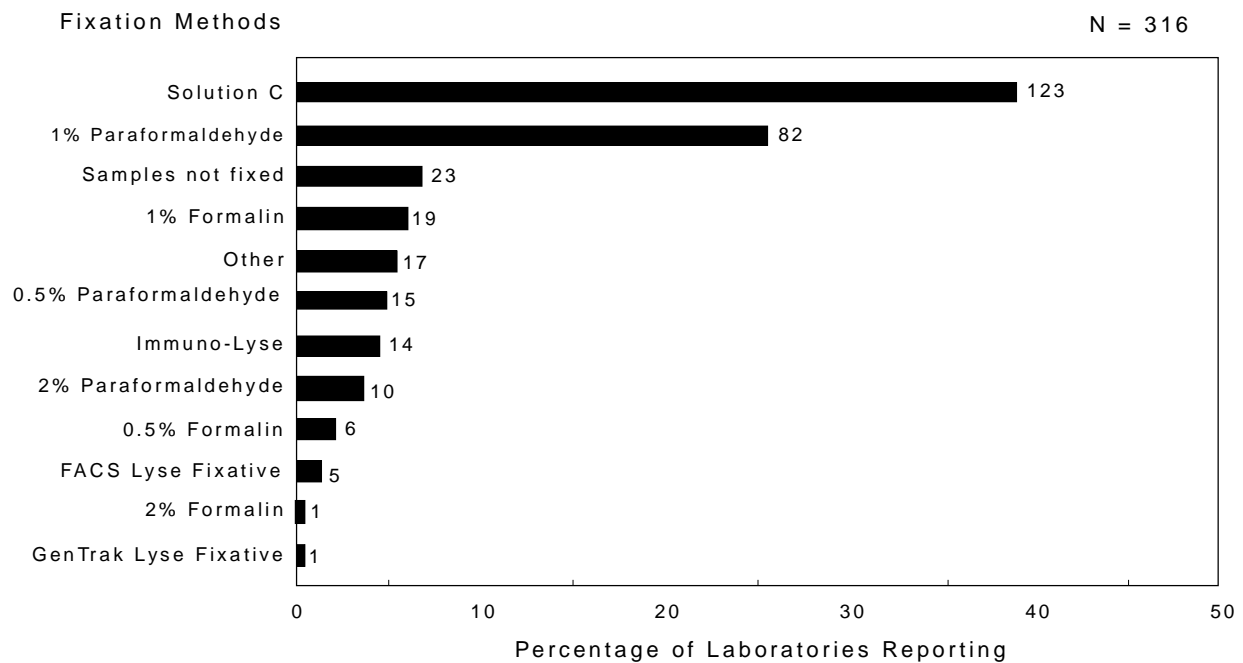


Table 1. Frequency of 2-color laboratory results for the September 1995 shipment, by cell marker, within, above, or below the 90% reference ranges\*

Cell Marker (Population)	CDC Donor Number - HIV Status **											
	1 - H		2 - H		3 - H		4 - H		5 - H		6 - H	
	Range	No. <sup>a</sup>	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+	> 99	3	> 100	0	> 100	1	> 100	0	> 99	1	> 100	0
	93 - 99	27	95 - 100	22	82 - 100	27	88 - 100	27	93 - 99	24	95 - 100	24
	< 93	0	< 95	2	< 82	0	< 88	1	< 93	3	< 95	0
CD14+	> 1	2	> 1	0	> 3	0	> 0	1	> 1	2	> 5	2
	0 - 1	26	0 - 1	24	0 - 3	28	0 - 0	26	0 - 1	24	0 - 5	22
	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0
CD3+CD4+	> 46	0	> 40	1	> 46	0	> 30	1	> 51	5	> 39	0
	40 - 46	23	36 - 40	23	39 - 46	24	23 - 30	22	46 - 51	19	30 - 39	24
	< 40	1	< 36	0	< 39	2	< 23	1	< 46	2	< 30	0
CD3+CD8+	> 51	0	> 43	1	> 39	2	> 65	0	> 32	1	> 57	0
	45 - 51	23	36 - 43	21	29 - 39	23	54 - 65	23	24 - 32	24	51 - 57	20
	< 45	3	< 36	2	< 29	1	< 54	1	< 24	1	< 51	4
CD3-CD19+	> 6	0	> 10	0	> 12	0	> 5	0	> 14	0	> 5	0
	4 - 6	20	8 - 10	14	7 - 12	18	1 - 5	20	9 - 14	16	1 - 5	16
	< 4	0	< 8	0	< 7	0	< 1	0	< 9	0	< 1	0
CD3-(CD56 & CD16)+	> 6	0	> 9	0	> 13	0	> 7	0	> 9	0	> 16	0
	3 - 6	12	2 - 9	16	5 - 13	14	2 - 7	20	7 - 9	10	10 - 16	10
	< 3	0	< 2	0	< 5	0	< 2	0	< 7	2	< 10	2
CD3+ Average	> 92	0	> 85	0	> 82	0	> 94	0	> 81	2	> 89	0
	87 - 92	24	81 - 85	14	72 - 82	27	86 - 94	24	75 - 81	22	78 - 89	22
	< 87	2	< 81	0	< 72	1	< 86	0	< 75	2	< 78	0

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500)

<sup>a</sup>No. = frequency of laboratories

Table 1. Frequency of 2-color laboratory results for the September 1995 shipment, by cell marker, within, above, or below the 90% reference ranges\*

Cell Marker (Population)	CDC Donor Number - HIV Status **											
	7 - H		8 - L		9 - L		10 - L		11 - L		12 - N	
	Range	No. <sup>A</sup>	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+	> 100	0	> 99	1	> 100	0	> 100	1	> 100	0	> 100	1
	87 - 100	23	83 - 99	23	92 - 100	26	80 - 100	25	97 - 100	12	94 - 100	53
	< 87	1	< 83	0	< 92	0	< 80	0	< 97	0	< 94	1
CD14+	> 1	0	> 1	1	> 1	0	> 4	1	> 1	0	> 1	1
	0 - 1	24	0 - 1	22	0 - 1	25	0 - 4	25	0 - 1	12	0 - 1	53
	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0
CD3+CD4+	> 39	0	> 3	0	> 3	0	> 17	1	> 13	0	> 56	1
	31 - 39	21	1 - 3	20	1 - 3	25	10 - 17	24	9 - 13	11	48 - 56	47
	< 31	1	< 1	0	< 1	0	< 10	0	< 9	0	< 48	1
CD3+CD8+	> 50	0	> 50	1	> 58	1	> 50	0	> 50	0	> 27	0
	39 - 50	21	30 - 50	20	49 - 58	21	33 - 50	25	40 - 50	11	21 - 27	49
	< 39	1	< 30	0	< 49	3	< 33	0	< 40	0	< 21	1
CD3-CD19+	> 12	0	> 35	4	> 34	0	> 11	0	> 23	0	> 13	1
	5 - 12	20	24 - 35	9	27 - 34	15	6 - 11	17	17 - 23	9	7 - 13	35
	< 5	0	< 24	4	< 27	0	< 6	0	< 17	1	< 7	1
CD3-(CD56 & CD16)+	> 9	0	> 23	0	> 14	0	> 35	0	> 20	0	> 16	1
	3 - 9	16	13 - 23	13	7 - 14	14	24 - 35	11	11 - 20	8	9 - 16	25
	< 3	0	< 13	0	< 7	0	< 24	2	< 11	0	< 9	3
CD3+ Average	> 91	0	> 60	1	> 65	0	> 63	0	> 64	0	> 78	1
	77 - 91	22	41 - 60	17	56 - 65	18	49 - 63	25	61 - 64	9	72 - 78	47
	< 77	0	< 41	3	< 56	2	< 49	0	< 61	2	< 72	2

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500)

<sup>A</sup>No. = frequency of laboratories

Table 1. Frequency of 2-color laboratory results for the September 1995 shipment, by cell marker, within, above, or below the 90% reference ranges\*

Cell Marker (Population)	CDC Donor Number - HIV Status **											
	13 - N		14 - N		15 - N		16 - H		17 - H		18 - H	
	Range	No. <sup>^</sup>	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+	> 100	0	> 100	0	> 99	5	> 100	0	> 100	0	> 100	0
	92 - 100	53	96 - 100	34	91 - 99	34	91 - 100	26	94 - 100	32	93 - 100	25
	< 92	2	< 96	2	< 91	1	< 91	2	< 94	2	< 93	1
CD14+	> 1	1	> 1	3	> 1	2	> 2	2	> 2	0	> 1	2
	0 - 1	52	0 - 1	33	0 - 1	37	0 - 2	26	0 - 2	30	0 - 1	24
	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0
CD3+CD4+	> 52	2	> 38	2	> 57	0	> 32	0	> 49	2	> 30	2
	47 - 52	46	33 - 38	32	49 - 57	33	24 - 32	26	39 - 49	20	25 - 30	21
	< 47	1	< 33	2	< 49	4	< 24	0	< 39	2	< 25	1
CD3+CD8+	> 26	2	> 29	1	> 33	1	> 63	2	> 31	0	> 67	1
	21 - 26	46	23 - 29	32	27 - 33	34	54 - 63	25	26 - 31	23	57 - 67	21
	< 21	2	< 23	3	< 27	2	< 54	3	< 26	1	< 57	2
CD3-CD19+	> 19	0	> 20	1	> 6	1	> 8	0	> 19	0	> 3	2
	12 - 19	35	12 - 20	23	4 - 6	25	2 - 8	20	11 - 19	24	1 - 3	22
	< 12	0	< 12	1	< 4	1	< 2	0	< 11	0	< 1	0
CD3-(CD56 & CD16)+	> 9	0	> 17	0	> 10	0	> 15	0	> 8	0	> 4	0
	6 - 9	29	9 - 17	22	2 - 10	21	9 - 15	17	4 - 8	14	2 - 4	18
	< 6	1	< 9	1	< 2	0	< 9	1	< 4	0	< 2	0
CD3+ Average	> 78	2	> 75	1	> 89	1	> 87	0	> 80	2	> 96	0
	73 - 78	41	66 - 75	27	81 - 89	34	79 - 87	28	67 - 80	18	85 - 96	21
	< 73	2	< 66	3	< 81	3	< 79	0	< 67	0	< 85	1

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500)

<sup>^</sup>No. = frequency of laboratories



Table 1. Frequency of 2-color laboratory results for the September 1995 shipment, by cell marker, within, above, or below the 90% reference ranges\*

Cell Marker (Population)	CDC Donor Number - HIV Status **											
	19 - H		20 - H		21 - H		22 - H		23 - M		24 - L	
	Range	No. <sup>a</sup>	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+	> 100	1	> 100	0	> 97	13	> 100	0	> 100	1	> 100	0
	94 - 100	27	80 - 100	30	94 - 97	6	96 - 100	36	93 - 100	26	91 - 100	31
	< 94	0	< 80	0	< 94	0	< 96	0	< 93	1	< 91	1
CD14+	> 2	0	> 20	0	> 2	0	> 2	1	> 1	1	> 7	0
	0 - 2	28	0 - 20	30	0 - 2	19	0 - 2	33	0 - 1	27	0 - 7	30
	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0
CD3+CD4+	> 42	0	> 43	2	> 36	0	> 25	1	> 20	2	> 12	1
	38 - 42	25	35 - 43	21	33 - 36	14	18 - 25	35	16 - 20	23	8 - 12	23
	< 38	1	< 35	3	< 33	1	< 18	0	< 16	1	< 8	1
CD3+CD8+	> 48	1	> 43	0	> 44	0	> 74	1	> 51	2	> 73	0
	39 - 48	25	31 - 43	25	41 - 44	8	61 - 74	34	39 - 51	24	63 - 73	24
	< 39	0	< 31	1	< 41	7	< 61	1	< 39	2	< 63	1
CD3-CD19+	> 10	1	> 12	0	> 16	0	> 9	0	> 13	0	> 10	0
	6 - 10	15	9 - 12	20	13 - 16	10	4 - 9	27	7 - 13	18	7 - 10	21
	< 6	0	< 9	2	< 13	0	< 4	1	< 7	0	< 7	2
CD3-(CD56 & CD16)+	> 5	1	> 6	2	> 6	0	> 3	0	> 21	0	> 9	0
	2 - 5	17	2 - 6	12	3 - 6	8	1 - 3	19	16 - 21	17	2 - 9	14
	< 2	0	< 2	0	< 3	0	< 1	1	< 16	1	< 2	0
CD3+ Average	> 87	0	> 88	0	> 82	2	> 95	1	> 73	1	> 92	0
	79 - 87	23	79 - 88	24	80 - 82	7	88 - 95	27	61 - 73	25	81 - 92	21
	< 79	1	< 79	2	< 80	8	< 88	1	< 61	0	< 81	2

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500)

<sup>a</sup>No. = frequency of laboratories

Table 1. Frequency of 2-color laboratory results for the September 1995 shipment, by cell marker, within, above, or below the 90% reference ranges\*

Cell Marker (Population)	CDC Donor Number - HIV Status **											
	25 - L		26 - M		27 - N		28 - N		29 - N		30 - N	
	Range	No. <sup>^</sup>	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+	> 100	0	> 100	0	> 100	1	> 100	1	> 100	0	> 100	0
	77 - 100	23	92 - 100	18	94 - 100	48	96 - 100	55	95 - 100	48	93 - 100	39
	< 77	0	< 92	0	< 94	2	< 96	4	< 95	2	< 93	1
CD14+	> 1	1	> 2	0	> 1	4	> 2	1	> 3	1	> 2	1
	0 - 1	22	0 - 2	17	0 - 1	47	0 - 2	57	0 - 3	46	0 - 2	38
	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0
CD3+CD4+	> 16	0	> 22	0	> 48	3	> 53	1	> 46	3	> 69	0
	14 - 16	19	18 - 22	18	35 - 48	42	42 - 53	47	41 - 46	35	63 - 69	37
	< 14	1	< 18	0	< 35	1	< 42	3	< 41	5	< 63	0
CD3+CD8+	> 64	0	> 52	1	> 27	3	> 24	4	> 22	2	> 21	1
	49 - 64	20	45 - 52	17	19 - 27	43	16 - 24	46	15 - 22	39	18 - 21	33
	< 49	0	< 45	0	< 19	2	< 16	3	< 15	2	< 18	3
CD3-CD19+	> 11	0	> 19	0	> 23	2	> 16	2	> 18	0	> 9	1
	7 - 11	17	12 - 19	13	16 - 23	29	11 - 16	38	13 - 18	37	6 - 9	30
	< 7	0	< 12	1	< 16	4	< 11	1	< 13	0	< 6	0
CD3-(CD56 & CD16)+	> 12	0	> 11	0	> 13	0	> 14	2	> 16	1	> 8	0
	7 - 12	13	8 - 11	9	9 - 13	29	10 - 14	27	12 - 16	23	4 - 8	23
	< 7	0	< 8	1	< 9	2	< 10	3	< 12	0	< 4	0
CD3+ Average	> 89	0	> 76	0	> 72	3	> 76	2	> 71	0	> 89	1
	75 - 89	20	69 - 76	14	63 - 72	41	68 - 76	45	65 - 71	37	84 - 89	31
	< 75	0	< 69	1	< 63	2	< 68	2	< 65	1	< 84	2

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500)

<sup>^</sup>No. = frequency of laboratories

Table 1. Frequency of 2-color laboratory results for the September 1995 shipment, by cell marker, within, above, or below the 90% reference ranges\*

Cell Marker (Population)	CDC Donor Number - HIV Status **											
	31 - H		32 - H		33 - H		34 - H		35 - H		36 - H	
	Range	No. <sup>Δ</sup>	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+	> 100	0	> 99	0	> 100	0	> 100	0	> 100	0	> 100	0
	95 - 100	26	86 - 99	29	94 - 100	33	95 - 100	30	94 - 100	33	94 - 100	26
	< 95	4	< 86	1	< 94	0	< 95	2	< 94	1	< 94	2
CD14+	> 2	1	> 4	0	> 1	0	> 2	0	> 2	1	> 1	2
	0 - 2	29	0 - 4	30	0 - 1	33	0 - 2	32	0 - 2	33	0 - 1	24
	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0
CD3+CD4+	> 24	0	> 39	1	> 30	2	> 41	0	> 50	0	> 22	3
	19 - 24	24	31 - 39	30	23 - 30	28	32 - 41	30	40 - 50	28	18 - 22	25
	< 19	0	< 31	1	< 23	1	< 32	0	< 40	2	< 18	0
CD3+CD8+	> 63	1	> 47	0	> 63	1	> 46	0	> 33	1	> 74	0
	51 - 63	23	39 - 47	31	52 - 63	26	33 - 46	30	23 - 33	29	67 - 74	25
	< 51	0	< 39	1	< 52	4	< 33	0	< 23	0	< 67	3
CD3-CD19+	> 9	0	> 17	0	> 10	0	> 16	0	> 14	0	> 6	0
	6 - 9	20	11 - 17	24	5 - 10	27	8 - 16	20	10 - 14	24	3 - 6	20
	< 6	0	< 11	0	< 5	0	< 8	0	< 10	2	< 3	0
CD3-(CD56 & CD16)+	> 4	0	> 6	0	> 6	1	> 9	0	> 9	0	> 7	0
	1 - 4	9	4 - 6	12	1 - 6	25	2 - 9	12	7 - 9	14	5 - 7	14
	< 1	1	< 4	2	< 1	0	< 2	0	< 7	0	< 5	0
CD3+ Average	> 89	1	> 83	0	> 90	1	> 81	2	> 81	3	> 90	0
	79 - 89	23	72 - 83	24	84 - 90	26	69 - 81	26	72 - 81	30	87 - 90	21
	< 79	0	< 72	0	< 84	2	< 69	0	< 72	1	< 87	3

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500)

<sup>Δ</sup>No. = frequency of laboratories

Table 1. Frequency of 2-color laboratory results for the September 1995 shipment, by cell marker, within, above, or below the 90% reference ranges\*

CDC Donor Number -

Cell Marker (Population)	38 - L		39 - L		40 - L		42 - N		43 - N		44 - N		45 - N	
	Range	No. <sup>^</sup>	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+	> 100 92 - 100 < 92	0 27 3	> 100 80 - 100 < 80	0 32 0	> 100 90 - 100 < 90	0 29 1	> 100 94 - 100 < 94	0 58 4	> 100 93 - 100 < 93	0 58 5	> 100 88 - 100 < 88	0 30 1	> 100 92 - 100 < 92	0 30 1
CD14+	> 2 0 - 2 < 0	0 30 0	> 5 0 - 5 < 0	0 32 0	> 2 0 - 2 < 0	1 28 0	> 3 0 - 3 < 0	2 59 0	> 1 0 - 1 < 0	1 62 0	> 2 0 - 2 < 0	1 30 0	> 1 0 - 1 < 0	1 29 0
CD3+CD4+	> 2 0 - 2 < 0	0 27 0	> 2 0 - 2 < 0	1 30 0	> 8 5 - 8 < 5	1 28 1	> 29 17 - 29 < 17	2 52 4	> 47 39 - 47 < 39	1 56 1	> 52 46 - 52 < 46	1 28 2	> 66 55 - 66 < 55	2 27 0
CD3+CD8+	> 48 36 - 48 < 36	0 24 3	> 60 54 - 60 < 54	1 28 2	> 81 69 - 81 < 69	0 27 3	> 53 35 - 53 < 35	4 49 5	> 28 22 - 28 < 22	1 54 3	> 11 8 - 11 < 8	2 28 1	> 27 17 - 27 < 17	0 29 0
CD3-CD19+	> 25 15 - 25 < 15	2 16 2	> 30 16 - 30 < 16	0 24 1	> 12 5 - 12 < 5	1 22 1	> 12 5 - 12 < 5	0 43 2	> 19 13 - 19 < 13	0 44 1	> 30 22 - 30 < 22	2 21 2	> 13 7 - 13 < 7	0 23 0
CD3-(CD56 & CD16)+	> 21 13 - 21 < 13	4 4 3	> 12 8 - 12 < 8	0 13 1	> 7 1 - 7 < 1	0 20 0	> 20 9 - 20 < 9	1 26 5	> 11 8 - 11 < 8	1 24 0	> 14 8 - 14 < 8	0 19 1	> 6 3 - 6 < 3	0 14 0
CD3+	> 60 46 - 60 < 46	1 23 2	> 65 54 - 65 < 54	3 26 0	> 91 80 - 91 < 80	0 27 0	> 80 69 - 80 < 69	3 47 4	> 74 66 - 74 < 66	4 48 3	> 64 55 - 64 < 55	0 25 1	> 86 75 - 86 < 75	3 26 0
Average														

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500)

<sup>^</sup>No. = frequency of laboratories

Table 2. Range of all participant laboratory results for the March 1994 shipment for CD16 and CD56 cell markers. Insufficient data were reported by laboratories using the recommended monoclonal antibody panel to enable determination of 90% reference ranges. The ranges reported in this table are the maximum and minimum values

Donor Number	HIV * Status	CD3-/CD16+ Range			CD3-/CD56+ Range		
01	H	0	-	0	6	-	11
02	H		NA		4	-	4
03	H	2	-	3	0	-	1
04	H	1	-	2	3	-	5
05	H	7	-	9	2	-	6
06	H	8	-	12	4	-	6
07	L	0	-	5	8	-	11
08	M	5	-	5	2	-	6
09	L	10	-	12	3	-	8
10	N	2	-	8	4	-	11
11	N	6	-	9	5	-	9
12	N	9	-	11	7	-	26
13	H		NA		1	-	4
14	H	4	-	5	4	-	4
15	H	3	-	10	1	-	9
16	H		NA		4	-	7
17	H	0	-	7	2	-	7
18	H	2	-	3	1	-	1
19	L		NA		3	-	16
20	L	1	-	6	2	-	15
21	M	1	-	4	1	-	3
22	N	4	-	7	2	-	18
23	N	4	-	11	4	-	12
24	N	3	-	18	2	-	20
25	H		NA			NA	
26	H	7	-	9	5	-	10
27	H		NA		19	-	20
28	H	4	-	8	2	-	8
29	H		NA		1	-	4
30	H		NA		8	-	14
31	L	2	-	10	1	-	7
32	M	4	-	4	1	-	6
33	M		NA		7	-	14
34	N	5	-	10	2	-	10
35	N	5	-	6	2	-	9
36	N	20	-	21	15	-	25

Table 3. Percentage of 2-color laboratory results for the September 1995 shipment, by monoclonal antibody manufacturer, that are within the 90% reference ranges\*

Becton-Dickinson (N=125)\*\*

Cell Marker (Population)	CDC Donor Number																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
HIV Status***	H	H	H	H	H	H	H	L	L	L	L	N	N	N	N	H	H	H
CD45+	88	83	93	93	75	100	100	91	100	92	100	93	92	89	88	100	100	100
CD14+	100	100	100	92	100	100	100	100	100	100	100	100	100	100	94	100	100	100
CD3+CD4+	93	100	100	93	75	100	100	100	100	100	100	100	96	89	100	100	63	94
CD3+CD8+	93	75	86	93	88	83	100	100	80	100	100	96	88	84	88	100	88	94
CD3-CD19+	100	100	100	100	100	100	100	50	100	100	83	96	100	86	88	100	100	100
CD3-(CD56 & CD16)+	100	100	100	100	100	75	100	100	100	82	100	83	100	94	100	100	100	100
CD3+ Average	93	100	100	100	88	100	100	100	100	100	100	96	91	88	94	100	100	100

Coulter (N=66)\*\*

Cell Marker (Population)	CDC Donor Number																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
HIV Status***	H	H	H	H	H	H	H	L	L	L	L	N	N	N	N	H	H	H
CD45+	100	100	100	100	90	100	83	100	100	100	100	100	100	100	85	100	100	100
CD14+	67	100	100	100	100	67	100	83	100	88	100	93	92	75	100	100	NA	100
CD3+CD4+	100	75	80	88	70	100	83	100	100	88	100	93	93	88	77	100	50	50
CD3+CD8+	75	100	90	100	90	67	83	86	71	100	100	100	93	88	92	75	100	50
CD3-CD19+	100	NA	100	100	100	NA	100	50	100	100	100	100	100	100	100	100	100	NA
CD3-(CD56 & CD16)+	NA	NA	NA	100	NA	NA	NA	100	NA	NA	NA	100	100	NA	NA	NA	NA	NA
CD3+ Average	88	NA	90	100	100	100	100	67	80	100	100	93	92	60	82	100	0	100

Other Manufacturers (N=100)\*\*\*\*

Cell Marker (Population)	CDC Donor Number																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
HIV Status***	H	H	H	H	H	H	H	L	L	L	L	N	N	N	N	H	H	H
CD45+	83	100	100	100	90	100	100	100	100	100	100	100	100	100	80	80	92	88
CD14+	100	100	100	100	80	100	100	100	100	100	100	100	100	90	90	80	100	75
CD3+CD4+	100	100	100	100	75	100	100	100	100	100	100	86	91	89	86	100	100	83
CD3+CD8+	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100	70	100	83
CD3-CD19+	100	100	NA	100	100	100	100	67	100	100	100	83	100	100	100	100	100	75
CD3-(CD56 & CD16)+	NA	100	NA	100	67	100	100	100	100	100	100	100	88	100	100	83	100	100
CD3+ Average	100	100	100	100	63	100	100	50	86	100	67	89	91	100	89	100	100	83

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\*Laboratories using Becton Dickinson or Coulter monoclonal antibodies exclusively for all tests.

\*\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500)

\*\*\*\*Results from laboratories using monoclonal antibodies from more than one manufacturer or from Dako, Caltag, Gei Immunotech, In-house, Ortho, Pharmingen, or Sigma.

NA = no data returned by any laboratory for specified marker

Table 3. Percentage of 2-color laboratory results for the September 1995 shipment, by monoclonal antibody manufacturer, that are within the 90% reference ranges\*

Becton-Dickinson (N=125)\*\*

Cell Marker (Population)	CDC Donor Number																	
	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
HIV Status***	H	H	H	H	M	L	L	M	N	N	N	N	H	H	H	H	H	H
CD45+	94	100	100	100	93	100	100	100	96	83	94	95	90	90	100	100	92	100
CD14+	100	100	100	94	100	100	100	100	96	100	94	100	90	100	100	100	100	100
CD3+CD4+	94	70	100	94	93	78	100	100	88	96	88	100	100	80	94	100	92	86
CD3+CD8+	94	90	100	94	93	89	100	88	92	83	82	95	90	100	94	100	92	86
CD3-CD19+	93	75	100	100	100	100	100	100	82	88	100	94	100	100	100	100	90	100
CD3-(CD56 & CD16)+	93	100	100	100	92	100	100	100	100	94	100	100	75	100	93	100	100	100
CD3+ Average	94	75	100	93	93	86	100	86	83	90	100	88	90	100	94	100	100	83

Coulter (N=66)\*\*

Cell Marker (Population)	CDC Donor Number																	
	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
HIV Status***	H	H	H	H	M	L	L	M	N	N	N	N	H	H	H	H	H	H
CD45+	100	100	0	100	100	100	100	100	100	100	100	100	100	100	100	100	100	80
CD14+	100	100	100	100	100	100	100	100	88	100	100	100	100	100	100	100	92	75
CD3+CD4+	100	100	100	100	75	100	100	100	100	86	83	100	100	100	60	100	100	90
CD3+CD8+	100	100	0	100	60	100	100	100	89	88	100	83	100	93	60	100	100	90
CD3-CD19+	NA	100	NA	100	100	100	NA	67	100	100	100	100	100	100	100	100	90	100
CD3-(CD56 & CD16)+	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
CD3+ Average	100	100	0	100	100	100	100	100	100	86	100	100	100	100	0	83	83	88

Other Manufacturers (N=100)\*\*\*\*

Cell Marker (Population)	CDC Donor Number																	
	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
HIV Status***	H	H	H	H	M	L	L	M	N	N	N	N	H	H	H	H	H	H
CD45+	100	100	0	100	89	95	100	100	88	97	96	100	81	100	100	86	100	100
CD14+	100	100	100	100	89	100	88	100	88	97	100	93	100	100	100	100	100	100
CD3+CD4+	100	83	75	100	88	100	80	100	92	90	75	100	100	100	100	100	83	100
CD3+CD8+	100	100	50	93	88	100	100	100	85	90	95	83	100	100	80	100	100	100
CD3-CD19+	100	100	100	88	100	87	100	100	80	95	100	100	100	100	100	100	100	100
CD3-(CD56 & CD16)+	100	75	100	88	100	100	100	75	71	71	92	100	100	50	100	100	100	100
CD3+ Average	100	100	13	91	100	92	100	100	93	95	95	92	100	100	92	93	88	100

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\*Laboratories using Becton Dickinson or Coulter monoclonal antibodies exclusively for all tests.

\*\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500);

\*\*\*\*Results from laboratories using monoclonal antibodies from more than one manufacturer or from Dako, Caltag, Gei Immunotech, In-house, Ortho, Pharmingen, or Sigma.

NA = no data returned by any laboratory for specified marker

Table 3. Percentage of 2-color laboratory results for the September 1995 shipment, by monoclonal antibody manufacturer, that are within the 90% reference ranges\*

Becton-Dickinson (N=125)\*\*

Cell Marker (Population)	CDC Donor Number							
	38	39	40	42	43	44	45	
HIV Status***	L	L	L	N	N	N	N	
CD45+	100	100	100	92	90	92	100	
CD14+	100	100	100	96	100	100	100	
CD3+CD4+	100	100	100	100	100	85	100	
CD3+CD8+	100	100	100	88	90	92	100	
CD3-CD19+	67	100	93	95	94	85	100	
CD3-(CD56 & CD16)	20	100	100	89	100	100	100	
CD3+ Average	100	100	100	83	95	92	100	

Coulter (N=66)\*\*

Cell Marker (Population)	CDC Donor Number							
	38	39	40	42	43	44	45	
HIV Status***	L	L	L	N	N	N	N	
CD45+	83	100	88	93	94	100	91	
CD14+	100	100	86	92	100	100	90	
CD3+CD4+	100	100	75	79	89	89	82	
CD3+CD8+	67	85	75	79	95	78	100	
CD3-CD19+	100	100	100	100	100	100	100	
CD3-(CD56 & CD16)	NA	NA	NA	NA	NA	NA	NA	
CD3+ Average	80	82	100	80	75	100	70	

Other Manufacturers (N=100)\*\*\*\*

Cell Marker (Population)	CDC Donor Number							
	38	39	40	42	43	44	45	
HIV Status***	L	L	L	N	N	N	N	
CD45+	86	100	100	96	92	100	100	
CD14+	100	100	100	100	96	90	100	
CD3+CD4+	100	86	100	83	100	100	100	
CD3+CD8+	91	86	86	83	94	100	100	
CD3-CD19+	82	80	86	94	100	71	100	
CD3-(CD56 & CD16)	50	75	100	71	90	88	100	
CD3+ Average	83	86	100	95	95	100	100	

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\*Laboratories using Becton Dickinson or Coulter monoclonal antibodies exclusively for all tests.

\*\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500)

\*\*\*\*Results from laboratories using monoclonal antibodies from more than one manufacturer or from Dako, Caltag, Gei Immunotech, In-house, Ortho, Pharmingen, or Sigma.

NA = no data returned by any laboratory for specified marker



Table 4. Percentage of 2-color laboratory results for the September 1995 shipment, by equipment manufacturer, that are within the 90% reference ranges\*

Becton-Dickinson (N=121)

Cell Marker (Population)	CDC Donor Number																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
HIV Status**	H	H	H	H	H	H	H	L	L	L	L	N	N	N	N	H	H	H
CD45+	100	80	88	90	70	100	100	100	100	89	100	95	95	94	100	100	86	100
CD14+	100	100	100	89	80	100	100	100	100	100	100	100	100	100	87	100	100	100
CD3+CD4+	100	100	100	90	80	100	100	100	100	100	100	100	95	88	93	100	70	100
CD3+CD8+	100	90	75	90	90	100	100	100	90	100	100	100	90	88	93	100	90	93
CD3-CD19+	100	100	100	100	100	100	100	75	100	100	83	100	100	86	85	100	100	100
CD3-(CD56 & CD16)+	100	100	100	100	100	100	100	100	100	100	100	94	100	100	100	100	100	100
CD3+ Average	100	100	100	100	88	100	100	88	100	100	100	100	89	88	93	100	100	100

Coulter (N=151)

Cell Marker (Population)	CDC Donor Number																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
HIV Status**	H	H	H	H	H	H	H	L	L	L	L	N	N	N	N	H	H	H
CD45+	79	100	100	100	94	100	92	93	100	100	100	97	97	94	74	89	100	90
CD14+	83	100	100	100	100	83	100	92	100	93	100	97	96	83	100	89	100	80
CD3+CD4+	90	92	100	93	79	100	90	100	100	93	100	100	96	94	90	100	90	63
CD3+CD8+	75	83	100	100	93	67	90	91	77	100	100	96	92	88	95	85	100	75
CD3-CD19+	100	100	100	100	100	100	100	43	100	100	100	94	100	100	100	100	100	75
CD3-(CD56 & CD16)+	100	100	100	100	67	0	100	100	100	50	100	80	92	86	100	92	100	100
CD3+ Average	83	100	100	100	94	100	100	73	80	100	75	96	96	83	90	100	75	88

Ortho (N=19)

Cell Marker (Population)	CDC Donor Number																	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
HIV Status**	H	H	H	H	H	H	H	L	L	L	L	N	N	N	N	H	H	H
CD45+	100	100	100	NA	100	100	NA	100	100	100	NA	100	100	100	100	100	100	100
CD14+	100	100	100	NA	100	100	NA	100	100	100	NA	100	100	100	100	100	100	100
CD3+CD4+	100	100	0	NA	0	100	NA	100	100	100	NA	50	75	50	50	100	100	100
CD3+CD8+	100	100	50	NA	100	100	NA	100	100	100	NA	100	100	100	50	50	100	100
CD3-CD19+	100	100	NA	NA	100	100	NA	0	100	100	NA	67	100	100	100	NA	100	100
CD3-(CD56 & CD16)+	100	NA	NA	NA	NA	100	NA	100	NA	100	NA	50	100	100	NA	NA	100	NA
CD3+ Average	100	100	50	NA	0	100	NA	100	100	100	NA	50	75	100	50	100	100	100

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500)

NA = no data returned by any laboratory for specified marker

Table 4. Percentage of 2-color laboratory results for the September 1995 shipment, by equipment manufacturer, that are within the 90% reference ranges\*

Becton-Dickinson (N=121)

Cell Marker (Population)	CDC Donor Number																		
	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	
	HIV Status**		H	H	H	H	M	L	L	M	N	N	N	N	H	H	H	H	H
CD45+	94	100	60	100	92	92	100	100	96	84	90	95	100	93	100	86	90	100	0
CD14+	100	100	100	94	100	100	100	100	96	100	95	100	100	100	100	100	100	100	0
CD3+CD4+	94	75	88	94	92	91	91	100	87	91	74	100	100	86	93	100	90	89	
CD3+CD8+	94	92	100	94	92	91	100	88	91	83	79	95	83	100	93	100	90	89	
CD3-CD19+	93	80	100	93	100	89	100	100	80	89	100	94	100	100	100	100	88	100	0
CD3-(CD56 & CD16)+	93	75	100	100	90	100	100	100	100	88	92	100	100	100	92	100	100	100	0
CD3+ Average	94	80	70	86	91	89	100	86	82	90	94	89	100	100	100	100	100	88	

Coulter (N=151)

Cell Marker (Population)	CDC Donor Number																		
	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	
	HIV Status**		H	H	H	H	M	L	L	M	N	N	N	N	H	H	H	H	H
CD45+	100	100	0	100	93	100	100	100	92	97	100	100	80	100	100	100	100	80	
CD14+	100	100	100	100	93	100	90	100	88	97	100	94	95	100	100	100	95	75	
CD3+CD4+	100	83	100	100	83	91	100	100	95	91	95	100	100	100	85	100	100	90	
CD3+CD8+	100	100	0	95	79	100	100	100	86	88	100	82	100	94	85	100	100	90	
CD3-CD19+	100	100	100	100	100	91	100	86	86	95	100	100	100	100	100	100	94	100	0
CD3-(CD56 & CD16)+	100	100	100	90	100	100	100	80	82	75	100	100	83	50	100	100	100	NA	
CD3+ Average	100	100	0	100	100	91	100	100	95	92	100	93	94	100	82	86	85	88	

Ortho (N=19)

Cell Marker (Population)	CDC Donor Number																		
	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	
	HIV Status**		H	H	H	H	M	L	L	M	N	N	N	N	H	H	H	H	H
CD45+	NA	100	NA	NA	100	100	100	NA	100	100	100	100	100	NA	100	100	100	NA	
CD14+	NA	100	NA	NA	100	100	100	NA	100	100	100	100	100	NA	100	100	100	NA	
CD3+CD4+	NA	100	NA	NA	100	100	100	NA	100	100	33	100	100	NA	100	100	50	NA	
CD3+CD8+	NA	100	NA	NA	100	100	100	NA	100	100	100	100	100	NA	50	100	100	NA	
CD3-CD19+	NA	100	NA	NA	NA	100	100	NA	100	100	100	100	100	NA	100	100	100	NA	
CD3-(CD56 & CD16)+	NA	100	NA	NA	NA	100	NA	NA	NA	100	100	NA	100	NA	100	NA	NA	NA	
CD3+ Average	NA	100	NA	NA	100	100	100	NA	100	100	100	100	100	NA	75	100	100	NA	

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500)

NA = no data returned by any laboratory for specified marker

Table 4. Percentage of 2-color laboratory results for the September 1995 shipment, by equipment manufacturer, that are within the 90% reference ranges\*

Becton-Dickinson (N=121)

Cell Marker (Population)	CDC Donor Number							
	38				45			
	L		L		N		N	
CD45+	90	100	100	92	91	93	100	
CD14+	100	100	100	96	95	93	100	
CD3+CD4+	100	100	100	96	100	86	100	
CD3+CD8+	100	100	100	88	91	93	100	
CD3-CD19+	71	100	100	95	94	92	100	
CD3-(CD56 & CD16)+	33	100	100	95	93	100	100	
CD3+ Average	100	100	100	83	95	92	100	

Coulter (N=151)

Cell Marker (Population)	CDC Donor Number							
	38				45			
	L		L		N		N	
CD45+	88	100	92	97	95	100	94	
CD14+	100	100	92	97	100	100	93	
CD3+CD4+	100	94	83	85	94	93	86	
CD3+CD8+	79	83	83	81	97	87	100	
CD3-CD19+	80	93	71	94	100	70	100	
CD3-(CD56 & CD16)+	50	80	100	44	100	86	100	
CD3+ Average	80	81	100	88	87	100	79	

Ortho (N=19)

Cell Marker (Population)	CDC Donor Number							
	38				45			
	L		L		N		N	
CD45+	100	100	100	83	75	100	100	
CD14+	100	100	100	100	100	100	100	
CD3+CD4+	100	100	100	83	100	100	100	
CD3+CD8+	100	100	50	83	75	100	100	
CD3-CD19+	100	100	100	100	100	100	100	
CD3-(CD56 & CD16)+	0	NA	100	100	100	100	NA	
CD3+ Average	100	100	100	100	67	100	100	

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500)

NA = no data returned by any laboratory for specified marker

Table 5. Frequency of laboratory results for the October 1994 instrument performance control sample within, above, or below the 90% reference ranges\*

Event Population

Green Unstained Orange/Red Unstained		Green Stained Orange/Red Unstained		Green Unstained Orange/Red Stained		Green Stained Orange/Red Stained	
Range	Frequency	Range	Frequency	Range	Frequency	Range	Frequency
>25		>21	8	>23	7	>22	8
25-30	252	21-27	252	23-27	251	22-26	247
>30	9	>27	7	>27	9	>26	12

\*The 90% reference ranges were determined from results from the same laboratories whose results were used to determine the 90% reference ranges for Table 1.

Table 6. Frequency of 3-color laboratory results for the September 1995 shipment, by cell marker, within, above, or below the 90% reference ranges\*

Cell Marker (Population)	CDC Donor Number - HIV Status **											
	1 - H		2 - H		3 - H		4 - H		5 - H		6 - H	
	Range	No. <sup>Δ</sup>	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+, CD3+, CD4+	> 46 40 - 46 < 40	0 2 0	> 40 36 - 40 < 36	0 2 0	> 46 39 - 46 < 39	0 2 0	NA		NA		NA	
CD3+, CD4+, CD8-	> 46 40 - 46 < 40	0 1 1	> 40 36 - 40 < 36	0 4 0	> 46 39 - 46 < 39	0 2 0	> 30 23 - 30 < 23	0 4 0	> 51 46 - 51 < 46	0 5 1	> 39 30 - 39 < 30	0 2 0
CD45+, CD3+, CD8+	NA		> 43 36 - 43 < 36	2 0 0	> 39 29 - 39 < 29	0 2 0	NA		NA		NA	
CD3+, CD4-, CD8+	> 51 45 - 51 < 45	0 2 0	> 43 36 - 43 < 36	0 4 0	> 39 29 - 39 < 29	0 2 0	> 65 54 - 65 < 54	0 4 0	> 32 24 - 32 < 24	0 6 0	> 57 51 - 57 < 51	0 2 0
CD45+, CD3-, CD19+	NA		> 10 8 - 10 < 8	0 1 1	> 12 7 - 12 < 7	0 2 0	NA		NA		NA	
CD45+, CD3-, CD(56&16)+	NA		> 9 2 - 9 < 2	0 2 0	> 13 5 - 13 < 5	0 2 0	NA		NA		NA	

Cell Marker (Population)	CDC Donor Number - HIV Status **											
	7 - H		8 - L		9 - L		10 - L		11 - L		12 - N	
	Range	No. <sup>Δ</sup>	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+, CD3+, CD4+	> 39 31 - 39 < 31	0 2 0	> 3 1 - 3 < 1	0 2 0	> 3 1 - 3 < 1	0 1 0	> 17 10 - 17 < 10	0 1 0	> 13 9 - 13 < 9	0 1 0	> 56 48 - 56 < 48	0 2 0
CD3+, CD4+, CD8-	> 39 31 - 39 < 31	0 4 0	> 3 1 - 3 < 1	0 3 0	> 3 1 - 3 < 1	0 5 0	> 17 10 - 17 < 10	0 2 0	> 13 9 - 13 < 9	0 2 0	> 56 48 - 56 < 48	1 4 0
CD45+, CD3+, CD8+	> 50 39 - 50 < 39	0 2 0	> 50 30 - 50 < 30	0 1 0	> 58 49 - 58 < 49	0 1 0	> 50 33 - 50 < 33	0 1 0	> 50 40 - 50 < 40	0 1 0	> 27 21 - 27 < 21	0 1 0
CD3+, CD4-, CD8+	> 50 39 - 50 < 39	0 3 1	> 50 30 - 50 < 30	0 3 0	> 58 49 - 58 < 49	1 3 1	> 50 33 - 50 < 33	0 2 0	> 50 40 - 50 < 40	0 2 0	> 27 21 - 27 < 21	0 4 1
CD45+, CD3-, CD19+	> 12 5 - 12 < 5	0 2 0	> 35 24 - 35 < 24	0 1 0	> 34 27 - 34 < 27	0 1 0	> 11 6 - 11 < 6	0 1 0	> 23 17 - 23 < 17	0 1 0	> 13 7 - 13 < 7	0 1 0
CD45+, CD3-, CD(56&16)+	> 9 3 - 9 < 3	0 2 0	> 23 13 - 23 < 13	0 1 0	> 14 7 - 14 < 7	0 1 0	> 35 24 - 35 < 24	0 1 0	> 20 11 - 20 < 11	0 1 0	> 16 9 - 16 < 9	0 1 0

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500)

<sup>Δ</sup>No. = frequency of laboratories

NA = no data returned by any laboratory for specified marker

Table 6. Frequency of 3-color laboratory results for the September 1995 shipment, by cell marker, within, above, or below the 90% reference ranges\*

Cell Marker (Population)	CDC Donor Number - HIV Status **											
	13 - N		14 - N		15 - N		17 - H		18 - H		19 - H	
	Range	No. <sup>Δ</sup>	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+, CD3+, CD4+	> 52 47 - 52 < 47	0 2 0	> 38 33 - 38 < 33	0 2 0	> 57 49 - 57 < 49	0 2 0	> 49 39 - 49 < 39	0 2 0	> 30 25 - 30 < 25	0 2 0	> 42 38 - 42 < 38	1 5 0
CD3+, CD4+, CD8-	> 52 47 - 52 < 47	1 7 0	> 38 33 - 38 < 33	1 4 0	> 57 49 - 57 < 49	0 6 0	> 49 39 - 49 < 39	0 6 0	NA		> 42 38 - 42 < 38	0 2 0
CD45+, CD3+, CD8+	> 26 21 - 26 < 21	0 1 0	> 29 23 - 29 < 23	0 1 1	> 33 27 - 33 < 27	0 1 1	> 31 26 - 31 < 26	0 2 0	> 67 57 - 67 < 57	0 2 0	> 48 39 - 48 < 39	0 4 2
CD3+, CD4-, CD8+	> 26 21 - 26 < 21	0 8 0	> 29 23 - 29 < 23	0 4 1	> 33 27 - 33 < 27	0 5 1	> 31 26 - 31 < 26	0 6 0	NA		> 48 39 - 48 < 39	0 2 0
CD45+, CD3-, CD19+	> 19 12 - 19 < 12	0 1 0	> 20 12 - 20 < 12	0 2 0	> 6 4 - 6 < 4	0 2 0	NA		> 3 1 - 3 < 1	0 2 0	> 10 6 - 10 < 6	2 4 0
CD45+, CD3-, CD(56&16)+	> 9 6 - 9 < 6	0 1 0	> 17 9 - 17 < 9	0 2 0	> 10 2 - 10 < 2	0 2 0	NA		> 4 2 - 4 < 2	0 2 0	> 5 2 - 5 < 2	0 4 2

Cell Marker (Population)	CDC Donor Number - HIV Status **											
	20 - H		21 - H		23 - M		24 - L		25 - L		27 - N	
	Range	No. <sup>Δ</sup>	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+, CD3+, CD4+	NA		> 36 33 - 36 < 33	2 2 0	> 20 16 - 20 < 16	0 3 0	> 12 8 - 12 < 8	0 1 0	> 16 14 - 16 < 14	0 2 1	> 48 35 - 48 < 35	1 5 0
CD3+, CD4+, CD8-	> 43 35 - 43 < 35	2 2 0	> 36 33 - 36 < 33	1 1 0	> 20 16 - 20 < 16	0 1 0	> 12 8 - 12 < 8	1 4 0	> 16 14 - 16 < 14	0 1 0	> 48 35 - 48 < 35	0 2 0
CD45+, CD3+, CD8+	NA		> 44 41 - 44 < 41	0 3 1	> 51 39 - 51 < 39	0 2 1	> 73 63 - 73 < 63	0 1 0	> 64 49 - 64 < 49	0 3 0	> 27 19 - 27 < 19	0 5 1
CD3+, CD4-, CD8+	> 43 31 - 43 < 31	0 4 0	> 44 41 - 44 < 41	0 1 1	> 51 39 - 51 < 39	0 1 0	> 73 63 - 73 < 63	0 5 0	> 64 49 - 64 < 49	0 1 0	> 27 19 - 27 < 19	1 1 0
CD45+, CD3-, CD19+	NA		> 16 13 - 16 < 13	0 0 2	> 13 7 - 13 < 7	2 1 0	NA		> 11 7 - 11 < 7	0 2 0	> 23 16 - 23 < 16	1 4 0
CD45+, CD3-, CD(56&16)+	NA		> 6 3 - 6 < 3	0 2 0	> 21 16 - 21 < 16	1 1 1	NA		> 12 7 - 12 < 7	0 2 0	> 13 9 - 13 < 9	0 4 1

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500)

<sup>Δ</sup>No. = frequency of laboratories

NA = no data returned by any laboratory for specified marker

Table 6. Frequency of 3-color laboratory results for the September 1995 shipment, by cell marker, within, above, or below the 90% reference ranges\*

Cell Marker (Population)	28 - N		29 - N		30 - N		31 - H		33 - H		34 - H	
	Range	No. <sup>Δ</sup>	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+, CD3+, CD4+	> 53 42 - 53 < 42	0 3 1	> 46 41 - 46 < 41	0 1 0	> 69 63 - 69 < 63	0 2 1	NA		NA		> 41 32 - 41 < 32	0 4 0
CD3+, CD4+, CD8-	> 53 42 - 53 < 42	0 6 0	> 46 41 - 46 < 41	0 5 0	> 69 63 - 69 < 63	0 1 0	> 24 19 - 24 < 19	2 5 1	> 30 23 - 30 < 23	0 2 2	NA	
CD45+, CD3+, CD8+	> 24 16 - 24 < 16	0 3 1	> 22 15 - 22 < 15	0 1 0	> 21 18 - 21 < 18	0 3 0	NA		NA		> 46 33 - 46 < 33	0 2 0
CD3+, CD4-, CD8+	> 24 16 - 24 < 16	0 6 0	> 22 15 - 22 < 15	0 5 0	> 21 18 - 21 < 18	0 1 0	> 63 51 - 63 < 51	0 7 1	> 63 52 - 63 < 52	0 2 2	NA	
CD45+, CD3-, CD19+	> 16 11 - 16 < 11	1 2 0	NA		9 6 - 9 < 6	0 2 0	NA		NA		NA	
CD45+, CD3-, CD(56&16)+	14 10 - 14 < 10	0 1 2	NA		> 8 4 - 8 < 4	0 2 0	NA		NA		> 9 2 - 9 < 2	0 2 0

Cell Marker (Population)	35 - H		36 - H		38 - L		39 - L		40 - L		42 - N	
	Range	No. <sup>Δ</sup>	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+, CD3+, CD4+	> 50 40 - 50 < 40	0 2 0	> 22 18 - 22 < 18	0 2 2	> 2 0 - 2 < 0	0 2 0	> 2 0 - 2 < 0	0 1 0	> 8 5 - 8 < 5	0 2 0	> 29 17 - 29 < 17	0 2 2
CD3+, CD4+, CD8-	> 50 40 - 50 < 40	0 6 0	> 22 18 - 22 < 18	4 0 2	> 2 0 - 2 < 0	0 3 0	> 2 0 - 2 < 0	0 3 0	> 8 5 - 8 < 5	0 5 0	> 29 17 - 29 < 17	1 6 1
CD45+, CD3+, CD8+	> 33 23 - 33 < 23	0 2 0	> 74 67 - 74 < 67	0 2 0	> 48 36 - 48 < 36	0 1 0	> 60 54 - 60 < 54	0 1 0	> 81 69 - 81 < 69	0 1 0	> 53 35 - 53 < 35	0 2 0
CD3+, CD4-, CD8+	> 33 23 - 33 < 23	1 5 0	> 74 67 - 74 < 67	0 3 3	> 48 36 - 48 < 36	1 2 0	> 60 54 - 60 < 54	0 2 1	> 81 69 - 81 < 69	1 4 0	> 53 35 - 53 < 35	0 6 2
CD45+, CD3-, CD19+	> 14 10 - 14 < 10	0 4 0	> 6 3 - 6 < 3	0 4 0	NA		> 30 16 - 30 < 16	0 2 0	> 12 5 - 12 < 5	0 2 0	> 12 5 - 12 < 5	0 1 1
CD45+, CD3-, CD(56&16)+	> 9 7 - 9 < 7	0 4 0	> 7 5 - 7 < 5	1 3 0	> 21 13 - 21 < 13	1 0 0	> 12 8 - 12 < 8	0 1 1	> 7 1 - 7 < 1	0 2 0	> 20 9 - 20 < 9	1 1 1

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500)

<sup>Δ</sup>No. = frequency of laboratories

NA = no data returned by any laboratory for specified marker

Table 6. Frequency of 3-color laboratory results for the September 1995 shipment, by cell marker, within, above, or below the 90% reference ranges\*

Cell Marker (Population)	CDC Donor Number - HIV Status **					
	43 - N		44 - N		45 - N	
	Range	No. <sup>A</sup>	Range	No.	Range	No.
CD45+, CD3+, CD4+	> 47	0	NA		> 66	1
	39 - 47	3			55 - 66	1
	< 39	0			< 55	1
CD3+, CD4+, CD8-	> 47	2	> 52	0	> 66	1
	39 - 47	5	46 - 52	1	55 - 66	5
	< 39	0	< 46	0	< 55	0
CD45+, CD3+, CD8+	> 28	0	NA		> 27	0
	22 - 28	2			17 - 27	3
	< 22	0			< 17	0
CD3+, CD4-, CD8+	> 28	1	> 11	0	> 27	0
	22 - 28	5	8 - 11	0	17 - 27	6
	< 22	1	< 8	1	< 17	0
CD45+, CD3-, CD19+	> 19	0	NA		> 13	0
	13 - 19	2			7 - 13	4
	< 13	0			< 7	0
CD45+, CD3-, CD(56&16)+	> 11	0	NA		> 6	1
	8 - 11	3			3 - 6	3
	< 8	0			< 3	0

\*The 90% reference ranges were determined from results provided by participant laboratories which used the monoclonal antibody panel recommended in "1994 Revised Guidelines for the Performance of CD4+ T-Cell Determinations in Persons with Human Immunodeficiency Virus (HIV) Infection," MMWR 1994; 43(No.RR-3).

\*\* HIV status: N=Negative; Positive --- L=Low CD4 ct (<200), M=Moderate CD4 ct (>200 but <500), H=High CD4 ct (>500)

<sup>A</sup>No. = frequency of laboratories

NA = no data returned by any laboratory for specified marker