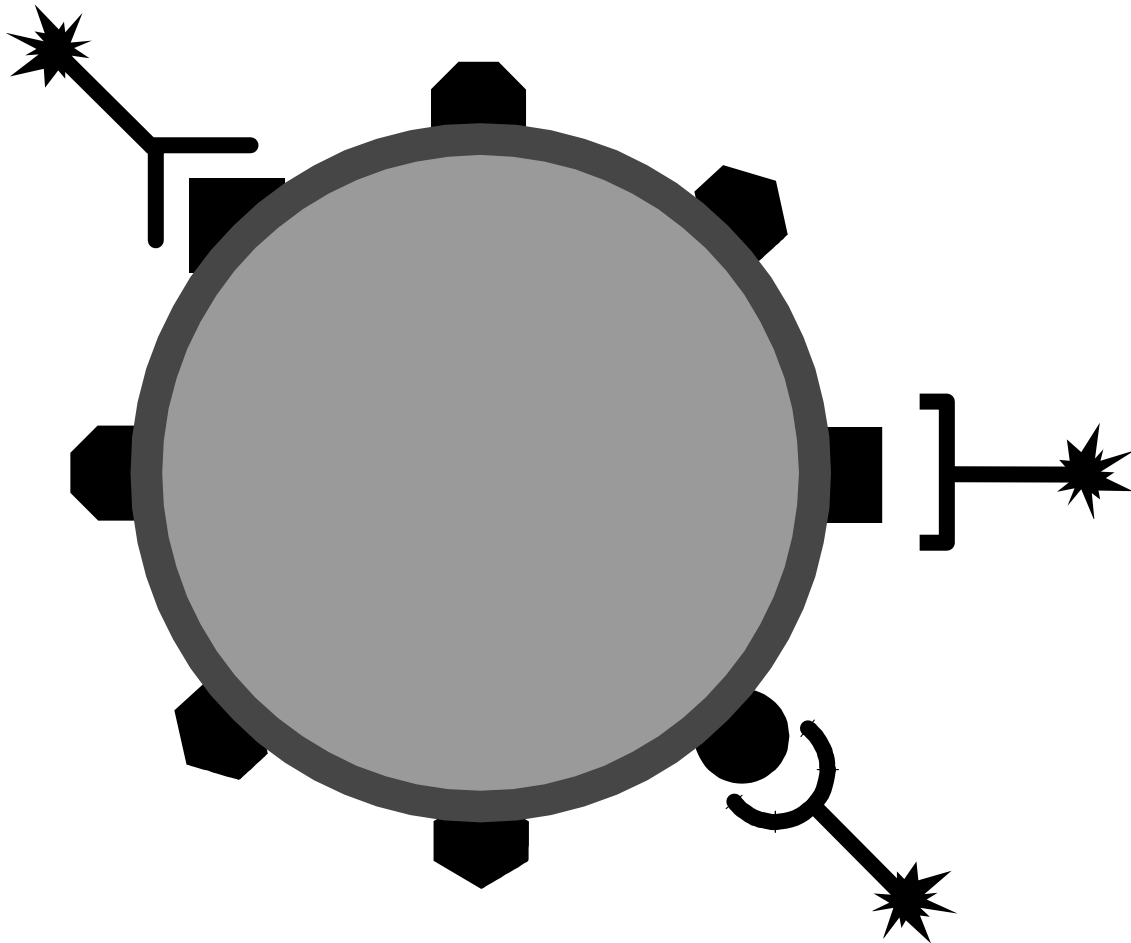


**Results of the 2004 CD4+ T-Cell
Determinations Questionnaire Survey
Mailed to Laboratories Participating
in the Model Performance Evaluation Program**



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention



This report provides the results of a **2004 CD4⁺ T-cell Determinations Laboratory Questionnaire Survey** mailed to laboratories participating in the Model Performance Evaluation Program, Centers for Disease Control and Prevention (CDC).

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

Introductory Comments

The aggregate results from a mailed questionnaire survey conducted by the Model Performance Evaluation Program (MPEP) in May 2004 of laboratories in the United States performing CD4⁺ T-cell determinations are presented in the following figures and tables. Of the 269 laboratories receiving this survey, 194 (72.1%) reported results. The "N" numbers appearing in each figure or table reflect the total number of laboratories responding to the specific question. For multiple response questions, the total number of responses may exceed the actual number of laboratories responding to that specific question.

The map located on page 2 reflects the enrollment in the MPEP CD4⁺ T-cell determinations program at the time this survey was mailed, and may not reflect the current enrollment in this program.

The primary classification of all the laboratories in the MPEP CD4⁺ T-cell determinations program at the time the survey was mailed is shown in the top figure on page 4. The primary classification of only those laboratories responding to the survey is shown in the bottom figure on the same page. The further classifications of the responding laboratories are shown in the responses for questions 5(a)-5(e).

The term "single-platform method" was defined to be those methods for obtaining absolute CD4⁺ T-cell counts using a single-instrument, for example, FACSCount or FlowCount, or laboratory test, for example, Manual CD4 Count kit. The term "multi-platform method" was defined to be those methods that derive absolute CD4⁺ T-cell counts by using the percent CD4⁺ T-cells obtained from a flow cytometer in combination with the absolute lymphocyte count obtained from a hematology instrument.

Responses to question 8 reflect the amount of experience necessary to perform either single-platform or multi-platform methods.

Question 18 requested information regarding when participant laboratories began performing CD4⁺ T-cell determinations. For those laboratories beginning to perform CD4⁺ T-cell determinations in the last two years (2003-2004), the majority began by offering single-platform rather than multi-platform testing.

As reflected in Question 25(d), fewer laboratories are routinely using isotype controls as part of their staining procedure (22.5%) than was reflected in the responses to this question in the 2001 questionnaire survey (45.4%) or 1999 questionnaire survey (58.3%); indicating a decreasing trend over time for the use of isotype controls. This correlates with the responses in question 30(b) showing that fewer laboratories (18.8%) are currently subtracting isotype controls to adjust reported phenotype values, when compared to the 2001 questionnaire survey (58.1%) or the 1999 questionnaire survey (65.1%); indicating a decreasing trend over time for the use of isotype controls to adjust reported phenotype values.

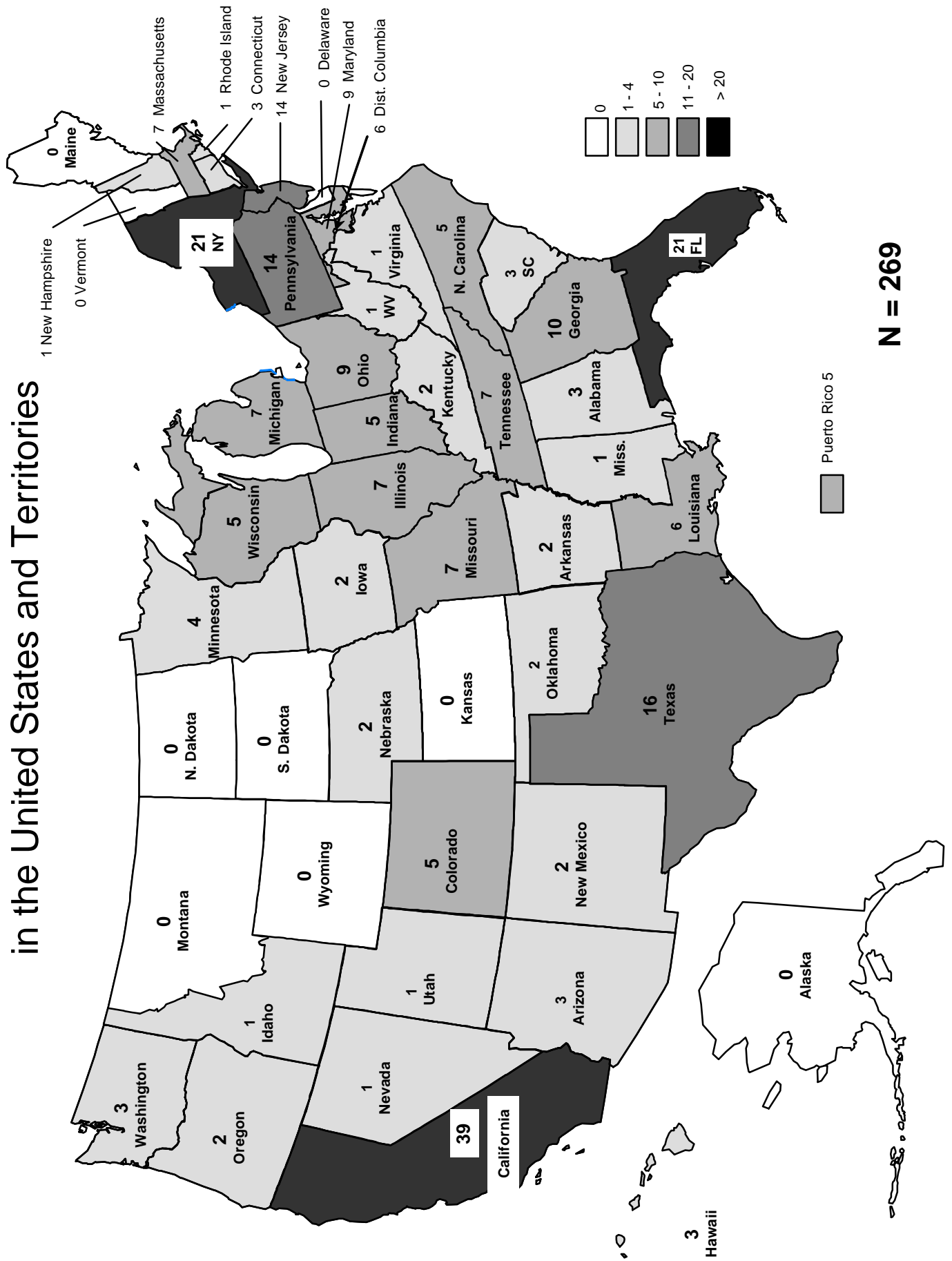
Question 27 requested information regarding the monoclonal antibody manufacturer associated with reagents for each of the cell marker combinations routinely used for performing CD4⁺ T-cell determinations. The first page of results for this question, page 35, shows the reagents used for two-color, three-color, and four-color tests. A summary of monoclonal antibody reagents used by participant laboratories is shown on page 36. Pages 37 through 39 show the monoclonal antibody reagent panels used by the participant laboratories. As reflected in the responses to question 27, laboratories are mixing their own monoclonal antibody cocktails, using reagents from 2 manufacturing sources, in a single cocktail.

Question 44 requested information regarding the price charged for CD4⁺ T-cell determinations performed by single-platform or multi-platform methods.

Responses to Question 45 reflect the external proficiency testing programs in which participant laboratories are enrolled.

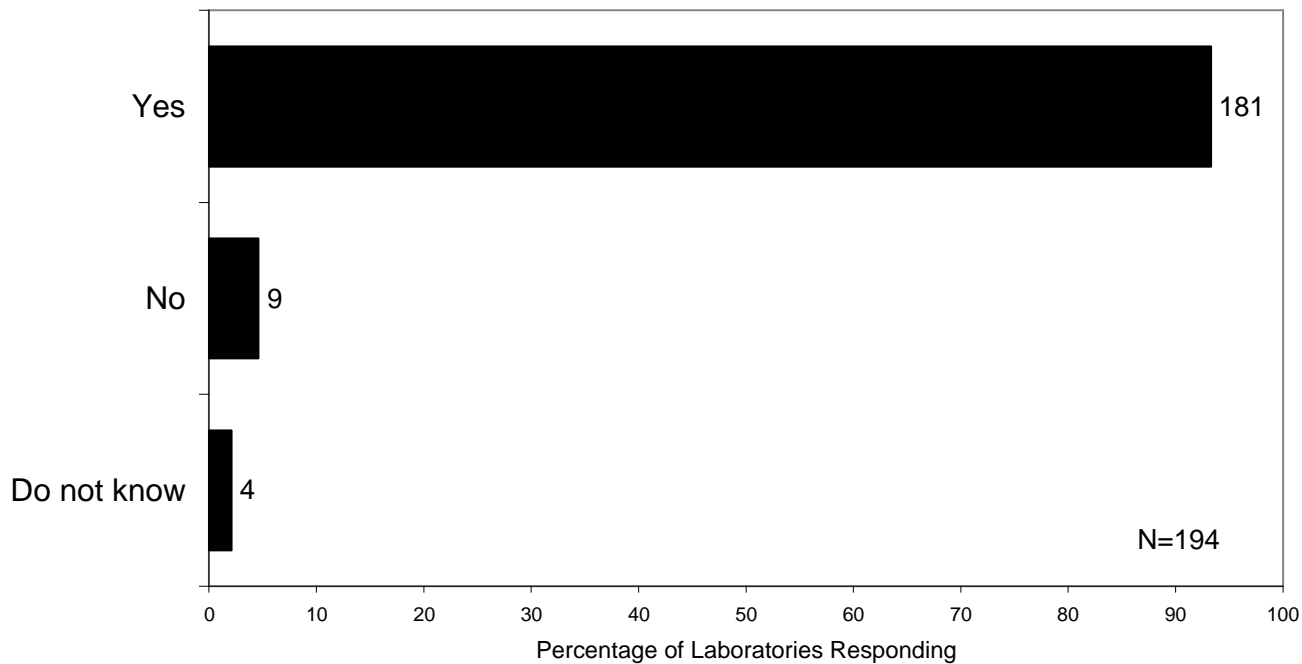
Questions 46 and 47 requested information regarding the surrogate-marker tests and the other tests for HIV infection which are performed by participant laboratories.

Number of MPEP CD4+ T-cell Determinations Laboratories in the United States and Territories



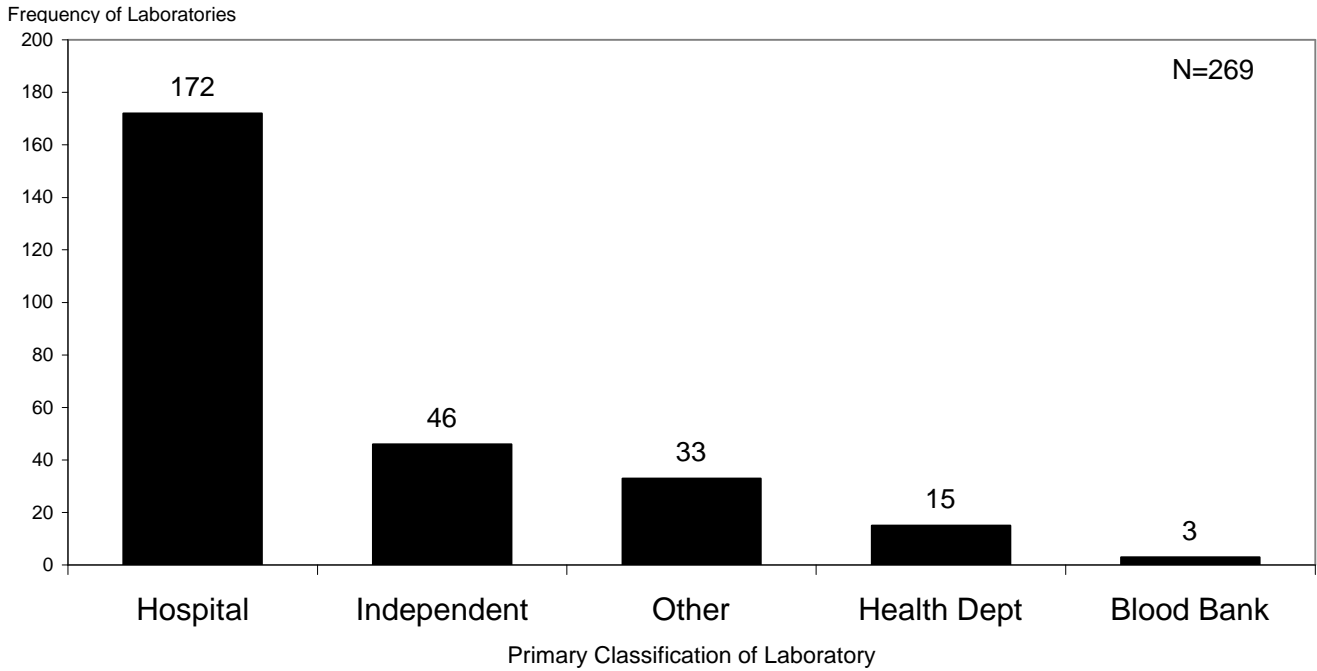
N = 269

4. In the last year, has your laboratory performed CD4⁺ T-cell determinations for HIV-infected patients?

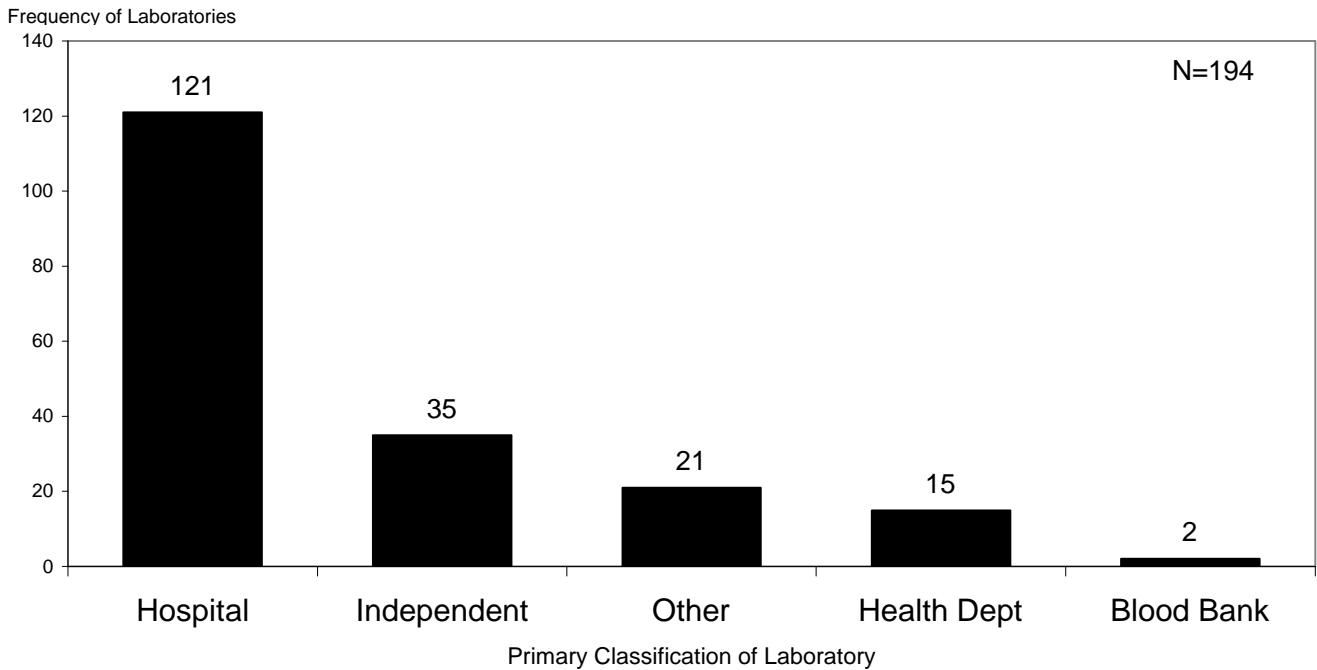


Primary Classification of MPEP CD4⁺ T-cell determinations Testing Laboratories

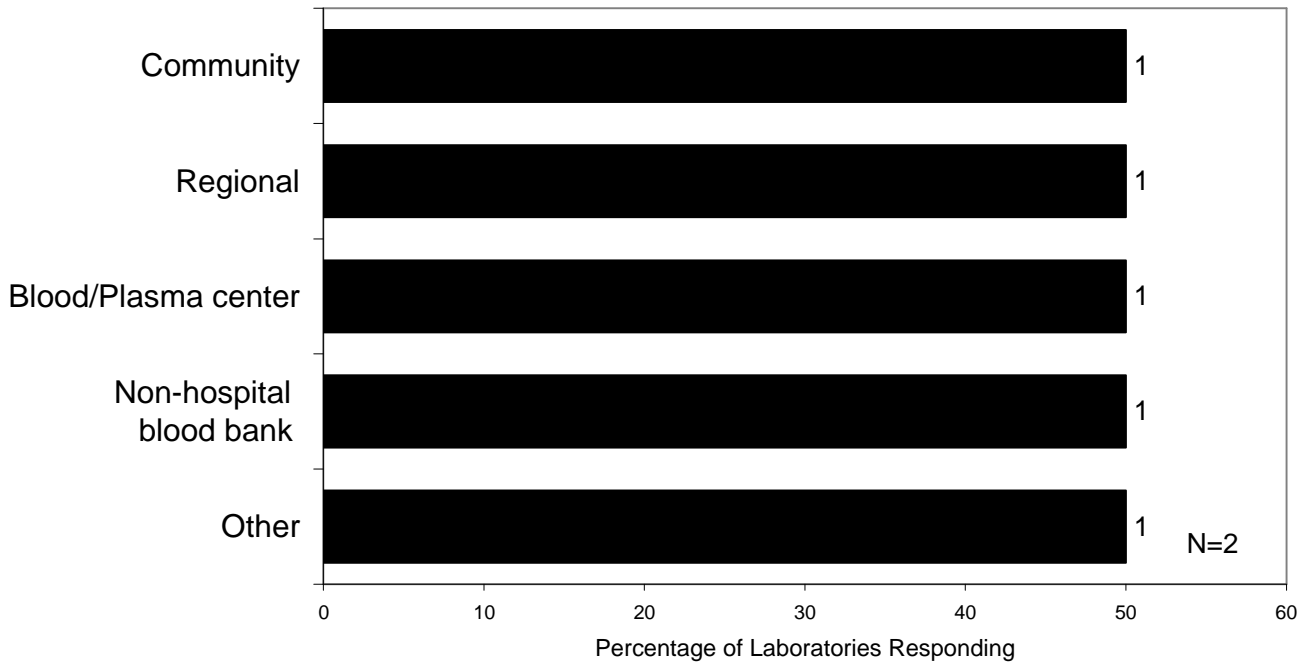
Total Number of Laboratories in CD4⁺ Program



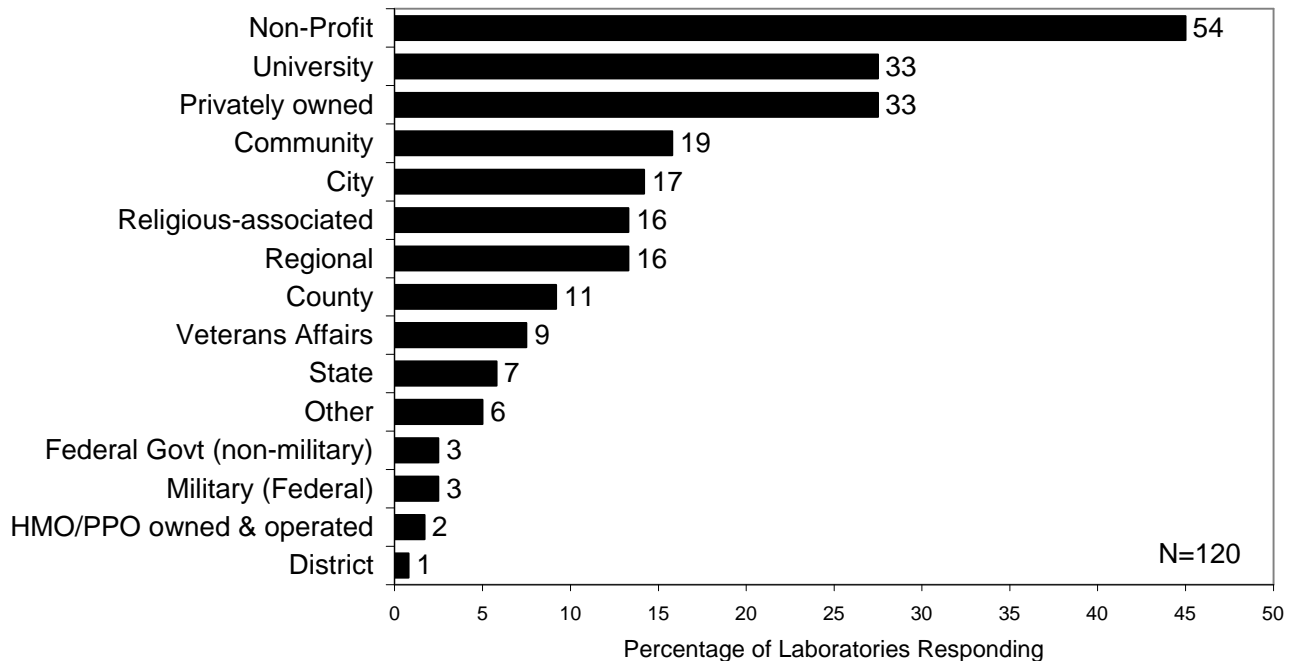
Laboratories Responding to Questionnaire Survey



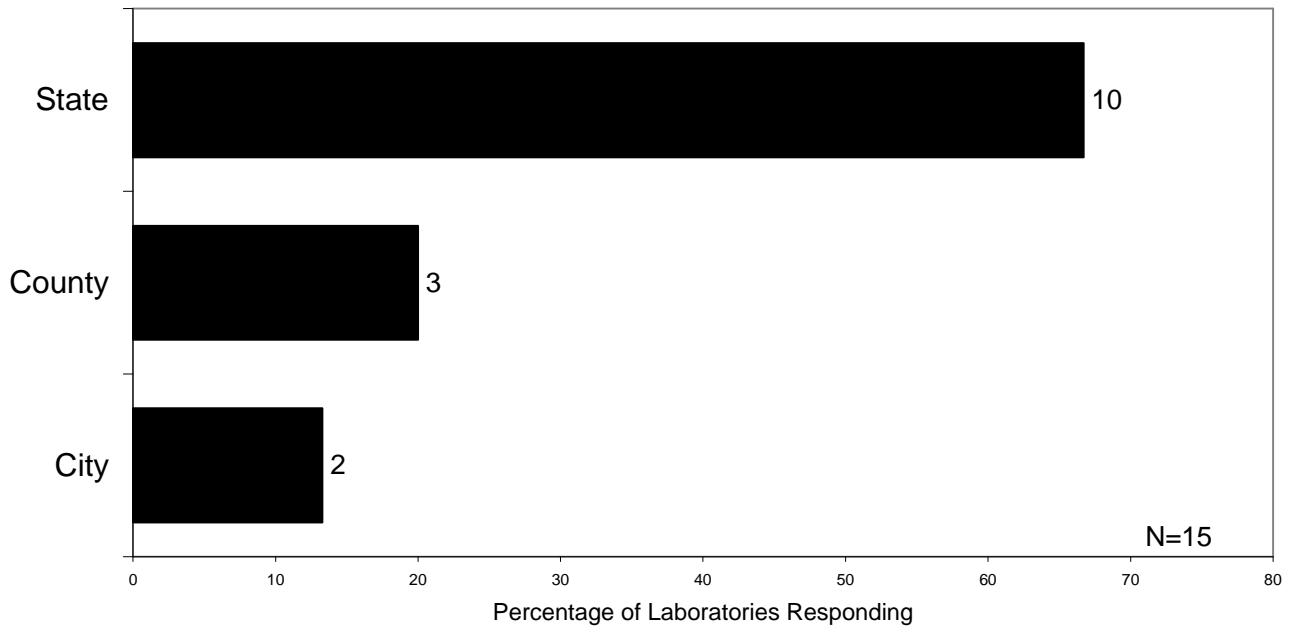
5.(a) If the laboratory type shown on your mailing label (located on page one) is **BLOOD BANK**, please further describe your CD4⁺ T-cell determinations testing laboratory (Check all that apply within your Blood Bank laboratory classification.):



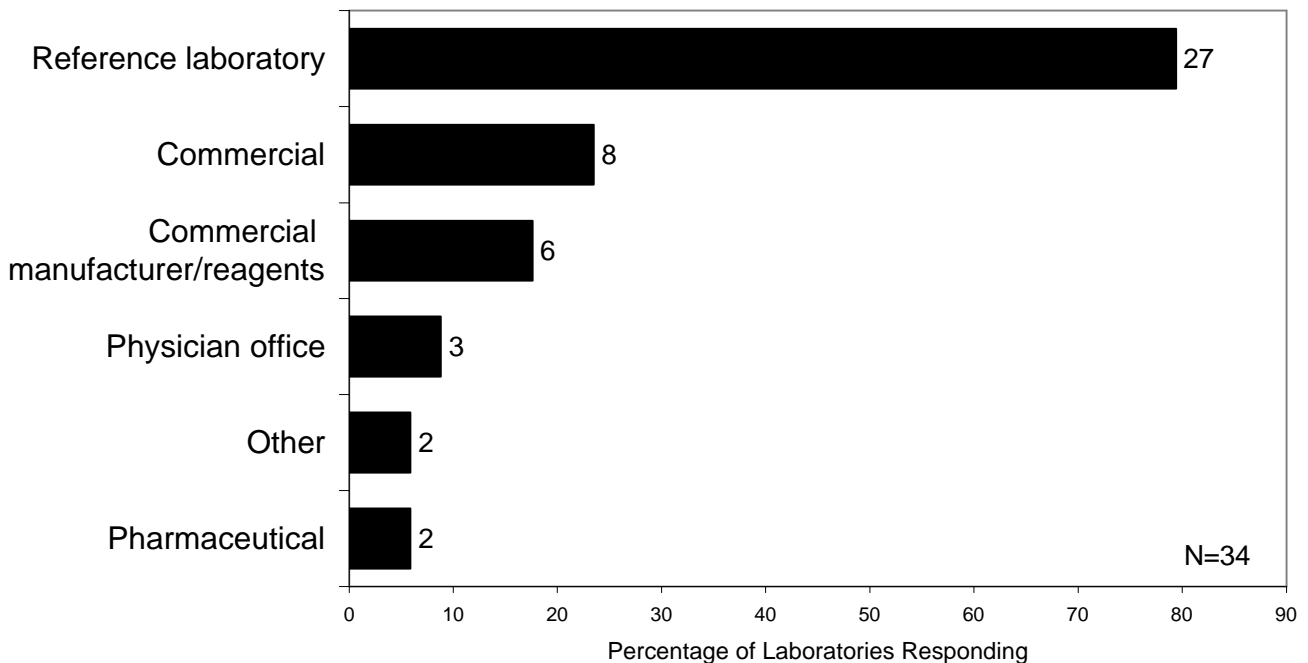
5.(b) If the laboratory type shown on your mailing label (located on page one) is **HOSPITAL**, please further describe your CD4⁺ T-cell determinations testing laboratory (Check all that apply within your Hospital laboratory classification.):



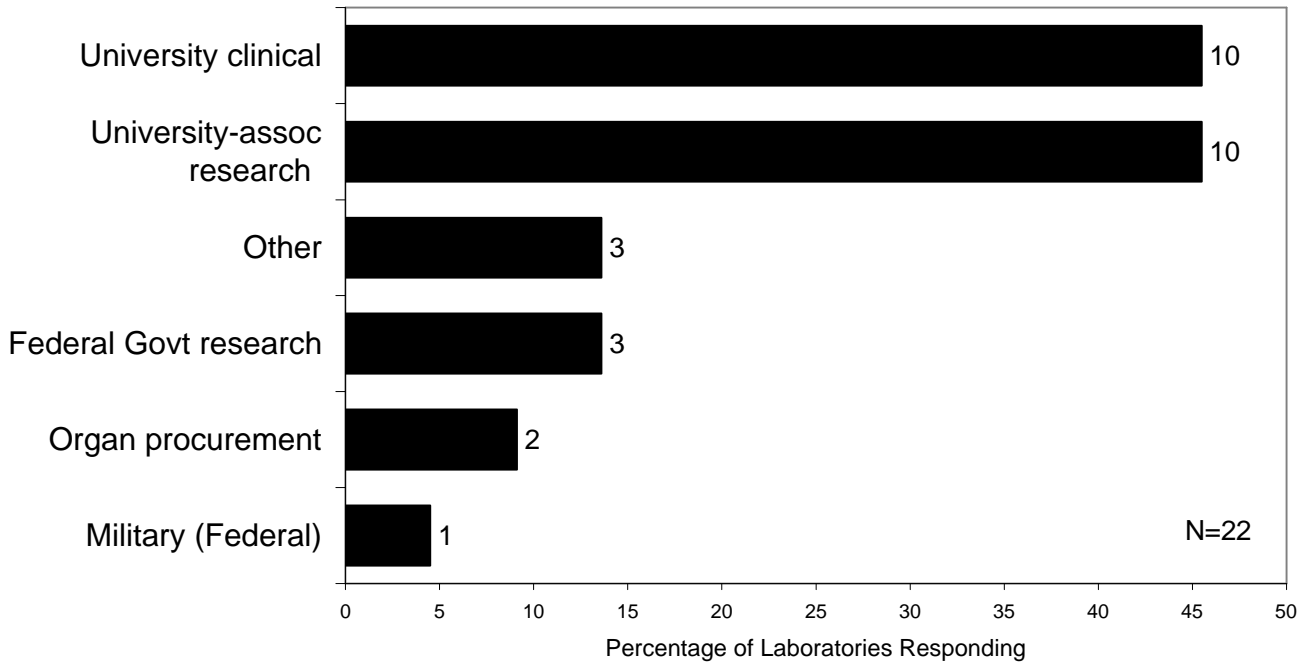
5.(c) If the laboratory type shown on your mailing label (located on page one) is **HEALTH DEPARTMENT**, please further describe your CD4⁺ T-cell determinations testing laboratory (Check all that apply within your Health Department laboratory classification.):



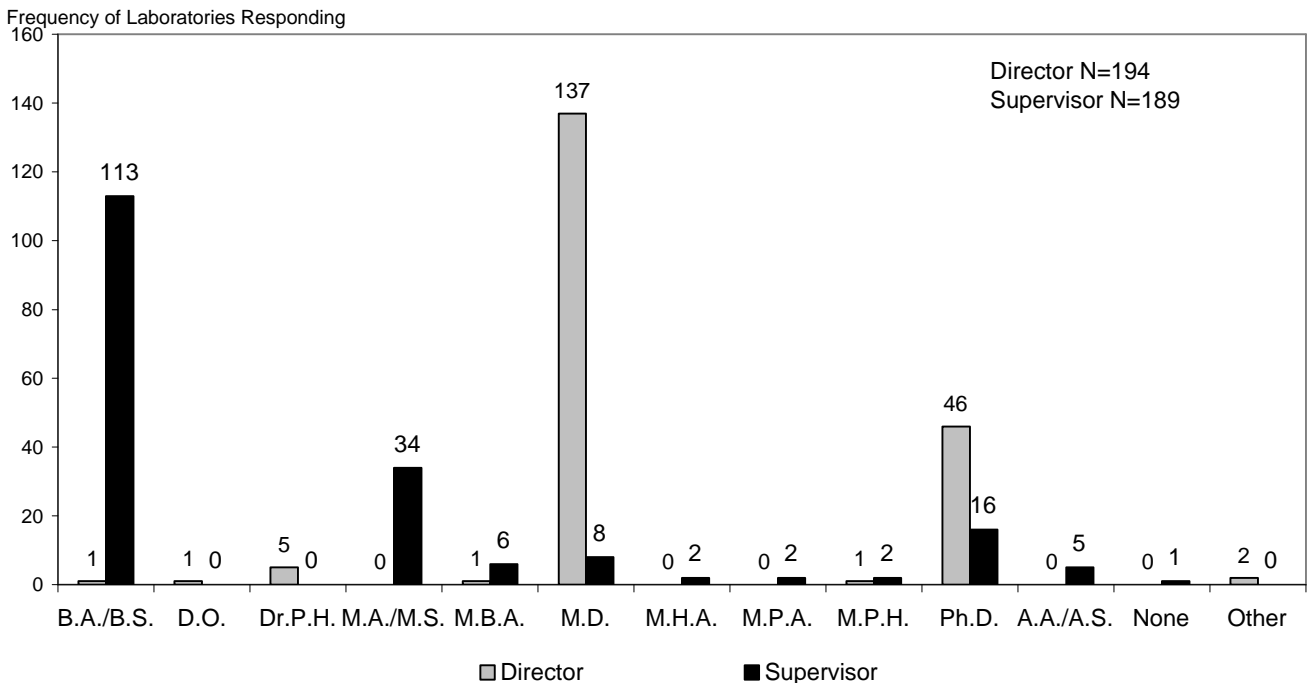
5.(d) If the laboratory type shown on your mailing label (located on page one) is **INDEPENDENT**, please further describe your CD4⁺ T-cell determinations testing laboratory (Check all that apply within your Independent laboratory classification.):



5.(e) If the laboratory type shown on your mailing label (located on page one) is **OTHER**, please further describe your CD4⁺ T-cell determinations testing laboratory (Check all that apply with in your Other laboratory classification.):

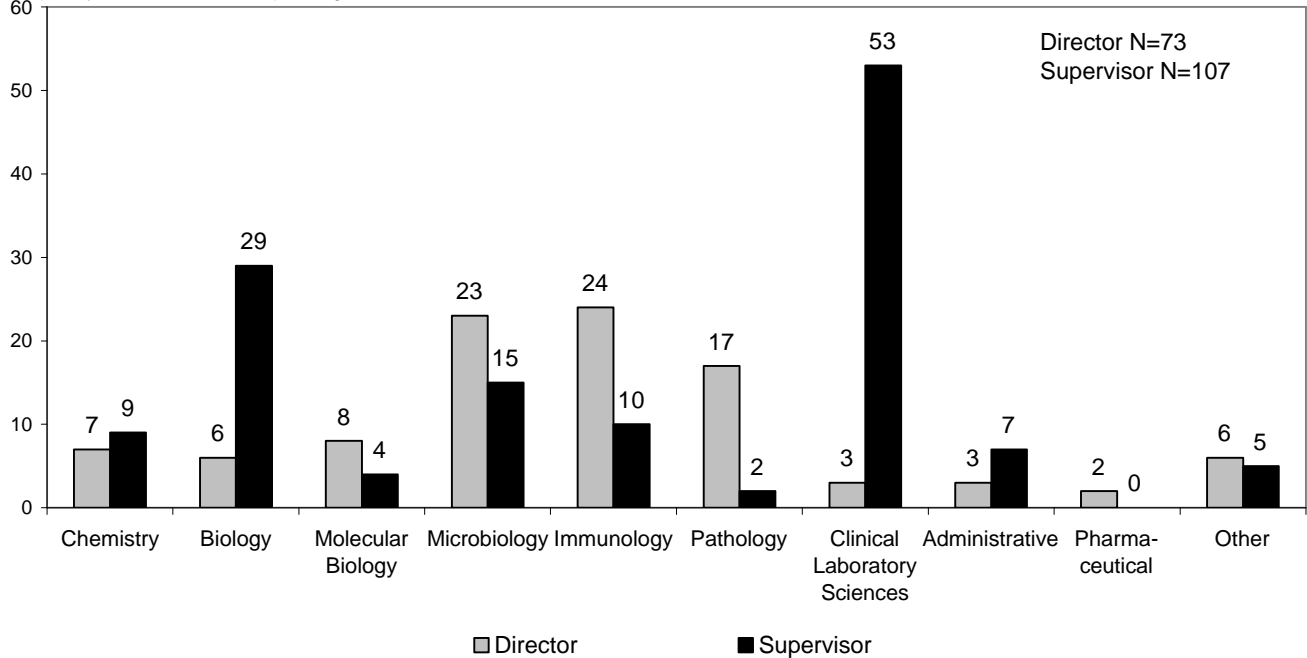


6.(a) Please choose from the list below the highest academic degree that has been awarded to your Laboratory Director and Laboratory Supervisor (Choose only one degree for each person.):

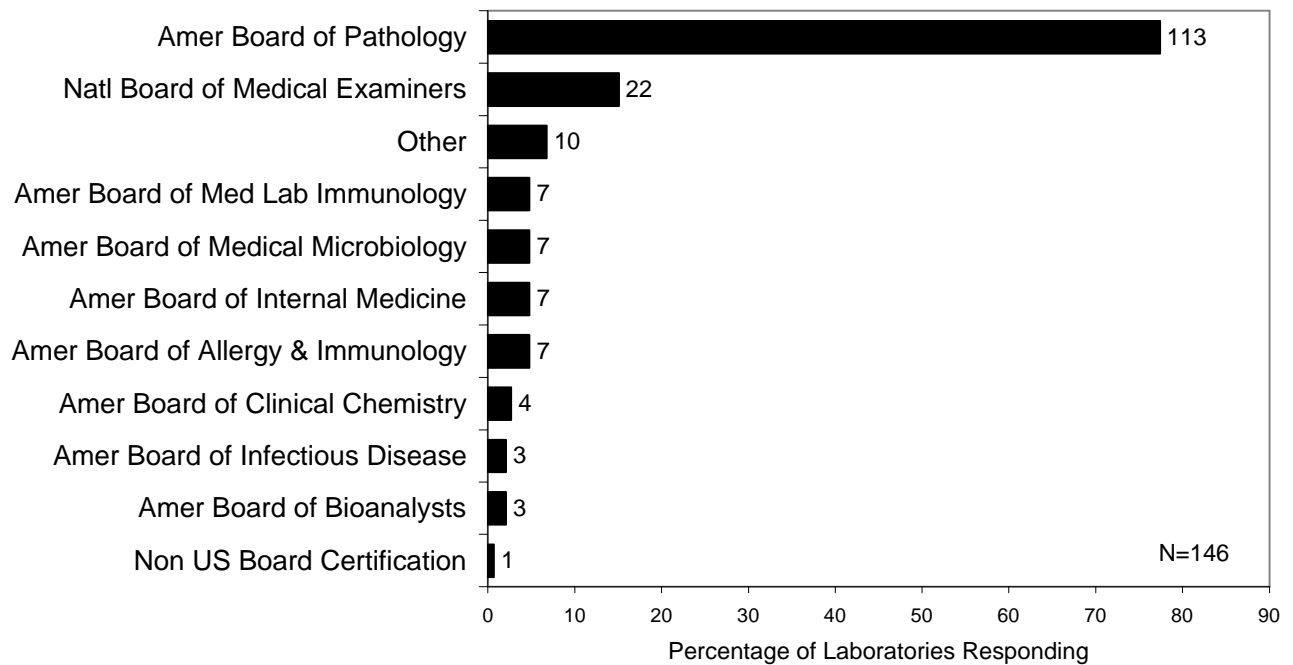


6.(b) If your Laboratory Director or Laboratory Supervisor has a degree other than M.D. or D.O., please indicate the academic discipline in which the degree was awarded (Check all that apply.):

Frequency of Laboratories Responding

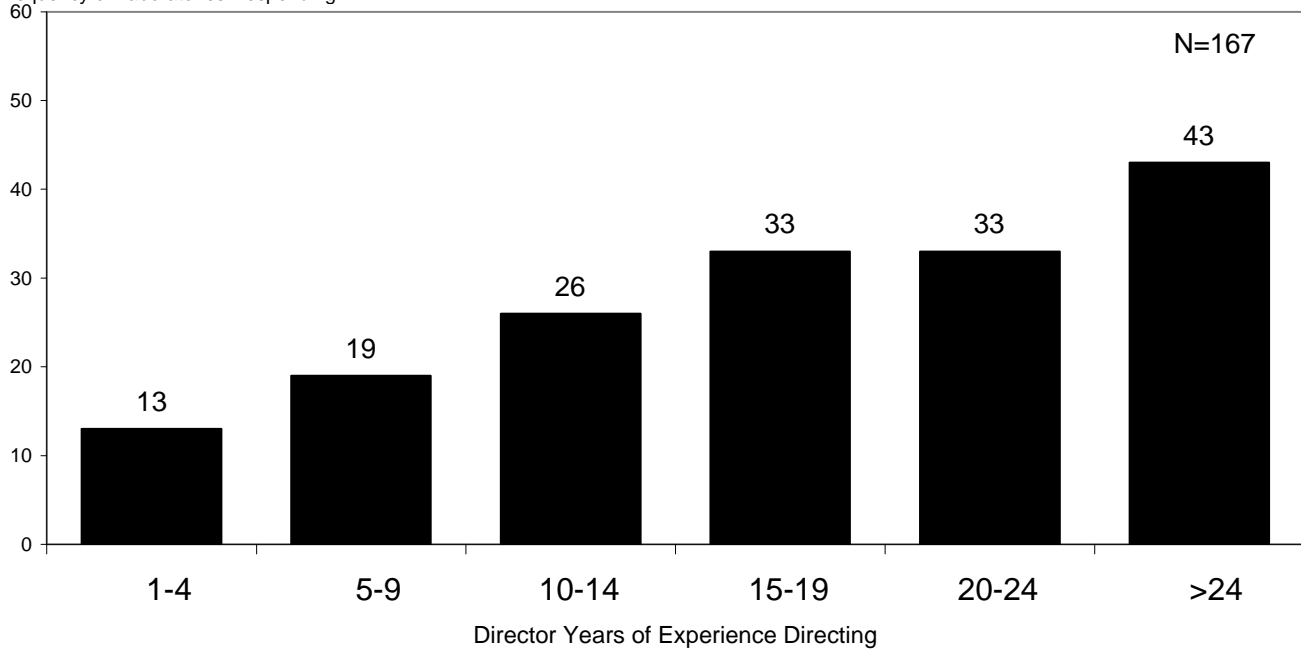


6.(c) What board certifications have been awarded to your Laboratory Director? (Check all that apply.)



6.(d) Please indicate the years of experience your Laboratory Director has in directing or supervising laboratory testing (Round off to the nearest whole number.):

Frequency of Laboratories Responding



6.(e) Is your Laboratory Supervisor available to provide supervision on-site?

N=193

Supervisor on-site	Number of Laboratories (%)
Yes	187 (96.9%)
No	6 (3.1%)

6.(f) If no, is there another person on-site that has been assigned to provide supervision?

N=6

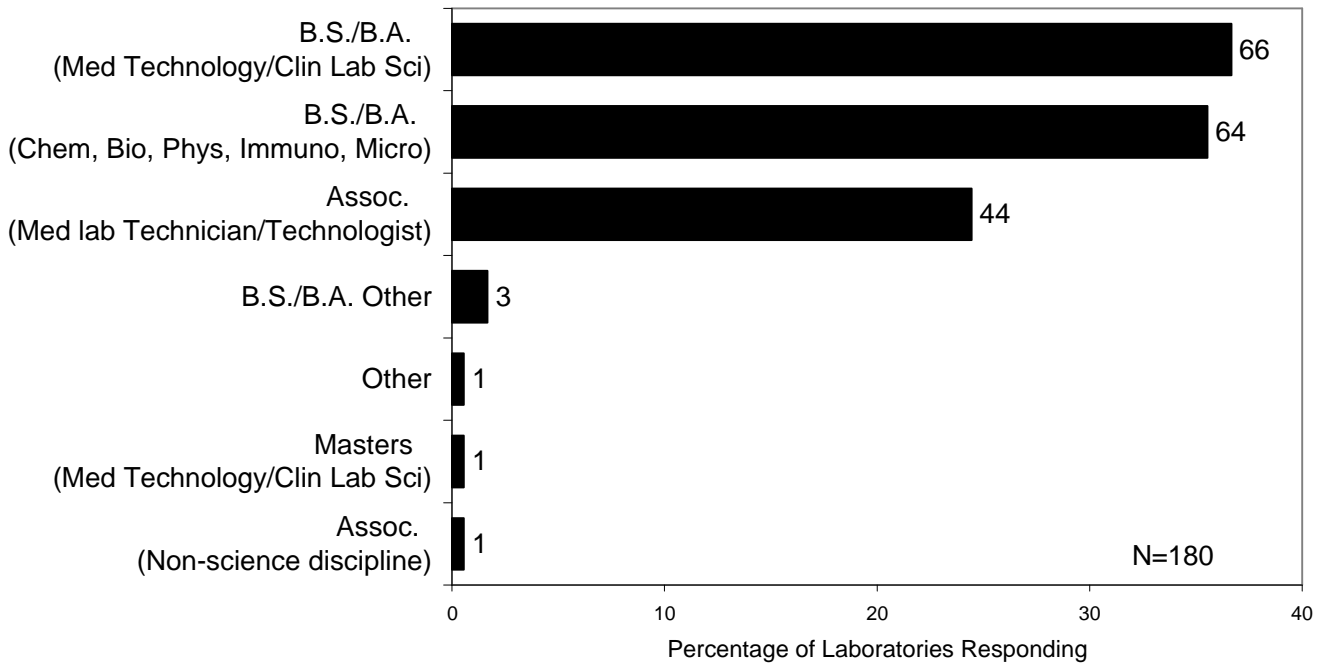
Someone other than Supervisor	Number of Laboratories (%)
Yes	5 (83.3%)
No	1 (16.7%)

7.(a) Does your laboratory require that personnel who perform CD4⁺ T-cell determinations have a minimum educational degree?

N=193

Require Minimum Degree	Number of Laboratories (%)
Yes	186 (96.4%)
No	7 (3.6%)

7.(b) What minimum educational degree is required of your CD4⁺ T-cell determinations testing personnel? (Choose only one degree.)

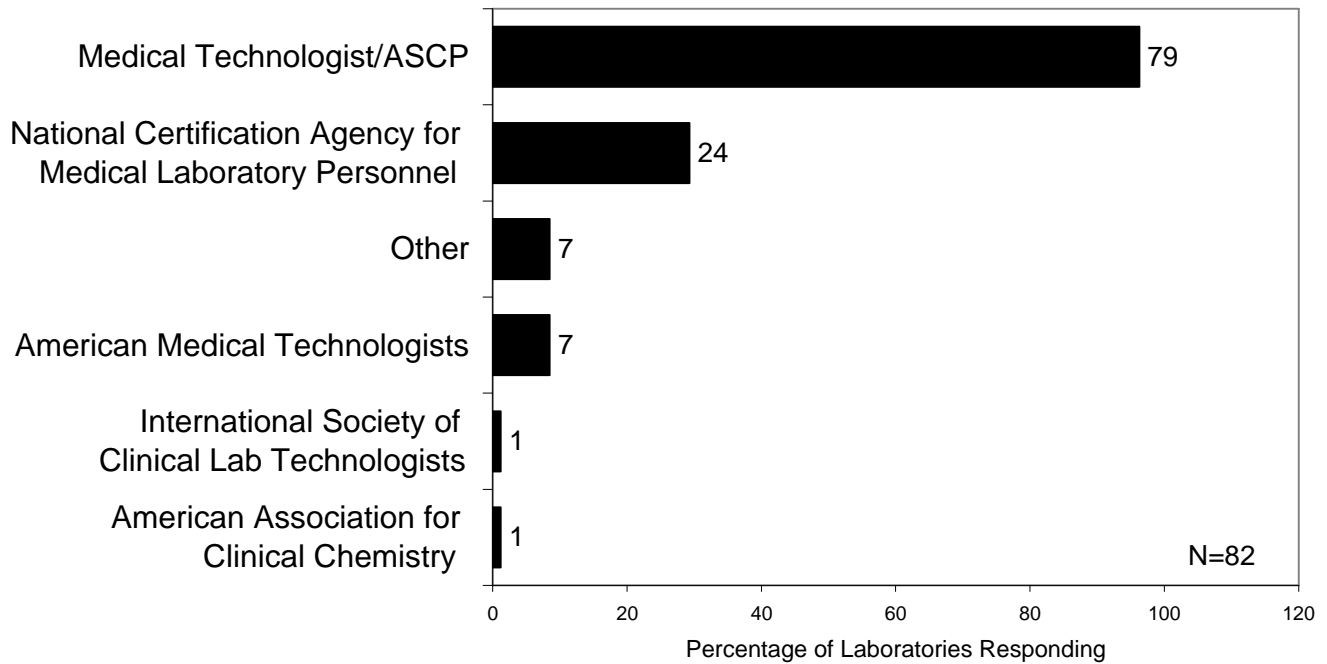


7.(c) Does your laboratory require that your CD4⁺ T-cell determinations testing personnel have certification by a professional organization? (Do not include licensing by city, state, or county.)

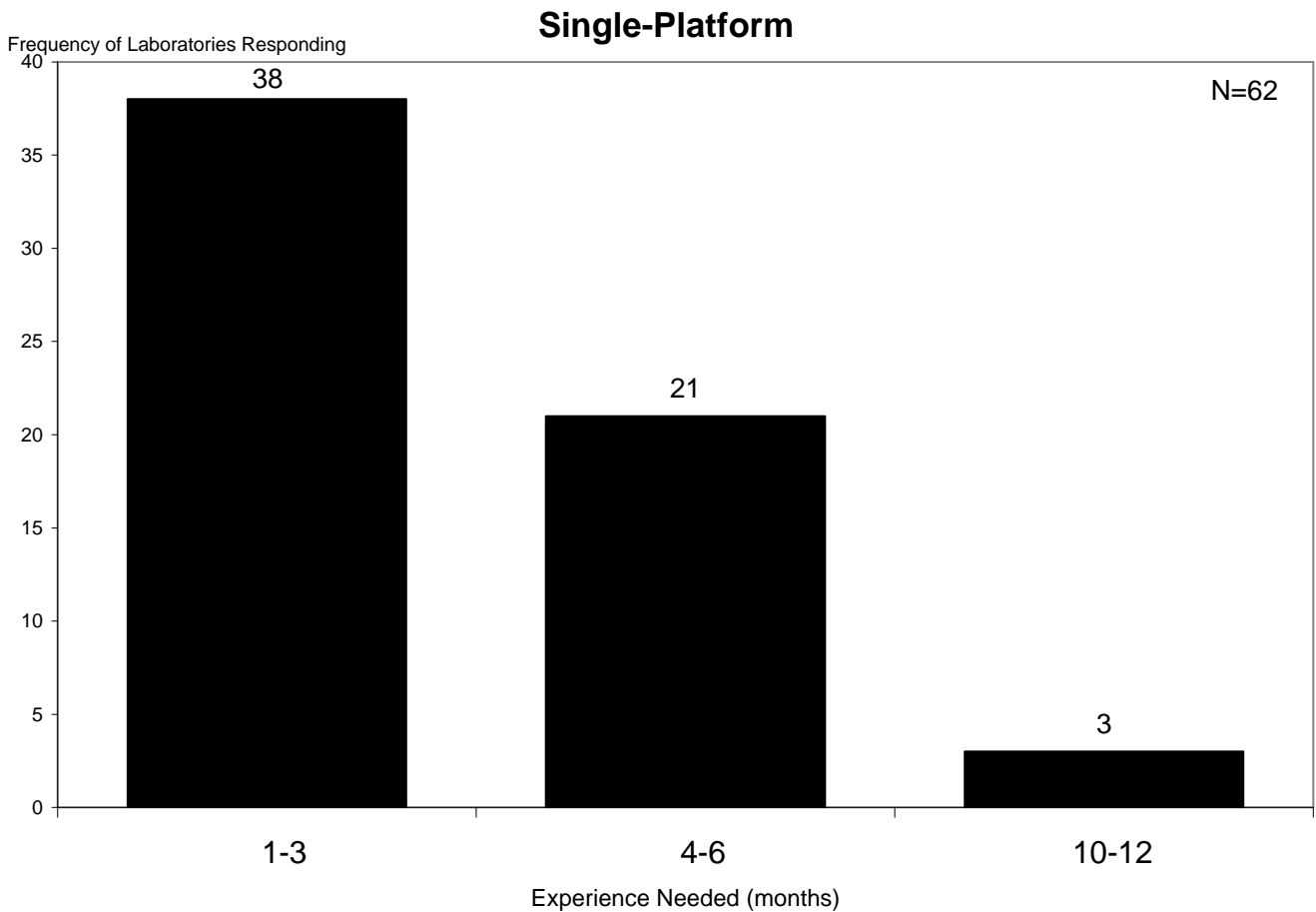
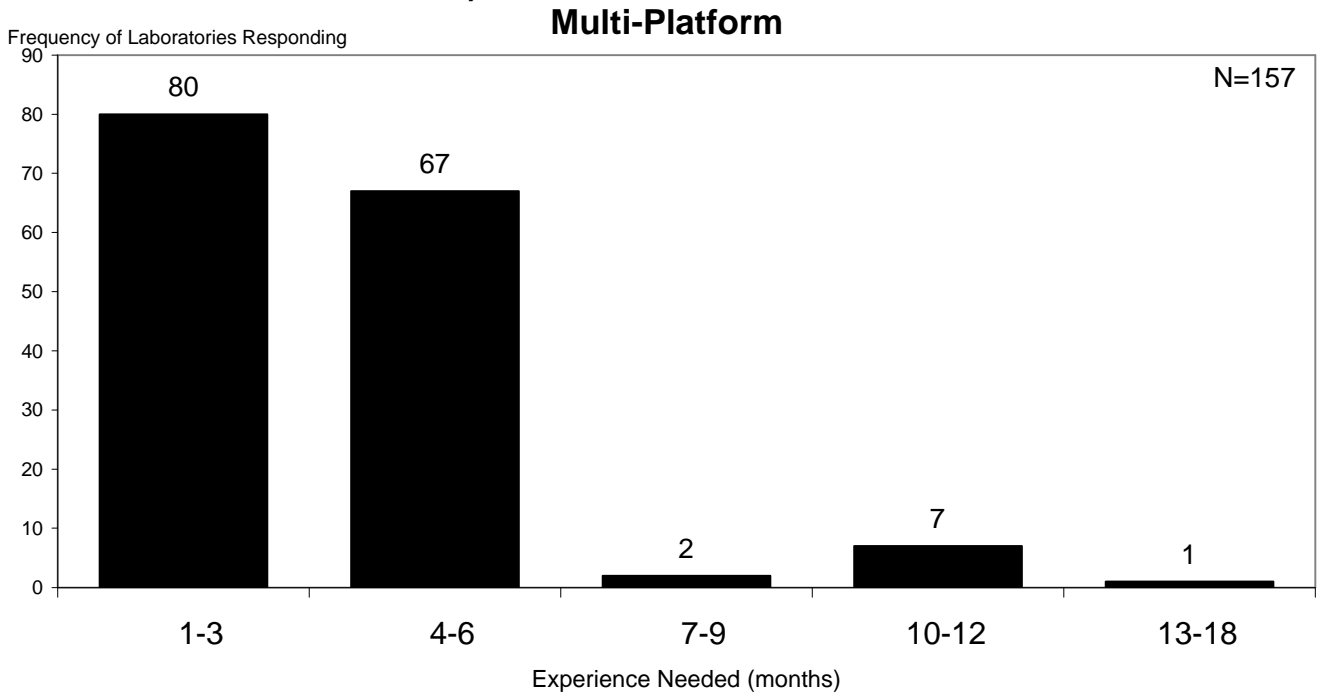
N=190

Require Certification	Number of Laboratories (%)
Yes	89 (46.8%)
No	101 (53.2%)

7.(d) Please check the professional organizations that have awarded the required certification to your CD4⁺T-cell determinations testing personnel (Check all that apply.):



8. On average, how many months of experience do your personnel need to become proficient in performing CD4⁺ T-cell determinations and analyzing the resultant data? (Indicate number of months of experience needed only for those methods currently in use in your laboratory. Round off to the nearest whole number.)

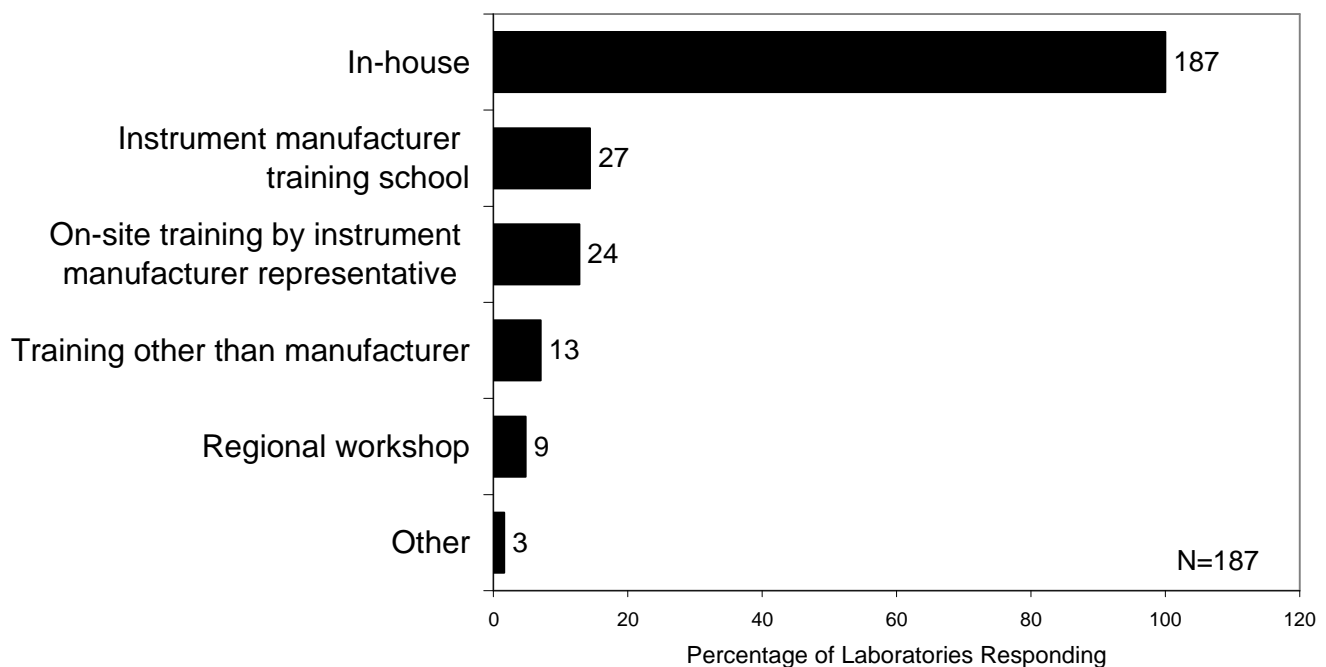


9.(a) Does your laboratory require that personnel who perform CD4⁺ T-cell determinations have training?

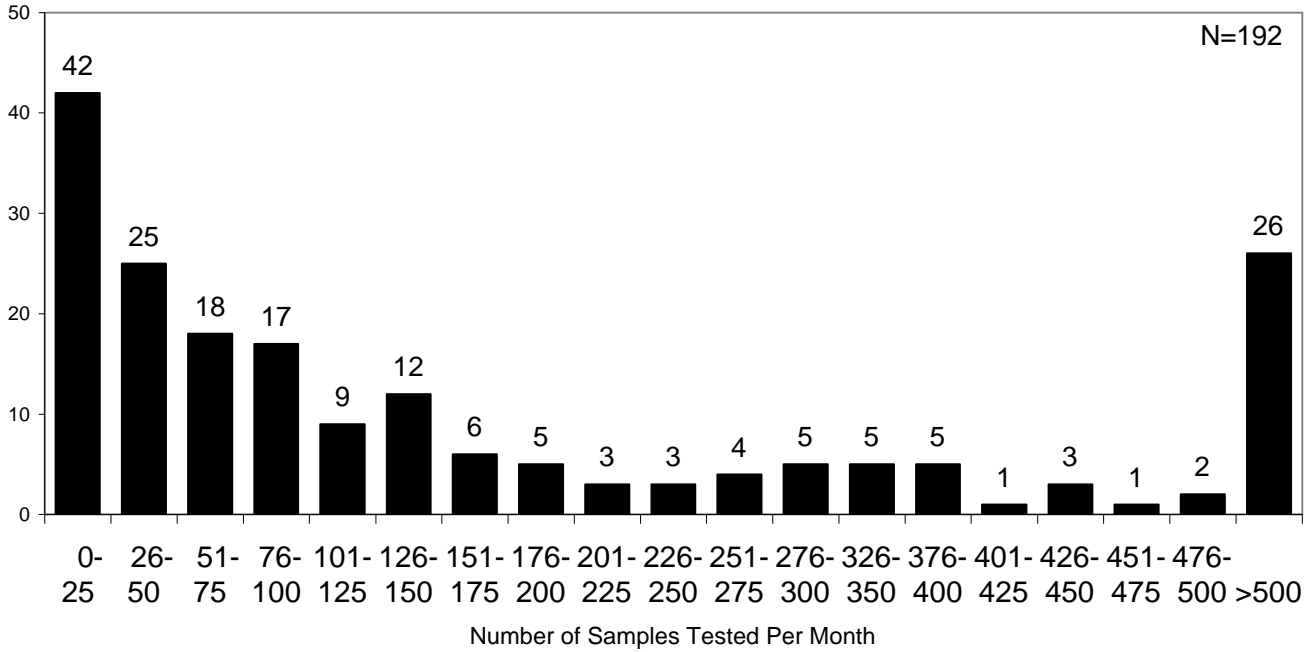
N=193

Require Training	Number of Laboratories (%)
Yes	193 (100%)
No	0 (0%)

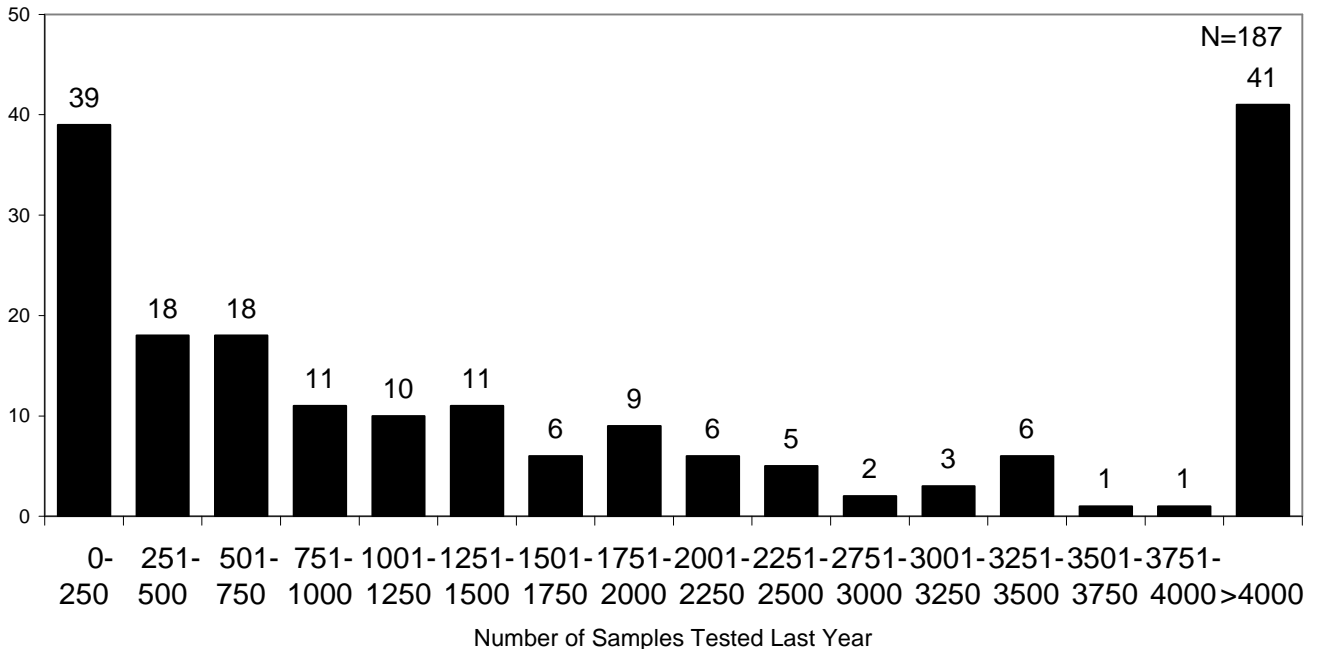
9.(b) If yes, what training must your laboratory personnel complete before they are considered qualified to perform CD4⁺ T-cell determinations? (Check all that apply.)



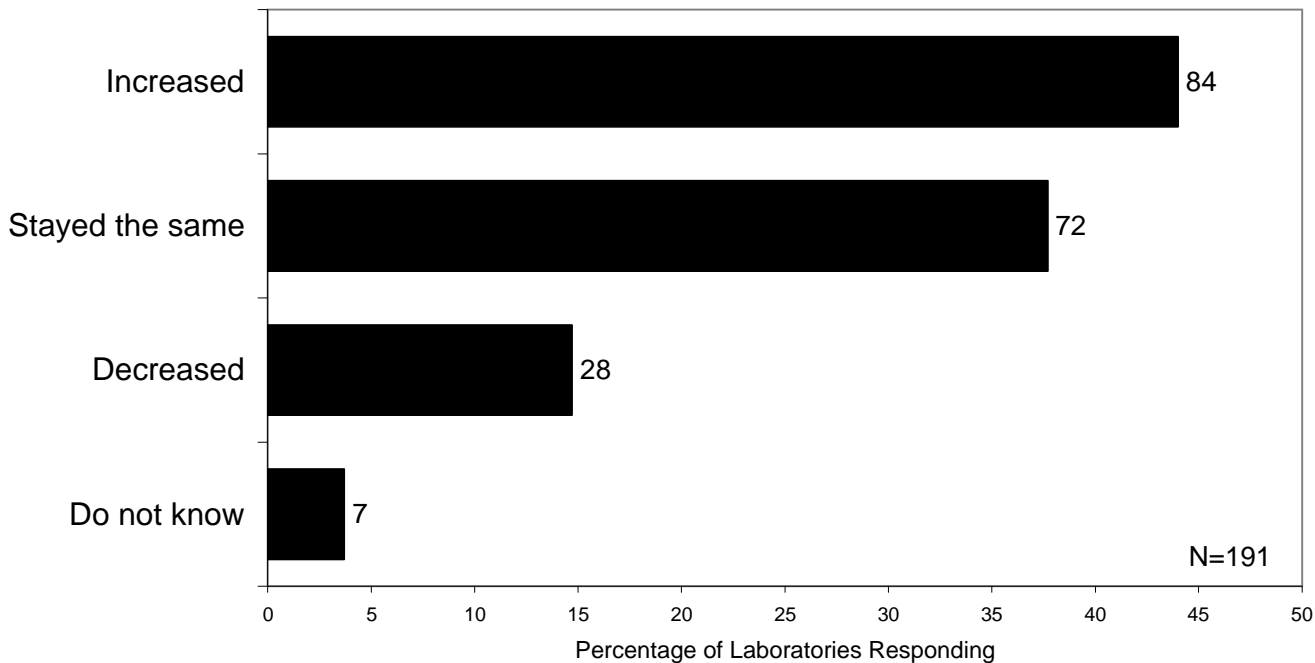
10.(a) On average, how many CD4⁺ T-cell determination specimens are tested in your laboratory in a month? (Number of single patient and/or blood donor specimens, not tests. Round off to the nearest whole number.)



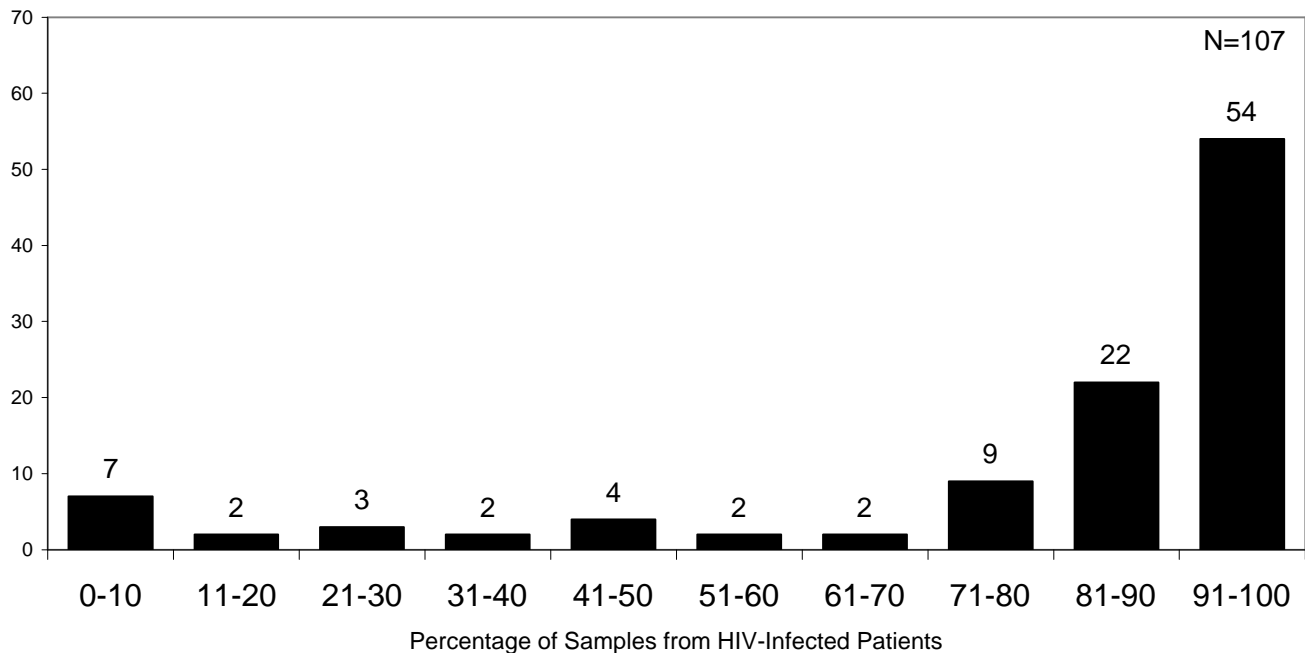
10.(b) How many CD4⁺ T-cell determination specimens were tested in your laboratory in the last year? (Number of single patient and/or blood donor specimens, not tests. Round off to the nearest whole number.)



10.(c) Has the number of requests per month for CD4⁺ T-cell determinations to be performed by your laboratory increased, decreased, or stayed the same compared to twelve months ago? (Choose only one.)



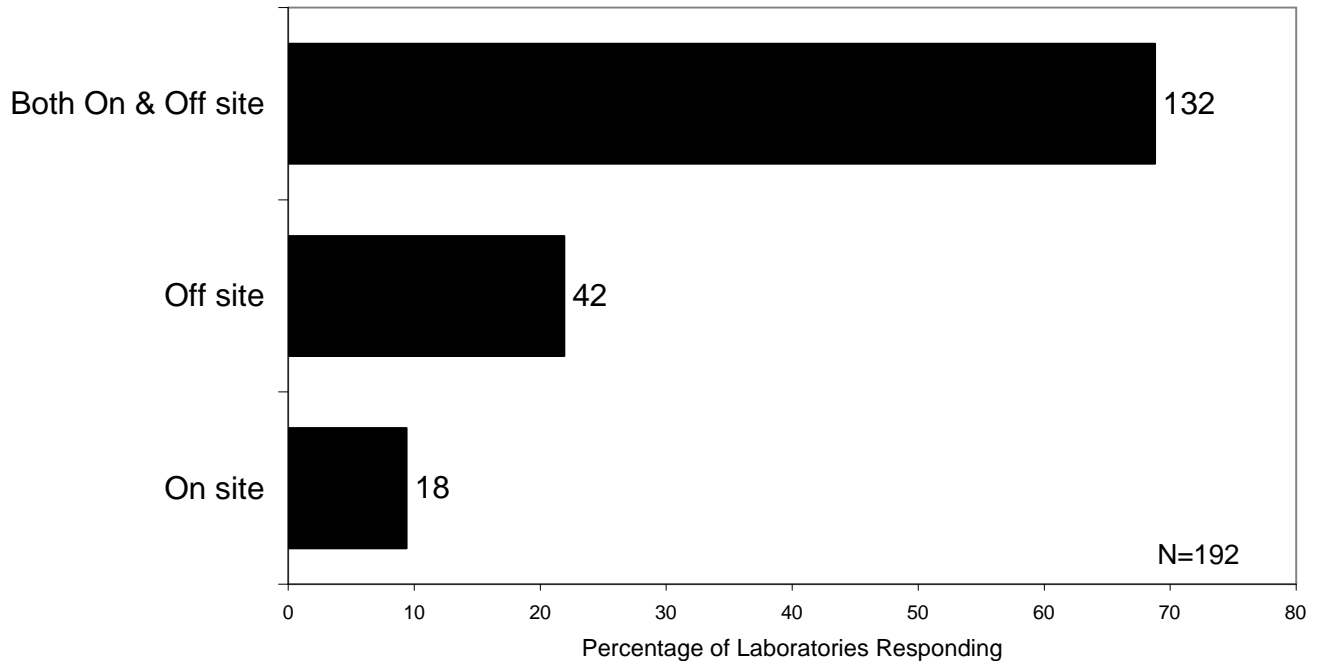
11. In the last year, what percentage of your CD4⁺ T-cell determination specimens have come from patients known by your laboratory to be HIV-infected? (Round off to the nearest whole number.)



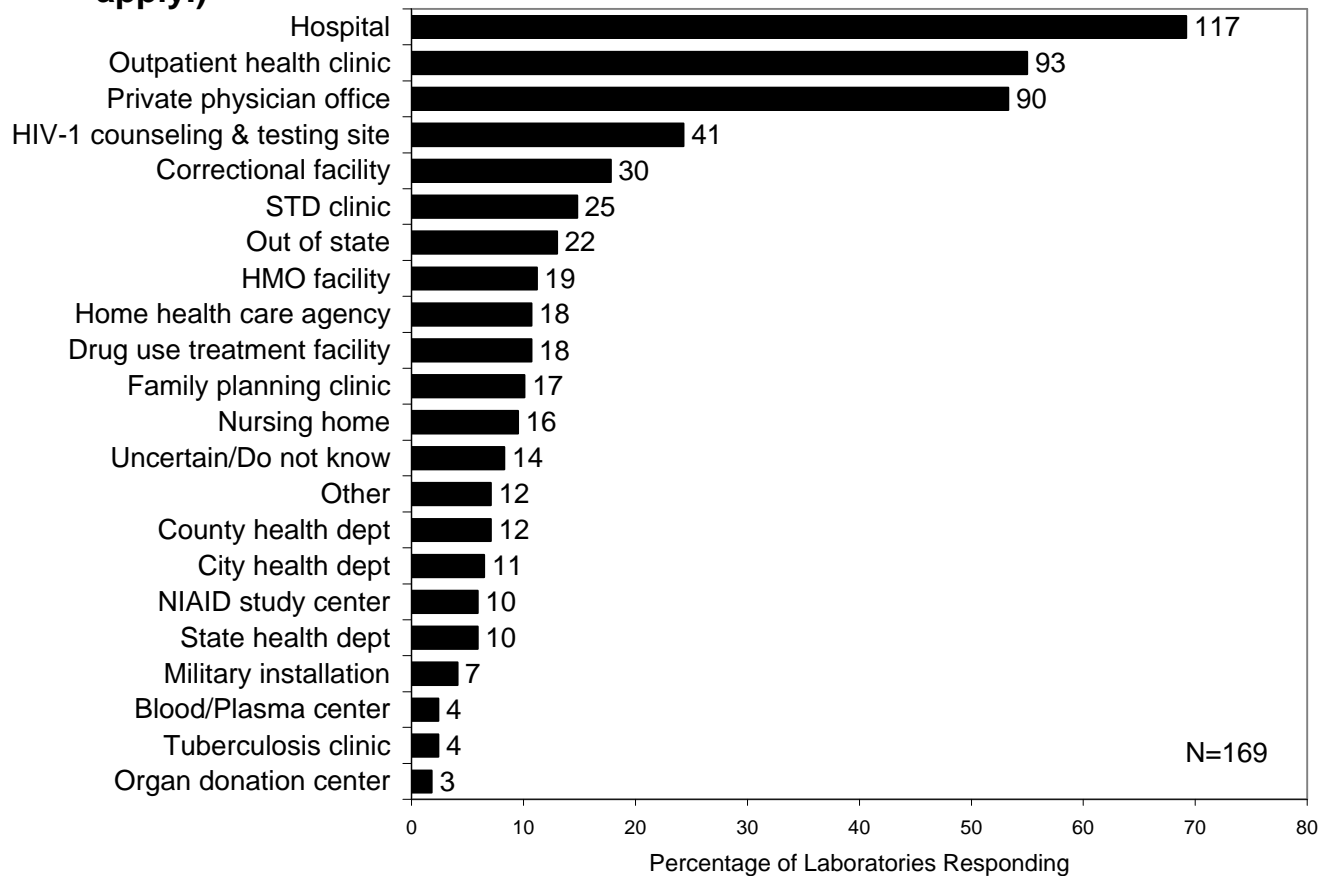
12.(a) If written instructions (SOPs) are provided to collection site personnel for collecting, labeling and transporting CD4⁺ T-cell determination specimens, who provides these instructions? (Check all that apply.)

Type of Instruction	Instructions NOT Provided	Testing Laboratory	Associated Institution	Person Ordering Test	Other	N=
Collecting	8	154	31	10	10	190
Labeling	8	152	33	12	10	190
Transporting	7	160	28	9	10	190

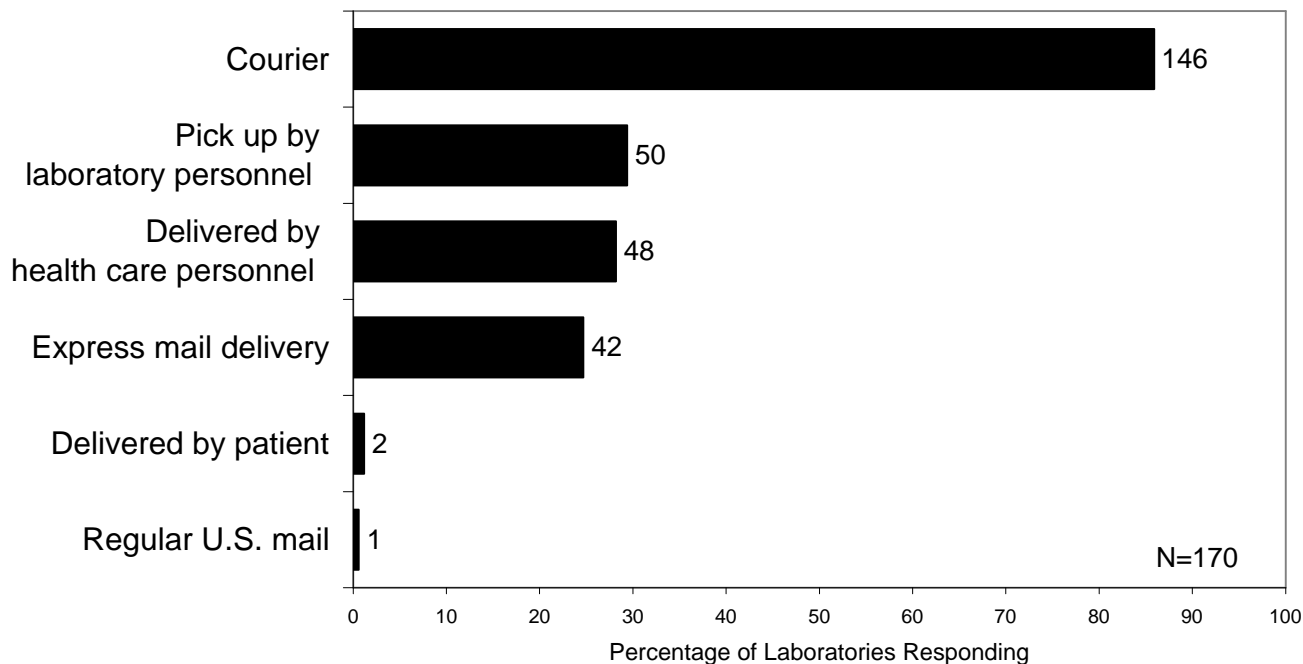
12.(b) Where are your specimens collected for CD4⁺ T-cell determinations? (Choose only one.)



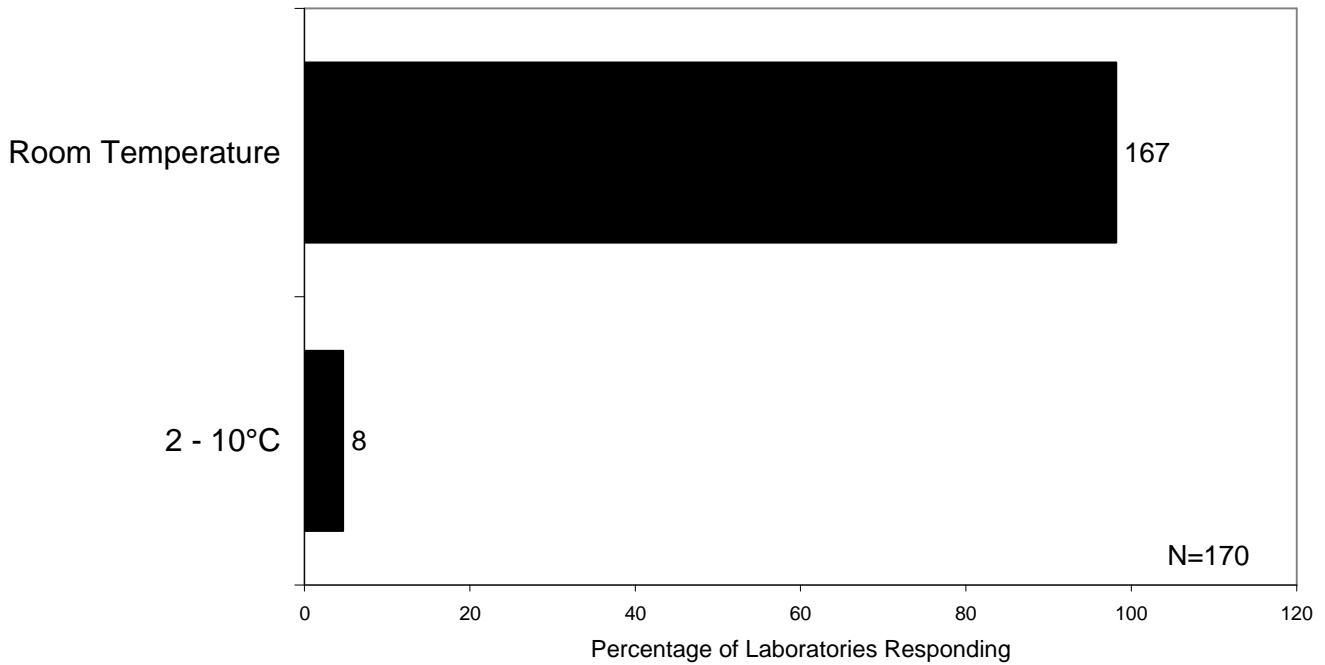
12.(c) When your laboratory tests CD4⁺ T-cell determination specimens that are collected off-site, where are the specimens collected? (Check all that apply.)



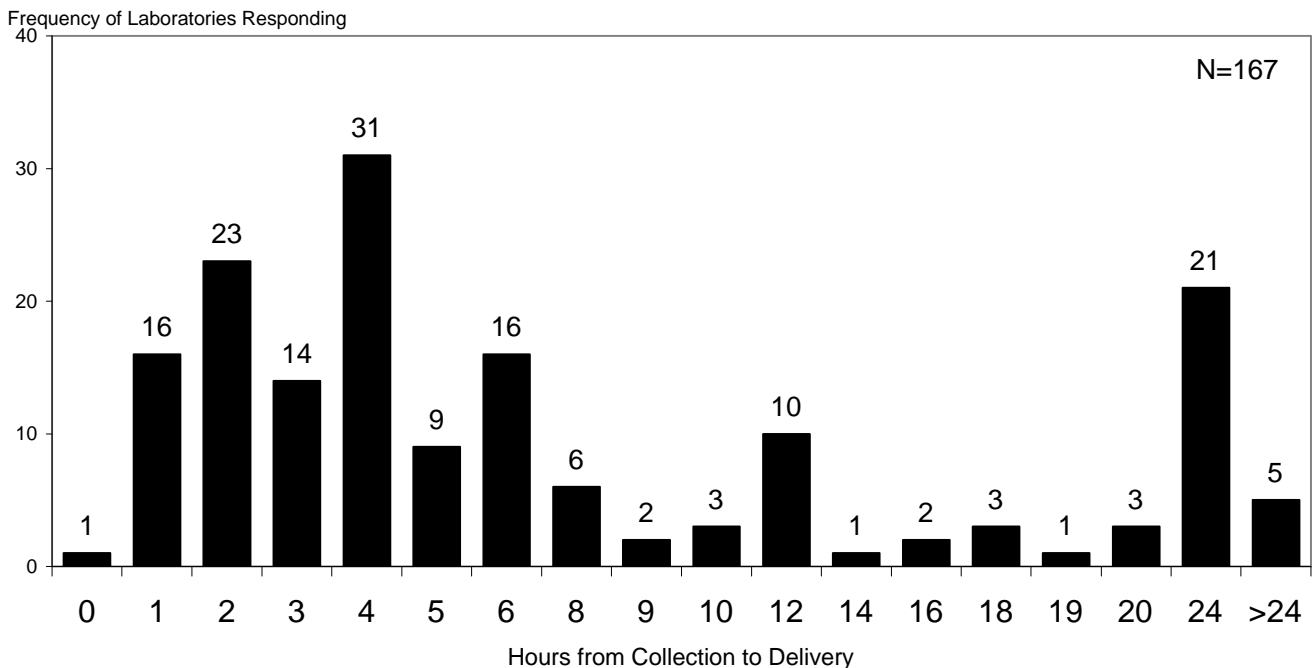
12.(d) How are the off-site CD4⁺ T-cell determination specimens delivered to your laboratory? (Check all that apply.)



12.(e) At what temperature are CD4⁺ T-cell determination specimens transported to your laboratory? (Check all that apply.)



13. On average, how many hours does it take from the time a CD4⁺ T-cell determination specimens is collected until the time it is delivered to your laboratory? (Round off to the nearest whole number.)



14.(a) Are the procedures your laboratory uses for labeling a suspected HIV-1 positive specimen different from the procedures you use for other specimens?

N=192

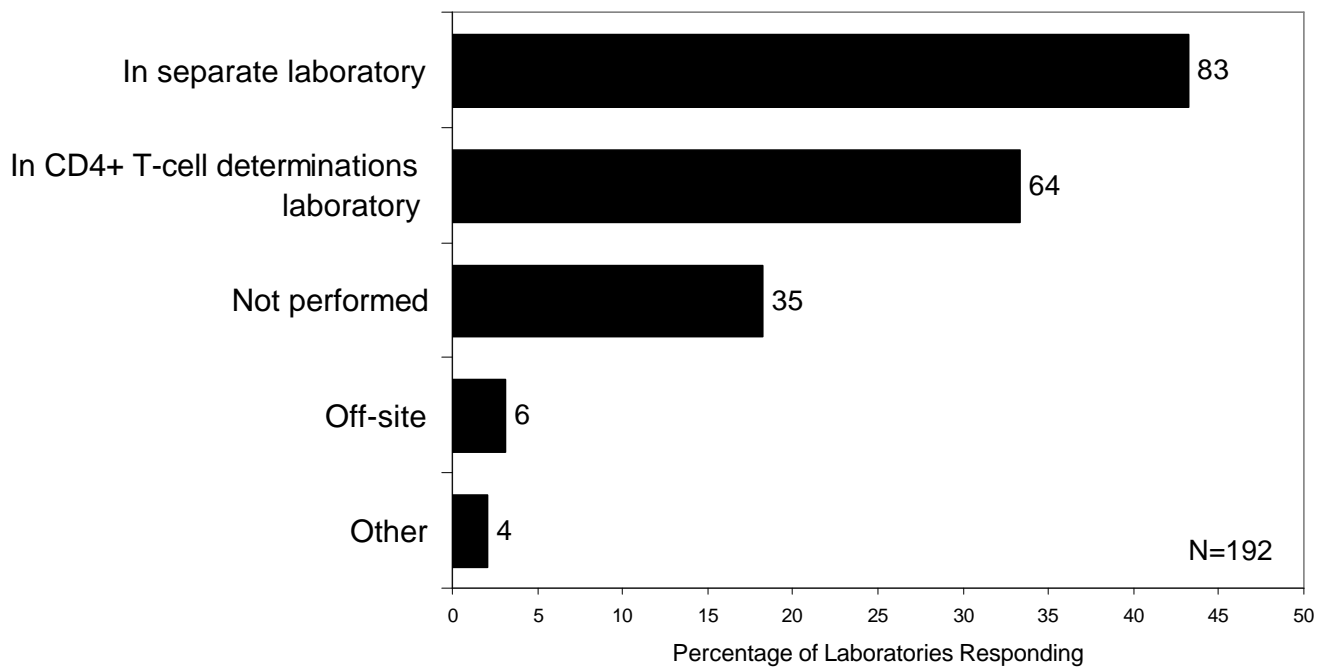
Different Requirements	Number of Laboratories (%)
Yes	4 (2.1%)
No	188 (97.9%)

14.(b) Universal precautions assume that all blood and body fluids are potentially infectious for blood borne pathogens. How often do your laboratory employees follow universal precautions when handling specimens for CD4⁺ T-cell determinations? (Choose only one.)

N=192

Use of Universal Precautions	Number of Laboratories (%)
Always	188 (97.9%)
Most of the Time	4 (2.1%)

15. Where is the hematology testing (e.g., complete blood count [CBC]) for your laboratory's CD4⁺ T-cell determination specimens usually performed? (Choose only one.)

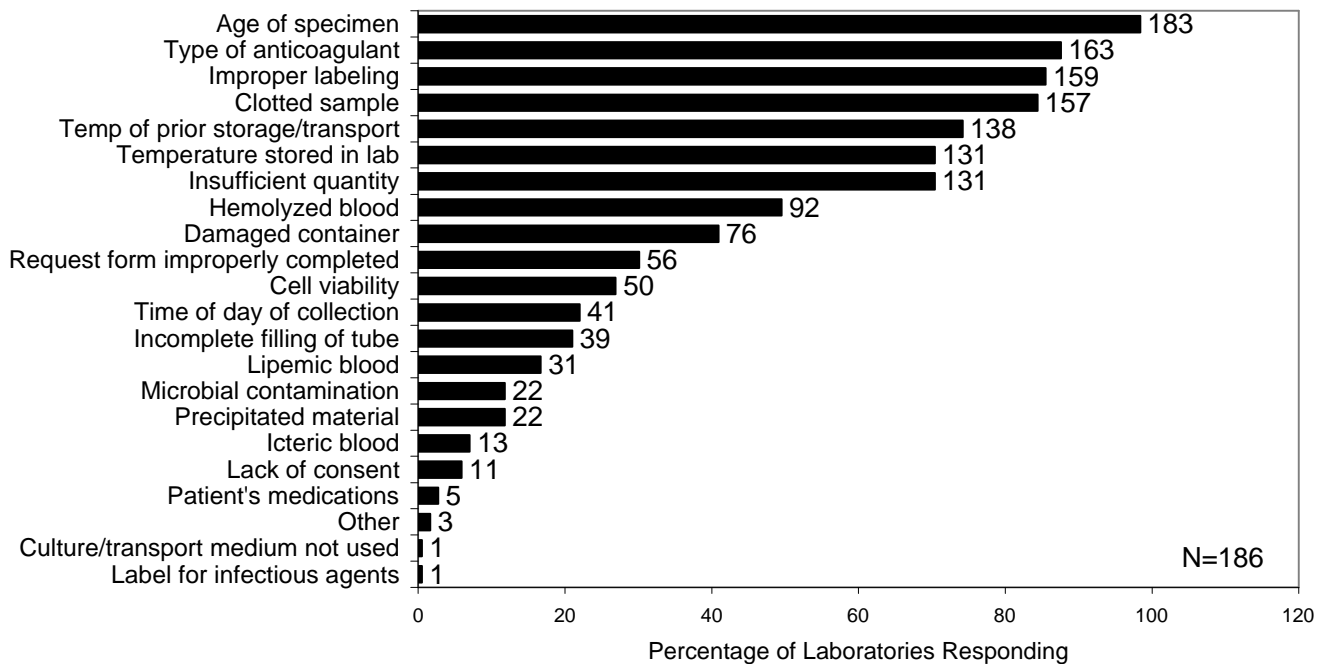


16.(a) Does your laboratory use written CD4⁺ T-cell determination specimen collection criteria to determine whether or not a specimen is acceptable for CD4⁺ T-cell determinations?

N=192

Use Written Criteria	Number of Laboratories (%)
Yes	187 (97.4%)
No	5 (2.6%)

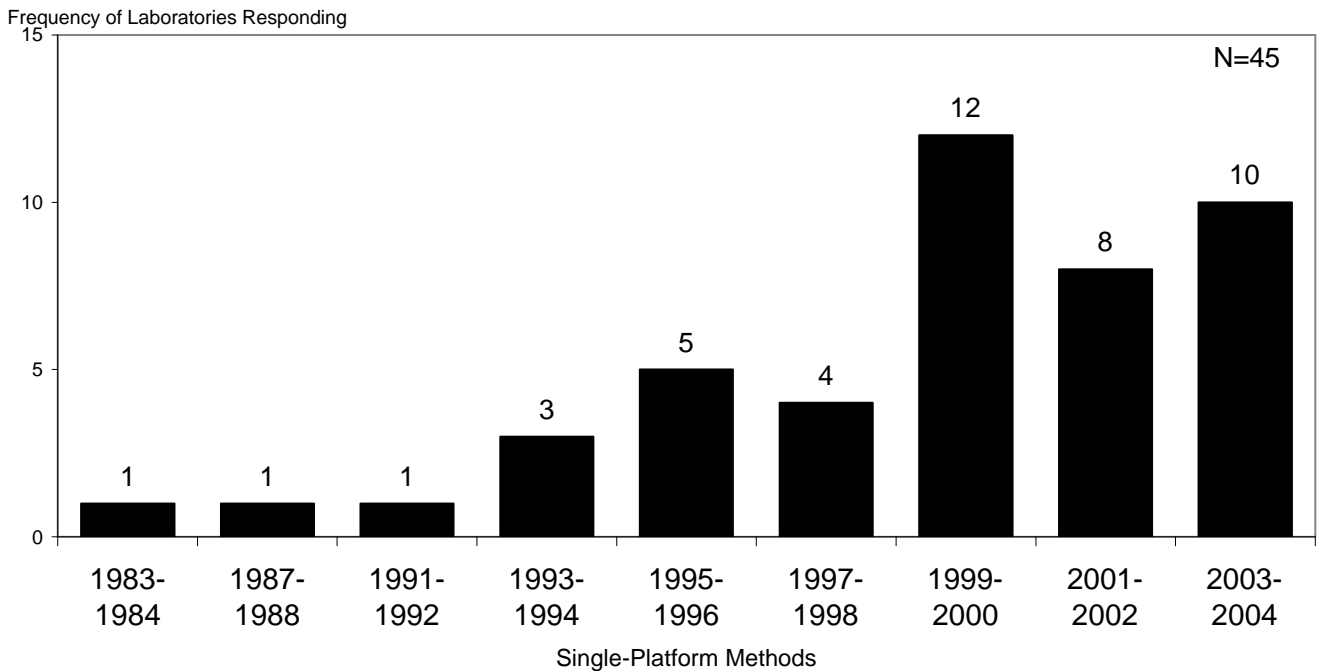
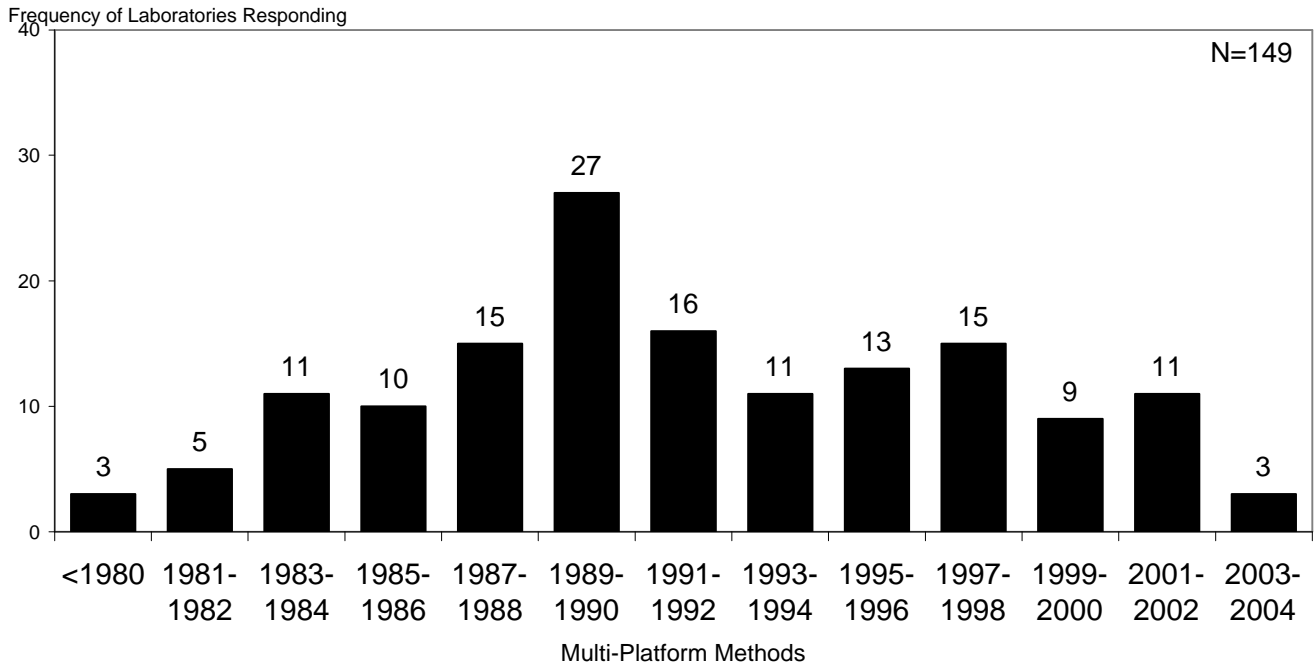
16.(b) What written specimen collection criteria are used at your laboratory to determine whether or not a specimen is acceptable for CD4⁺ T-cell determinations? (Check all that apply.)



17. At what temperatures does your laboratory store CD4⁺ T-cell determination specimens until they are processed? (Check all that apply.)

Type of Specimen	Room Temperature	2-10 °C	N=
Whole Blood	190	7	192
Separated Cells	19	19	36
Other	21	11	30

**18. When did your laboratory begin performing CD4⁺ T-cell determination?
(Please indicate month and year only for those methods currently in use in
your laboratory.)**

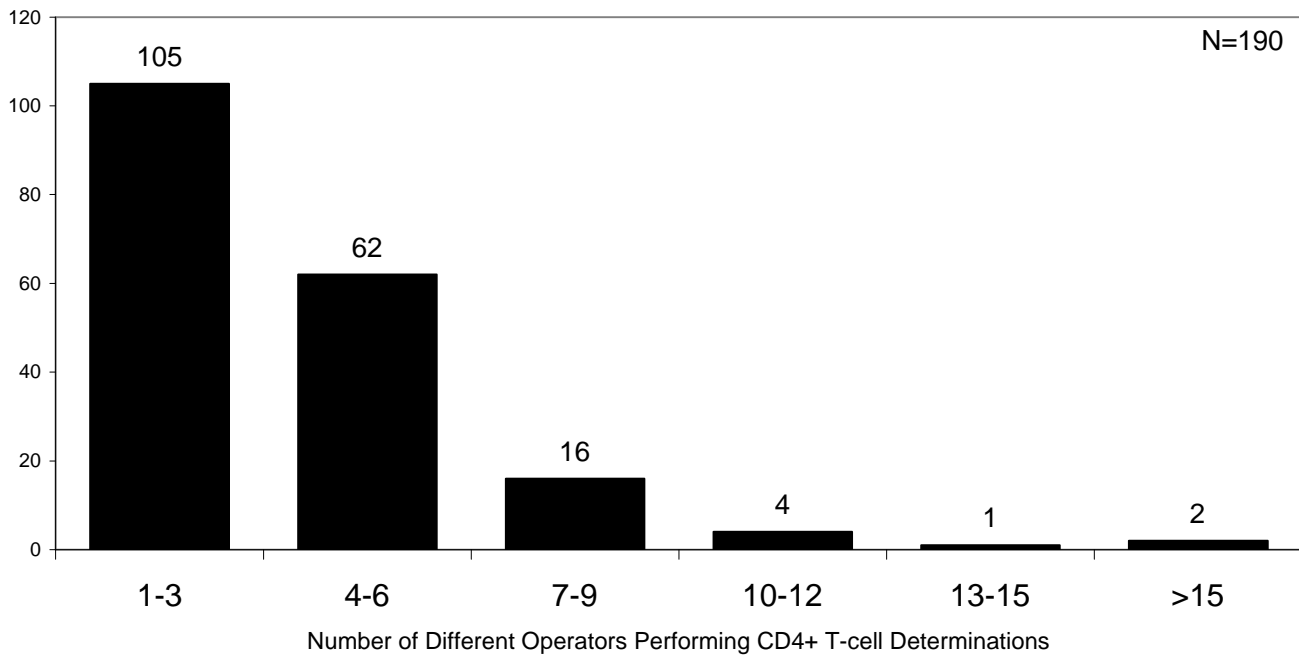


19. Does your laboratory perform CD4⁺ T-cell determinations using a flow cytometry instrument?

N=193

Use Flow Cytometry Instrument	Number of Laboratories (%)
Yes	192 (99.5%)
No	1 (0.5%)

20.(a) How many flow cytometer operators actually performed CD4⁺ T-cell determinations in your laboratory over the last 12 months?



20.(b) Do any of your laboratory's flow cytometer operators routinely perform CD4⁺ T-cell determinations on more than one flow cytometer?

N=191

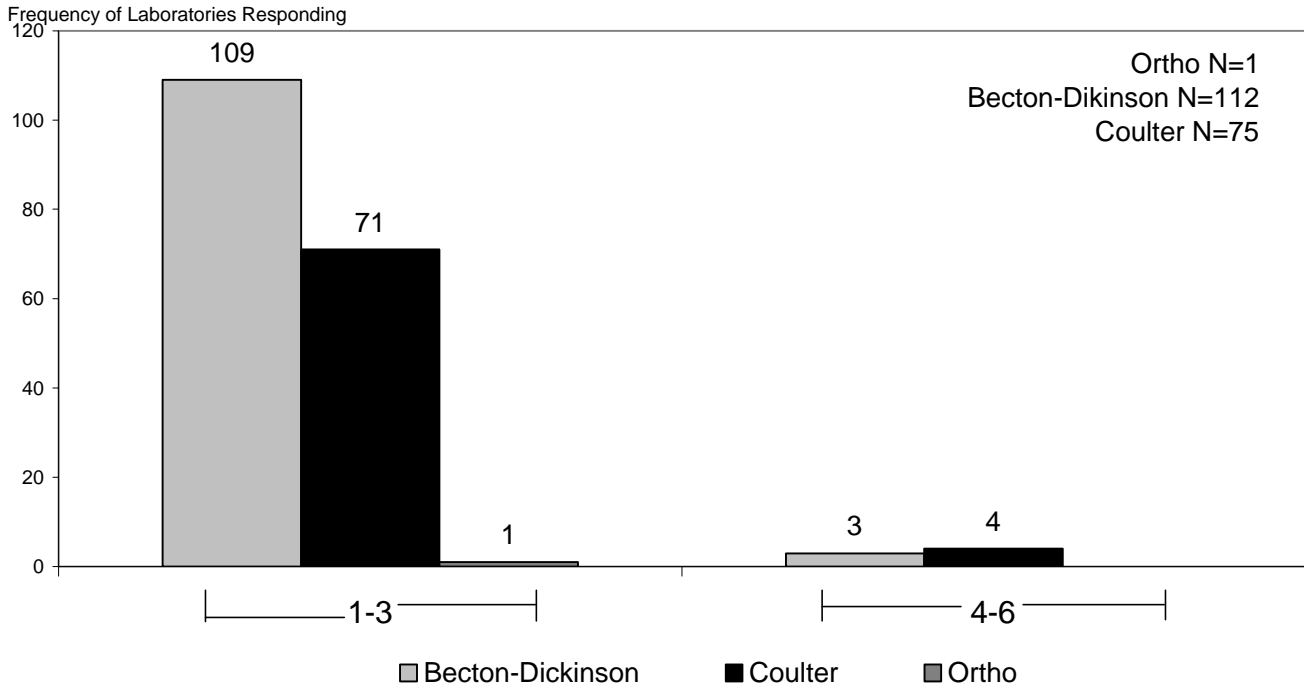
Perform CD4 ⁺ T-cell Determinations on More Than One Flow Cytometer	Number of Laboratories (%)
Yes	52 (27.2%)
No	139 (72.8%)

20.(c) Have your flow cytometer operators received training on each of the instruments that they are require to operate?

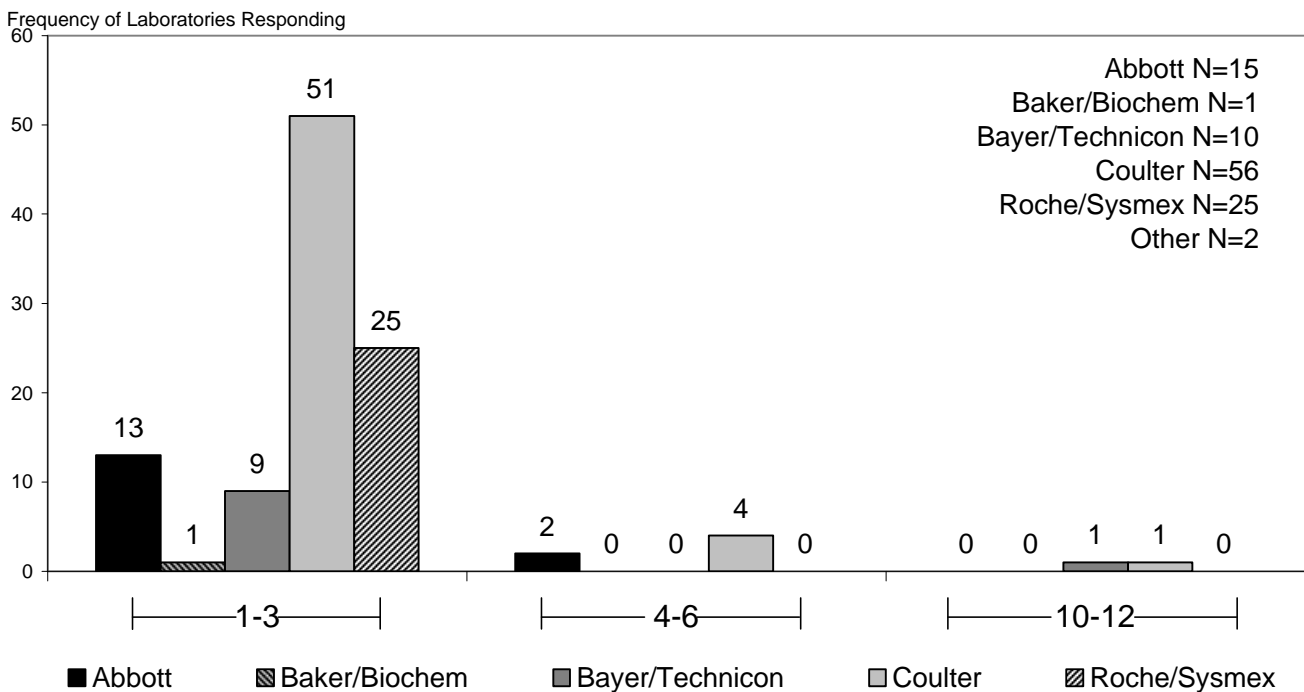
N=185

Training on Each Instrument	Number of Laboratories (%)
Yes	183 (98.9%)
No	2 (1.1%)

21. What are the quantities and manufacturers of your laboratory's flow cytometers that are used for CD4⁺ T-cell determinations?



21. What are the quantities and manufacturers of your laboratory's hematology analyzers that are used for CD4⁺ T-cell determinations?

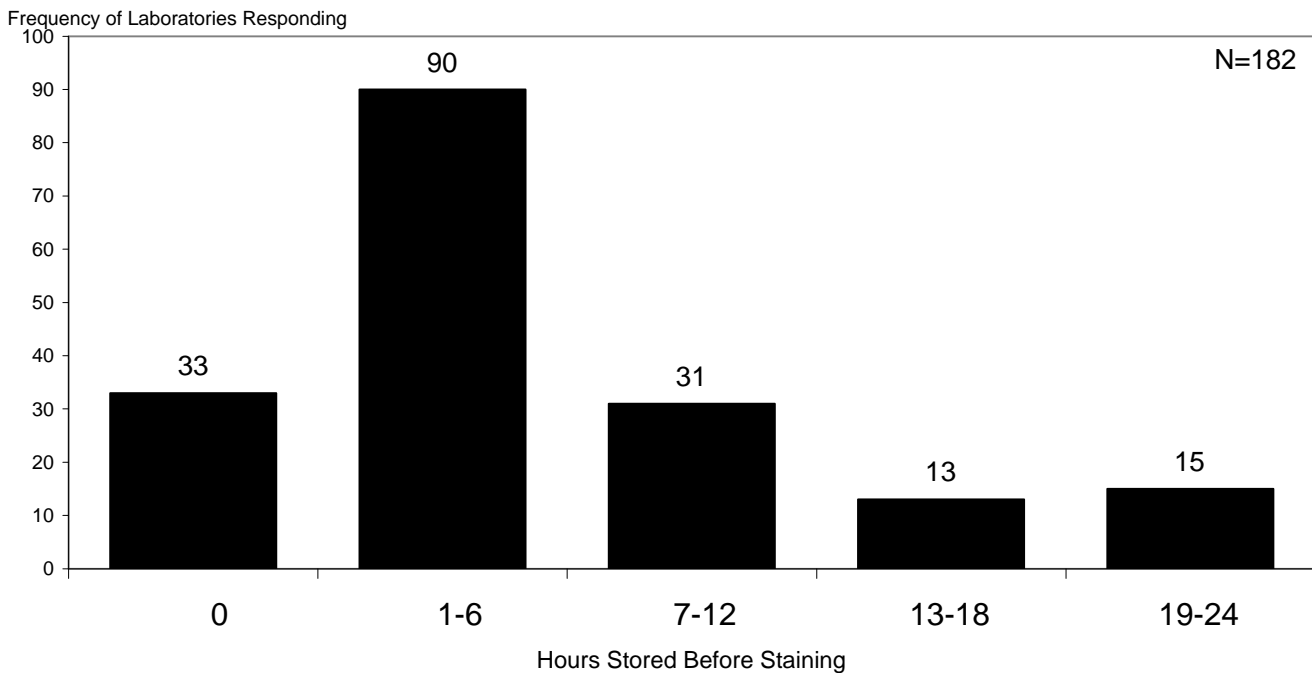


22. Can multicolor analysis techniques (two or more markers tagged with different color fluorochromes as a single test) be used to perform CD4⁺ T-cell determinations on any of the flow cytometry instruments you indicated?

N=191

Multicolor Analysis	Number of Laboratories (%)
Yes	189 (99.0%)
No	2 (1.0%)

23. On average, how many hours is a specimen stored at your laboratory before it is stained for CD4⁺ T-cell determinations? (If the specimen is processed immediately upon receipt, please indicate 0 hours, otherwise, round off to the nearest whole number.)

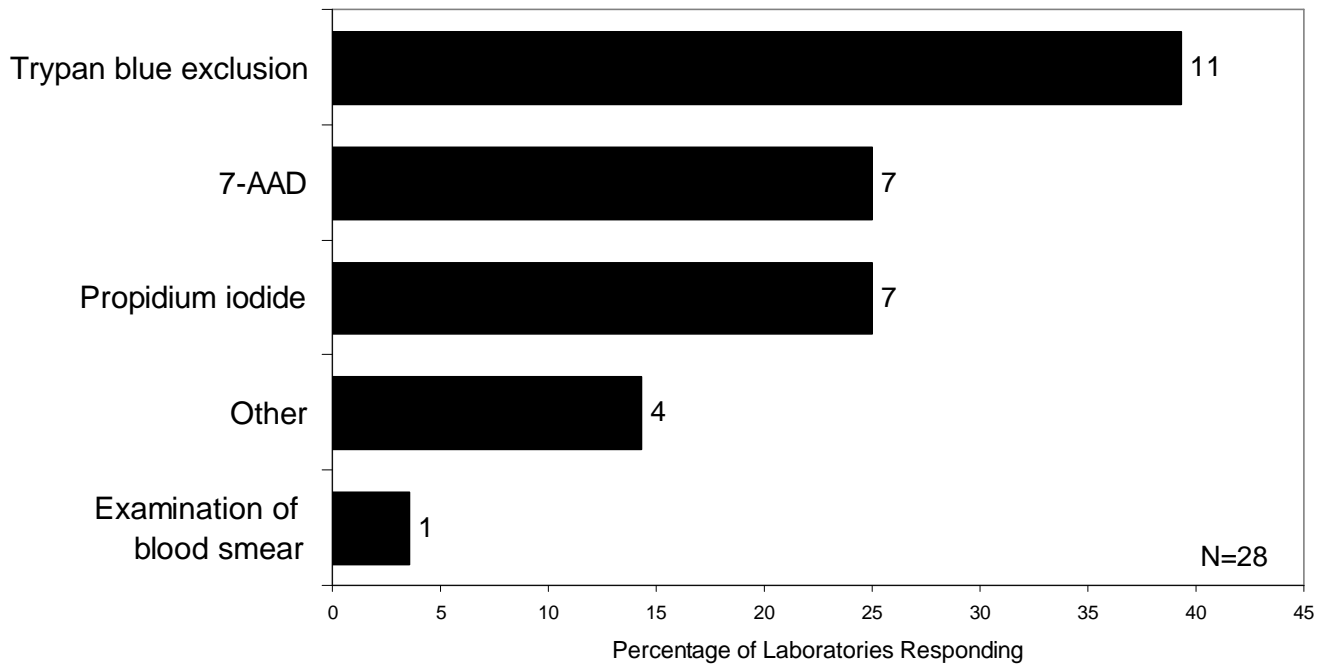


24.(a) Is testing for viability of CD4⁺ T-cell determination specimens performed by your laboratory?

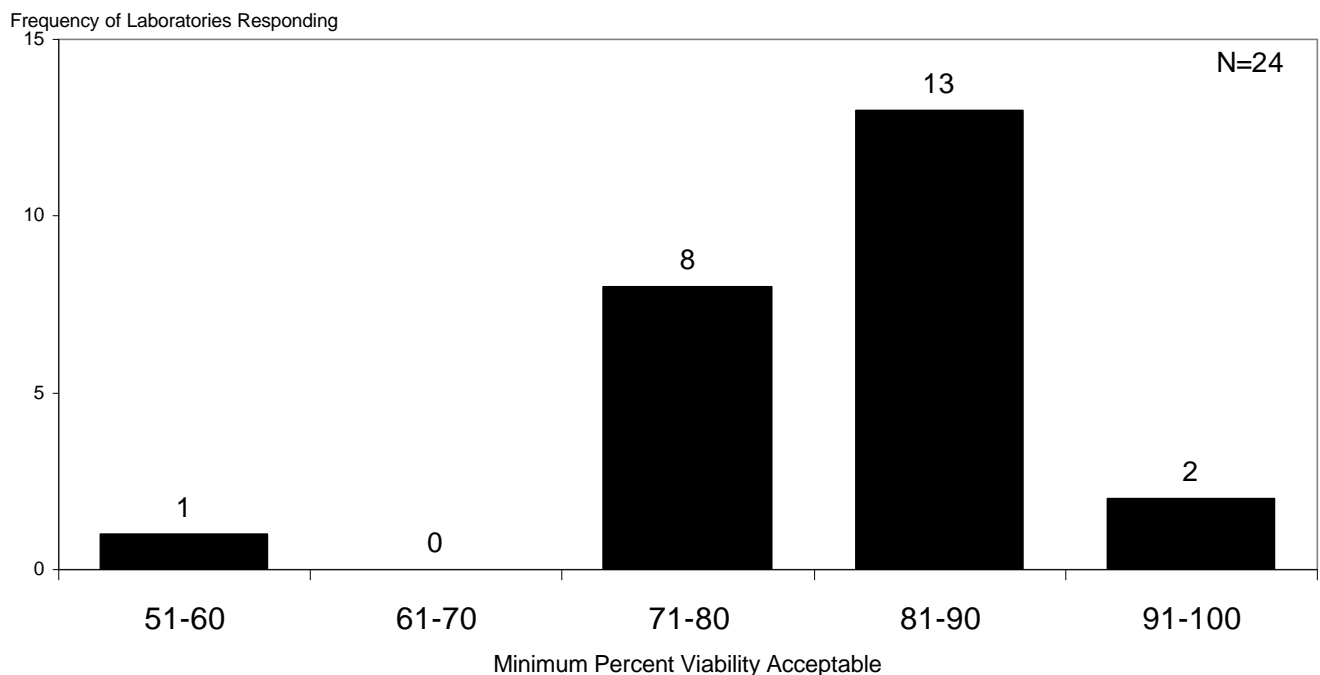
N=192

Testing for Viability	Number of Laboratories (%)
Yes	29 (15.1%)
No	163 (84.9%)

24.(b) How is testing for viability performed? (Check all that apply.)



24.(c) What is the minimum percent viability acceptable by your laboratory for CD4⁺ T-cell determinations? (Round off to the nearest whole number.)

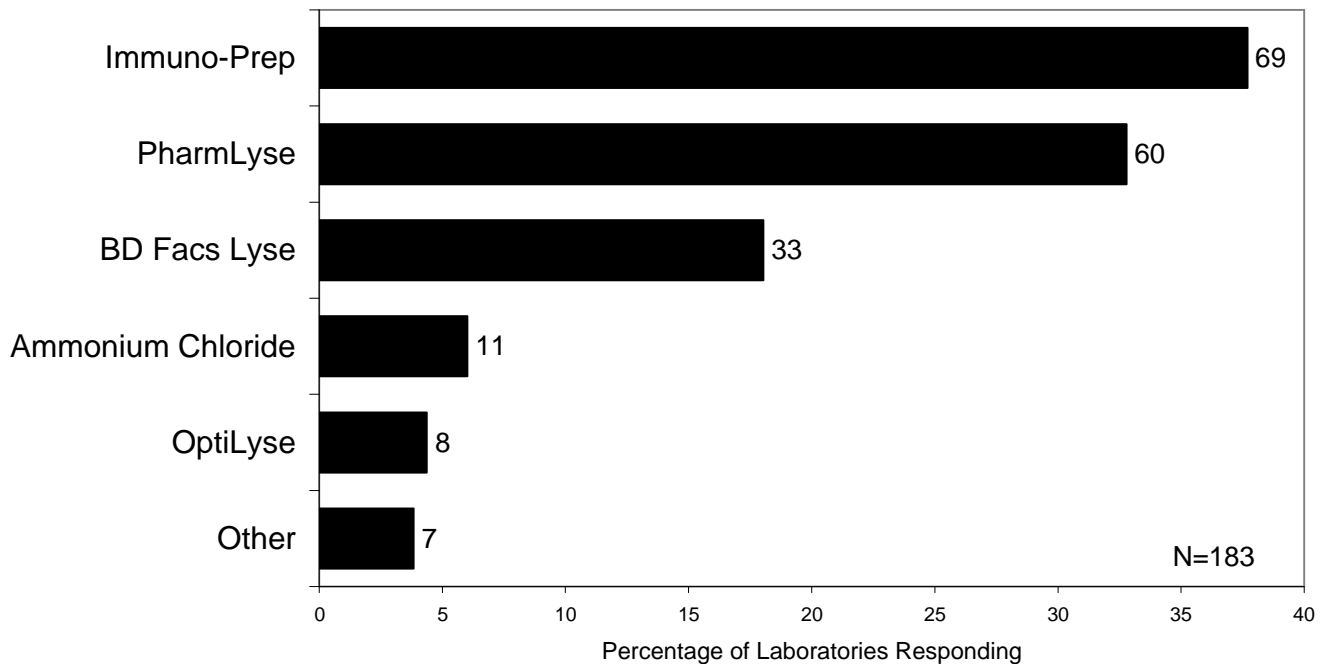


25.(a) Does your laboratory use a whole blood lysis method for staining CD4⁺ T-cell determination specimens?

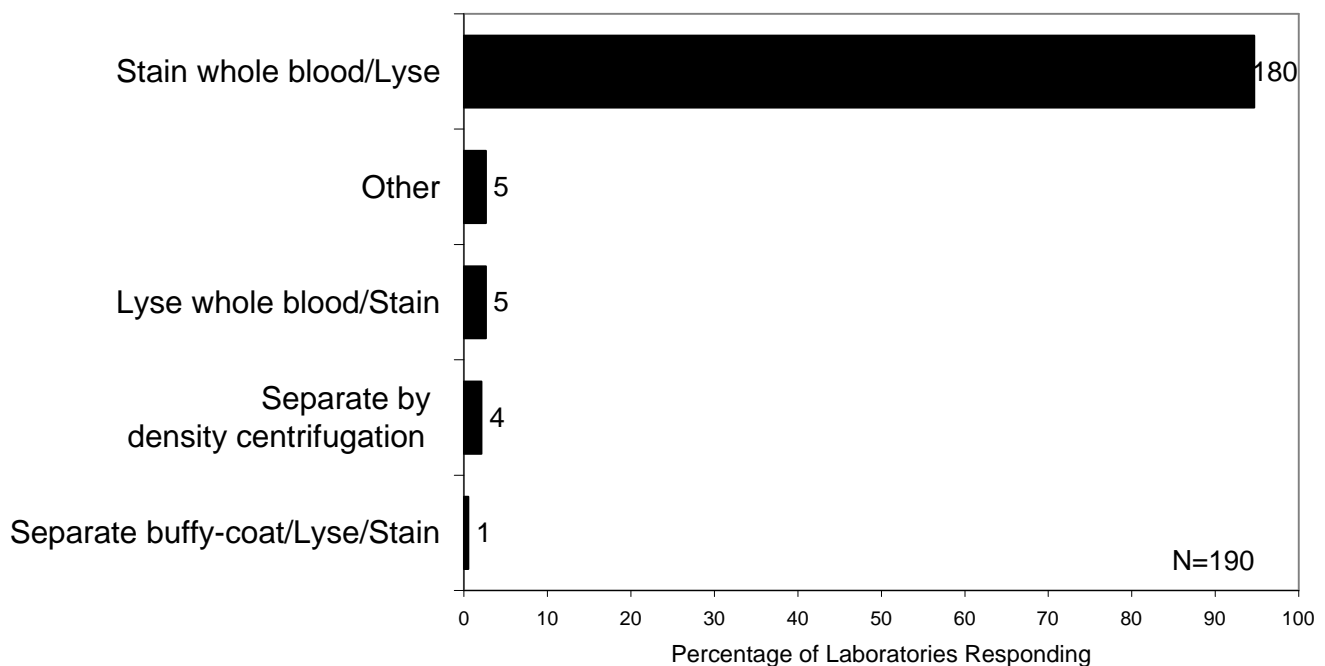
N=192

Use Whole Blood Lysis	Number of Laboratories (%)
Yes	185 (96.4%)
No	7 (3.6%)

25.(b) Which lysis method does your laboratory use? (Check all that apply.)



25.(c) What sample staining procedure(s) does your laboratory use for CD4⁺ T-cell determinations? (Check all that apply.)

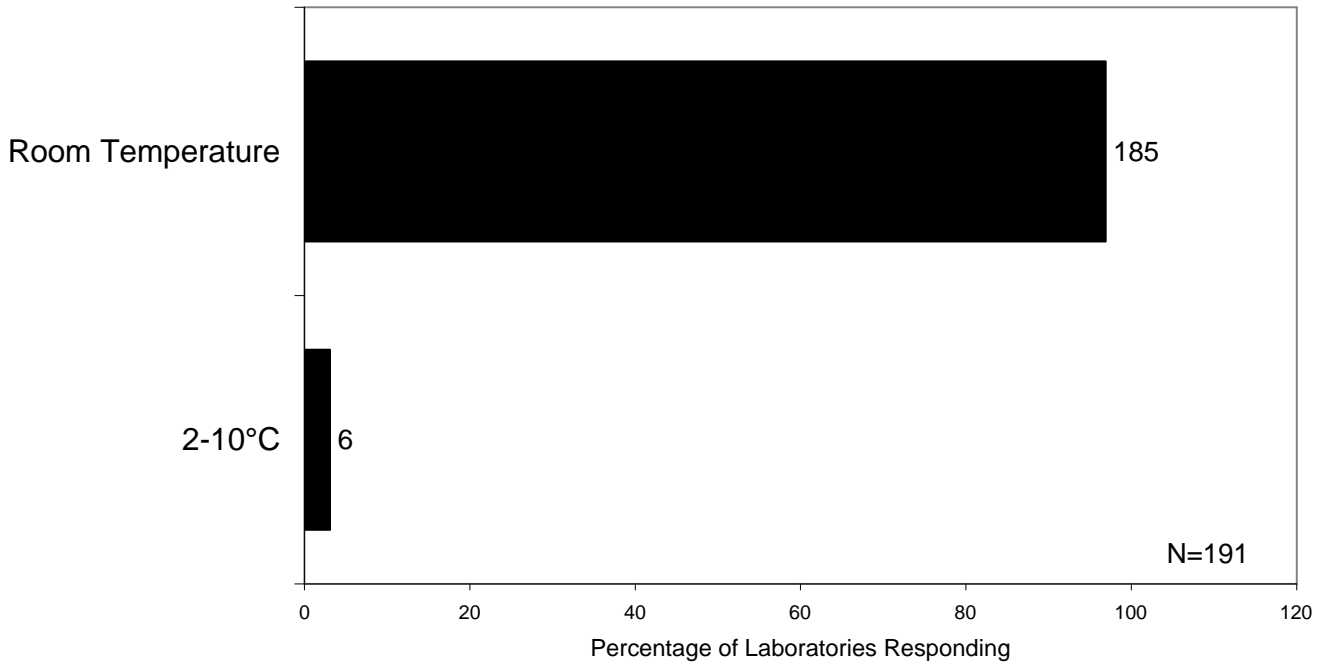


25.(d) Does your laboratory routinely use isotype controls as part of the staining procedure?

N=191

Use Isotype Controls	Number of Laboratories (%)
Yes	43 (22.5%)
No	148 (77.5%)

25.(e) At what temperature does your laboratory routinely perform the staining procedure? (Choose only one.)

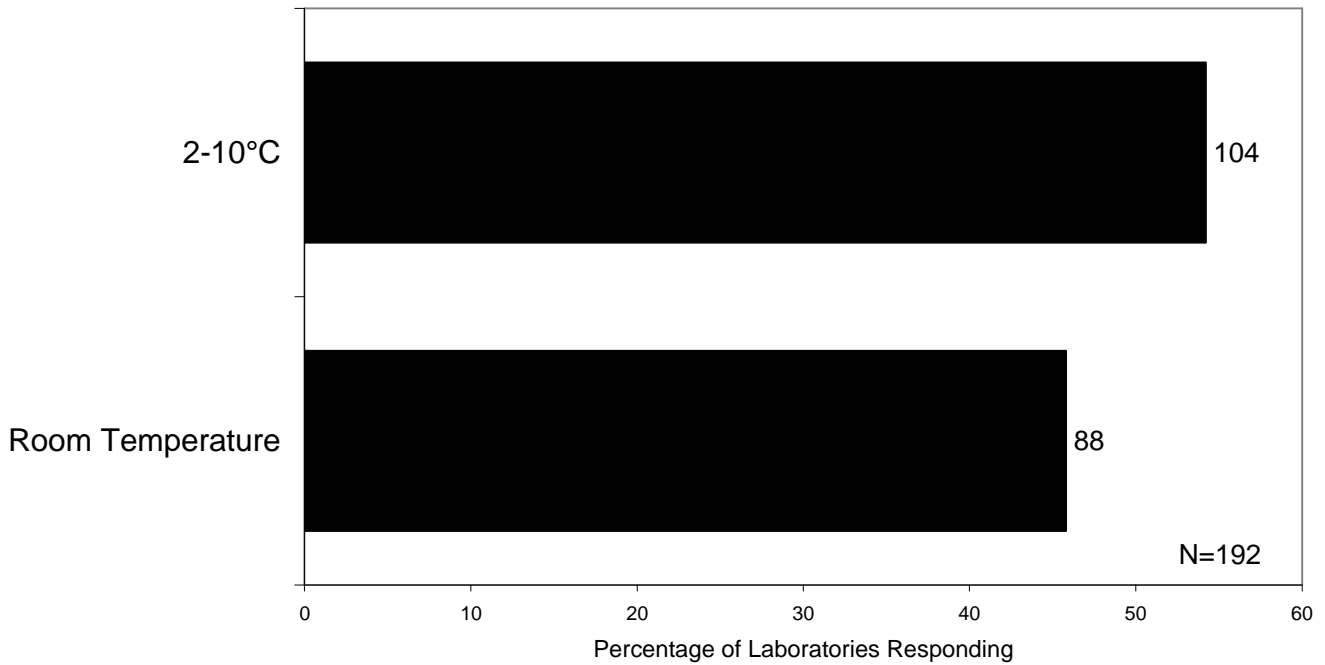


25.(f) Does your laboratory fix cells before CD4⁺ T-cell determinations flow cytometry is performed?

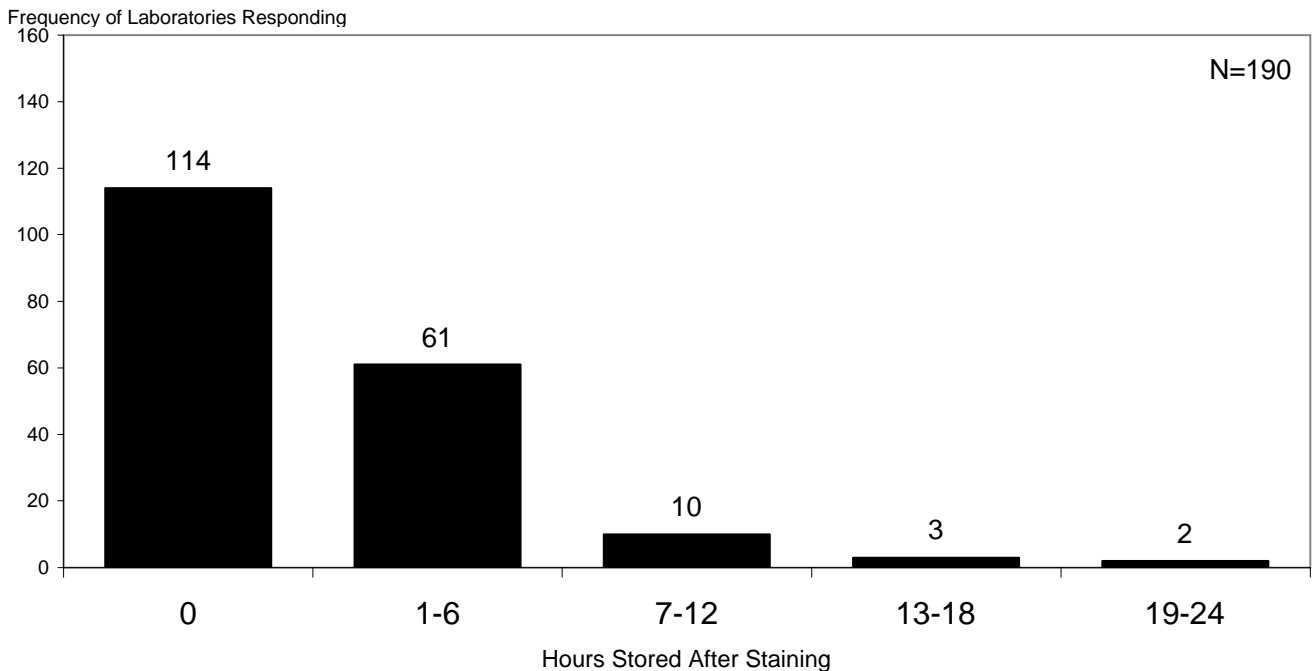
N=192

Require Minimum Degree	Number of Laboratories (%)
Yes	147 (76.6%)
No	45 (23.4%)

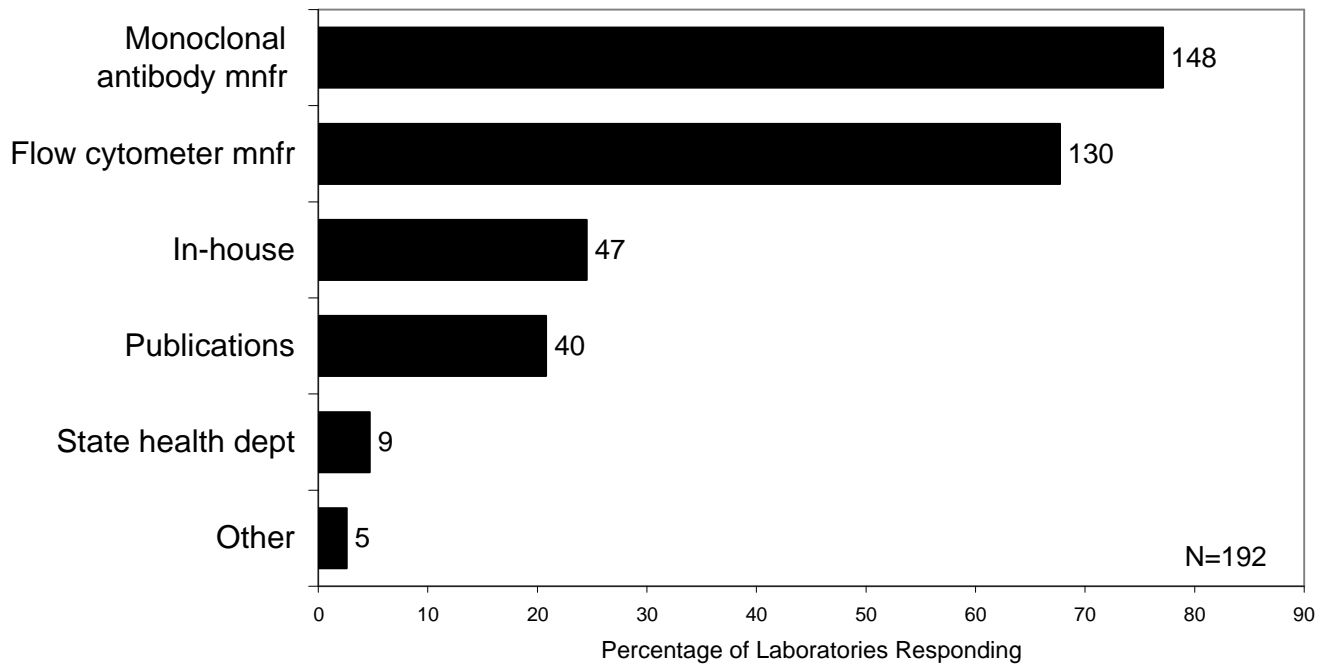
25.(g) At what temperature does your laboratory routinely store cells after staining (Chose only one.)



25.(h) On average, how many hours is a specimen stored at your laboratory after staining before being analyzed? (If the specimen is analyzed immediately after staining, please indicate 0 hours, otherwise round off to the nearest whole number.)



26. From what source did your laboratory obtain its CD4⁺ T-cell determinations staining procedure? (Check all that apply.)



27. Please complete the table below and the tables on the following pages by choosing from the list below, the monoclonal antibody manufacturer associated with reagents for each cell marker combinations you routinely use for performing CD4⁺ T-cell determinations.

Two-color Tests
Combinations of Monoclonal Antibody Manufacturers Used

Cell Marker	A/A	B/B	D/D	C/B	C/A	A/B	A/D
CD45/CD14	16	17	1				
CD3/CD4	9	20	1	1			
CD3/CD8	10	20	1		1		
CD3/CD19	4	16	1			1	1
CD3/CD16	1	4	1				1
CD3/CD56	4	5	1		1		1
CD3/CD56+16	1	17	1			1	

Three-color Tests
Combinations of Monoclonal Antibody Manufacturers Used

Cell Marker	A/A/A	A/B/B	B/B/B	B/A/B	C/B/A	D/D/D
CD45/CD3/CD4	9		44	1		1
CD45/CD3/CD8	7		36	1		1
CD45/CD3/CD19	5		27	1		2
CD45/CD3/CD56+16	2	1	21			
CD45/CD14/CD56	2		3			
CD3/CD4/CD8	9		2		1	
CD3/CD19/CD16	1		2			
CD3/CD19/CD56	4		2			
CD3/CD19/CD56+16	1		2	2		

Four-color Tests
Combinations of Monoclonal Antibody Manufacturers Used

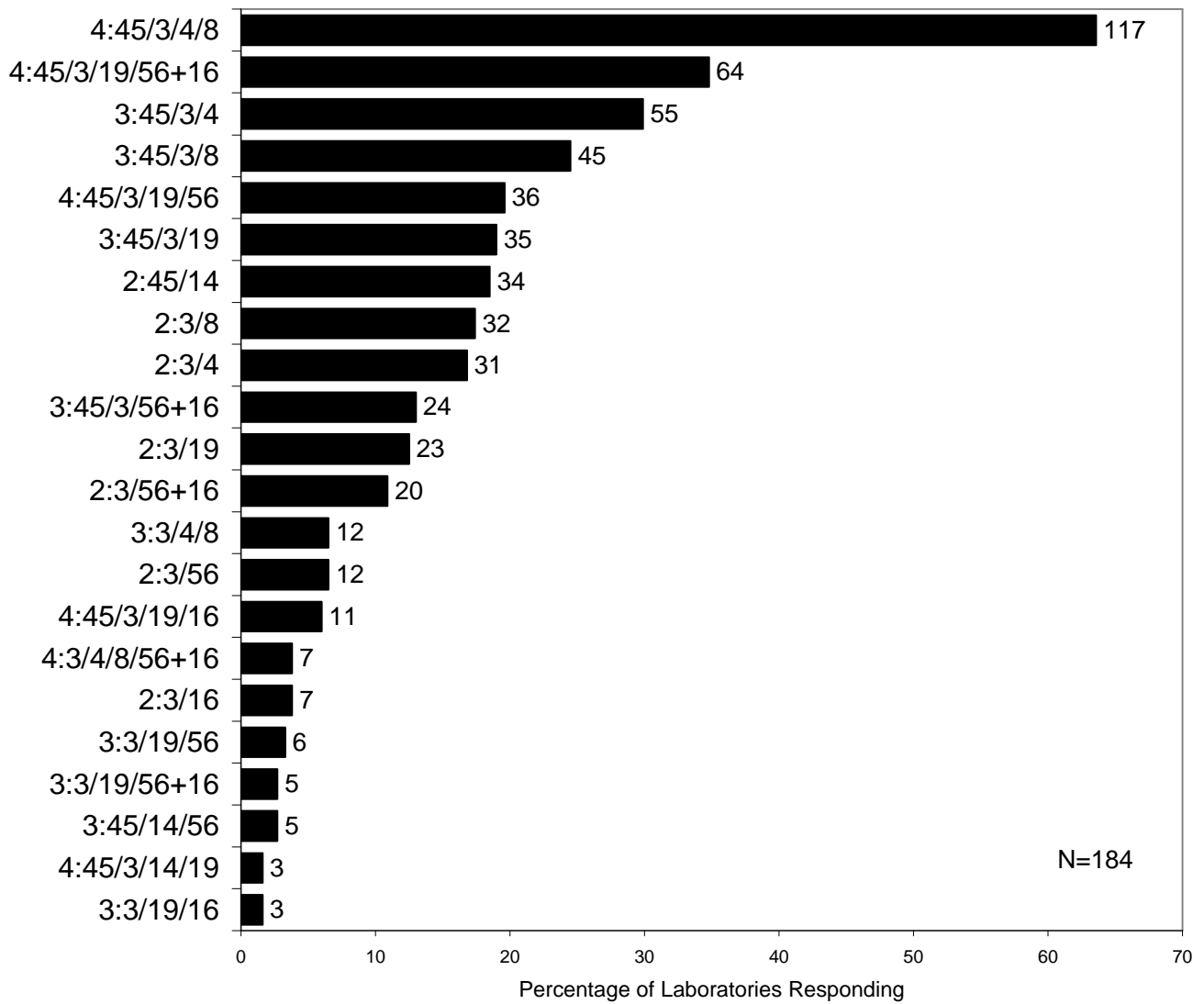
Cell Marker	A/A/A/A	A/B/B/A	A/B/B/B	B/B/B/B	K/K/K/K
CD45/CD3/CD4/CD8	52		1	63	1
CD45/CD3/CD19/CD16	5			6	
CD45/CD3/CD19/CD56	33			3	
CD45/CD3/CD19/CD56+16	8			54	1
CD45/CD3/CD14/CD19	1			2	
CD3/CD4/CD8/CD56&16	3	1		3	

Manufacturer Key:

A=Beckman Coulter/Immunotech B=BD Biosciences/Pharmingen C=Caltag D=Dako E=GenTrak F=Tago
G=Olympus H=Ortho I=In-House J=Noncommercial K=Other

27. continued:

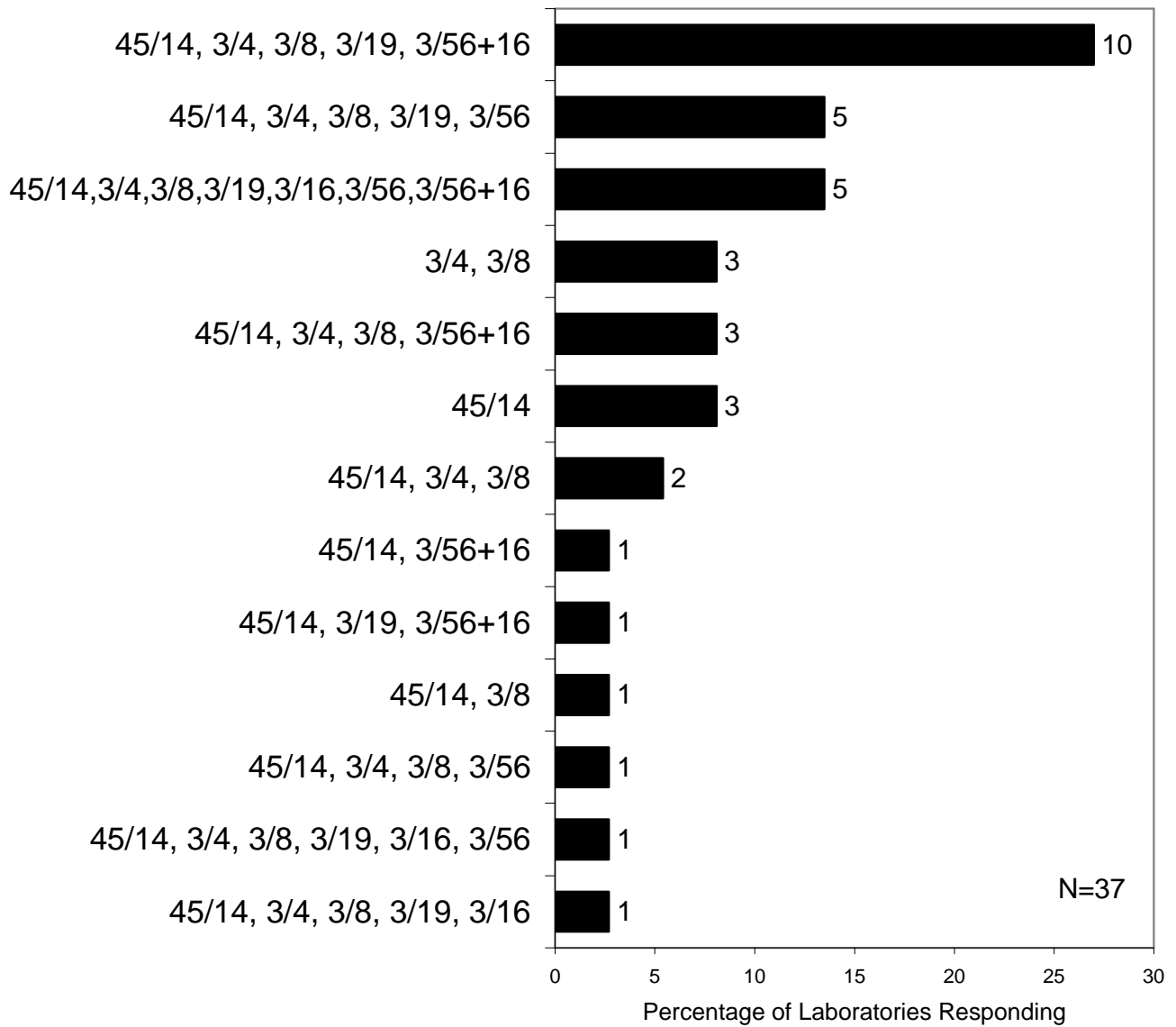
Summary of monoclonal antibody reagents used by participant laboratories



Key for interpretation
 1: one-color 2: two-color 3: three-color 4: four-color

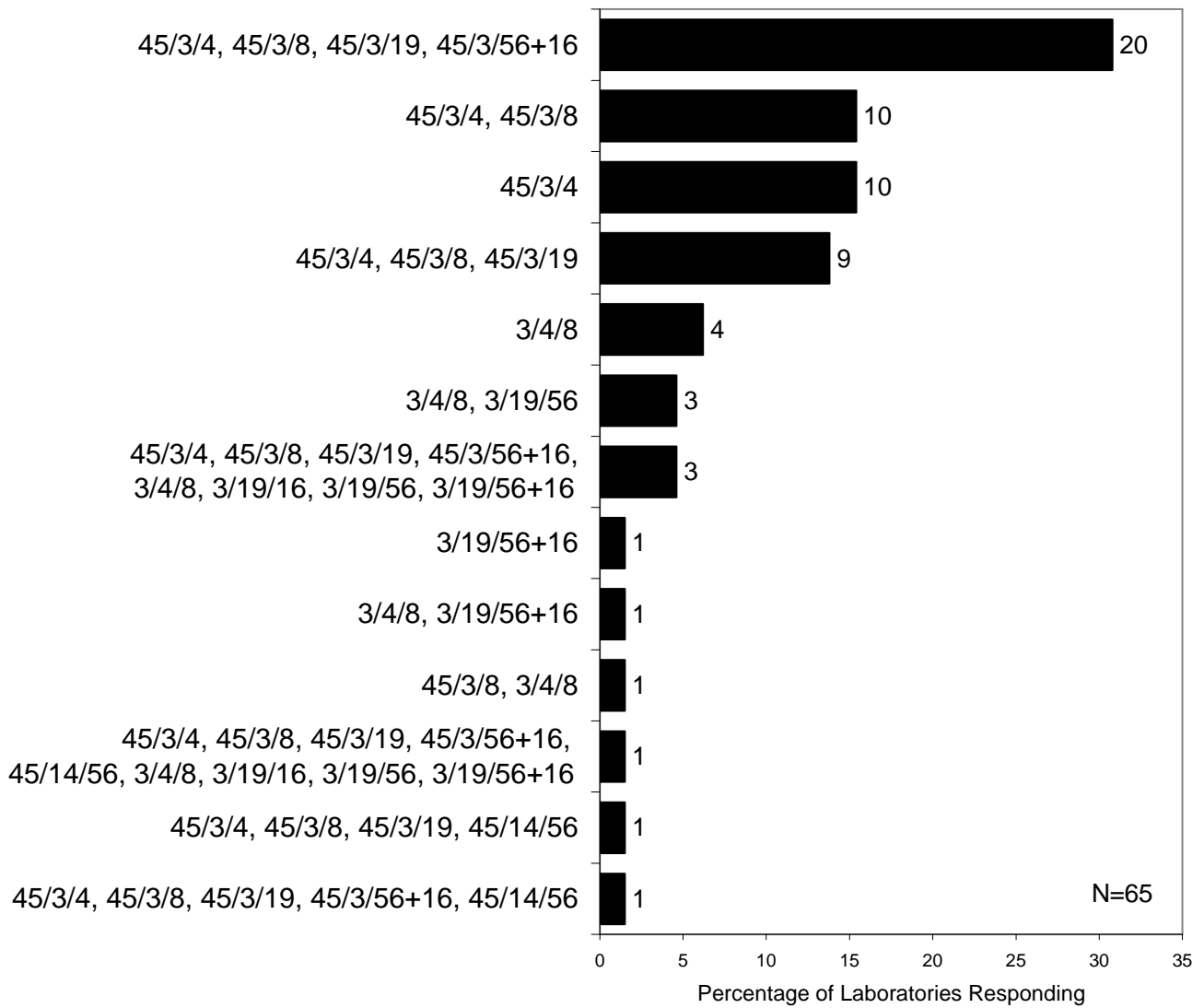
27. continued:

Two-color monoclonal antibody reagent panels used by participant laboratories



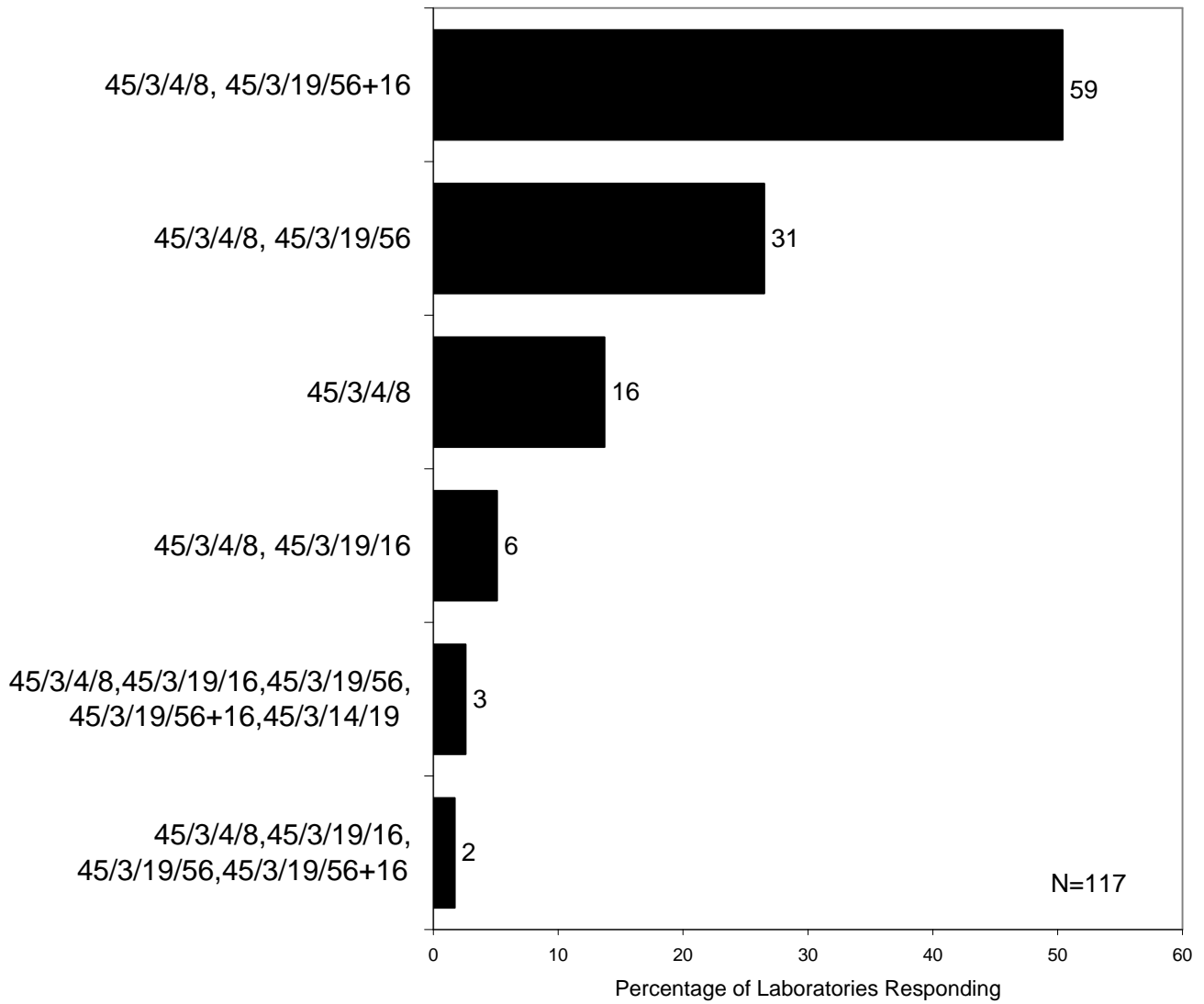
27. continued:

Three-color monoclonal antibody reagent panels used by participant laboratories

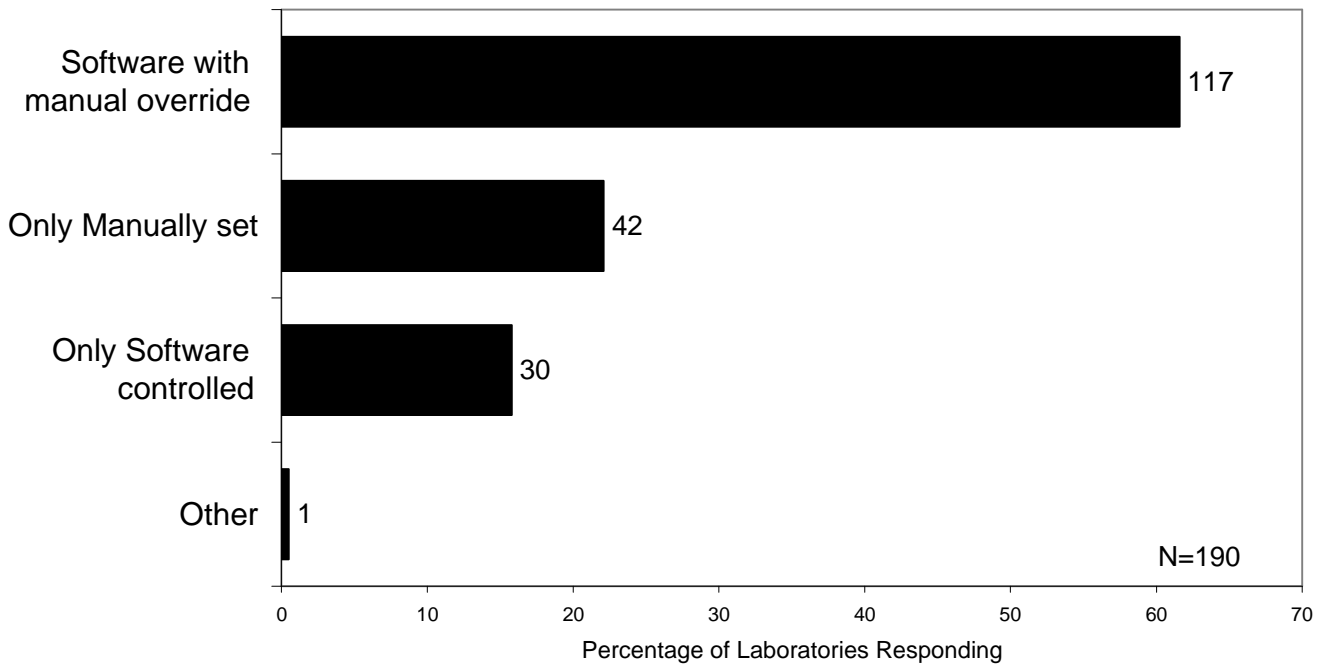


27. continued:

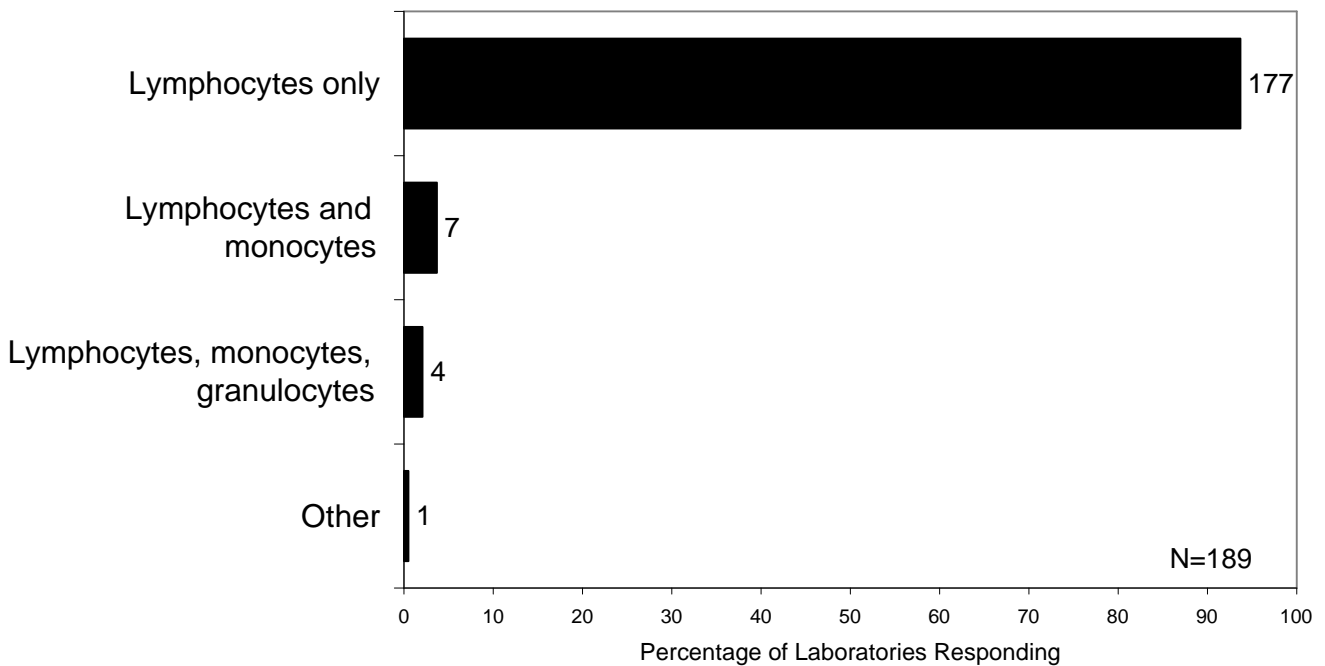
Four-color monoclonal antibody reagent panels used by participant laboratories



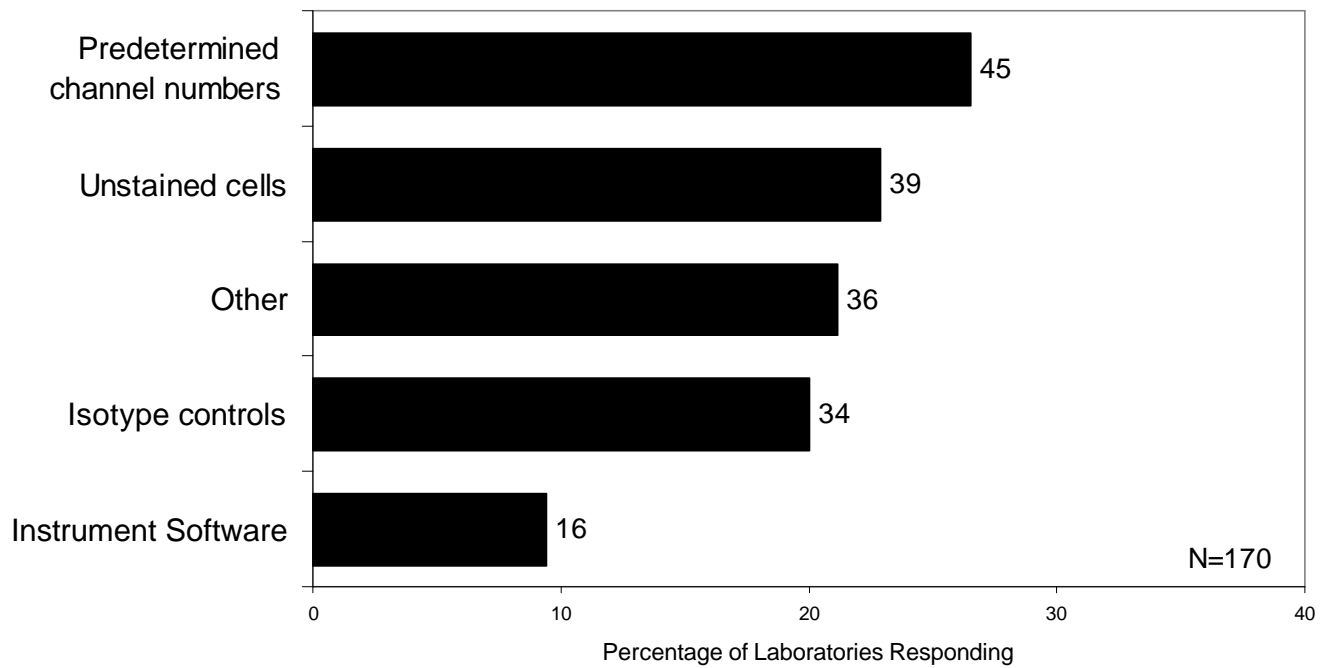
28.(a) How is the gating set when performing CD4⁺ T-cell determinations on your flow cytometers? (Choose only one.)



28.(b) Which cell populations are included in the gates for analyses of lymphocyte phenotypes? (Choose only one.)



29. How are the integration windows set? (Choose only one.)

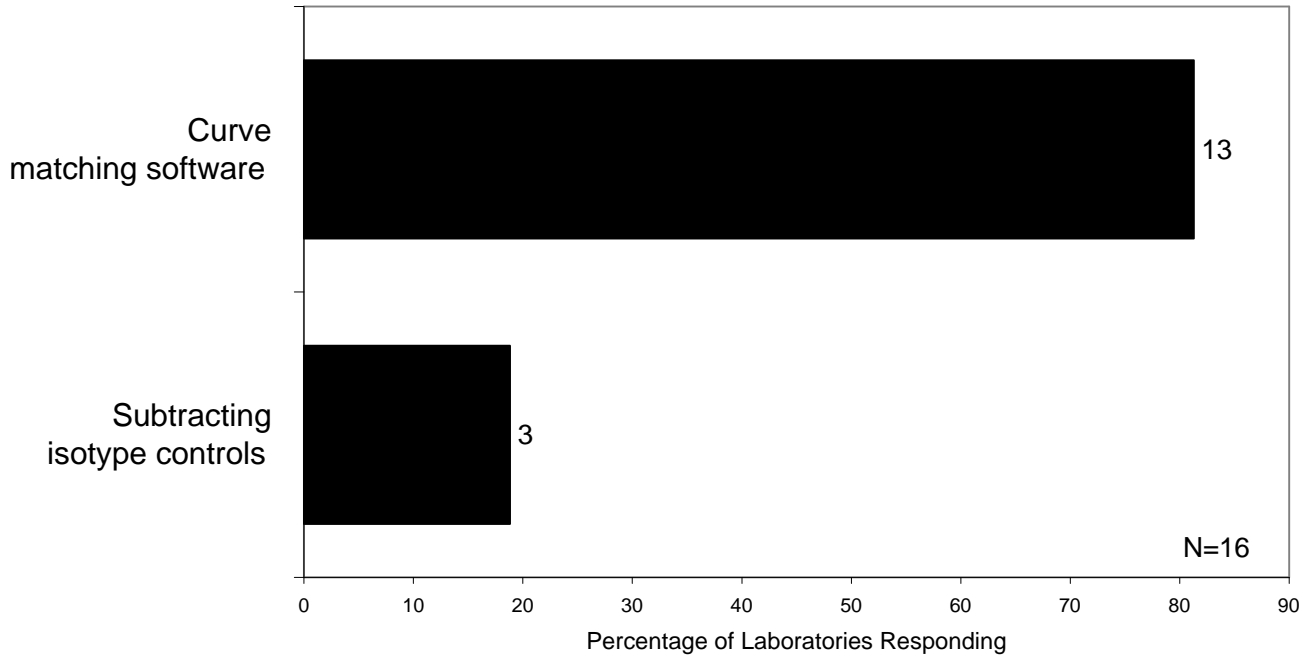


30.(a) Do you mathematically adjust your phenotype values for isotype control values?

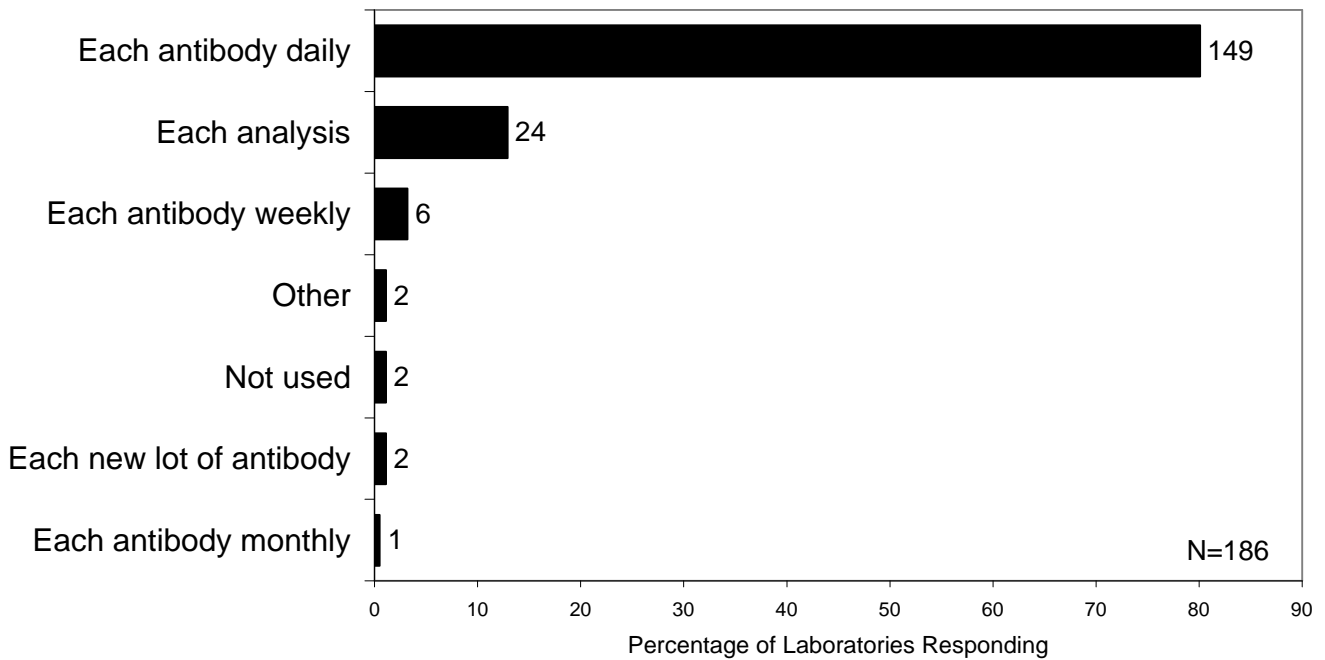
N=186

Mathematically Adjust for Isotype Control Values	Number of Laboratories (%)
Yes	17 (9.1%)
No	169 (90.9%)

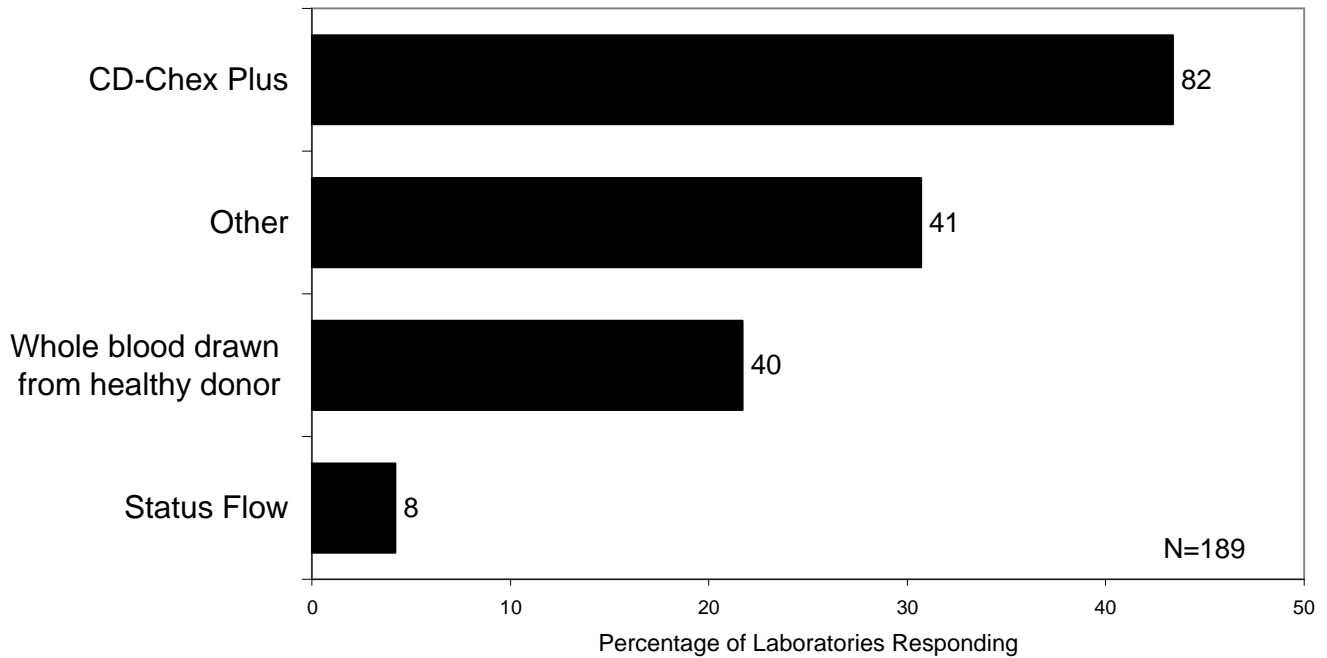
30.(b) How do you adjust your phenotype values? (Choose only one.)



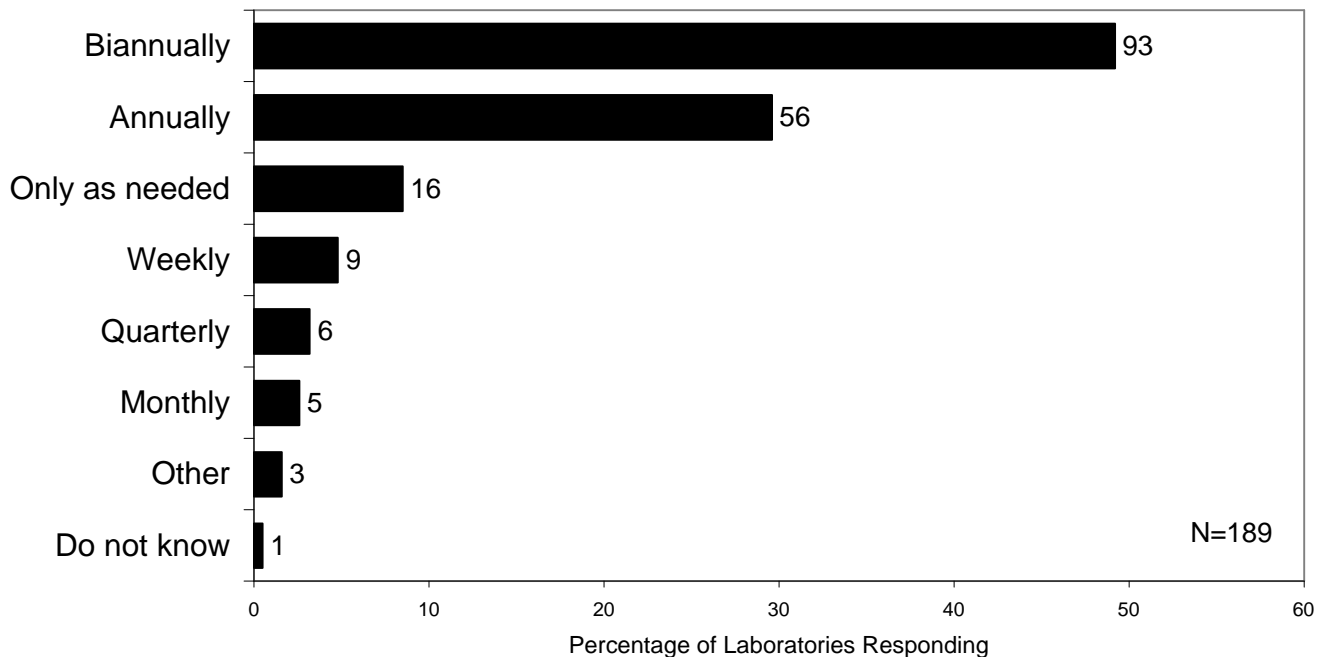
31.(a) How often are normal cell controls used? (Choose only one.)



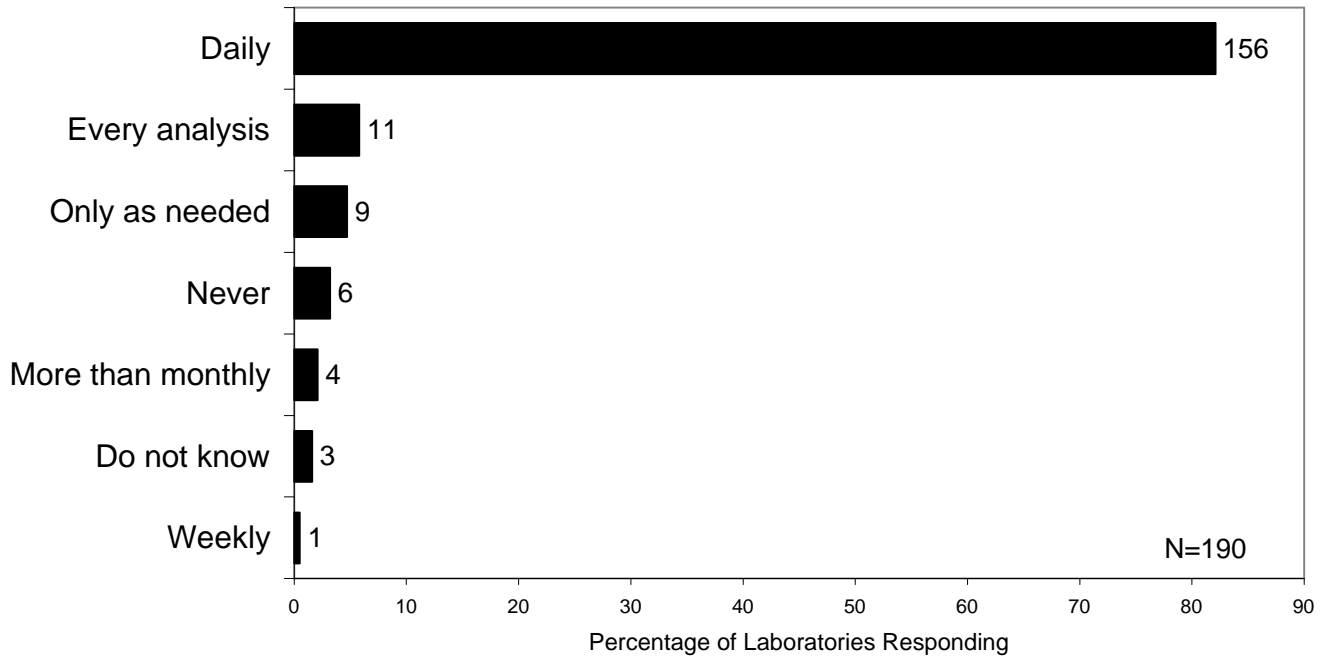
31.(b) Which normal cell control is primarily used in your laboratory? (Choose only one.)



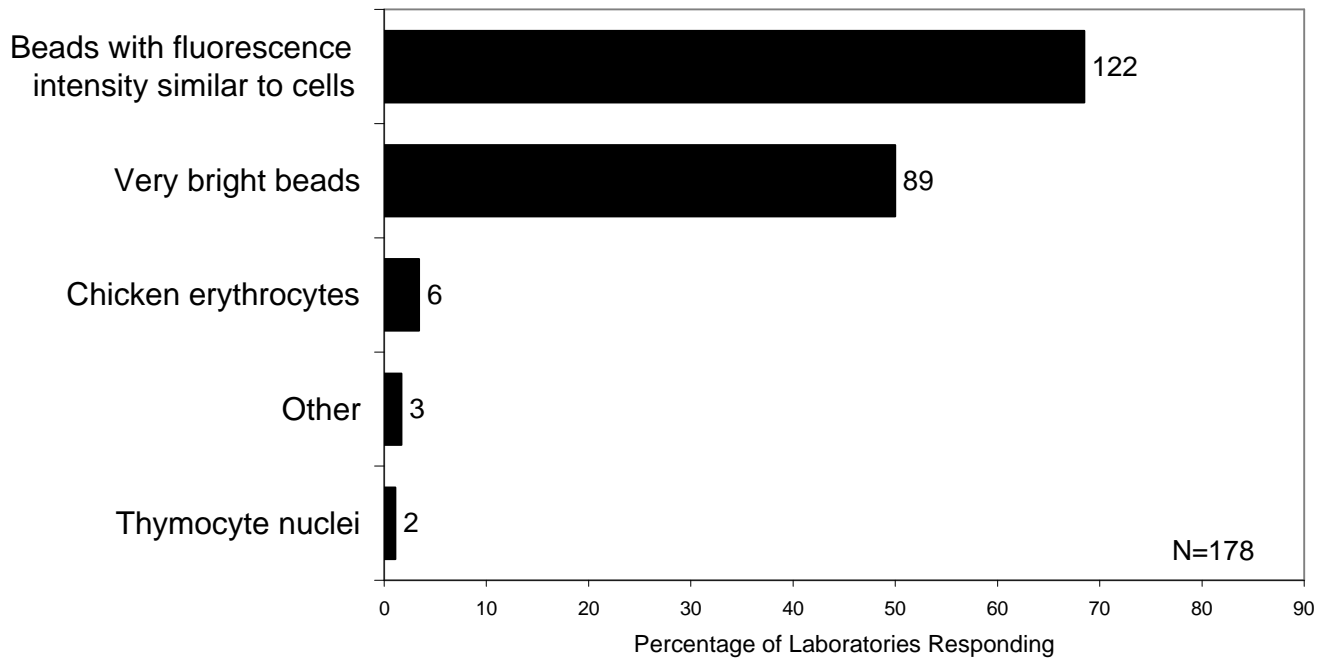
32. How often do your flow cytometer(s) receive preventative maintenance (e.g., cleaning of optical filters and lenses, and fluidics check)? (Choose only one.)



33.(a) How often does your laboratory check the optical alignment of your flow cytometer(s)? (Choose only one.)



33.(b) What types of particles are used by your laboratory to align your flow cytometers? (Check all that apply.)

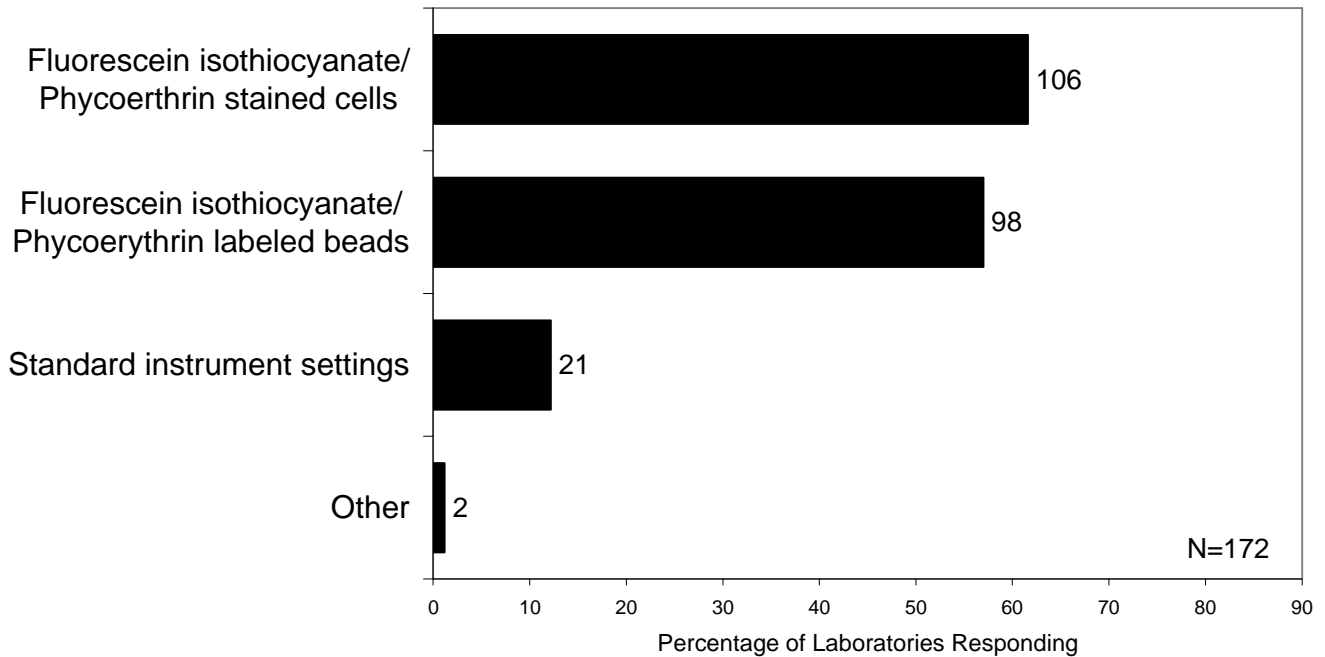


34.(a) Does your laboratory set fluorescence overlap compensation?

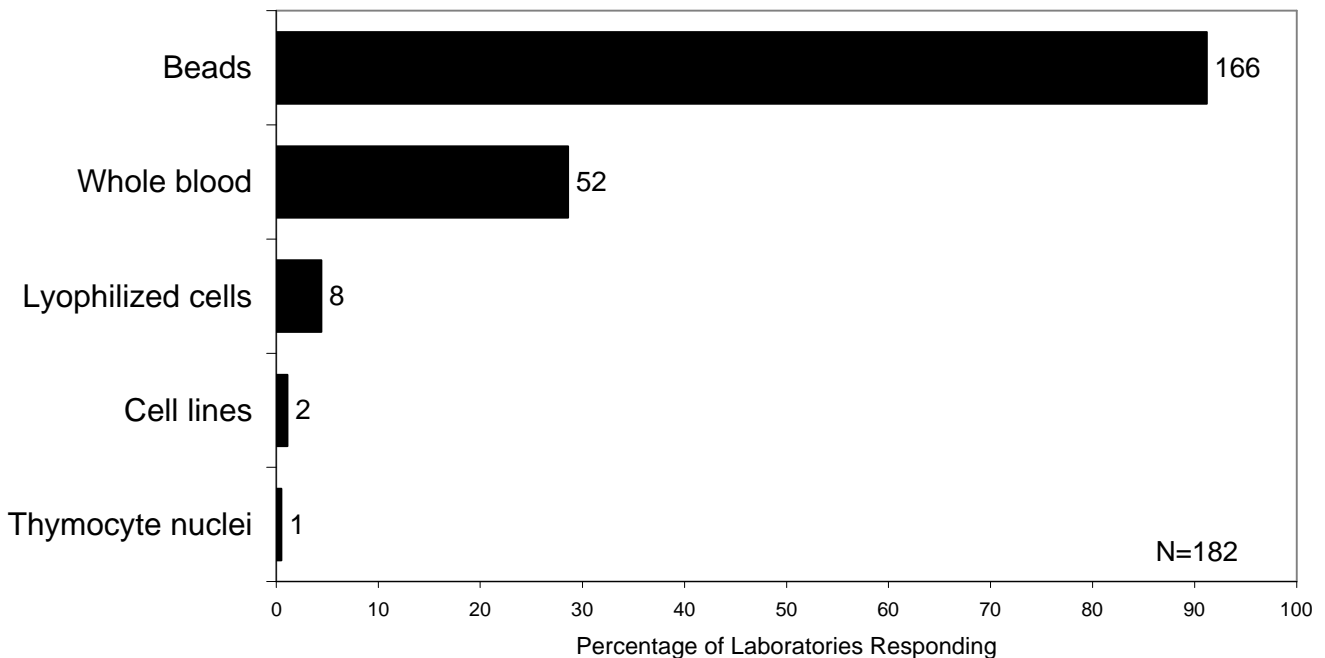
N=190

Set Fluorescence Overlap Compensation	Number of Laboratories (%)
Yes	179 (94.2%)
No	11 (5.8%)

34.(b) What reference materials are used to set fluorescence overlap compensation (Check all that apply.)



35.(a) What reference materials does your laboratory use to achieve the target conditions for forward angle light scatter (FALS) and fluorescence intensity (FI)? (Check all that apply.)



35.(b) Does your laboratory routinely record the instrument settings used to reach the target conditions for FALS?

N=189

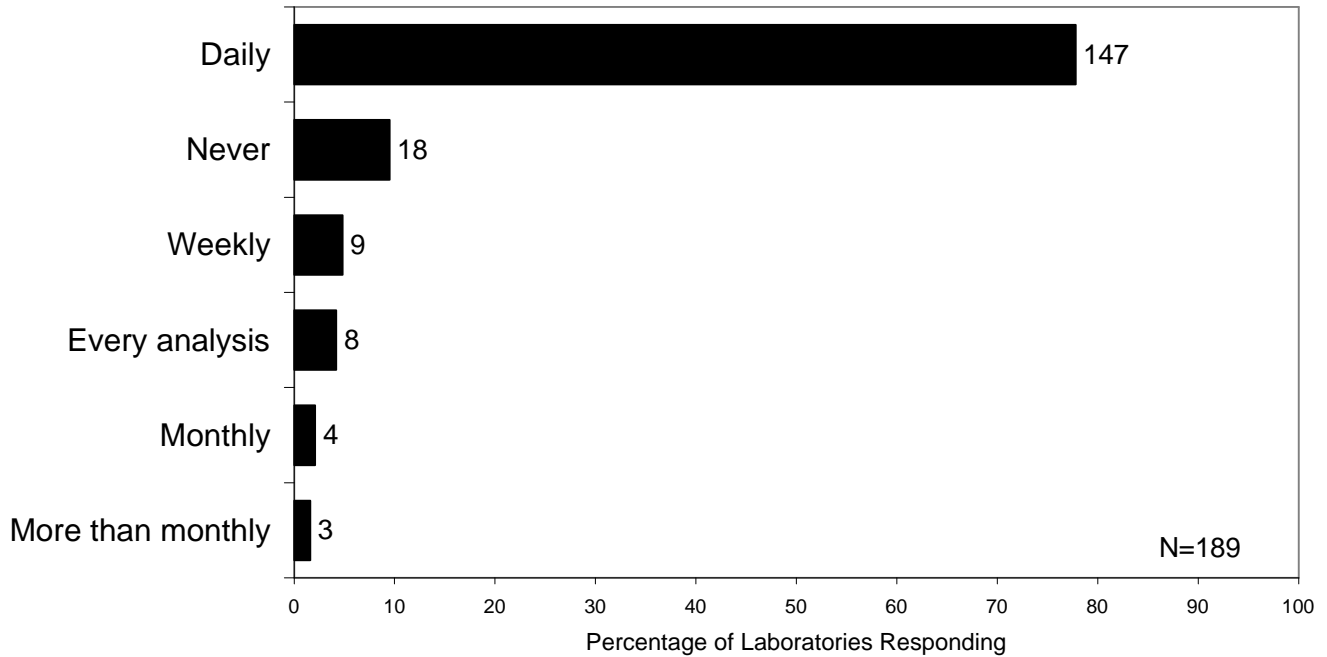
Record Instrument Settings	Number of Laboratories (%)
Yes	172 (91.0%)
No	17 (9.0%)

35.(c) Are these data analyzed to monitor trends or changes in instrument performance?

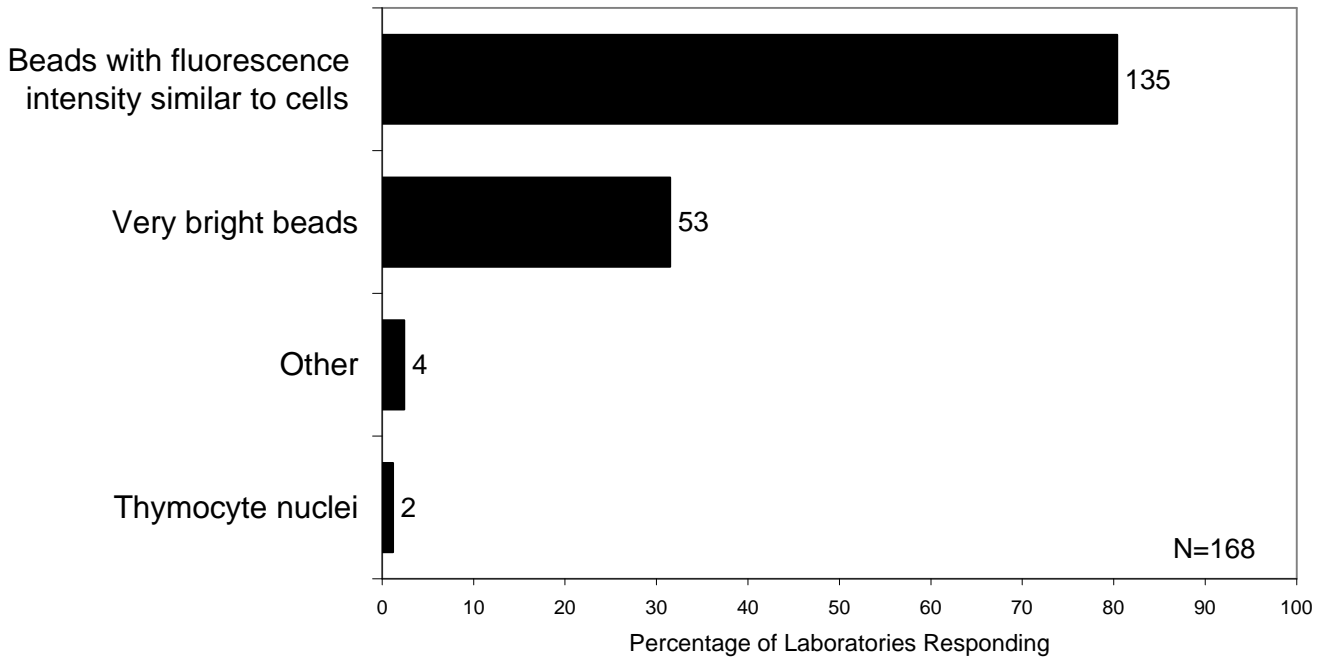
N=167

Data Analyzed	Number of Laboratories (%)
Yes	160 (95.8%)
No	7 (4.2%)

36.(a) How often does your laboratory standardize your flow cytometer(s)? (Choose only one.)



36.(b) What material(s) does your laboratory use to standardize your flow cytometer(s)? (Check all that apply.)



36.(c) Does your laboratory use reference standards to plot standard curves of mean channel fluorescence vs. molecules of equivalent soluble fluorochrome?

N=168

Use Reference Standards	Number of Laboratories (%)
Yes	30 (17.9%)
No	138 (82.1%)

36.(d) Does your laboratory maintain written records of the slope, intercept and correlation coefficients of the standard curves?

N=29

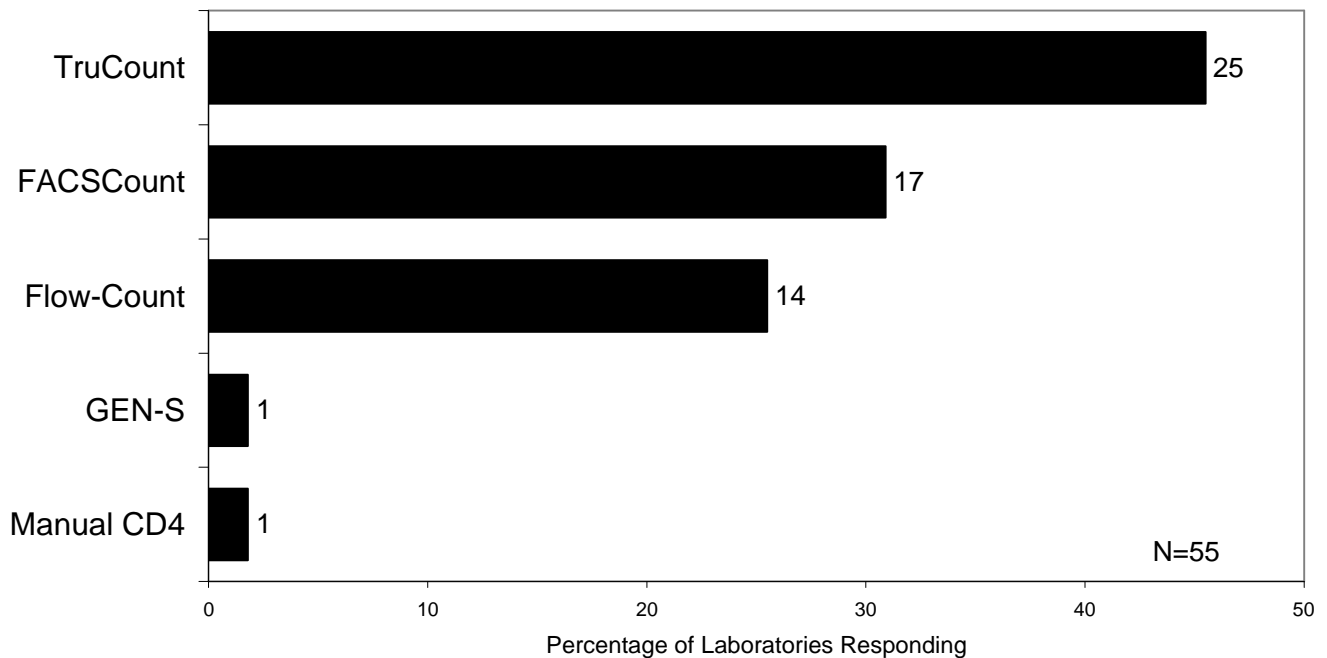
Maintain Written Records of Standard Curve Statistics	Number of Laboratories (%)
Yes	25 (86.2%)
No	4 (13.8%)

37. Does your laboratory obtain marker-specific absolute counts (e.g., absolute CD4 count) using a single-platform method?

N=191

Marker-specific Absolute Counts	Number of Laboratories (%)
Yes	57 (29.8%)
No	134 (70.2%)

38. What single-platform method(s) does your laboratory use? (Check all that apply.)

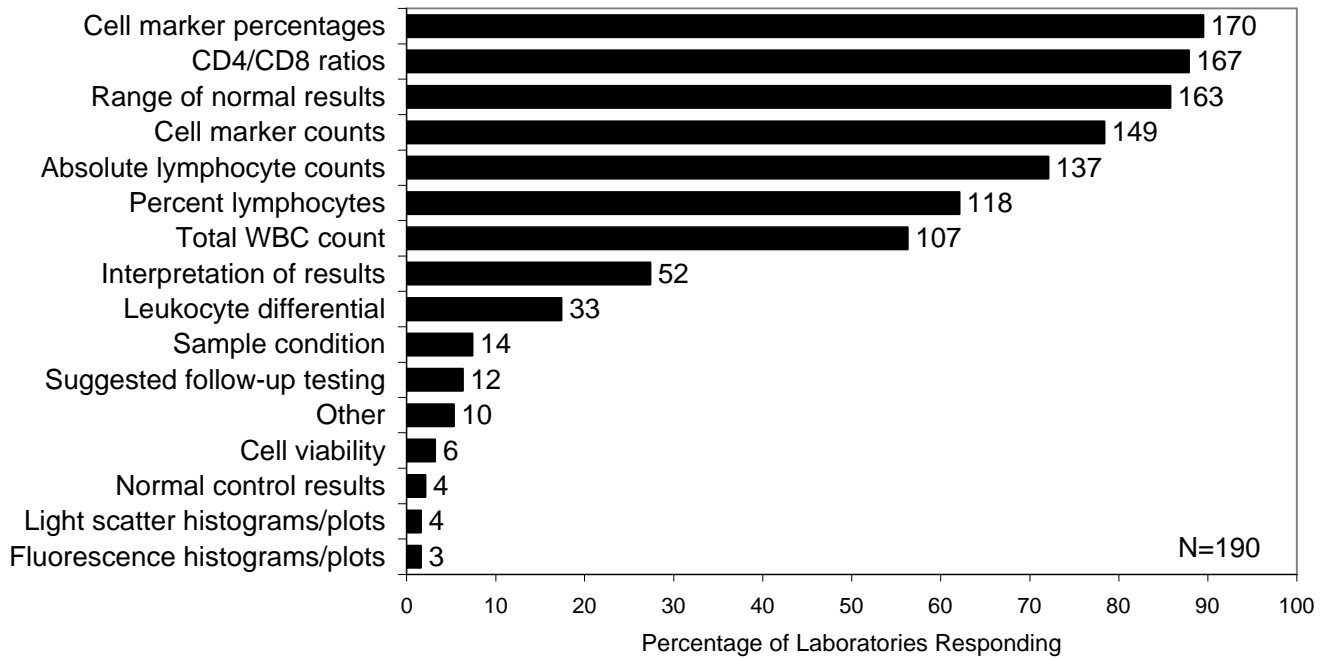


39. Before CD4⁺ T-cell determination results are reported, are they routinely reviewed by someone other than the person(s) who performed the tests?

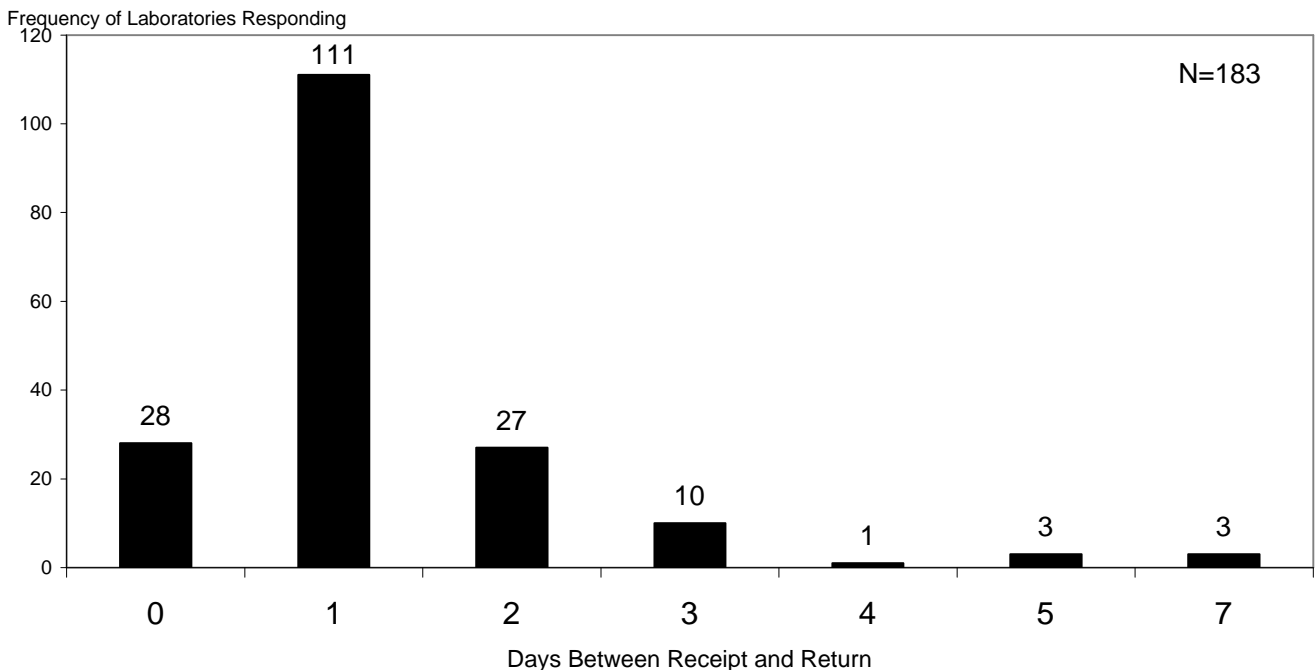
N=190

Results Reviewed by Someone Else	Number of Laboratories (%)
Yes	132 (69.5%)
No	58 (30.5%)

40. What information is included in the report returned to the person or institution initiating the request for CD4⁺ T-cell determinations? (Check all that apply.)



41. On average, how many days elapse between receipt of the specimen in your laboratory and the time the results of the test are returned to the person or institution initiating the request for CD4⁺ T-cell determinations? (If results are returned on the same day the specimen is received, please indicate 0 days, otherwise, round off to the nearest whole number.)

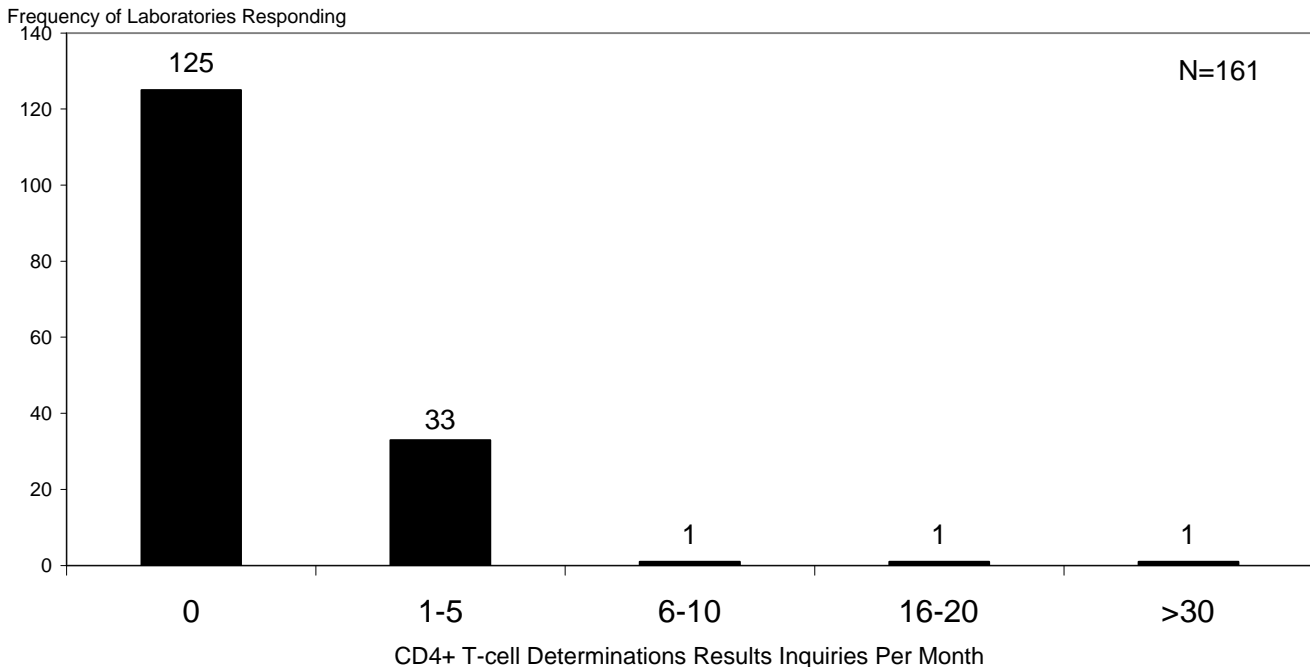


42. Does your laboratory have procedures for protecting the confidentiality of CD4⁺ T-cell determination results?

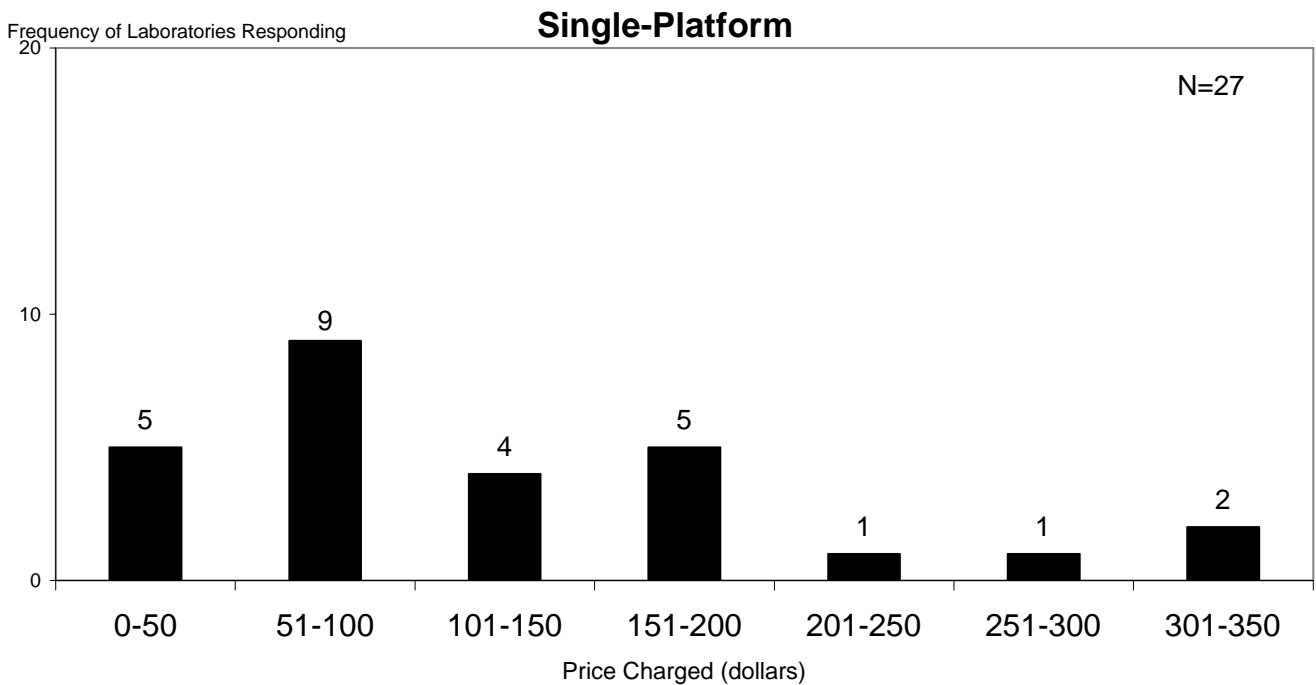
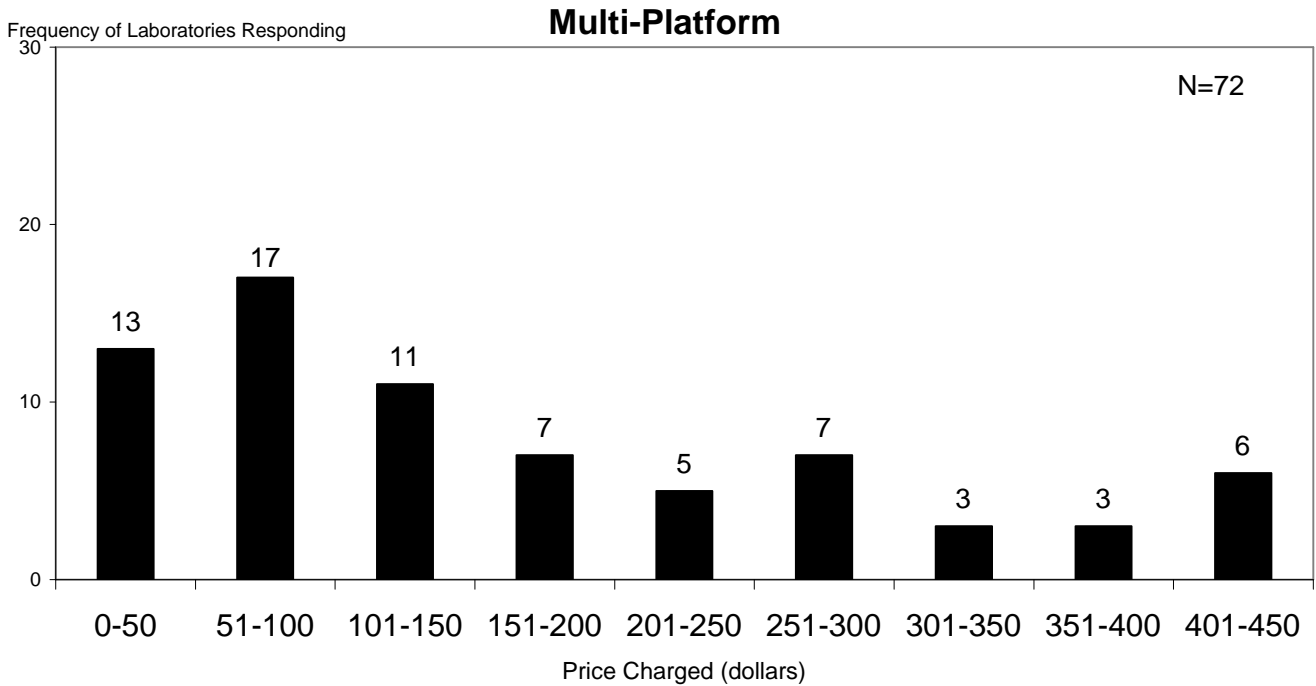
N=192

Procedures for Protecting Confidentiality	Number of Laboratories (%)
Yes	181 (94.3%)
No	11 (5.7%)

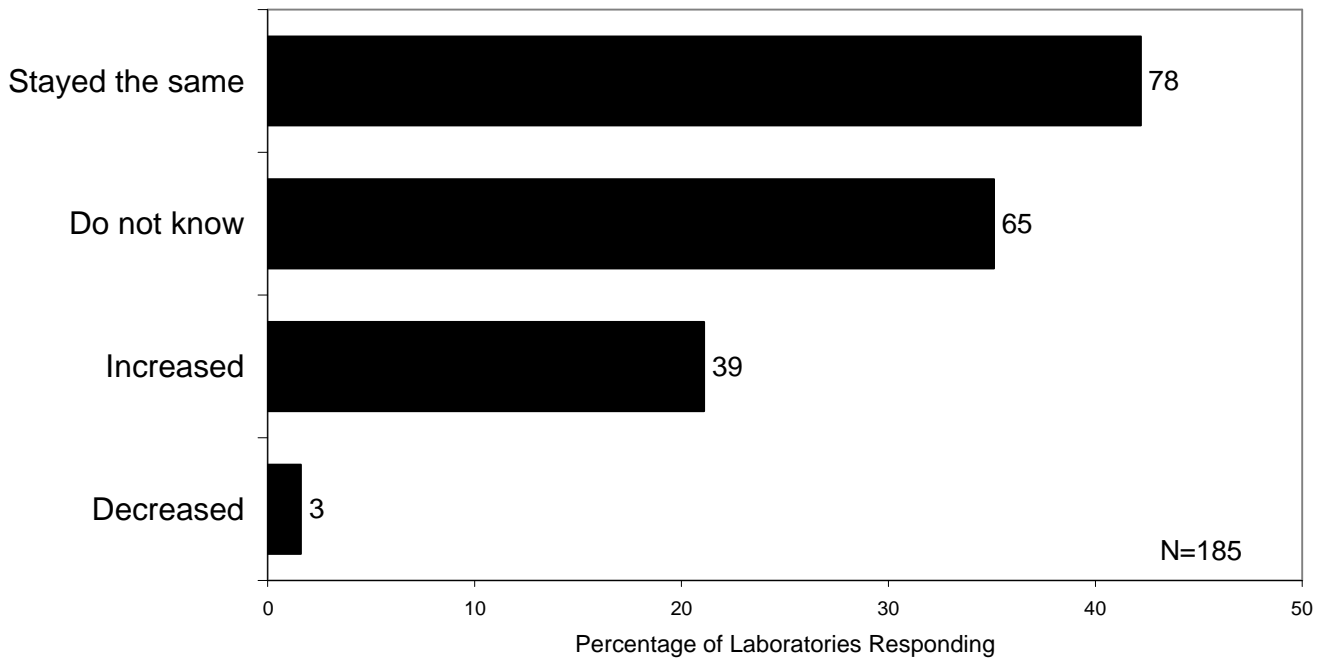
43. On average, how many times in a month does your laboratory receive inquiries from clinicians requesting interpretation of CD4⁺ T-cell determinations results? (Round off to the nearest whole number.)



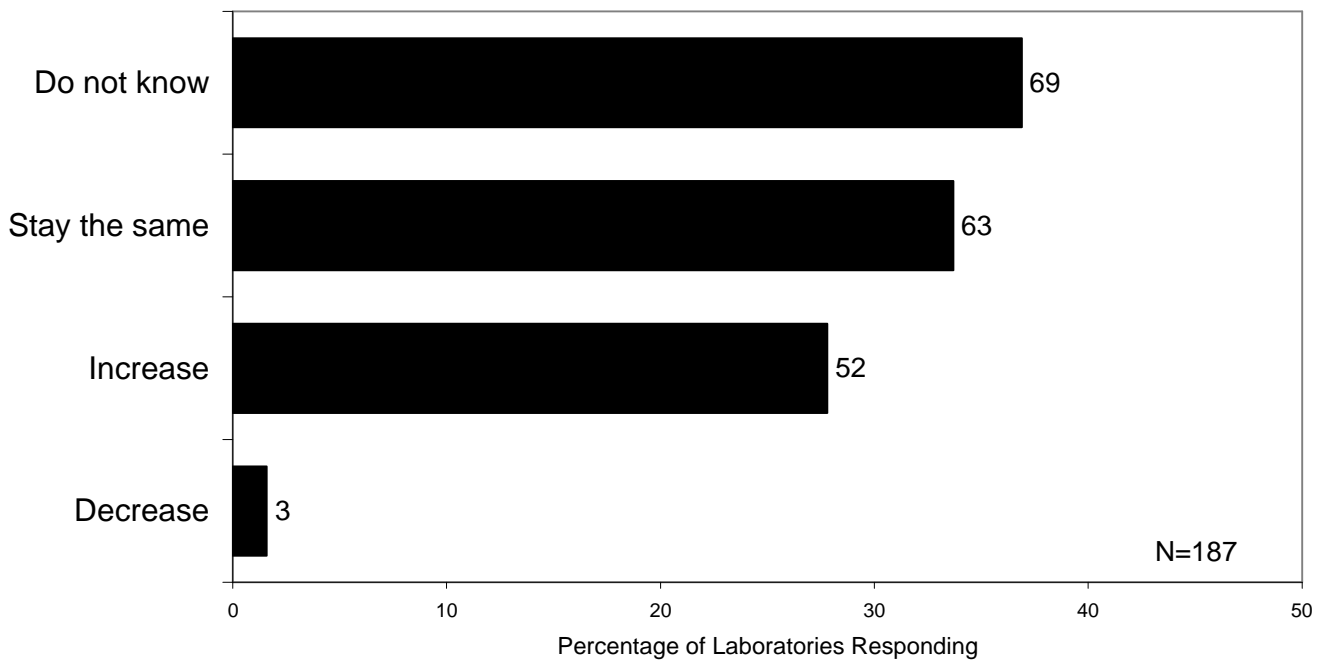
44.(a) What is the average full price currently charged by your laboratory for CD4⁺ T-cell determinations for each patient/blood donor sample? (Please indicate the price charged only for those methods currently in use in your laboratory. Round off to the nearest whole dollar.)



44.(b) Has the average full price that your laboratory charges for CD4⁺ T-cell determinations for each patient/blood donor sample increased, decreased, or stayed the same compared to twelve months ago? (Chose only one.)



44.(c) Do you anticipate the price charged for CD4⁺ T-cell determinations by your laboratory will increase, decrease, or stay the same in the next twelve months? (Chose only one.)

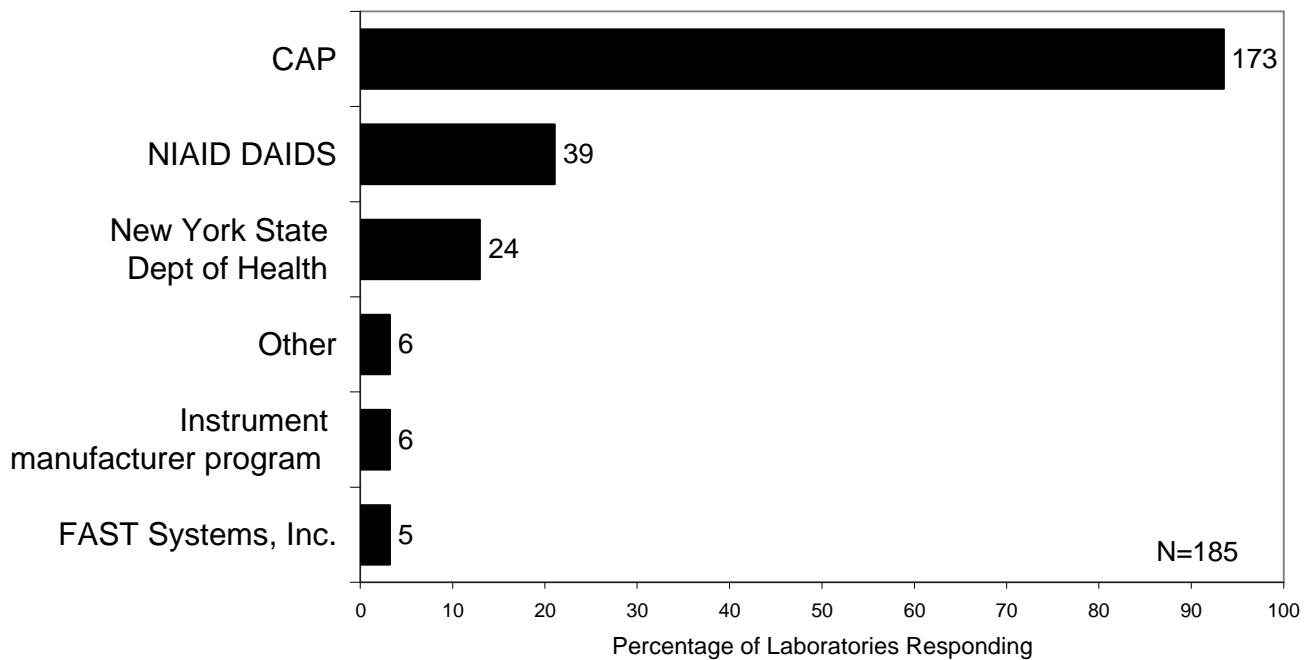


45.(a) Does your laboratory participate in an external CD4⁺ T-cell determinations proficiency testing program?

N=193

Participate in External PT Program	Number of Laboratories (%)
Yes	187 (96.9%)
No	6 (3.1%)

45.(b) In which program(s) does your laboratory participate? Please exclude the CDC Model Performance Evaluation Program, since it is not designed for proficiency testing. (Check all that apply.)

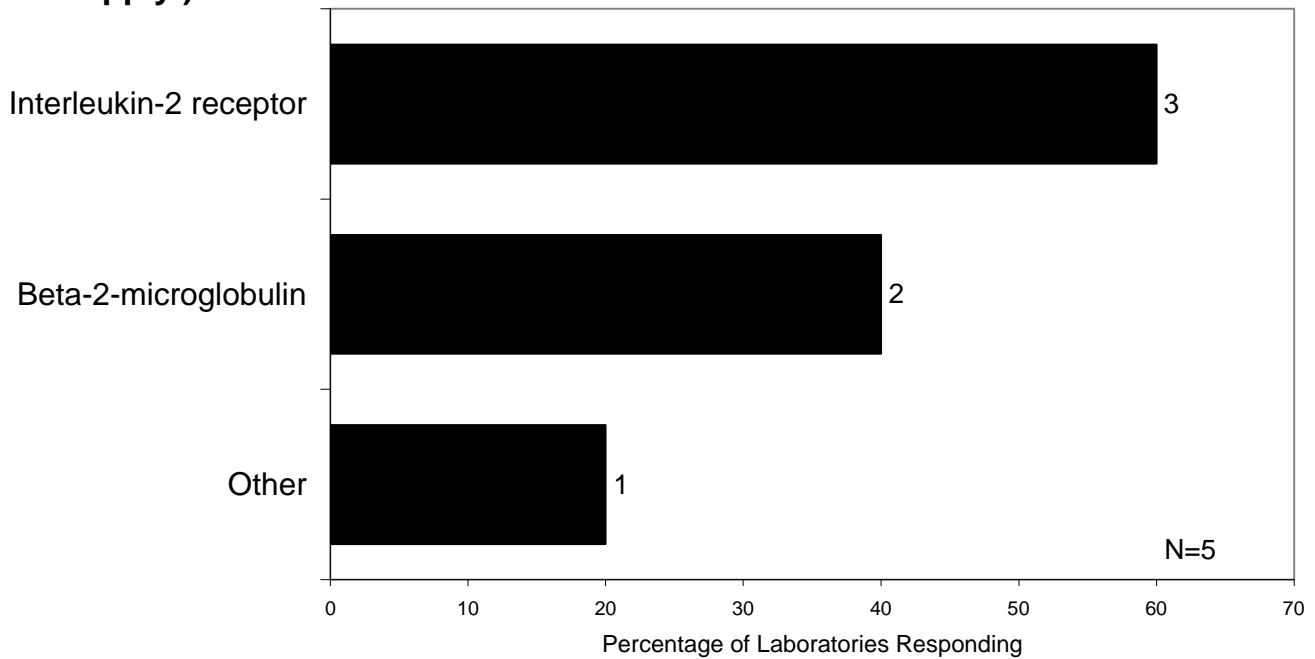


46.(a) In the last year, has your laboratory performed surrogate-marker tests for CD4⁺ T-cell determinations in HIV-infected patients?

N=191

Performed Surrogate-Marker Tests	Number of Laboratories (%)
Yes	6 (3.1%)
No	185 (96.9%)

46.(b) Which surrogate-marker tests did your laboratory perform? (Check all that apply.)

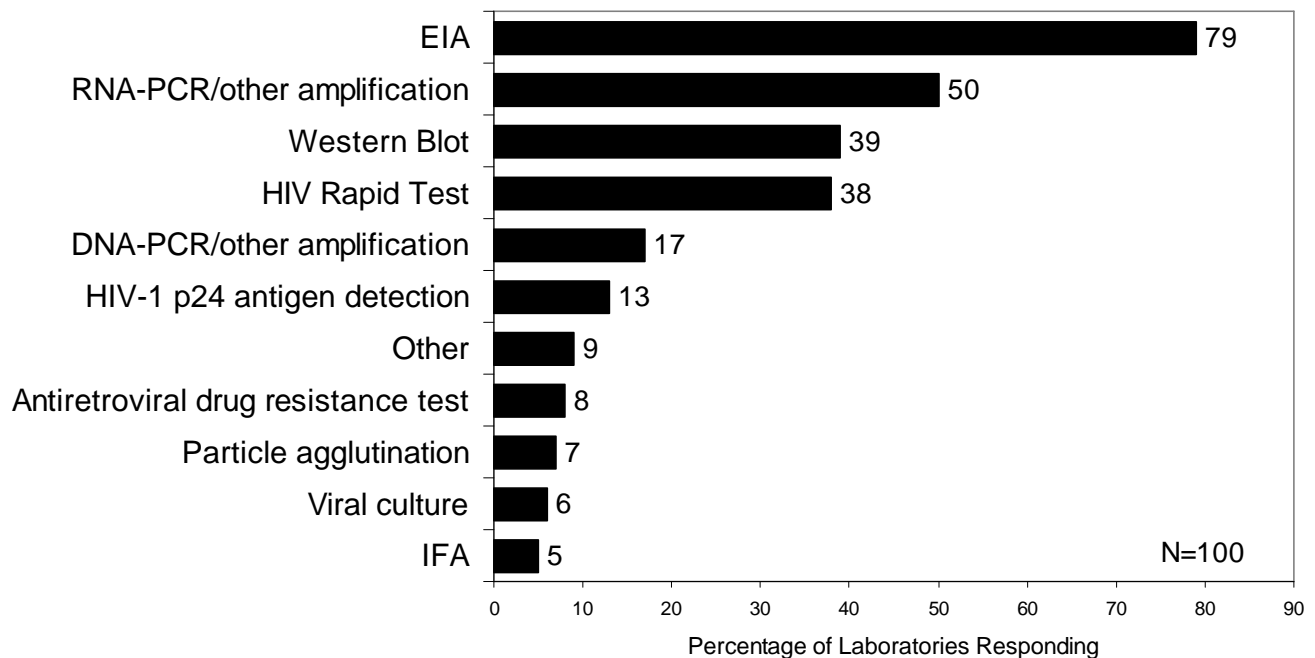


47.(a) In the last year, has your laboratory performed other tests for HIV-1 infection?

N=192

Other Tests for HIV-1	Number of Laboratories (%)
Yes	105 (54.7%)
No	87 (45.3%)

47.(b) Which HIV-1 tests did your laboratory perform? (Check all that apply.)



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