

***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 1996 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

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Figures and Tables Used for the Analysis of the September 1996 Specimen Shipment
Results Submitted by Laboratories Participating in the Model Performance
Evaluation Program for T-Lymphocyte Immunophenotyping

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**Centers for Disease Control and Prevention (CDC) - Model Performance Evaluation Program
for T-Lymphocyte Immunophenotyping (TLI)
Donor Specimen Identification for September 10, 1996 TLI Shipment Specimens**

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

^aHuman 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 17, 1996 TLI Shipment Specimens**

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

^aHuman 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 24, 1996 TLI Shipment Specimens**

Panel Letter	Participant Lab Vial Label	CDC Donor Number	Donor Information (HIV-1^a status and CD4⁺ cell count)
O	O1	44	HIV-1 Antibody-Negative
	O2, O3	33	HIV-1 Antibody-Positive, CD4 ⁺ count ≥ 500
	O4	42	HIV-1 Antibody-Negative
	O5	40	HIV-1 Antibody-Positive, CD4 ⁺ count ≤ 200
P	P1, P3	34	HIV-1 Antibody-Positive, CD4 ⁺ count ≥ 500
	P2	43	HIV-1 Antibody-Negative
	P4	38	HIV-1 Antibody-Positive, CD4 ⁺ count ≤ 200
	P5	42	HIV-1 Antibody-Negative
Q	Q1	39	HIV-1 Antibody-Positive, CD4 ⁺ count ≤ 200
	Q2, Q4	35	HIV-1 Antibody-Positive, CD4 ⁺ count ≥ 500
	Q3	45	HIV-1 Antibody-Negative
	Q5	43	HIV-1 Antibody-Negative
R	R1, R5	36	HIV-1 Antibody-Positive, CD4 ⁺ count ≥ 500
	R2	40	HIV-1 Antibody-Positive, CD4 ⁺ count ≤ 200
	R3	42	HIV-1 Antibody-Negative
	R4	45	HIV-1 Antibody-Negative
S	S1, S5	31	HIV-1 Antibody-Positive, CD4 ⁺ count ≥ 500
	S2	42	HIV-1 Antibody-Negative
	S3	43	HIV-1 Antibody-Negative
	S4	38	HIV-1 Antibody-Positive, CD4 ⁺ count ≤ 200
T	T1	43	HIV-1 Antibody-Negative
	T2	39	HIV-1 Antibody-Positive, CD4 ⁺ count ≤ 200
	T3, T4	32	HIV-1 Antibody-Positive, CD4 ⁺ count ≥ 500
	T5	44	HIV-1 Antibody-Negative
U	U1	44	HIV-1 Antibody-Negative
	U2	41	HIV-1 Antibody-Positive, CD4 ⁺ count ≤ 200
	U3	45	HIV-1 Antibody-Negative
	U4, U5	37	HIV-1 Antibody-Positive, CD4 ⁺ count ≥ 500

^aHuman immunodeficiency virus type 1

Figure 1. Primary classification of laboratories participating in the September 1996 shipment.

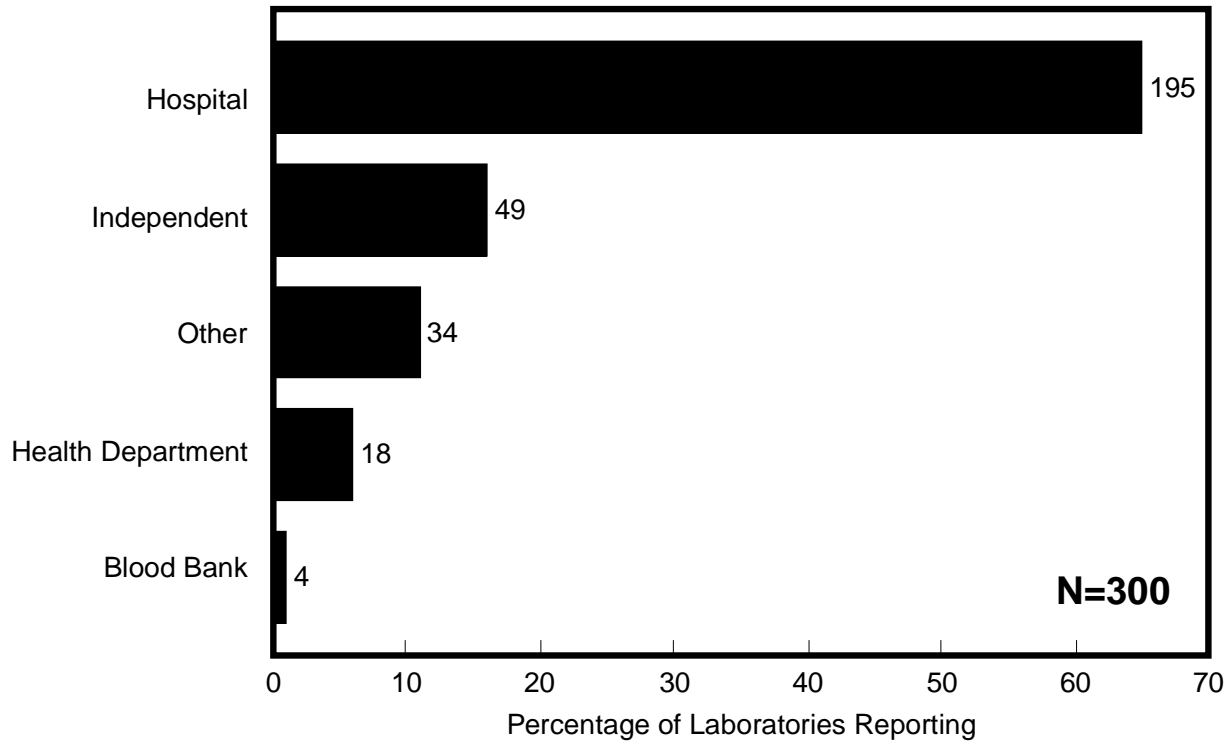
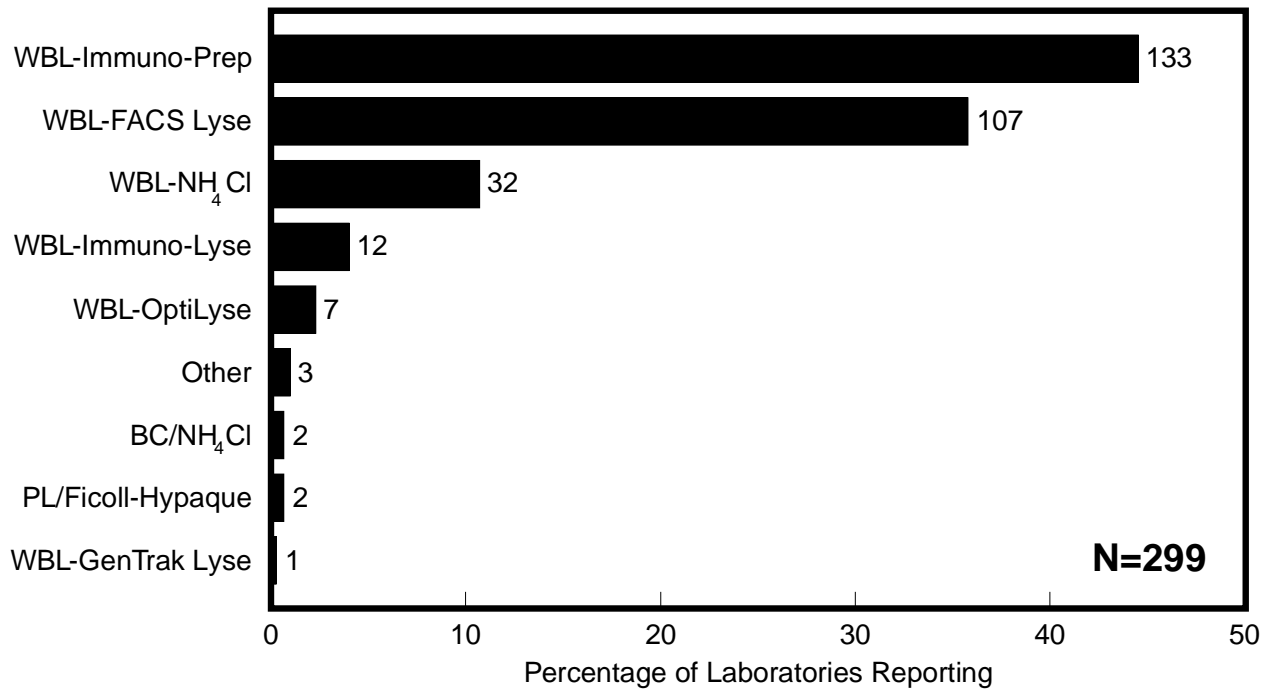


Figure 2. Methods used to prepare specimens for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the September 1996 shipment.



WBL - Whole Blood Lysis
BC - Buffy Coat Lysis

PL - Purified Lymphocytes
NH₄Cl - Ammonium Chloride

Figure 3. Methods used to fix specimens for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the September 1996 shipment.

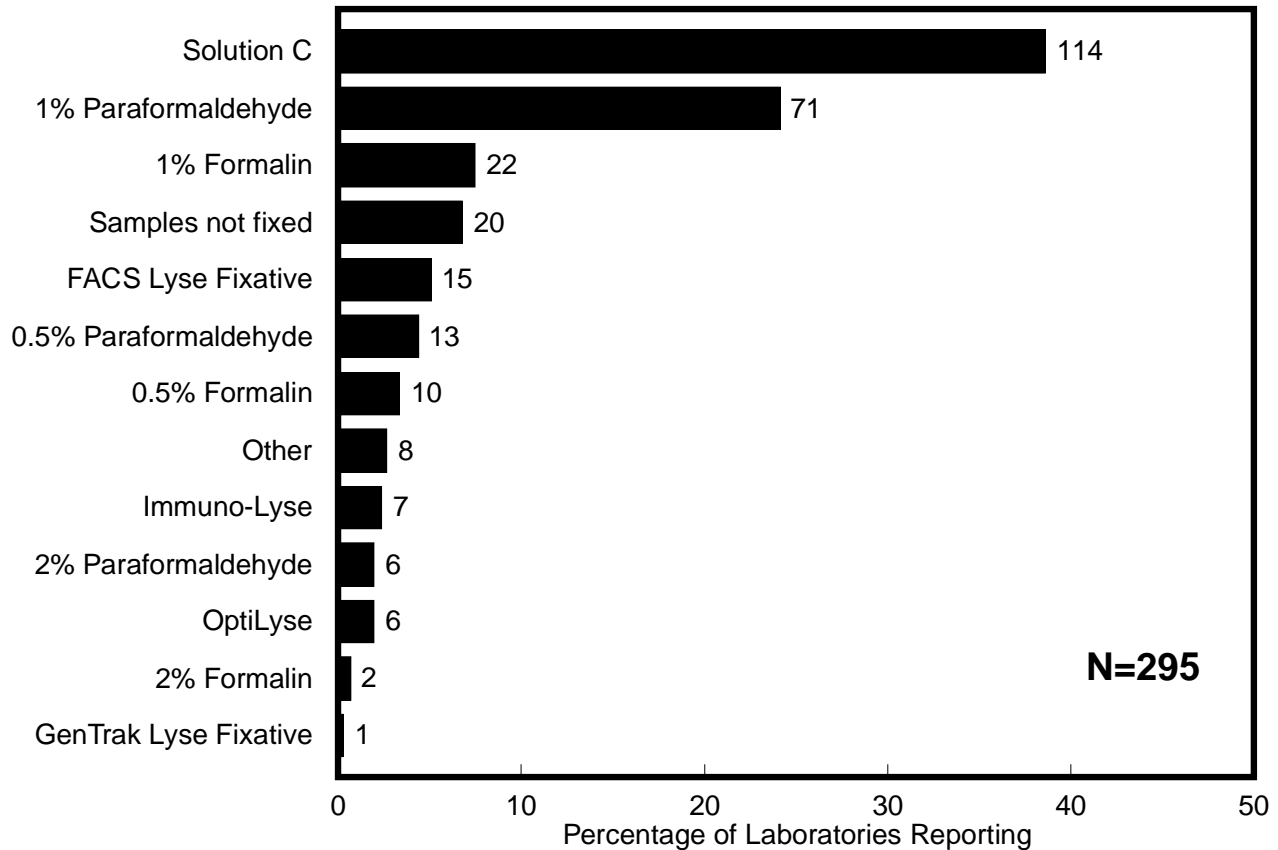


Figure 4. Types of flow cytometers used for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the September 1996 shipment.

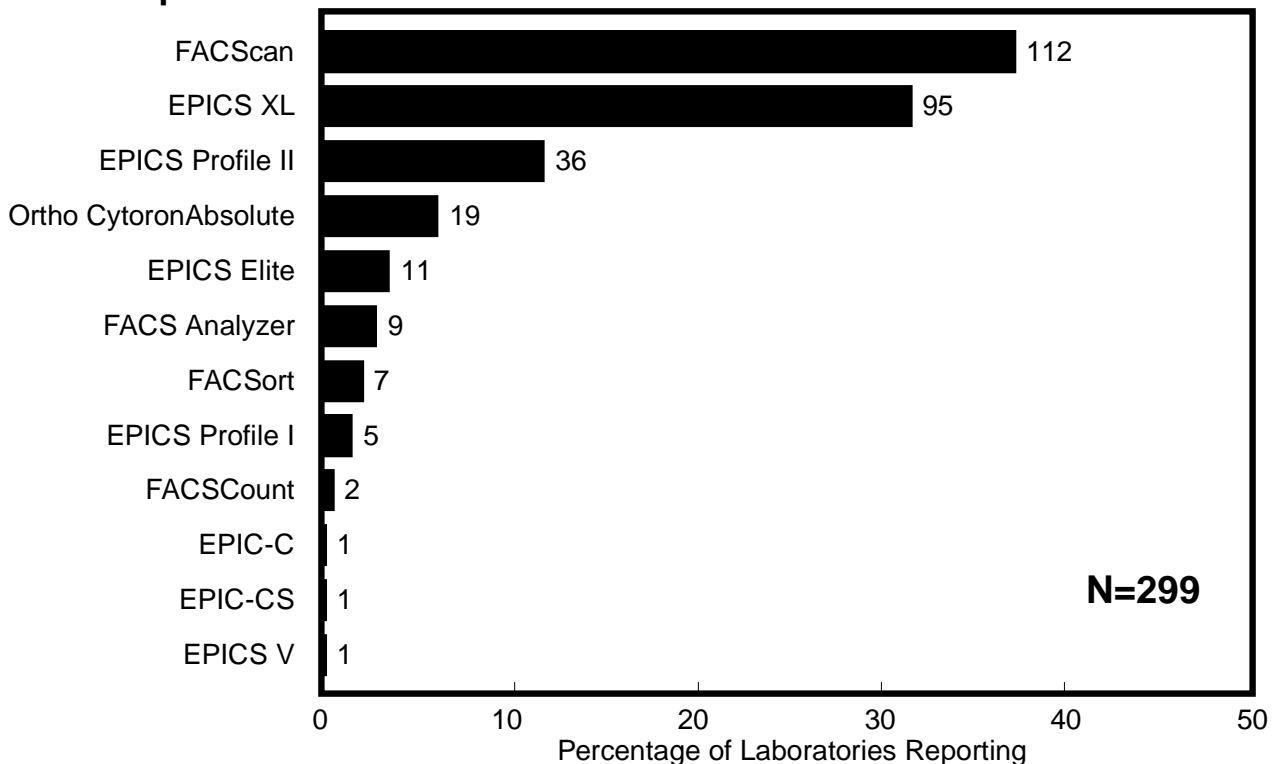


Table 1. Frequency of 2-color laboratory results for the September 1996 shipment, by cell marker, within, above, or below the 90% reference ranges*

Cell Marker (Population)	CDC Donor Number - HIV Status **											
	1 - H		2 - M		3 - H		4 - H		5 - H		6 - H	
	Range	No. [^]	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+	> 100	0	> 100	0	> 99	0	> 99	0	> 100	0	> 99	5
	86 - 100	24	92 - 100	24	94 - 99	18	94 - 99	18	92 - 100	24	93 - 99	21
	< 86	0	< 92	0	< 94	4	< 94	0	< 92	0	< 93	0
CD14+	> 1	0	> 1	0	> 0	2	> 2	0	> 1	0	> 2	0
	0 - 1	24	0 - 1	24	0 - 0	18	0 - 2	18	0 - 1	24	0 - 2	22
	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0
CD3+CD4+	> 53	0	> 37	0	> 34	2	> 32	0	> 49	0	> 51	3
	39 - 53	24	32 - 37	20	32 - 34	9	27 - 32	16	37 - 49	22	46 - 51	18
	< 39	0	< 32	0	< 32	5	< 27	0	< 37	0	< 46	1
CD3+CD8+	> 49	0	> 47	0	> 44	3	> 53	0	> 45	0	> 43	1
	38 - 49	23	40 - 47	20	36 - 44	12	46 - 53	15	36 - 45	20	35 - 43	21
	< 38	1	< 40	0	< 36	1	< 46	1	< 36	2	< 35	0
CD3-CD19+	> 8	0	> 15	0	> 20	0	> 20	0	> 8	0	> 9	0
	4 - 8	14	10 - 15	16	14 - 20	14	14 - 20	14	4 - 8	14	6 - 9	16
	< 4	0	< 10	0	< 14	0	< 14	0	< 4	0	< 6	0
CD3-(CD56 & CD16)+	> 3	0	> 8	0	> 9	2	> 5	0	> 7	0	> 5	0
	1 - 3	8	4 - 8	14	6 - 9	6	1 - 5	8	5 - 7	14	3 - 5	8
	< 1	0	< 4	0	< 6	2	< 1	0	< 5	0	< 3	0
CD3+ Average	> 95	0	> 80	0	> 74	3	> 84	0	> 91	0	> 91	4
	88 - 95	22	74 - 80	18	67 - 74	8	78 - 84	14	86 - 91	20	88 - 91	18
	< 88	0	< 74	0	< 67	1	< 78	0	< 86	2	< 88	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)

[^] = frequency of laboratories

Table 1. Frequency of 2-color laboratory results for the September 1996 shipment, by cell marker, within, above, or below the 90% reference ranges*

CDC Donor Number -		HIV Status **										
Cell Marker (Population)	7 - M		8 - L		9 - L		10 - L		11 - L		12 - N	
	Range	No. ^a	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+	> 100	0	> 100	0	> 100	0	> 99	3	> 100	0	> 100	0
	90 - 100	26	90 - 100	18	88 - 100	23	92 - 99	21	94 - 100	13	90 - 100	45
	< 90	0	< 90	1	< 88	0	< 92	1	< 94	0	< 90	1
CD14+	> 1	2	> 1	1	> 1	0	> 1	2	> 1	1	> 1	1
	0 - 1	24	0 - 1	18	0 - 1	23	0 - 1	20	0 - 1	12	0 - 1	42
	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0
CD3+CD4+	> 48	0	> 22	0	> 3	1	> 14	2	> 16	1	> 40	0
	38 - 48	24	15 - 22	19	1 - 3	19	10 - 14	17	10 - 16	11	29 - 40	38
	< 38	0	< 15	0	< 1	0	< 10	0	< 10	0	< 29	1
CD3+CD8+	> 50	0	> 52	0	> 42	0	> 65	1	> 75	1	> 29	1
	44 - 50	21	40 - 52	19	34 - 42	19	57 - 65	17	71 - 75	9	21 - 29	36
	< 44	3	< 40	0	< 34	1	< 57	1	< 71	2	< 21	2
CD3-CD19+	> 6	0	> 13	0	> 44	1	> 16	1	> 8	0	> 24	2
	2 - 6	24	6 - 13	13	32 - 44	14	9 - 16	13	2 - 8	12	15 - 24	25
	< 2	0	< 6	0	< 32	0	< 9	1	< 2	0	< 15	2
CD3-(CD56 & CD16)+	> 4	0	> 22	0	> 15	0	> 13	1	> 3	0	> 11	2
	2 - 4	16	14 - 22	8	9 - 15	13	8 - 13	7	2 - 3	8	8 - 11	14
	< 2	0	< 14	0	< 9	1	< 8	1	< 2	0	< 8	1
CD3+ Average	> 93	0	> 71	0	> 53	0	> 76	2	> 93	0	> 77	0
	86 - 93	15	60 - 71	16	44 - 53	18	70 - 76	15	88 - 93	7	67 - 77	32
	< 86	1	< 60	1	< 44	2	< 70	0	< 88	1	< 67	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)

^a = frequency of laboratories

Table 1. Frequency of 2-color laboratory results for the September 1996 shipment, by cell marker, within, above, or below the 90% reference ranges*

CDC Donor Number -		HIV Status **										
Cell Marker (Population)	13 - N		14 - N		15 - N		16 - H		17 - H		18 - H	
	Range	No. [^]	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+	> 100	0	> 100	0	> 99	2	> 100	0	> 100	0	> 99	0
	92 - 100	44	92 - 100	37	89 - 99	33	93 - 100	16	92 - 100	24	95 - 99	17
	< 92	1	< 92	1	< 89	1	< 93	0	< 92	0	< 95	1
CD14+	> 2	1	> 1	1	> 2	2	> 0	3	> 1	2	> 1	0
	0 - 2	44	0 - 1	35	0 - 2	33	0 - 0	11	0 - 1	22	0 - 1	16
	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0
CD3+CD4+	> 53	1	> 67	2	> 42	0	> 41	0	> 33	0	> 52	0
	46 - 53	39	60 - 67	29	33 - 42	30	32 - 41	12	27 - 33	24	46 - 52	17
	< 46	1	< 60	2	< 33	0	< 32	0	< 27	0	< 46	1
CD3+CD8+	> 27	1	> 21	1	> 31	0	> 50	2	> 60	1	> 22	0
	22 - 27	38	16 - 21	32	22 - 31	30	40 - 50	10	48 - 60	23	13 - 22	20
	< 22	2	< 16	0	< 22	0	< 40	0	< 48	0	< 13	0
CD3-CD19+	> 13	1	> 8	1	> 20	0	> 9	0	> 10	0	> 22	0
	9 - 13	27	6 - 8	26	15 - 20	25	6 - 9	14	7 - 10	20	17 - 22	18
	< 9	1	< 6	1	< 15	1	< 6	0	< 7	0	< 17	0
CD3-(CD56 & CD16)+	> 17	1	> 8	0	> 16	0	> 6	0	> 3	0	> 12	0
	11 - 17	20	5 - 8	19	11 - 16	17	5 - 6	10	2 - 3	16	10 - 12	6
	< 11	1	< 5	0	< 11	3	< 5	2	< 2	0	< 10	0
CD3+ Average	> 78	3	> 89	1	> 71	0	> 89	0	> 91	0	> 71	0
	73 - 78	33	80 - 89	27	63 - 71	25	84 - 89	12	84 - 91	20	65 - 71	16
	< 73	2	< 80	0	< 63	0	< 84	2	< 84	0	< 65	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)

[^] = frequency of laboratories

Table 1. Frequency of 2-color laboratory results for the September 1996 shipment, by cell marker, within, above, or below the 90% reference ranges*

CDC Donor Number -		HIV Status **										
Cell Marker (Population)	19 - H		20 - H		21 - H		22 - H		23 - L		24 - L	
	Range	No. ^a	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+	> 99	6	> 100	0	> 100	2	> 100	0	> 100	0	> 100	0
	95 - 99	16	93 - 100	32	97 - 100	20	95 - 100	22	93 - 100	19	94 - 100	27
	< 95	0	< 93	0	< 97	2	< 95	2	< 93	0	< 94	1
CD14+	> 1	0	> 1	0	> 1	0	> 1	2	> 2	0	> 1	1
	0 - 1	20	0 - 1	32	0 - 1	22	0 - 1	22	0 - 2	17	0 - 1	27
	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0
CD3+CD4+	> 39	3	> 46	0	> 53	0	> 36	1	> 8	0	> 8	2
	33 - 39	17	33 - 46	30	45 - 53	22	25 - 36	23	6 - 8	16	7 - 8	25
	< 33	0	< 33	0	< 45	0	< 25	0	< 6	0	< 7	0
CD3+CD8+	> 38	0	> 41	0	> 46	0	> 48	0	> 85	0	> 67	0
	34 - 38	18	33 - 41	30	35 - 46	22	40 - 48	20	77 - 85	15	57 - 67	25
	< 34	2	< 33	0	< 35	0	< 40	4	< 77	1	< 57	2
CD3-CD19+	> 16	0	> 14	0	> 10	1	> 16	0	> 6	0	> 25	0
	11 - 16	19	9 - 14	22	6 - 10	19	9 - 16	16	4 - 6	17	15 - 25	21
	< 11	1	< 9	2	< 6	0	< 9	0	< 4	0	< 15	1
CD3-(CD56 & CD16)+	> 14	0	> 11	0	> 7	0	> 11	0	> 6	0	> 13	0
	7 - 14	16	6 - 11	19	3 - 7	10	7 - 11	13	2 - 6	14	7 - 13	18
	< 7	0	< 6	1	< 3	0	< 7	1	< 2	0	< 7	0
CD3+ Average	> 76	1	> 84	0	> 92	0	> 83	0	> 92	0	> 75	0
	69 - 76	19	74 - 84	22	86 - 92	18	73 - 83	18	86 - 92	16	64 - 75	21
	< 69	0	< 74	0	< 86	0	< 73	0	< 86	1	< 64	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)

^a = frequency of laboratories

Table 1. Frequency of 2-color laboratory results for the September 1996 shipment, by cell marker, within, above, or below the 90% reference ranges*

Cell Marker (Population)	CDC Donor Number - HIV Status **											
	25 - M		26 - L		27 - N		28 - N		29 - N		30 - N	
	Range	No. [^]	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+	> 100	0	> 100	0	> 100	1	> 100	0	> 100	0	> 100	1
	94 - 100	20	85 - 100	11	95 - 100	37	93 - 100	46	89 - 100	38	94 - 100	28
	< 94	1	< 85	1	< 95	2	< 93	1	< 89	2	< 94	4
CD14+	> 1	0	> 1	1	> 1	0	> 1	1	> 1	2	> 2	1
	0 - 1	19	0 - 1	11	0 - 1	36	0 - 1	44	0 - 1	38	0 - 2	30
	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0
CD3+CD4+	> 14	0	> 24	1	> 55	1	> 45	0	> 62	0	> 45	2
	9 - 14	20	18 - 24	11	49 - 55	32	37 - 45	43	55 - 62	36	40 - 45	26
	< 9	0	< 18	0	< 49	3	< 37	0	< 55	2	< 40	4
CD3+CD8+	> 76	0	> 56	1	> 33	1	> 38	0	> 28	0	> 26	1
	67 - 76	19	46 - 56	9	26 - 33	34	32 - 38	41	22 - 28	36	22 - 26	28
	< 67	1	< 46	2	< 26	2	< 32	2	< 22	3	< 22	4
CD3-CD19+	> 14	0	> 23	0	> 8	0	> 13	0	> 11	0	> 22	0
	8 - 14	19	11 - 23	8	5 - 8	36	8 - 13	38	7 - 11	30	15 - 22	26
	< 8	0	< 11	0	< 5	0	< 8	1	< 7	0	< 15	1
CD3-(CD56 & CD16)+	> 4	1	> 7	0	> 10	0	> 11	1	> 7	1	> 20	0
	2 - 4	7	3 - 7	6	7 - 10	20	7 - 11	31	5 - 7	23	11 - 20	15
	< 2	0	< 3	1	< 7	2	< 7	0	< 5	1	< 11	0
CD3+ Average	> 90	0	> 81	2	> 87	1	> 85	0	> 88	1	> 70	0
	80 - 90	17	70 - 81	6	83 - 87	31	74 - 85	37	81 - 88	26	63 - 70	25
	< 80	0	< 70	1	< 83	2	< 74	1	< 81	3	< 63	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)

[^] = frequency of laboratories

Table 1. Frequency of 2-color laboratory results for the September 1996 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. [^]	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+	> 100	0	> 99	6	> 99	3	> 100	0	> 100	0	> 100	0
	96 - 100	28	92 - 99	19	93 - 99	20	95 - 100	26	98 - 100	19	93 - 100	18
	< 96	2	< 92	0	< 93	3	< 95	0	< 98	1	< 93	0
CD14+	> 1	0	> 1	1	> 2	1	> 1	2	> 0	2	> 1	0
	0 - 1	30	0 - 1	20	0 - 2	25	0 - 1	22	0 - 0	18	0 - 1	18
	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0
CD3+CD4+	> 42	2	> 32	0	> 30	1	> 36	0	> 39	0	> 45	0
	37 - 42	28	27 - 32	24	27 - 30	17	32 - 36	26	24 - 39	22	32 - 45	20
	< 37	2	< 27	1	< 27	2	< 32	0	< 24	0	< 32	0
CD3+CD8+	> 39	4	> 53	0	> 52	5	> 58	0	> 56	0	> 52	0
	35 - 39	26	47 - 53	21	47 - 52	11	53 - 58	24	49 - 56	19	39 - 52	20
	< 35	0	< 47	4	< 47	4	< 53	2	< 49	3	< 39	0
CD3-CD19+	> 7	0	> 15	0	> 15	2	> 6	2	> 9	0	> 10	0
	4 - 7	18	10 - 15	19	11 - 15	12	2 - 6	18	2 - 9	16	2 - 10	14
	< 4	0	< 10	0	< 11	2	< 2	0	< 2	0	< 2	0
CD3-(CD56 & CD16)+	> 18	0	> 8	0	> 5	3	> 5	0	> 6	1	> 9	0
	12 - 18	14	1 - 8	15	3 - 5	14	3 - 5	10	3 - 6	11	1 - 9	12
	< 12	0	< 1	0	< 3	1	< 3	0	< 3	0	< 1	0
CD3+ Average	> 79	9	> 86	0	> 83	3	> 93	0	> 93	0	> 87	0
	75 - 79	12	76 - 86	23	78 - 83	11	88 - 93	18	85 - 93	17	82 - 87	17
	< 75	1	< 76	0	< 78	2	< 88	0	< 85	3	< 82	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)

[^] = frequency of laboratories

Table 1. Frequency of 2-color laboratory results for the September 1996 shipment, by cell marker, within, above, or below the 90% reference ranges*

CDC Donor Number -

Cell Marker HIV Status **

Cell Marker (Populatio	37 - H		38 - L		39 - L		40 - L		41 - L	
	Range	No. [^]	Range	No.	Range	No.	Range	No.	Range	No.
CD45+	> 100	0	> 100	0	> 100	0	> 100	1	> 99	0
	87 - 100	22	93 - 100	28	91 - 100	21	93 - 100	21	95 - 99	10
	< 87	0	< 93	0	< 91	0	< 93	0	< 95	1
CD14+	> 1	0	> 2	1	> 1	0	> 2	1	> 1	0
	0 - 1	22	0 - 2	26	0 - 1	19	0 - 2	21	0 - 1	11
	< 0	0	< 0	0	< 0	0	< 0	0	< 0	0
CD3+CD4+	> 36	0	> 12	0	> 6	0	> 12	0	> 18	0
	31 - 36	22	8 - 12	29	3 - 6	22	9 - 12	20	15 - 18	11
	< 31	0	< 8	0	< 3	0	< 9	0	< 15	0
CD3+CD8+	> 41	0	> 64	0	> 82	1	> 68	0	> 56	0
	31 - 41	22	57 - 64	24	71 - 82	21	60 - 68	19	51 - 56	9
	< 31	0	< 57	4	< 71	0	< 60	1	< 51	2
CD3-CD19+	> 22	0	> 5	0	> 6	0	> 17	4	> 14	0
	10 - 22	18	1 - 5	19	1 - 6	17	13 - 17	11	9 - 14	9
	< 10	0	< 1	0	< 1	0	< 13	0	< 9	0
CD3-(CD56 & CD16)+	> 10	0	> 26	1	> 9	1	> 5	1	> 9	0
	2 - 10	14	20 - 26	9	5 - 9	12	3 - 5	14	7 - 9	7
	< 2	0	< 20	2	< 5	0	< 3	0	< 7	0
CD3+ Average	> 80	0	> 76	1	> 89	0	> 84	0	> 81	0
	69 - 80	22	69 - 76	19	78 - 89	20	71 - 84	16	75 - 81	9
	< 69	0	< 69	0	< 78	0	< 71	1	< 75	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)

[^] = frequency of laboratories

Table 1. Frequency of 2-color laboratory results for the September 1996 shipment, by cell marker, within, above, or below the 90% reference ranges*

CDC Donor Number -

Cell Marker (Populatio	42 - N		43 - N		44 - N		45 - N	
	Range	No. [^]	Range	No.	Range	No.	Range	No.
CD45+	> 100	1	> 100	0	> 100	1	> 100	0
	93 - 100	48	93 - 100	50	91 - 100	35	93 - 100	29
	< 93	1	< 93	1	< 91	0	< 93	1
CD14+	> 1	3	> 1	3	> 1	3	> 1	1
	0 - 1	46	0 - 1	45	0 - 1	31	0 - 1	29
	< 0	0	< 0	0	< 0	0	< 0	0
CD3+CD4+	> 57	3	> 63	3	> 54	2	> 54	3
	50 - 57	44	55 - 63	49	47 - 54	30	49 - 54	27
	< 50	2	< 55	1	< 47	1	< 49	2
CD3+CD8+	> 28	2	> 24	2	> 23	0	> 24	0
	22 - 28	41	17 - 24	47	18 - 23	30	18 - 24	31
	< 22	5	< 17	3	< 18	3	< 18	1
CD3-CD19+	> 9	2	> 16	0	> 16	0	> 9	0
	6 - 9	31	6 - 16	34	8 - 16	26	4 - 9	23
	< 6	1	< 6	3	< 8	0	< 4	1
CD3-(CD56 & CD16)+	> 14	0	> 11	0	> 18	0	> 19	1
	7 - 14	26	5 - 11	24	9 - 18	22	11 - 19	17
	< 7	1	< 5	2	< 9	1	< 11	1
CD3+ Average	> 81	2	> 81	2	> 74	1	> 77	1
	76 - 81	32	75 - 81	39	70 - 74	26	71 - 77	28
	< 76	3	< 75	1	< 70	3	< 71	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)

[^] = frequency of laboratories

Table 2. Range of all 2-color participant laboratory results for the September 1996 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 reported by all laboratories using these cell markers.

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

Table 3. Percentage of 2-color laboratory results for the September 1996 shipment, by monoclonal antibody manufacturer, that are within the 90% reference ranges*

Becton-Dickinson (N=117)**

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	M	H	H	H	H	M	L	L	L	L	N	N	N	N	H	H	H	
CD45+	100	100	60	100	100	100	100	80	100	90	100	94	94	93	94	100	100	10	0
CD14+	100	100	100	100	100	100	100	100	100	89	100	100	100	93	100	50	100	10	0
CD3+CD4+	100	100	50	100	100	80	100	100	100	80	100	100	94	87	100	100	100	5	0
CD3+CD8+	100	100	60	100	100	90	100	100	100	80	80	100	88	93	100	67	94	10	0
CD3-CD19+	100	100	100	100	100	100	100	100	88	86	100	100	93	100	100	100	100	10	0
CD3-(CD56 & CD16)+	100	100	50	100	100	100	100	100	90	71	100	77	88	100	86	100	100	N	A
CD3+ Average	100	100	50	100	100	80	100	80	90	89	100	100	93	100	100	67	100	10	0

Coulter (N=69)**

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	M	H	H	H	H	M	L	L	L	L	N	N	N	N	H	H	H	
CD45+	100	100	100	100	100	50	100	100	100	67	100	100	100	100	86	NA	100	8	8
CD14+	100	100	100	100	100	100	67	100	100	100	67	100	100	100	71	NA	0	10	0
CD3+CD4+	100	100	0	100	100	100	100	100	100	100	67	100	94	86	100	NA	100	10	0
CD3+CD8+	93	100	100	88	75	100	50	100	83	100	33	93	94	100	100	NA	100	10	0
CD3-CD19+	100	100	100	100	100	NA	100	100	100	0	100	50	100	67	75	NA	NA	10	0
CD3-(CD56 & CD16)+	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	N	A
CD3+ Average	100	100	100	100	67	100	50	100	80	100	0	92	80	100	100	NA	100	10	0

Other Manufacturers (N=68)****

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	M	H	H	H	H	M	L	L	L	L	N	N	N	N	H	H	H	
CD45+	100	100	100	100	100	75	100	100	100	83	100	100	100	100	92	100	100	10	0
CD14+	100	100	80	100	100	100	100	75	100	90	100	93	91	100	100	90	100	10	0
CD3+CD4+	100	100	100	100	100	75	100	100	80	100	100	89	100	91	100	100	100	10	0
CD3+CD8+	100	100	100	100	100	100	100	100	100	100	100	78	100	100	100	100	100	10	0
CD3-CD19+	100	100	100	100	100	100	100	100	100	100	100	90	86	92	100	100	100	10	0
CD3-(CD56 & CD16)+	100	100	100	100	100	100	100	100	100	100	100	100	100	100	83	75	100	10	0
CD3+ Average	100	100	100	100	100	75	100	100	100	80	100	75	88	91	100	100	100	10	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).

**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, GenTrak, 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 1996 shipment, by monoclonal antibody manufacturer, that are within the 90% reference ranges*

Becton-Dickinson (N=117)**

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	L	L	M	L	N	N	N	N	H	H	H	H	H
CD45+	100	100	83	100	100	94	100	100	87	96	96	83	86	87	70	100	83	10	0		
CD14+	100	100	100	100	100	100	100	100	100	100	100	100	100	93	90	100	67	10	0		
CD3+CD4+	80	100	100	100	100	89	100	80	80	100	96	92	88	94	83	100	100	10	0		
CD3+CD8+	100	100	100	100	88	100	100	80	93	100	96	92	81	100	33	75	75	10	0		
CD3-CD19+	90	89	92	100	100	100	100	100	100	96	100	92	100	100	60	100	100	10	0		
CD3-(CD56 & CD16)+	100	100	100	100	100	100	100	100	100	95	89	100	100	100	60	100	75	10	0		
CD3+ Average	90	100	100	100	88	100	100	60	80	96	90	100	58	100	50	100	75	8	3		

Coulter (N=69)**

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	L	L	M	L	N	N	N	N	H	H	H	H	H
CD45+	NA	100	100	67	NA	100	100	67	100	100	80	80	100	60	50	100	100	10	0		
CD14+	NA	100	100	67	NA	50	100	67	100	50	60	88	100	100	100	100	100	10	0		
CD3+CD4+	NA	100	100	100	NA	100	100	100	100	100	100	60	100	100	75	100	100	10	0		
CD3+CD8+	NA	100	100	50	NA	50	86	33	88	50	60	82	90	60	75	100	75	10	0		
CD3-CD19+	NA	NA	100	NA	NA	NA	100	NA	100	NA	NA	100	100	100	100	50	100	10	0		
CD3-(CD56 & CD16)+	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	100	100	NA	100	NA	NA	NA	NA	NA
CD3+ Average	NA	100	100	NA	NA	100	100	NA	100	100	50	80	38	100	100	NA	75	10	0		

Other Manufacturers (N=68)****

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	L	L	M	L	N	N	N	N	H	H	H	H	H
CD45+	50	100	67	100	100	100	86	100	94	100	100	91	100	NA	92	100	100	10	0		
CD14+	100	100	100	100	100	100	100	100	100	100	100	100	100	NA	100	83	100	10	0		
CD3+CD4+	90	100	100	88	100	100	100	100	93	100	90	90	67	NA	90	100	100	10	0		
CD3+CD8+	80	100	100	88	100	86	100	100	93	93	100	80	100	NA	60	100	100	10	0		
CD3-CD19+	100	100	100	100	100	83	100	100	100	100	100	100	100	NA	100	100	100	10	0		
CD3-(CD56 & CD16)+	100	75	100	83	100	100	75	67	82	100	100	100	100	NA	100	100	100	10	0		
CD3+ Average	100	100	100	100	100	100	100	75	100	100	86	100	100	NA	83	100	100	10	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).

**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, GenTrak, 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 1996 shipment, by monoclonal antibody manufacturer, that are within the 90% reference ranges*

Becton-Dickinson (N=117)**										
Cell Marker (Population)	CDC Donor Number									
	37	38	39	40	41	42	43	44	45	
	HIV Status***									
	H	L	L	L	L	N	N	N	N	
CD45+	100	100	100	86	100	89	95	94	100	
CD14+	100	91	100	100	100	94	95	89	100	
CD3+CD4+	100	100	100	100	100	83	96	89	93	
CD3+CD8+	100	83	90	100	100	89	100	100	100	
CD3-CD19+	100	100	100	86	100	86	94	100	100	
CD3-(CD56 & CD16)	100	88	88	100	100	100	94	94	90	
CD3+ Average	100	88	100	86	100	73	95	82	100	

Coulter (N=69)**										
Cell Marker (Population)	CDC Donor Number									
	37	38	39	40	41	42	43	44	45	
	HIV Status***									
	H	L	L	L	L	N	N	N	N	
CD45+	100	100	100	100	50	100	100	100	86	
CD14+	100	100	100	100	100	100	100	100	100	
CD3+CD4+	100	100	100	100	100	92	93	88	57	
CD3+CD8+	100	88	100	100	0	92	80	89	86	
CD3-CD19+	NA	100	100	67	NA	100	89	100	67	
CD3-(CD56 & CD16)	NA	50	100	NA	NA	50	67	100	NA	
CD3+ Average	100	100	100	100	0	100	100	100	71	

Other Manufacturers (N=68)****										
Cell Marker (Population)	CDC Donor Number									
	37	38	39	40	41	42	43	44	45	
	HIV Status***									
	H	L	L	L	L	N	N	N	N	
CD45+	100	100	100	100	100	100	100	100	100	
CD14+	100	100	100	90	100	89	86	89	92	
CD3+CD4+	100	100	100	100	100	94	86	100	91	
CD3+CD8+	100	88	100	89	100	76	85	71	100	
CD3-CD19+	100	100	100	60	100	92	92	100	100	
CD3-(CD56 & CD16)	100	50	100	86	100	100	100	100	89	
CD3+ Average	100	100	100	100	100	93	83	80	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, GenTrak, 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 1996 shipment, by equipment manufacturer, that are within the 90% reference ranges*

Becton-Dickinson (N=150)

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	M	H	H	H	H	M	L	L	L	L	N	N	N	N	H	H
CD45+	100	100	75	100	100	100	100	83	100	100	100	94	94	94	100	100	100	10	0
CD14+	100	100	100	100	100	100	100	100	100	90	100	100	100	94	100	50	100	10	0
CD3+CD4+	100	100	63	100	100	92	100	100	100	90	100	94	93	88	100	100	100	10	0
CD3+CD8+	100	100	75	100	100	92	100	100	100	90	83	100	93	94	100	67	94	10	0
CD3-CD19+	100	100	100	100	100	100	100	100	100	88	100	93	92	93	100	100	100	10	0
CD3-(CD56 & CD16)+	100	100	67	100	100	100	100	100	100	83	100	83	92	100	100	100	100	10	0
CD3+ Average	100	100	67	100	100	90	100	80	88	88	100	100	92	100	100	67	100	10	0

Coulter (N=130)

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	M	H	H	H	H	M	L	L	L	L	N	N	N	N	H	H
CD45+	100	100	86	100	100	58	100	100	100	69	100	100	100	100	89	100	100	9	3
CD14+	100	100	86	100	100	100	80	92	100	92	100	96	96	100	94	88	67	10	0
CD3+CD4+	100	100	50	100	100	88	100	100	92	88	100	100	96	93	100	100	100	9	3
CD3+CD8+	94	100	75	90	83	100	75	100	92	88	75	86	92	100	100	100	100	10	0
CD3-CD19+	100	100	100	100	100	100	100	100	89	83	100	77	94	92	92	100	100	10	0
CD3-(CD56 & CD16)+	100	100	50	100	100	NA	100	100	88	50	100	75	90	100	67	75	100	10	0
CD3+ Average	100	100	67	100	83	90	83	100	92	100	67	85	83	93	100	100	100	10	0

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	M	H	H	H	H	M	L	L	L	L	N	N	N	N	H	H
CD45+	100	NA	NA	NA	NA	100	100	100	NA	100	100	100	100	100	100	100	100	10	0
CD14+	100	NA	NA	NA	NA	NA	100	100	NA	NA	100	100	100	100	100	100	100	10	0
CD3+CD4+	100	NA	NA	NA	NA	0	100	100	NA	100	100	100	100	100	100	100	100	10	0
CD3+CD8+	100	NA	NA	NA	NA	100	100	100	NA	100	100	100	100	100	100	100	100	10	0
CD3-CD19+	100	NA	NA	NA	NA	100	100	100	NA	100	100	100	100	100	100	100	100	10	0
CD3-(CD56 & CD16)+	NA	NA	NA	NA	NA	100	NA	NA	NA	100	NA	100	NA	100	NA	NA	100	N	A
CD3+ Average	100	NA	NA	NA	NA	0	100	100	NA	0	100	100	100	100	100	100	100	10	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)

NA = no data returned by any laboratory for specified marker

Table 4. Percentage of 2-color laboratory results for the September 1996 shipment, by equipment manufacturer, that are within the 90% reference ranges*

Becton-Dickinson (N=150)

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	L	L	M	L	N	N	N	N	H	H	H	H	H	H	
CD45+	100	100	75	100	100	94	89	100	82	96	95	85	83	100	75	100	90	10	0
CD14+	100	100	100	100	100	100	100	100	100	100	100	100	100	100	92	100	80	10	0
CD3+CD4+	80	100	100	100	100	100	100	75	82	100	95	92	86	92	88	100	100	10	0
CD3+CD8+	100	100	100	100	88	100	100	75	94	100	100	100	79	100	50	100	83	10	0
CD3-CD19+	90	93	93	100	100	100	100	100	100	95	100	92	100	100	60	100	100	10	0
CD3-(CD56 & CD16)+	100	100	100	100	100	100	83	100	100	95	94	100	100	100	67	100	83	10	0
CD3+ Average	90	100	100	100	88	100	100	50	81	95	88	100	58	100	60	100	80	8	3

Coulter (N=130)

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	L	L	M	L	N	N	N	N	H	H	H	H	H	H	
CD45+	25	100	100	88	100	100	100	88	100	100	95	84	100	57	79	100	100	10	0
CD14+	100	100	100	88	100	91	100	88	100	95	89	94	100	90	100	88	100	10	0
CD3+CD4+	100	100	100	94	100	90	100	100	93	100	94	72	89	100	83	100	100	10	0
CD3+CD8+	83	100	100	75	100	80	90	75	88	87	83	74	94	71	58	89	88	10	0
CD3-CD19+	100	90	100	100	100	86	100	100	100	100	100	100	100	100	100	83	100	10	0
CD3-(CD56 & CD16)+	100	83	NA	88	100	100	100	75	78	100	88	100	100	100	100	100	100	10	0
CD3+ Average	100	100	100	100	100	100	100	80	100	100	83	92	50	100	83	100	88	10	0

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	L	L	M	L	N	N	N	N	H	H	H	H	H	H	
CD45+	100	NA	NA	NA	100	100	100	NA	100	100	100	100	NA	NA	NA	100	100	N	A
CD14+	100	NA	NA	NA	100	100	100	NA	100	100	100	100	NA	NA	NA	100	100	N	A
CD3+CD4+	75	NA	NA	NA	100	0	100	NA	100	100	100	100	NA	NA	NA	100	100	N	A
CD3+CD8+	75	NA	NA	NA	100	100	100	NA	100	100	100	100	NA	NA	NA	100	100	N	A
CD3-CD19+	100	NA	NA	NA	100	100	100	NA	100	100	100	100	NA	NA	NA	100	100	N	A
CD3-(CD56 & CD16)+	NA	NA	NA	NA	NA	100	NA	NA	NA	100	100	NA	NA	NA	NA	NA	100	N	A
CD3+ Average	100	NA	NA	NA	100	100	100	NA	100	100	100	100	NA	NA	NA	100	100	N	A

*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 1996 shipment, by equipment manufacturer, that are within the 90% reference ranges*

Becton-Dickinson (N=150)

Cell Marker (Population)	CDC Donor Number								
	HIV Status**								
	H	L	L	L	L	N	N	N	N
CD45+	100	100	100	88	100	88	95	94	100
CD14+	100	89	100	100	100	94	100	94	100
CD3+CD4+	100	100	100	100	100	82	96	88	93
CD3+CD8+	100	80	91	100	100	82	91	100	100
CD3-CD19+	100	100	100	86	100	79	100	100	100
CD3-(CD56 & CD16)+	100	83	88	89	100	100	100	100	90
CD3+ Average	100	89	100	88	100	71	89	80	100

Coulter (N=130)

Cell Marker (Population)	CDC Donor Number								
	HIV Status**								
	H	L	L	L	L	N	N	N	N
CD45+	100	100	100	100	80	100	100	100	94
CD14+	100	100	100	93	100	94	88	88	94
CD3+CD4+	100	100	100	100	100	94	93	94	73
CD3+CD8+	100	88	100	92	50	87	89	82	93
CD3-CD19+	100	100	100	63	100	100	89	100	91
CD3-(CD56 & CD16)+	100	67	100	100	100	92	80	86	86
CD3+ Average	100	100	100	100	50	100	100	93	86

Ortho (N=19)

Cell Marker (Population)	CDC Donor Number								
	HIV Status**								
	H	L	L	L	L	N	N	N	N
CD45+	100	100	100	NA	100	100	100	100	100
CD14+	100	100	100	NA	100	100	100	100	100
CD3+CD4+	100	100	100	NA	100	100	50	100	100
CD3+CD8+	100	100	100	NA	100	100	100	100	100
CD3-CD19+	100	100	100	NA	100	100	50	100	100
CD3-(CD56 & CD16)+	100	NA	100	NA	100	NA	100	100	100
CD3+ Average	100	100	100	NA	100	100	50	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 September 1996 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
<21	12	<22	13	<13	20	<18	19
21-35	248	22-36	244	13-26	239	18-30	241
>35	14	>36	17	>26	16	>30	14

*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 1996 shipment, by cell marker, within, above, or below the 90% reference ranges*

CDC Donor Number -

Cell Marker (Population)	HIV Status **											
	1 - H		2 - M		3 - H		4 - H		5 - H		6 - H	
	Range	No. [^]	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+, CD3+, CD4+	> 53	0	> 37	0	> 34	2			> 49	0	> 51	0
	39 - 53	4	32 - 37	4	32 - 34	4	NA		37 - 49	2	46 - 51	2
	< 39	0	< 32	0	< 32	0			< 37	0	< 46	0
CD3+, CD4+, CD8-	> 53	0	> 37	0	> 34	0	> 32	0	> 49	0	> 51	0
	39 - 53	2	32 - 37	3	32 - 34	4	27 - 32	6	37 - 49	2	46 - 51	6
	< 39	0	< 32	1	< 32	0	< 27	0	< 37	0	< 46	0
CD45+, CD3+, CD8+	> 49	0	> 47	0	> 44	0			> 45	0	> 43	2
	38 - 49	4	40 - 47	4	36 - 44	6	NA		36 - 45	2	35 - 43	0
	< 38	0	< 40	0	< 36	0			< 36	0	< 35	0
CD3+, CD4-, CD8+	> 49	0	> 47	0	> 44	0	> 53	0	> 45	0	> 43	0
	38 - 49	2	40 - 47	4	36 - 44	4	46 - 53	6	36 - 45	2	35 - 43	6
	< 38	0	< 40	0	< 36	0	< 46	0	< 36	0	< 35	0
CD45+, CD3-, CD19+	> 8	0	> 15	0	> 20	0			> 8	0	> 9	0
	4 - 8	2	10 - 15	2	14 - 20	4	NA		4 - 8	2	6 - 9	2
	< 4	0	< 10	0	< 14	0			< 4	0	< 6	0
CD45+, CD3-, CD(56&16)+	> 3	2	> 8	0	> 9	2					> 5	0
	1 - 3	0	4 - 8	2	6 - 9	2	NA		NA		3 - 5	2
	< 1	0	< 4	0	< 6	0					< 3	0
CD3+ Average	> 95	0	> 80	2	> 74	1	> 84	2	> 91	0	> 91	0
	88 - 95	6	74 - 80	2	67 - 74	7	78 - 84	0	86 - 91	4	88 - 91	6
	< 88	0	< 74	0	< 67	0	< 78	0	< 86	0	< 88	0

*The 90% reference ranges were determined from the 2-color 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)

[^] = frequency of laboratories

NA = no data returned by any laboratory for specified marker

Table 6. Frequency of 3-color laboratory results for the September 1996 shipment, by cell marker, within, above, or below the 90% reference ranges*

CDC Donor Number -		HIV Status **											
Cell Marker (Population)	13 - N		14 - N		15 - N		16 - H		17 - H		18 - H		
	Range	No. [^]	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.	
CD45+, CD3+, CD4+	> 53	0	> 67	0	> 42	0	> 41	0	> 33	0	> 52	0	
	46 - 53	5	60 - 67	5	33 - 42	6	32 - 41	8	27 - 33	2	46 - 52	8	
	< 46	0	< 60	0	< 33	0	< 32	0	< 27	0	< 46	0	
CD3+, CD4+, CD8-	> 53	0	> 67	2	> 42	0	> 41	1	> 33	0			
	46 - 53	7	60 - 67	4	33 - 42	5	32 - 41	3	27 - 33	2	NA		
	< 46	0	< 60	0	< 33	0	< 32	0	< 27	0			
CD45+, CD3+, CD8+	> 27	0	> 21	1	> 31	0	> 50	0	> 60	0	> 22	0	
	22 - 27	5	16 - 21	4	22 - 31	6	40 - 50	8	48 - 60	2	13 - 22	6	
	< 22	0	< 16	0	< 22	0	< 40	0	< 48	0	< 13	0	
CD3+, CD4+, CD8+	> 27	0	> 21	0	> 31	0	> 50	0	> 60	0			
	22 - 27	6	16 - 21	6	22 - 31	5	40 - 50	4	48 - 60	2	NA		
	< 22	1	< 16	0	< 22	0	< 40	0	< 48	0			
CD45+, CD3-, CD19+	> 13	0	> 8	2	> 20	0	> 9	1	> 10	0	> 22	0	
	9 - 13	2	6 - 8	2	15 - 20	5	6 - 9	7	7 - 10	2	17 - 22	6	
	< 9	1	< 6	0	< 15	0	< 6	0	< 7	0	< 17	0	
CD45+, CD3-, CD(56&16)+	> 17	0	> 8	0	> 16	1	> 6	0	> 3	0	> 12	0	
	11 - 17	2	5 - 8	4	11 - 16	3	5 - 6	3	2 - 3	2	10 - 12	6	
	< 11	0	< 5	0	< 11	0	< 5	3	< 2	0	< 10	0	
CD3+ Average	> 78	0	> 89	0	> 71	0	> 89	0	> 91	0	> 71	0	
	73 - 78	8	80 - 89	9	63 - 71	11	84 - 89	8	84 - 91	2	65 - 71	8	
	< 73	0	< 80	0	< 63	0	< 84	1	< 84	0	< 65	0	

*The 90% reference ranges were determined from the 2-color 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)

[^] = frequency of laboratories

NA = no data returned by any laboratory for specified marker

Table 6. Frequency of 3-color laboratory results for the September 1996 shipment, by cell marker, within, above, or below the 90% reference ranges*

Cell Marker (Population)		CDC Donor Number - HIV Status **											
		25 - M		26 - L		27 - N		28 - N		29 - N		30 - N	
		Range	No. [^]	Range	No.	Range	No.	Range	No.	Range	No.	Range	No.
CD45+, CD3+, CD4+		> 14	0	NA		> 55	0	> 45	0	> 62	0	> 45	0
		9 - 14	8			49 - 55	14	37 - 45	9	55 - 62	2	40 - 45	8
		< 9	0			< 49	1	< 37	0	< 55	0	< 40	0
CD3+, CD4+, CD8-		> 14	0	NA		> 55	0	> 45	0	> 62	0	> 45	0
		9 - 14	1			49 - 55	3	37 - 45	4	55 - 62	2	40 - 45	1
		< 9	0			< 49	0	< 37	0	< 55	0	< 40	0
CD45+, CD3+, CD8+		> 76	4	NA		> 33	0	> 38	1	> 28	0	> 26	0
		67 - 76	3			26 - 33	14	32 - 38	8	22 - 28	2	22 - 26	7
		< 67	0			< 26	0	< 32	0	< 22	0	< 22	0
CD3+, CD4+, CD8+		> 76	0	NA		> 33	0	> 38	0	> 28	0	> 26	0
		67 - 76	0			26 - 33	2	32 - 38	4	22 - 28	1	22 - 26	1
		< 67	1			< 26	1	< 32	0	< 22	1	< 22	0
CD45+, CD3-, CD19+		> 14	0	NA		> 8	1	> 13	0	> 11	0	> 22	0
		8 - 14	1			5 - 8	11	8 - 13	7	7 - 11	1	15 - 22	6
		< 8	5			< 5	0	< 8	0	< 7	0	< 15	0
CD45+, CD3-, CD(56&16)+		> 4	0	NA		> 10	0	> 11	0	> 7	0	> 20	0
		2 - 4	4			7 - 10	9	7 - 11	6	5 - 7	0	11 - 20	4
		< 2	0			< 7	0	< 7	0	< 5	1	< 11	0
CD3+ Average		> 90	4	NA		> 87	0	> 85	0	> 88	0	> 70	0
		80 - 90	2			83 - 87	12	74 - 85	9	81 - 88	3	63 - 70	6
		< 80	0			< 83	1	< 74	0	< 81	0	< 63	0

*The 90% reference ranges were determined from the 2-color 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)

[^] = frequency of laboratories

NA = no data returned by any laboratory for specified marker

Table 6. Frequency of 3-color laboratory results for the September 1996 shipment, by cell marker, within, above, or below the 90% reference ranges*

CDC Donor Number -

Cell Marker (Population)	37 - H		38 - L		39 - L		40 - L		41 - L	
	Range	No. [^]	Range	No.	Range	No.	Range	No.	Range	No.
CD45+, CD3+, CD4+	> 36 31 - 36 < 31	0 4 0	> 12 8 - 12 < 8	0 1 0	> 6 3 - 6 < 3	0 4 0	> 12 9 - 12 < 9	0 3 0	> 18 15 - 18 < 15	0 2 0
CD3+, CD4+, CD8-	> 36 31 - 36 < 31	0 4 0	NA		> 6 3 - 6 < 3	0 3 0	> 12 9 - 12 < 9	1 3 0	> 18 15 - 18 < 15	0 2 0
CD45+, CD3+, CD8+	> 41 31 - 41 < 31	0 4 0	> 64 57 - 64 < 57	0 1 0	> 82 71 - 82 < 71	0 3 0	> 68 60 - 68 < 60	0 3 0	> 56 51 - 56 < 51	0 2 0
CD3+, CD4-, CD8+	> 41 31 - 41 < 31	0 4 0	NA		> 82 71 - 82 < 71	1 2 0	> 68 60 - 68 < 60	1 1 2	> 56 51 - 56 < 51	0 2 0
CD45+, CD3-, CD19+	> 22 10 - 22 < 10	0 2 0	> 5 1 - 5 < 1	0 1 0	> 6 1 - 6 < 1	0 3 0	> 17 13 - 17 < 13	0 1 1	> 14 9 - 14 < 9	0 1 0
CD45+, CD3-, CD(56&16)+	> 10 2 - 10 < 2	0 2 0	> 26 20 - 26 < 20	0 1 0	> 9 5 - 9 < 5	0 2 0	> 5 3 - 5 < 3	0 2 0	> 9 7 - 9 < 7	0 1 0
CD3+ Average	> 80 69 - 80 < 69	0 6 0	> 76 69 - 76 < 69	0 1 0	> 89 78 - 89 < 78	1 1 0	> 84 71 - 84 < 71	1 5 0	> 81 75 - 81 < 75	0 3 0

*The 90% reference ranges were determined from the 2-color 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)
[^] = frequency of laboratories
 NA = no data returned by any laboratory for specified marker

Table 6. Frequency of 3-color laboratory results for the September 1996 shipment, by cell marker, within, above, or below the 90% reference ranges*

CDC Donor Number -

Cell Marker (Population)	HIV Status **							
	42 - N		43 - N		44 - N		45 - N	
	Range	No. [^]	Range	No.	Range	No.	Range	No.
CD45+, CD3+, CD4+	> 57	1	> 63	0	> 54	0	> 54	0
	50 - 57	3	55 - 63	5	47 - 54	4	49 - 54	7
	< 50	0	< 55	0	< 47	0	< 49	0
CD3+, CD4+, CD8-	> 57	0	> 63	0	> 54	0	> 54	1
	50 - 57	3	55 - 63	3	47 - 54	4	49 - 54	5
	< 50	1	< 55	0	< 47	0	< 49	1
CD45+, CD3+, CD8+	> 28	0	> 24	0	> 23	0	> 24	0
	22 - 28	3	17 - 24	2	18 - 23	3	18 - 24	7
	< 22	1	< 17	2	< 18	0	< 18	0
CD3+, CD4-, CD8+	> 28	1	> 24	0	> 23	0	> 24	1
	22 - 28	3	17 - 24	1	18 - 23	3	18 - 24	6
	< 22	0	< 17	2	< 18	1	< 18	0
CD45+, CD3-, CD19+	> 9	1	> 16	0	> 16	0	> 9	0
	6 - 9	2	6 - 16	4	8 - 16	2	4 - 9	5
	< 6	0	< 6	0	< 8	0	< 4	0
CD45+, CD3-, CD(56&16)+	> 14	0	> 11	0	> 18	0	> 19	0
	7 - 14	3	5 - 11	3	9 - 18	2	11 - 19	3
	< 7	0	< 5	0	< 9	0	< 11	1
CD3+ Average	> 81	0	> 81	0	> 74	1	> 77	0
	76 - 81	7	75 - 81	3	70 - 74	3	71 - 77	10
	< 76	0	< 75	0	< 70	1	< 71	0

*The 90% reference ranges were determined from the 2-color 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)

[^] = frequency of laboratories

NA = no data returned by any laboratory for specified marker