

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

**Figures and Table Used for the Analysis
of Participant Laboratory Results
for the April 2002 Shipment**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
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**Report of the April 2002 T-Lymphocyte Immunophenotyping (TLI) Results
Provided by Participant Laboratories in the Model Performance Evaluation
Program, Centers for Disease Control and Prevention (CDC).**

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

Donor Identification for April 2002 TLI Shipment Specimens

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

^aHuman immunodeficiency virus type 1

Figure 1. Primary classification of laboratories participating in the April 2002 shipment.

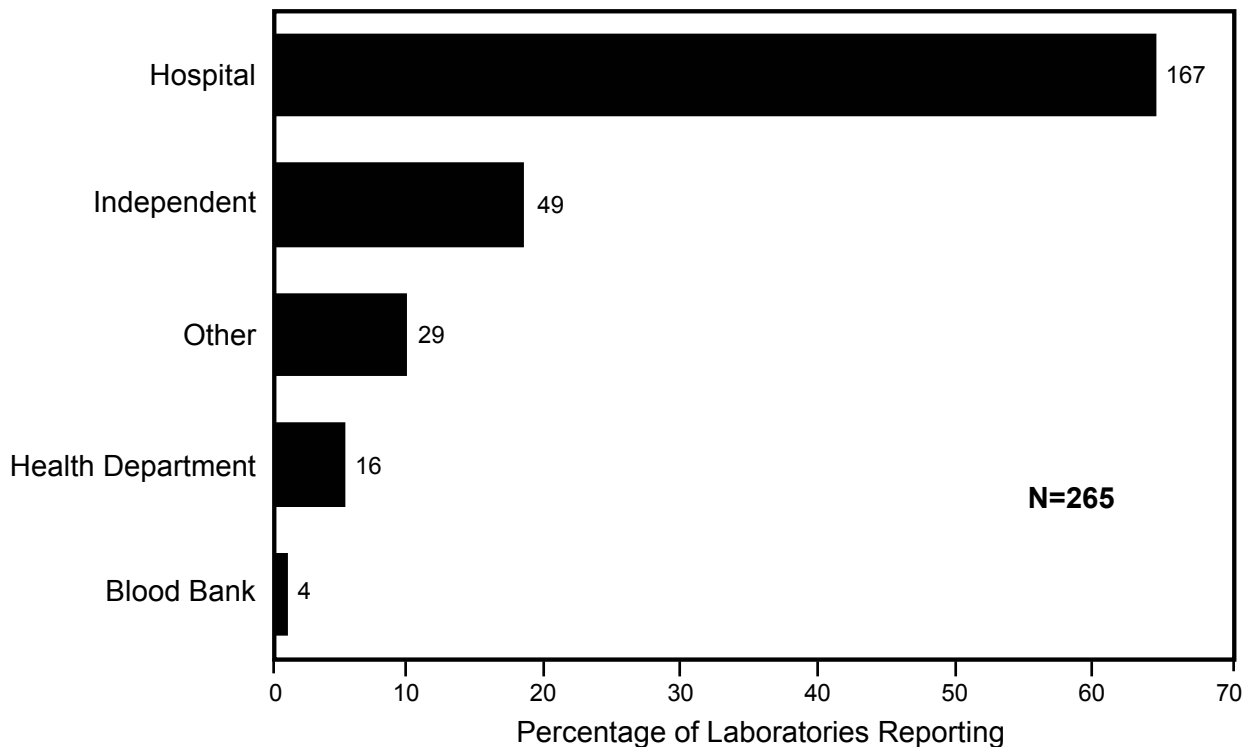


Figure 2. Methods used to prepare specimens for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the April 2002 shipment.

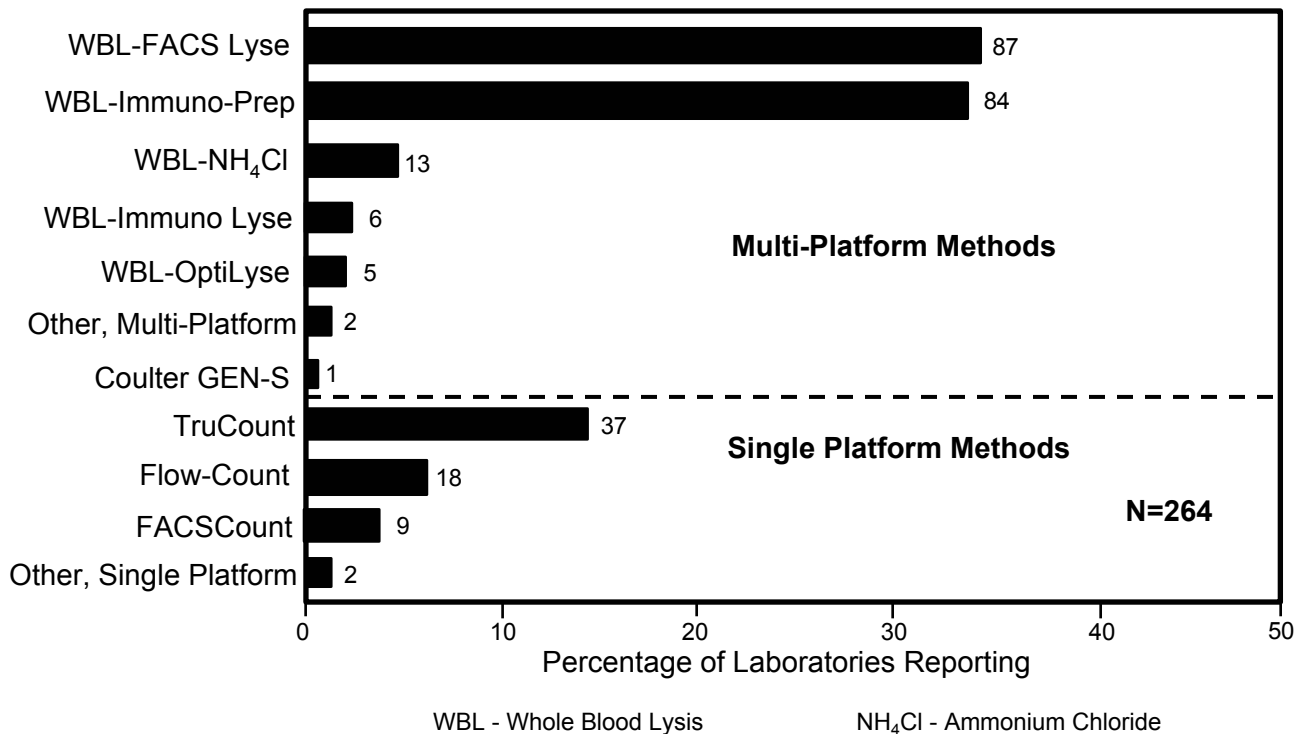


Figure 3. Methods used to fix specimens for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the April 2002 shipment.

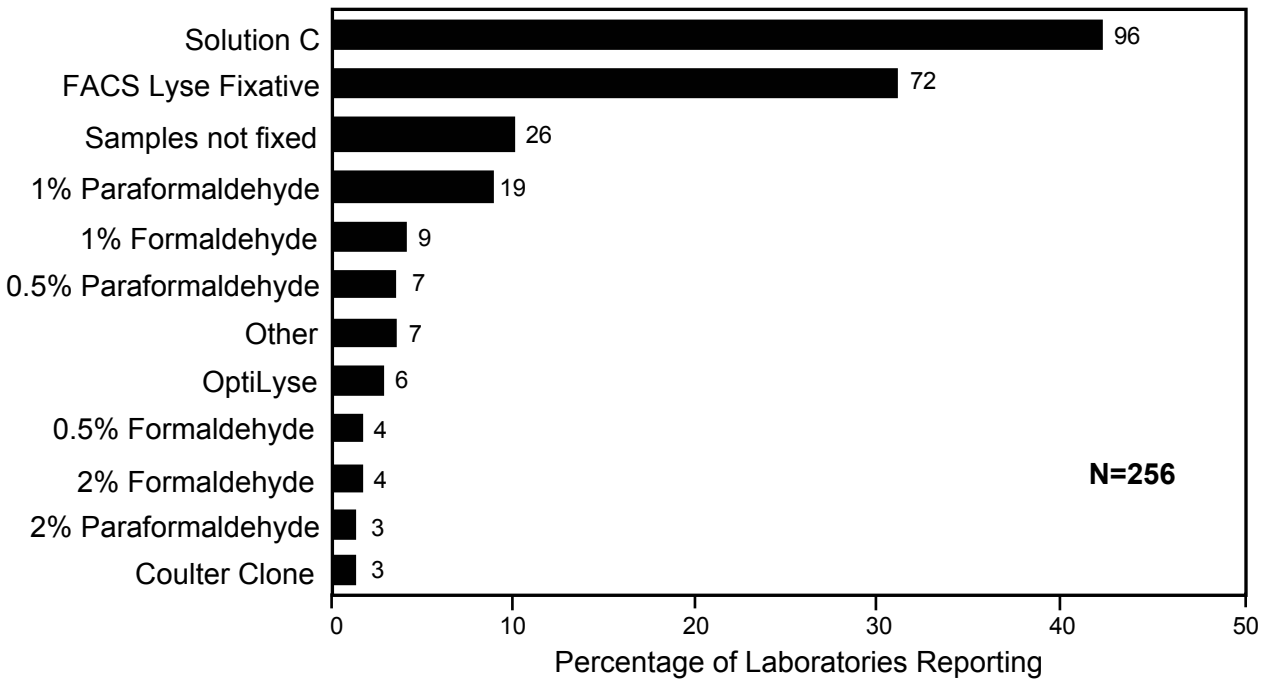


Figure 4. Types of flow cytometers used for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the April 2002 shipment.

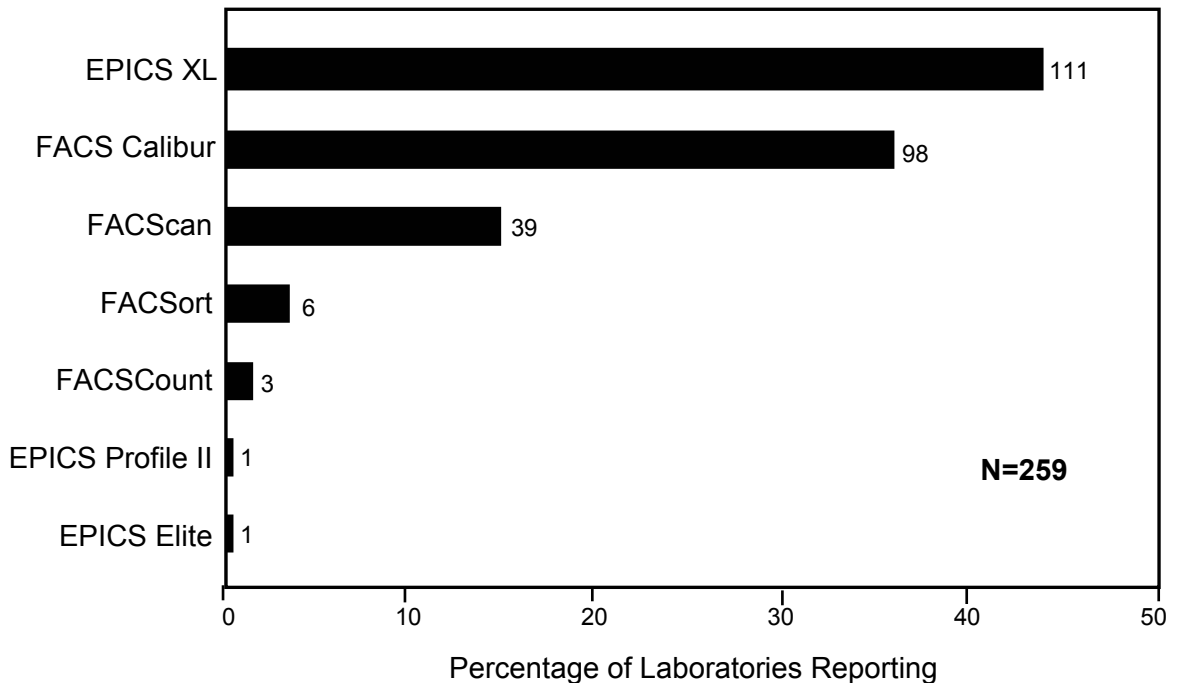
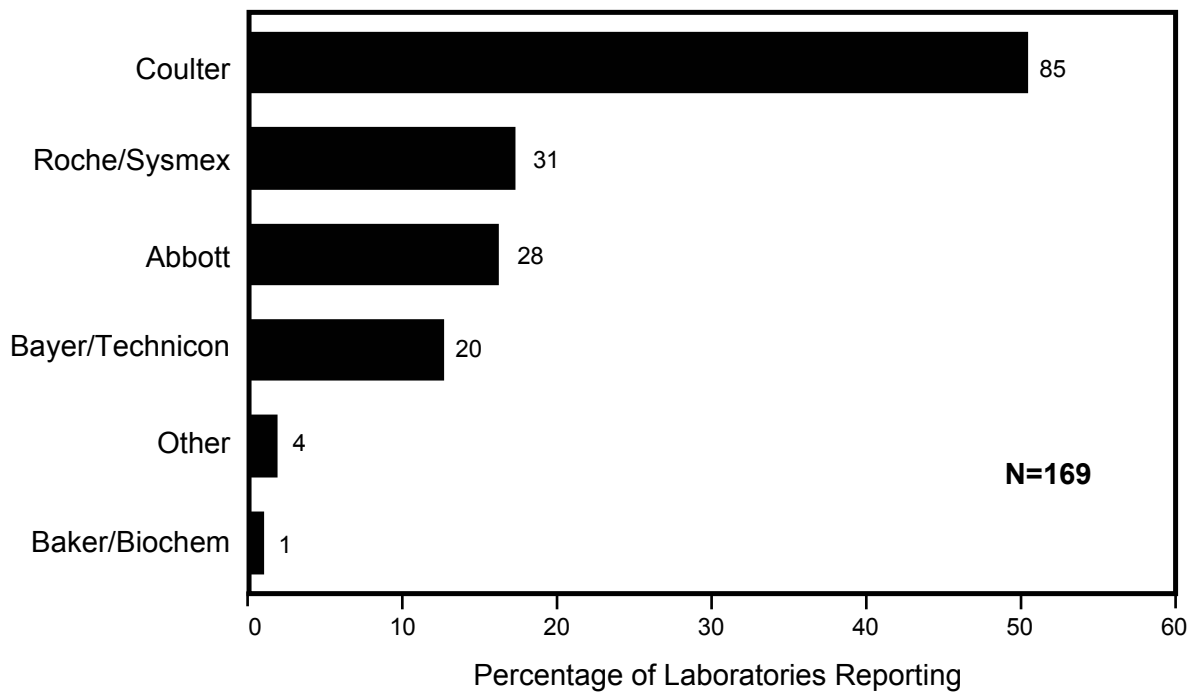


Figure 5. Hematology instruments, by manufacturer, used for T-lymphocyte immunophenotyping, reported by participant laboratories to CDC for the April 2002 shipment.



Explanation of Results Table

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

Cell Marker

The cell surface marker of interest. All results for this surface marker are shown regardless of the monoclonal antibody combination used for their determination:

CD45 -	results from 2-color CD45/CD14
CD14 -	results from 2-color CD45/CD14
CD4 -	combined results from 2-color CD3/CD4; 3-color CD45/CD3/CD4, CD3/CD4/CD8; and 4-color CD45/CD3/CD4/CD8
CD8 -	combined results from 2-color CD3/CD8; 3-color CD45/CD3/CD8, CD3/CD4/CD8; and 4-color CD45/CD3/CD4/CD8
CD19 -	combined results from 2-color CD3/CD19; 3-color CD45/CD3/CD19, CD3/CD19/CD56, CD3/CD19/CD16, CD3/CD19/CD56+16; and 4-color CD45/CD3/CD19/CD56, CD45/CD3/CD19/CD56+16
CD56+16 -	combined results from 2-color CD3/CD56+16; 3-color CD45/CD3/CD56+16, CD3/CD19/CD56+16; and 4-color CD45/CD3/CD19/CD56+16
CD3 average	combined results from 2-color CD3 average; 3-color CD3 average; and 4-color CD3 average
CD56 -	results from 2-color CD3/CD56; 3-color CD45/CD14/CD56, CD3/CD19/CD56; and 4-color CD45/CD3/CD19/CD56
CD16 -	results from 2-color CD3/CD16 and 3-color CD3/CD19/CD16

Percentage Results

The 95% confidence ranges are shown along with the number of reported results within, above, and below the established confidence range (see accompanying written analysis for the method of establishing the confidence range). **Note:** Due to a limited number of reported results for CD56 and CD16, no 95% confidence range was established for these markers. The ranges shown are the maximum and minimum values reported for these cell markers.

Absolute Counts

The results within, above, and below the 95% confidence ranges for the specified cell-marker specific absolute count derived either by multi-platform (flow cytometer/hematology analyzer) or single-platform (single instrument or alternate technique) methods.

Hematology Results

The 95% confidence ranges, the number of results within, above, and below the confidence ranges are listed for the following hematology parameters: white blood cell count (WBC), percent lymphocytes, absolute lymphocyte count.

Participant Laboratory Results for the April 2002 Shipment

Donor Number 1 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	83 - 100	22		
	< 83	3		
CD14	> 2	0		
	0 - 2	25		
	< 0	0		
CD4	> 3	8	> 29	5
	0 - 3	115	0 - 29	98
	< 0	0	< 0	0
CD8	> 51	9	> 476	6
	39 - 51	111	159 - 476	92
	< 39	3	< 159	4
CD19	> 30	1		
	18 - 30	96		
	< 18	6		
CD56+16	> 24	4		
	11 - 24	64		
	< 11	0		
CD3 Average	> 64	4		
	51 - 64	104		
	< 51	3		
CD56	3 - 26	31		
CD16	11 - 16	3		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 3,947	0
	2,092 - 3,947	75
	< 2,092	6
% Lymphs	> 34	4
	14 - 34	75
	< 14	1
Absolute Lymphs	> 1,117	4
	330 - 1,117	73
	< 330	4

Legend:

95% Confidence limits highlighted
 "No." represents number of laboratories reporting in these ranges.
 No confidence limits established for CD56 and CD16 - maximum and minimum values reported

Donor Number 2 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	93 - 100	30		
	< 93	1		
CD14	> 2	0		
	0 - 2	30		
	< 0	0		
CD4	> 52	5	> 1,229	5
	45 - 52	117	886 - 1,229	100
	< 45	5	< 886	3
CD8	> 29	4	> 666	6
	23 - 29	123	457 - 666	99
	< 23	0	< 457	2
CD19	> 19	0		
	14 - 19	98		
	< 14	7		
CD56+16	> 10	3		
	2 - 10	67		
	< 2	0		
CD3 Average	> 81	6		
	73 - 81	108		
	< 73	1		
CD56	1 - 10	31		
CD16	4 - 6	3		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 6,010	1
	4,912 - 6,010	80
	< 4,912	4
% Lymphs	> 45	5
	35 - 45	78
	< 35	2
Absolute Lymphs	> 2,614	2
	1,743 - 2,614	80
	< 1,743	4

Participant Laboratory Results for the April 2002 Shipment

Donor Number 3 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	95 - 100	30		
	< 95	2		
CD14	> 2	0		
	0 - 2	31		
	< 0	0		
CD4	> 52	4	> 1,766	7
	44 - 52	120	1,128 - 1,766	99
	< 44	3	< 1,128	1
CD8	> 37	2	> 1,286	7
	32 - 37	120	797 - 1,286	97
	< 32	5	< 797	2
CD19	> 10	1		
	8 - 10	100		
	< 8	5		
CD56+16	> 14	1		
	7 - 14	67		
	< 7	3		
CD3 Average	> 85	7		
	76 - 85	107		
	< 76	2		
CD56	1 - 14	31		
CD16	8 - 11	3		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 10,903	0
	9,104 - 10,903	80
	< 9,104	4
% Lymphs	> 37	5
	23 - 37	78
	< 23	1
Absolute Lymphs	> 3,815	5
	2,214 - 3,815	79
	< 2,214	1

Legend:

95% Confidence limits highlighted
 "No." represents number of laboratories reporting in these ranges.
 No confidence limits established for CD56 and CD16 - maximum and minimum values reported

Donor Number 4 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	92 - 100	39		
	< 92	1		
CD14	> 2	0		
	0 - 2	39		
	< 0	0		
CD4	> 45	8	> 968	5
	38 - 45	117	661 - 968	86
	< 38	3	< 661	1
CD8	> 33	1	> 707	6
	27 - 33	119	466 - 707	86
	< 27	8	< 466	0
CD19	> 25	1		
	17 - 25	96		
	< 17	5		
CD56+16	> 10	4		
	0 - 10	74		
	< 0	0		
CD3 Average	> 77	6		
	70 - 77	103		
	< 70	3		
CD56	2 - 9	22		
CD16	3 - 6	4		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 6,149	2
	5,070 - 6,149	75
	< 5,070	5
% Lymphs	> 42	4
	29 - 42	76
	< 29	2
Absolute Lymphs	> 2,466	6
	1,469 - 2,466	76
	< 1,469	2

Participant Laboratory Results for the April 2002 Shipment

Donor Number 5 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	91 - 100	21		
	< 91	2		
CD14	> 2	0		
	0 - 2	21		
	< 0	0		
CD4	> 50	4	> 939	10
	42 - 50	122	511 - 939	114
	< 42	2	< 511	0
CD8	> 32	2	> 578	9
	25 - 32	125	317 - 578	113
	< 25	1	< 317	0
CD19	> 16	0		
	11 - 16	103		
	< 11	7		
CD56+16	> 15	0		
	5 - 15	63		
	< 5	1		
CD3 Average	> 81	6		
	71 - 81	113		
	< 71	1		
CD56	2 - 6	40		
CD16	7 - 7	2		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 6,695	1
	5,106 - 6,695	83
	< 5,106	4
% Lymphs	> 38	7
	17 - 38	81
	< 17	0
Absolute Lymphs	> 2,228	7
	1,016 - 2,228	81
	< 1,016	0

Legend:

95% Confidence limits highlighted
 "No." represents number of laboratories reporting in these ranges.
 No confidence limits established for CD56 and CD16 - maximum and minimum values reported

Donor Number 6 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	92 - 100	29		
	< 92	0		
CD14	> 3	3		
	0 - 3	25		
	< 0	0		
CD4	> 66	3	> 1,954	6
	53 - 66	122	413 - 1,954	98
	< 53	4	< 413	1
CD8	> 28	1	> 799	4
	23 - 28	122	196 - 799	98
	< 23	5	< 196	1
CD19	> 9	1		
	3 - 9	101		
	< 3	1		
CD56+16	> 9	0		
	4 - 9	58		
	< 4	6		
CD3 Average	> 93	4		
	79 - 93	104		
	< 79	2		
CD56	1 - 90	36		
CD16	1 - 6	4		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 10,719	0
	5,581 - 10,719	72
	< 5,581	2
% Lymphs	> 38	5
	17 - 38	67
	< 17	0
Absolute Lymphs	> 3,461	4
	1,075 - 3,461	70
	< 1,075	0

Participant Laboratory Results for the April 2002 Shipment

Donor Number 7 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	95 - 100	36		
	< 95	0		
CD14	> 3	3		
	0 - 3	31		
	< 0	0		
CD4	> 54	11	> 897	6
	43 - 54	121	574 - 897	96
	< 43	0	< 574	4
CD8	> 29	2	> 500	1
	24 - 29	125	311 - 500	98
	< 24	3	< 311	5
CD19	> 19	1		
	13 - 19	97		
	< 13	6		
CD56+16	> 11	0		
	3 - 11	58		
	< 3	1		
CD3 Average	> 81	7		
	72 - 81	110		
	< 72	1		
CD56	2 - 100	42		
CD16	3 - 9	8		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 3,906	1
	3,257 - 3,906	76
	< 3,257	3
% Lymphs	> 53	7
	34 - 53	73
	< 34	0
Absolute Lymphs	> 1,789	7
	1,280 - 1,789	72
	< 1,280	1

Legend:

95% Confidence limits highlighted
 "No." represents number of laboratories reporting in these ranges.
 No confidence limits established for CD56 and CD16 - maximum and minimum values reported

Donor Number 8 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	95 - 100	30		
	< 95	0		
CD14	> 2	2		
	0 - 2	27		
	< 0	0		
CD4	> 9	1	> 208	5
	6 - 9	127	113 - 208	100
	< 6	0	< 113	2
CD8	> 69	7	> 1,723	3
	57 - 69	118	1,116 - 1,723	99
	< 57	2	< 1,116	3
CD19	> 25	1		
	15 - 25	93		
	< 15	8		
CD56+16	> 10	1		
	5 - 10	60		
	< 5	2		
CD3 Average	> 77	9		
	66 - 77	99		
	< 66	2		
CD56	3 - 100	35		
CD16	5 - 7	4		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 4,902	2
	3,998 - 4,902	72
	< 3,998	2
% Lymphs	> 57	5
	46 - 57	68
	< 46	2
Absolute Lymphs	> 2,745	4
	1,849 - 2,745	69
	< 1,849	3

Participant Laboratory Results for the April 2002 Shipment

Donor Number 9 - Donor Status: HIV-antibody Positive

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	92 - 100	24		
	< 92	0		
CD14	> 3	3		
	0 - 3	21		
	< 0	0		
CD4	> 36	3	> 845	8
	30 - 36	121	387 - 845	100
	< 30	2	< 387	0
CD8	> 52	3	> 1,297	9
	47 - 52	121	592 - 1,297	96
	< 47	2	< 592	1
CD19	> 12	0		
	7 - 12	94		
	< 7	7		
CD56+16	> 6	2		
	2 - 6	65		
	< 2	1		
CD3 Average	> 89	4		
	83 - 89	97		
	< 83	1		
CD56	2 - 5	30		
CD16	NA			

Hematology Results

Hematology Parameter	Range	No.
WBC	> 5,721	3
	4,948 - 5,721	69
	< 4,948	0
% Lymphs	> 45	6
	27 - 45	62
	< 27	2
Absolute Lymphs	> 2,590	7
	1,332 - 2,590	63
	< 1,332	2

Legend:

95% Confidence limits highlighted
 "No." represents number of laboratories reporting in these ranges.
 No confidence limits established for CD56 and CD16 - maximum and minimum values reported

Donor Number 10 - Donor Status: HIV-antibody Negative

Cell Marker	Percentage Results		Absolute Counts	
	Range	No.	Range	No.
CD45	> 100	0		
	95 - 100	28		
	< 95	2		
CD14	> 4	3		
	0 - 4	26		
	< 0	0		
CD4	> 59	5	> 2,086	8
	52 - 59	121	948 - 2,086	99
	< 52	3	< 948	0
CD8	> 21	3	> 691	8
	17 - 21	122	327 - 691	96
	< 17	3	< 327	1
CD19	> 20	0		
	16 - 20	98		
	< 16	5		
CD56+16	> 8	1		
	4 - 8	58		
	< 4	5		
CD3 Average	> 80	4		
	72 - 80	105		
	< 72	1		
CD56	2 - 100	36		
CD16	3 - 5	4		

Hematology Results

Hematology Parameter	Range	No.
WBC	> 11,166	3
	9,713 - 11,166	69
	< 9,713	4
% Lymphs	> 44	8
	13 - 44	67
	< 13	0
Absolute Lymphs	> 5,003	7
	1,117 - 5,003	69
	< 1,117	0