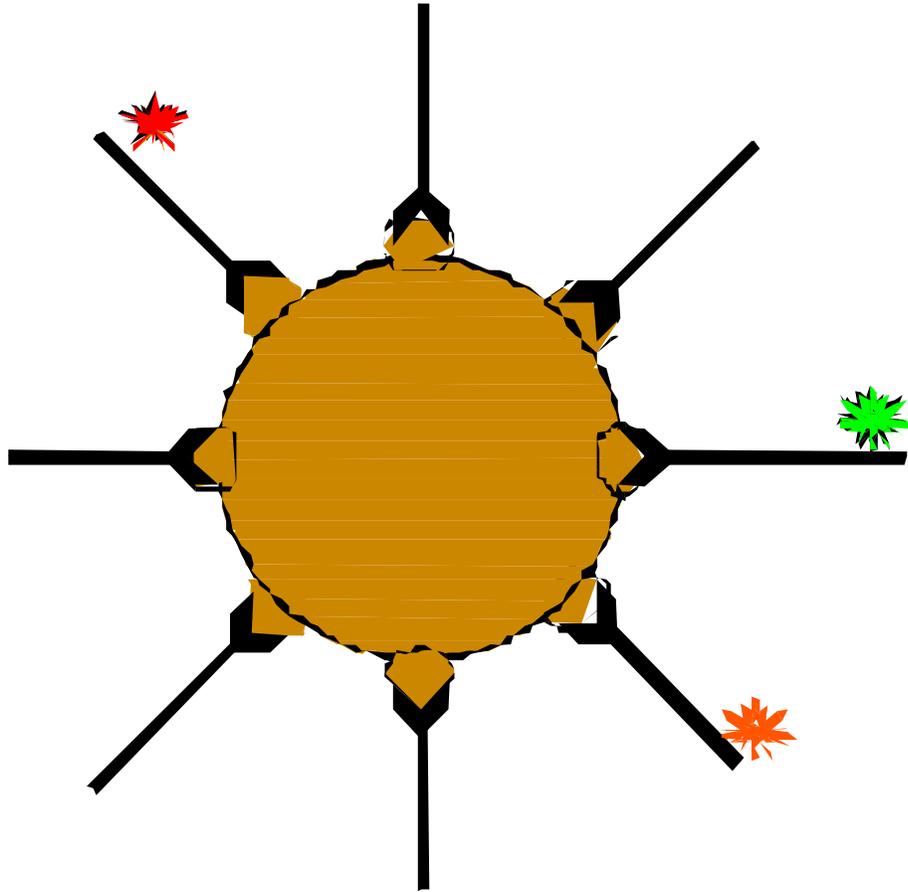


Results of the 1995 T-Lymphocyte
Immunophenotyping Questionnaire Survey
Mailed to Laboratories Participating in the
Model Performance Evaluation Program



T-Lymphocyte Immunophenotyping
By Flow Cytometry



Report of results for a 1995 T-lymphocyte Immunophenotyping (TLI) laboratory questionnaire survey mailed to laboratories participating in the Model Performance Evaluation Program, Centers for Disease Control and Prevention (CDC)

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

Information about this report should be addressed to the Model Performance Evaluation Program by calling (770) 488-4559 or (770) 488-4366.

Introductory Comments

The aggregate results from a mailed questionnaire survey conducted by the Model Performance Evaluation Program (MPEP) in May 1995 of laboratories in the United States performing T-lymphocyte immunophenotyping (TLI) by flow cytometry are presented in the following figures and tables. Of the 360 laboratories receiving this survey, 295 (81.9%) responded. 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 TLI program at the time this survey was mailed, and does not reflect the current enrollment in this program.

Please note that wording for questions 6 and 7, regarding the education and certification requirements of the laboratory director and supervisor, reflect current regulatory requirements related to the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), as published in CFR 42, Part 493.

Question 6a was worded "Check all that apply", however the combinations of degrees awarded to the Laboratory Director and Supervisor were determined and are displayed in this figure.

In question 6b, the academic discipline of Microbiology was inadvertently omitted as a response selection in the questionnaire. Fifty percent of the responses in the "Other" category were specified as "Microbiology", therefore, this response was subtracted from the "Other" category and presented as a unique response in the figure.

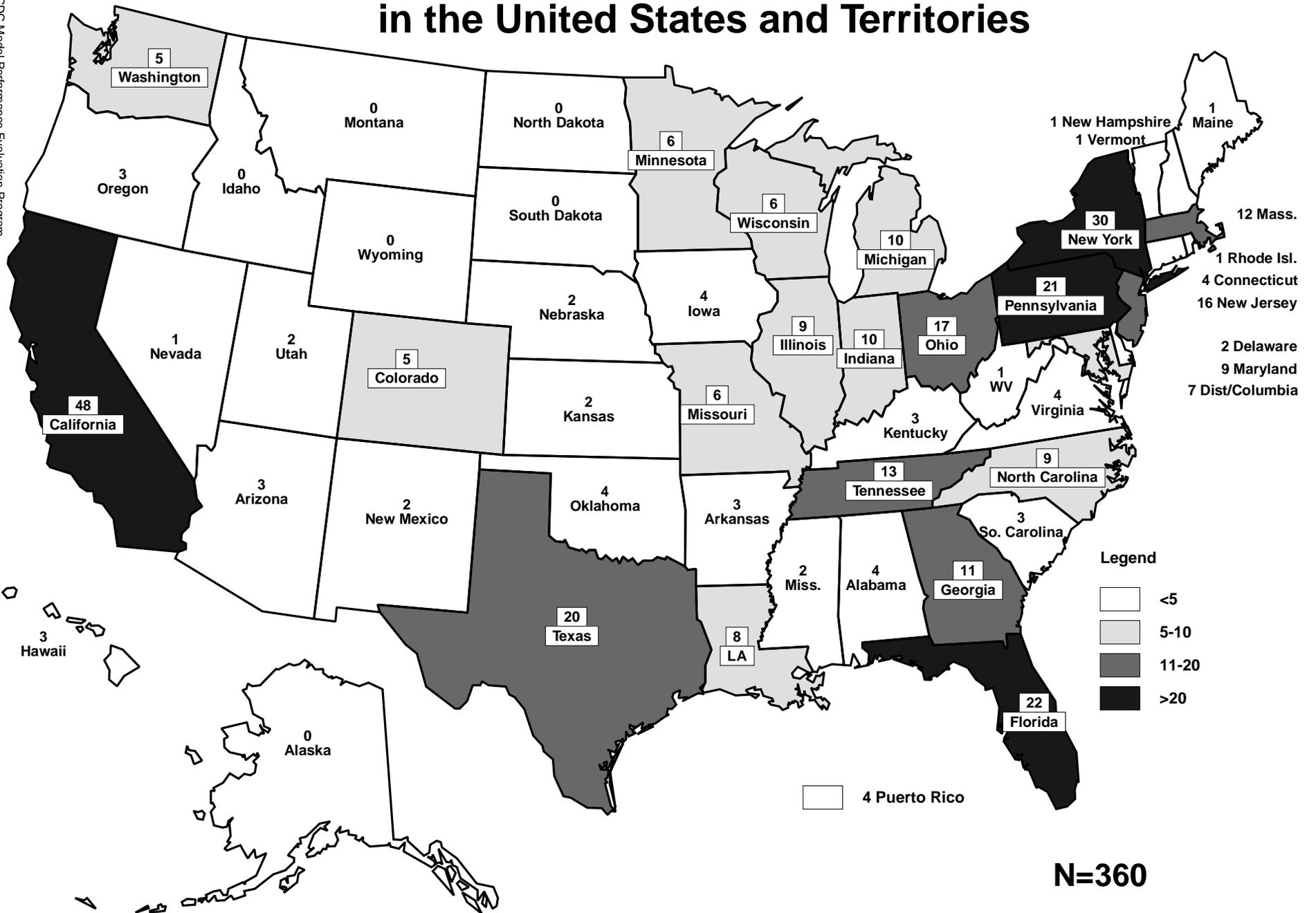
Similarly, in question 6c, the American Board of Pathology was inadvertently omitted as a response selection for an organization awarding board certification. More than 60% of the responses in the "Other" category were specified as "American Board of Pathology", therefore, this response was subtracted from the "Other" category and presented as a unique response in the figure.

The response percentages for Microbiology in question 6b and American Board of Pathology in question 6c may not reflect the number of responses that would have been obtained for these categories had these response selections not been omitted in the questionnaire.

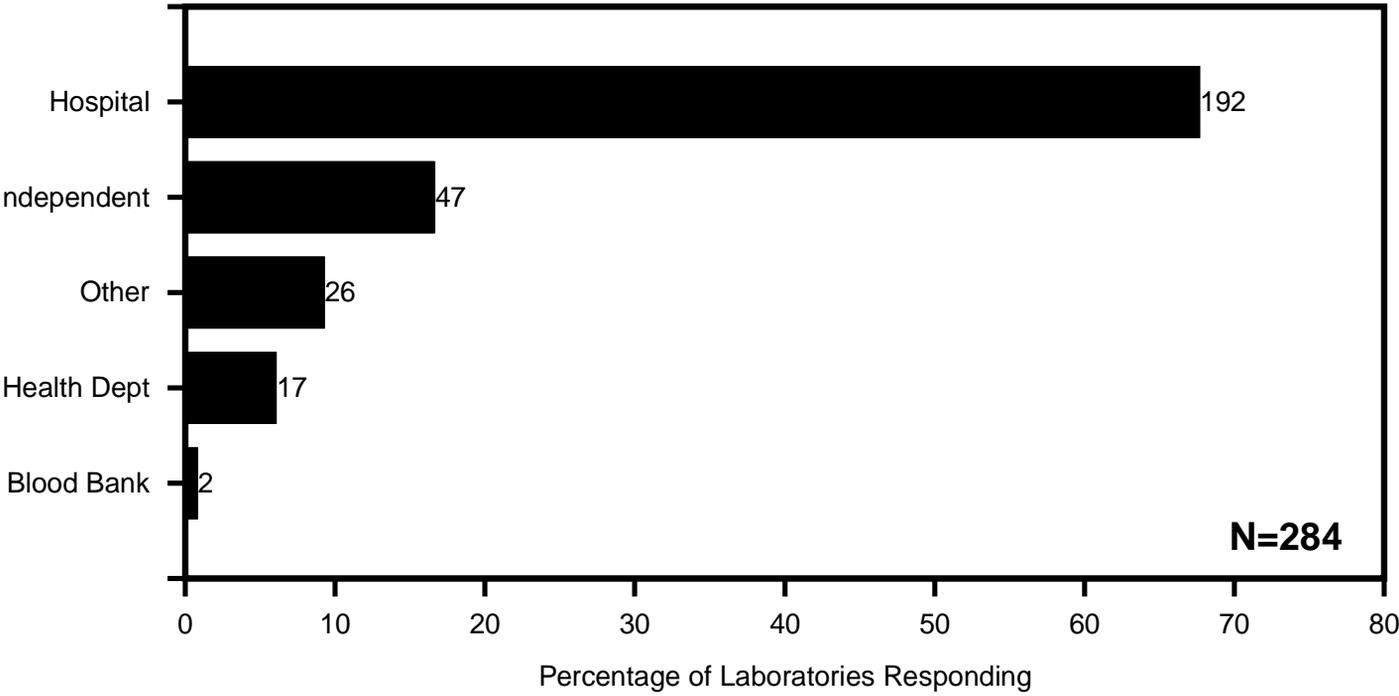
Question 12 requested information regarding the quantities, manufacturers, models and ages of the flow cytometers in use in the laboratories. For the sake of simplicity only the quantities, grouped by instrument manufacturer, are displayed for this question.

Question 25 requested information regarding the monoclonal antibody manufacturer, type of stain, and fluorochrome associated with reagents for each of the cell marker combinations routinely used for performing TLI. Again, for the sake of simplicity, only the monoclonal antibody combinations used for the various cell markers are displayed.

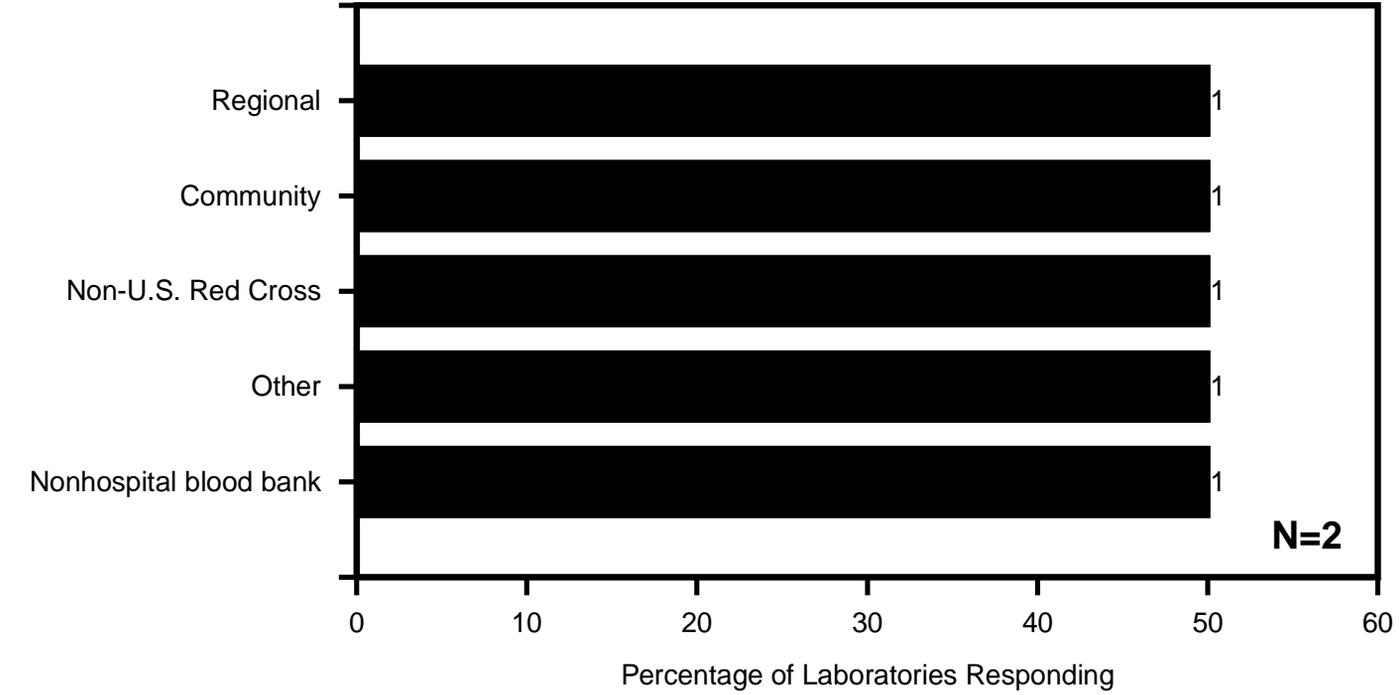
Number of TLI Laboratories in the United States and Territories



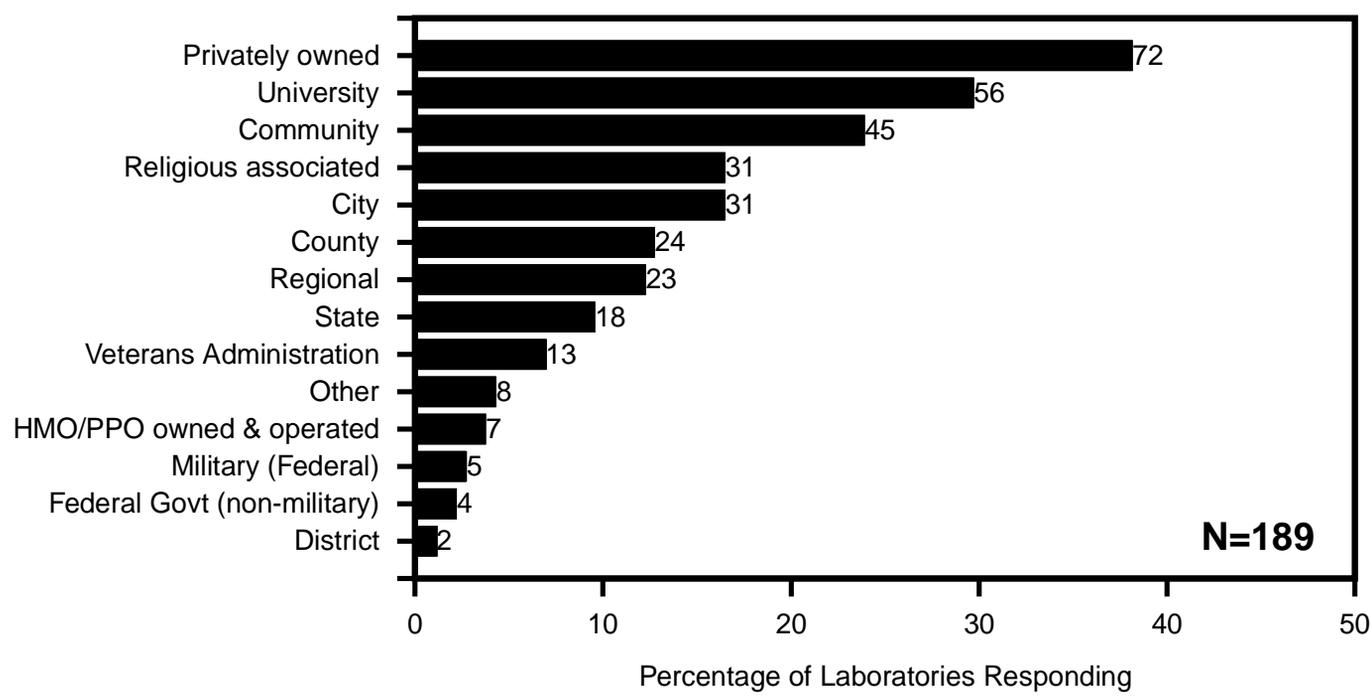
5.(a) Please use the following to describe the primary classification of your laboratory in regard to TLI testing (Choose only one.):



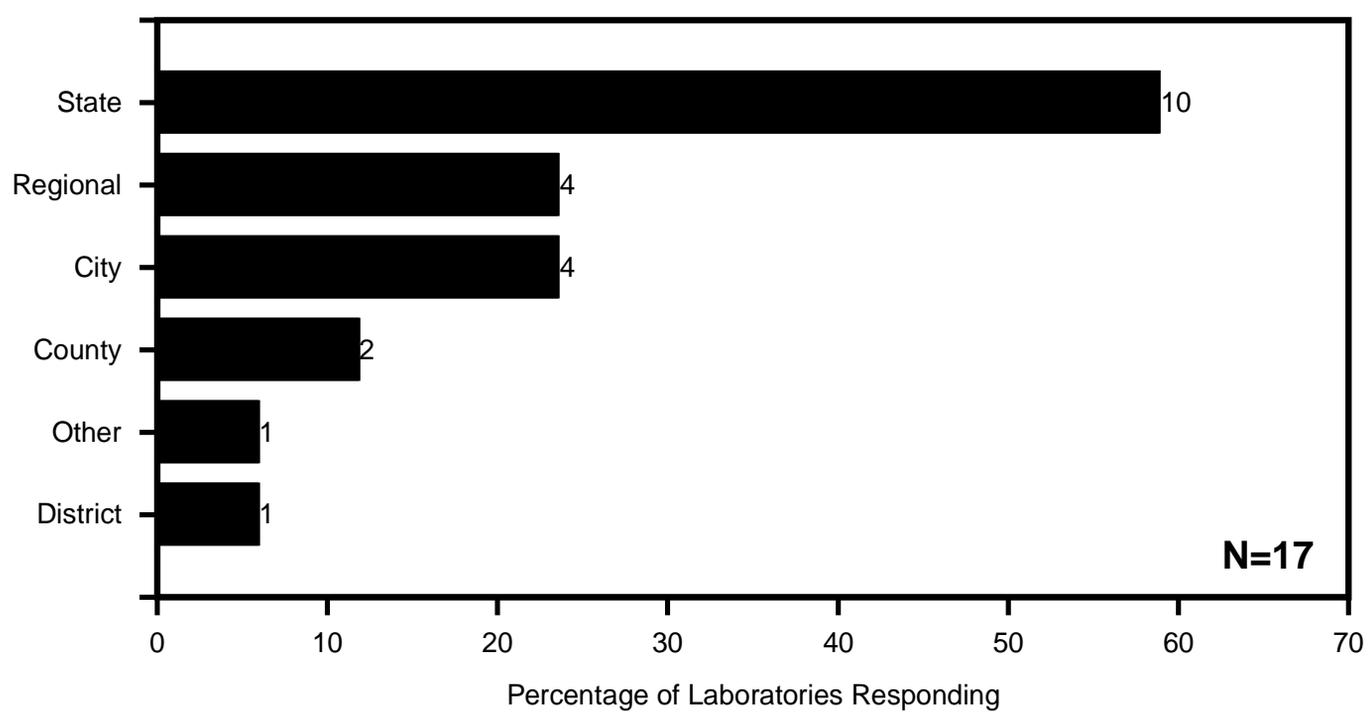
5.(b) If you selected BLOOD BANK in 5.(a), please further describe your TLI testing laboratory (Check all that apply within your Blood Bank laboratory classification):



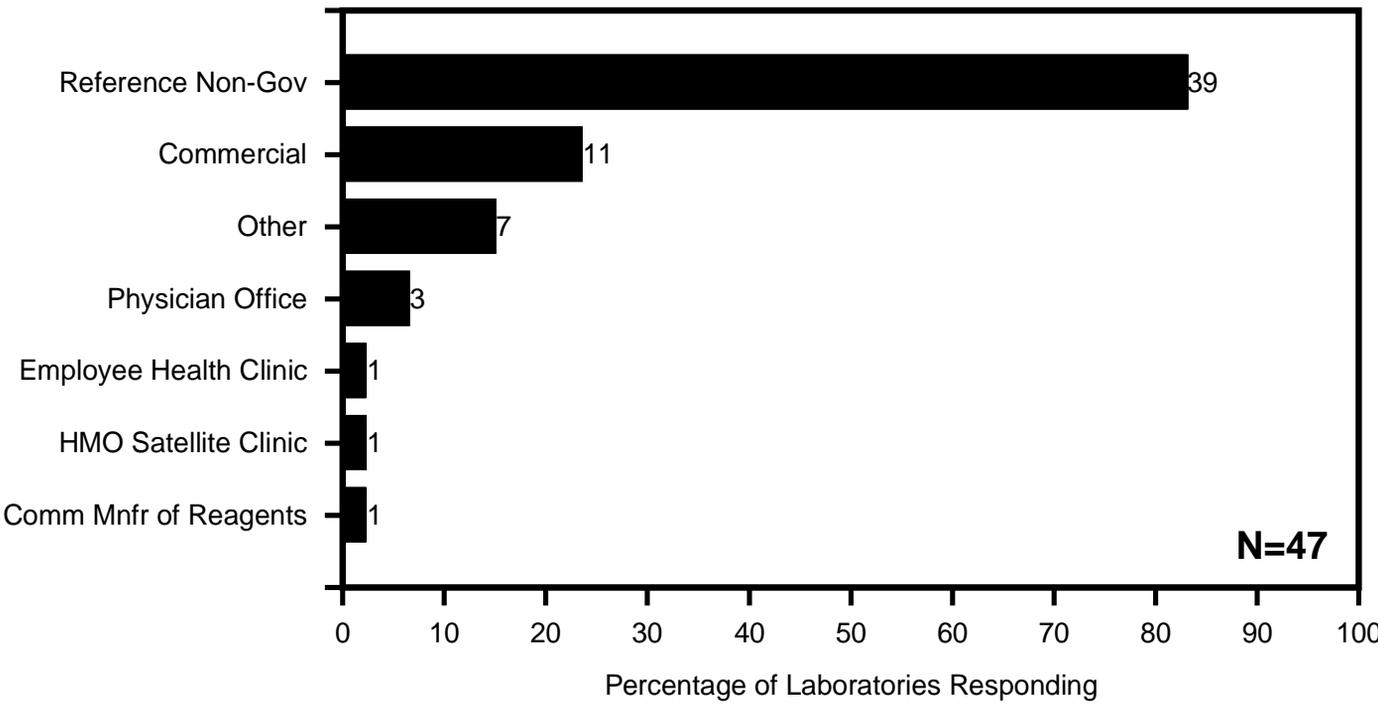
5.(c) If you selected HOSPITAL in 5.(a), please further describe your TLI testing laboratory (Check all that apply within your Hospital laboratory classification):



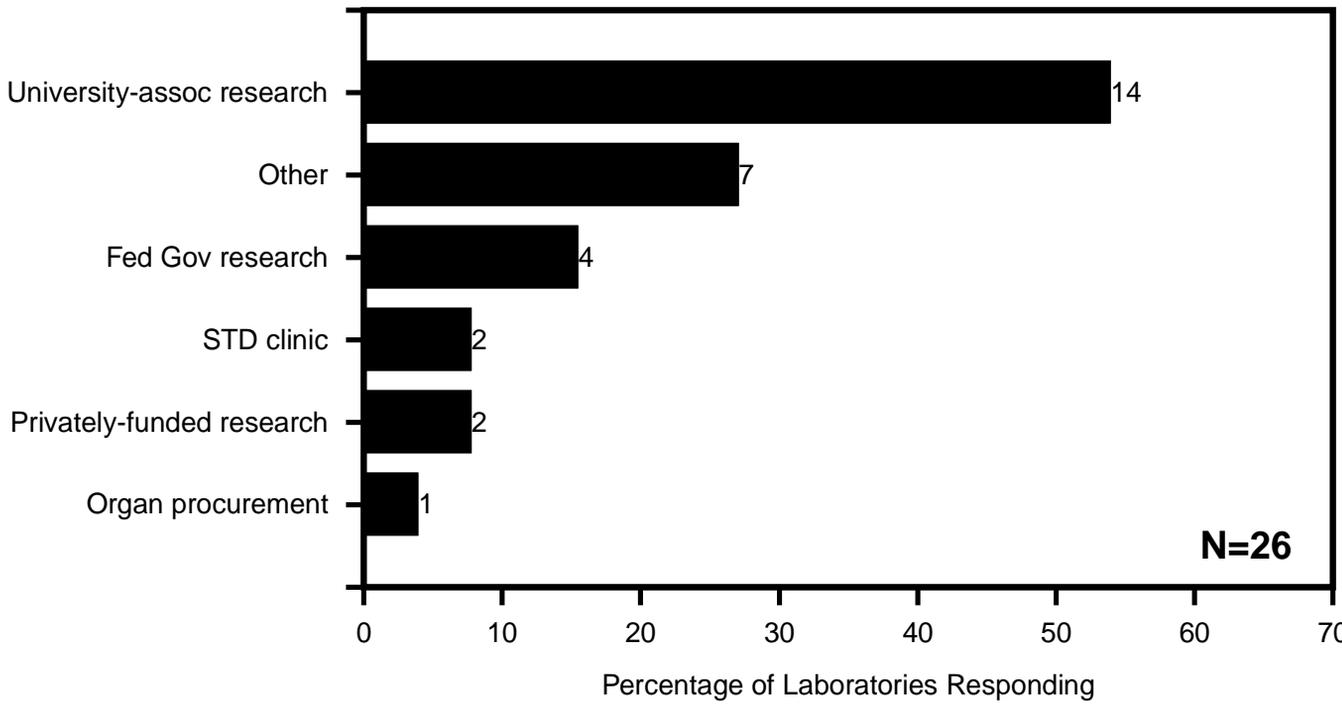
5.(d) If you selected HEALTH DEPARTMENT in 5.(a), please further describe your TLI testing laboratory (Check all that apply within your Health Department laboratory classification):



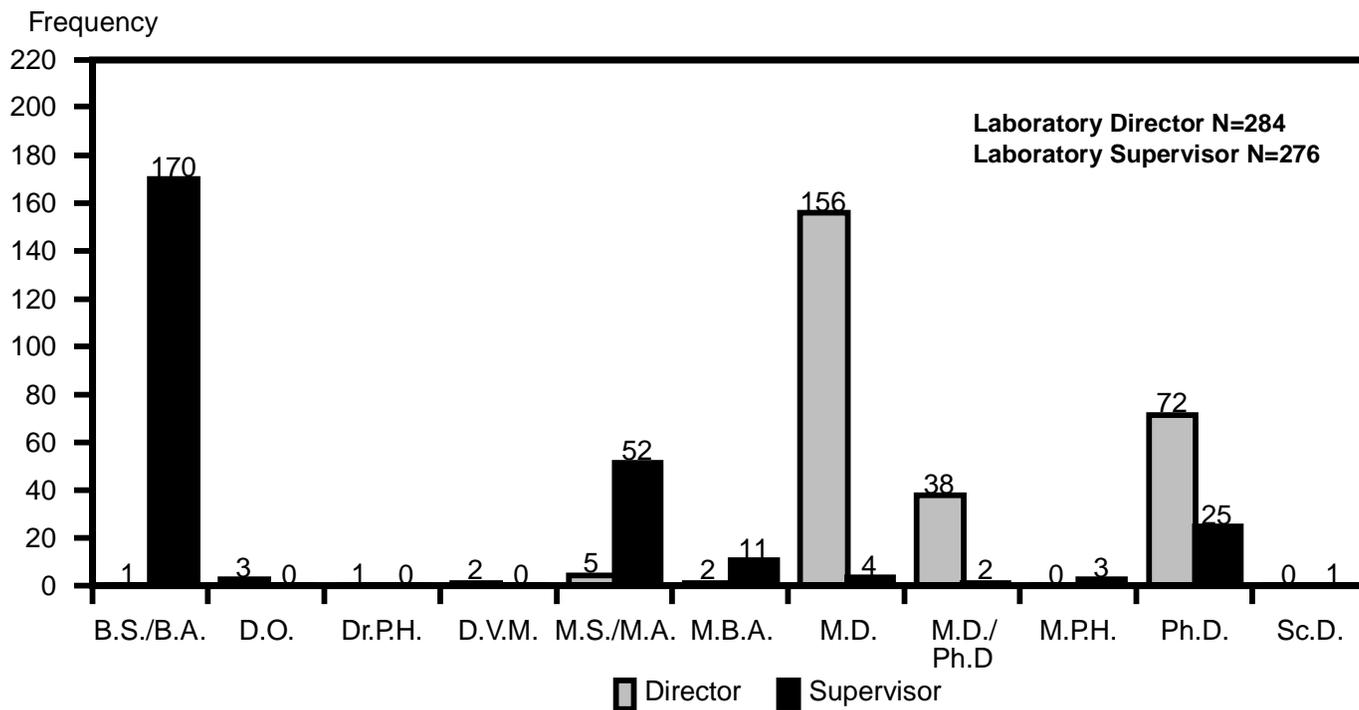
5.(e) If you selected INDEPENDENT in 5.(a), please further describe your TLI testing laboratory (Check all that apply within your Independent laboratory classification):



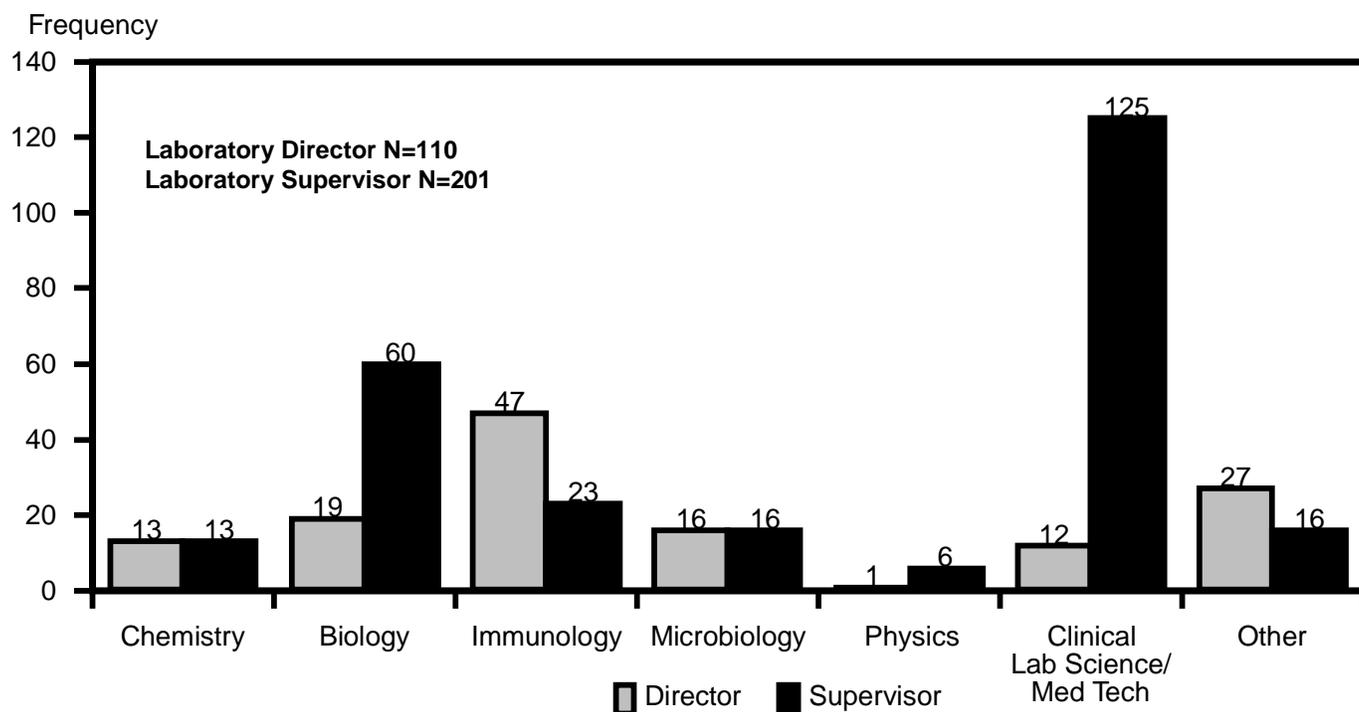
5.(f) If you selected OTHER in 5.(a), please further describe your TLI testing laboratory (Check all that apply within your Other laboratory classification):



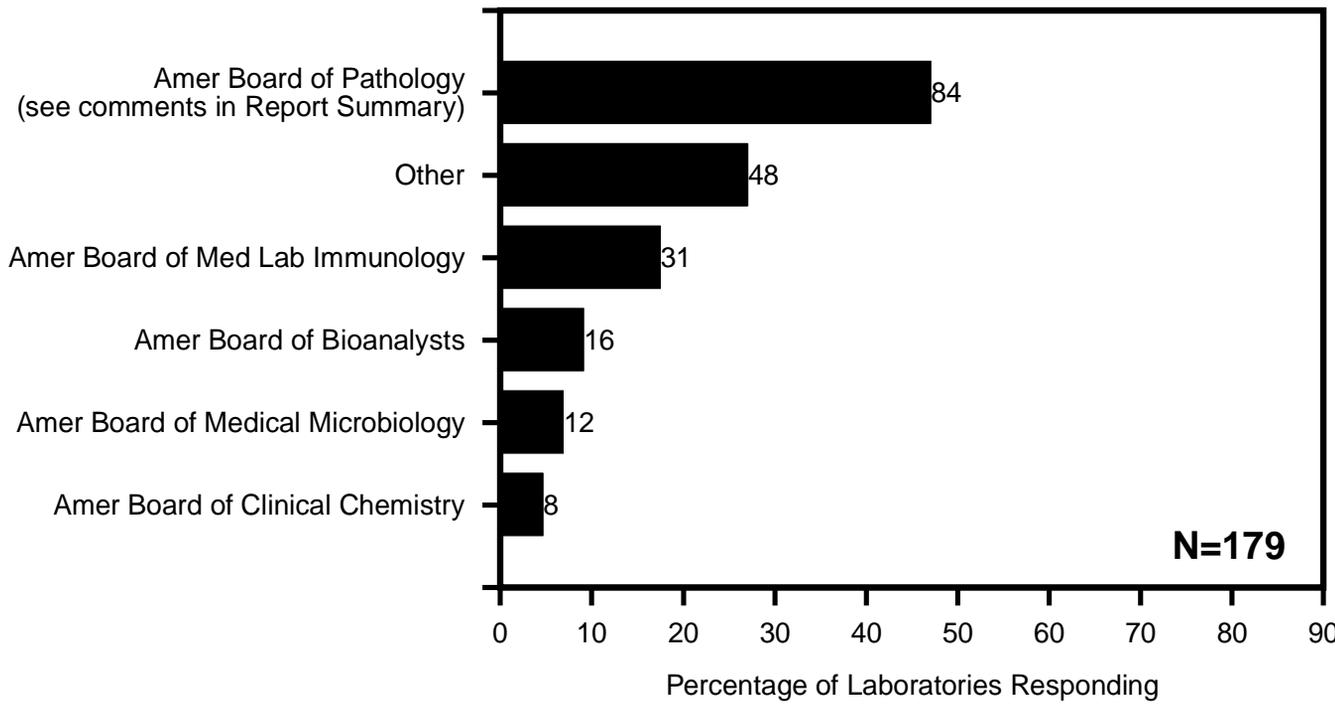
6.(a) Please check the degrees that have been awarded to your Laboratory Director and Laboratory Supervisor:



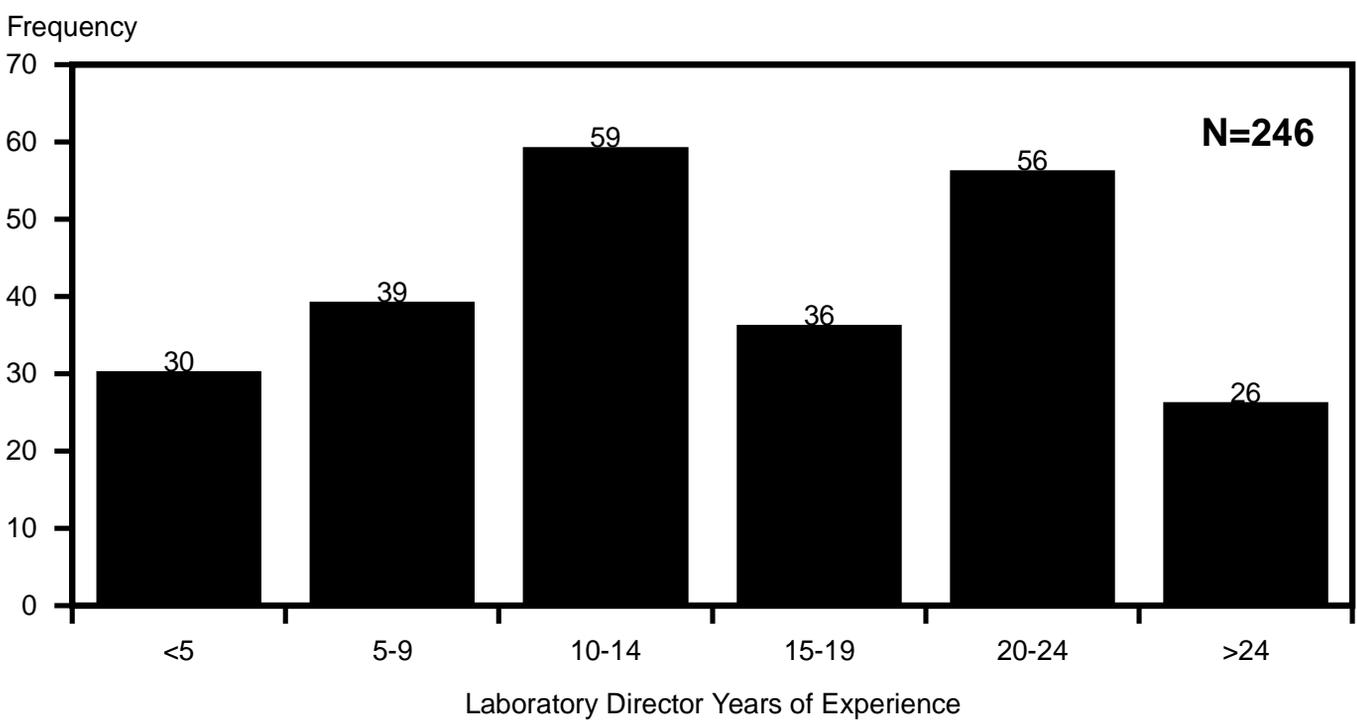
6.(b) If your Laboratory Director or Laboratory Supervisor has a degree other than M.D. or D.O., please indicate the academic discipline in which the degree was awarded:



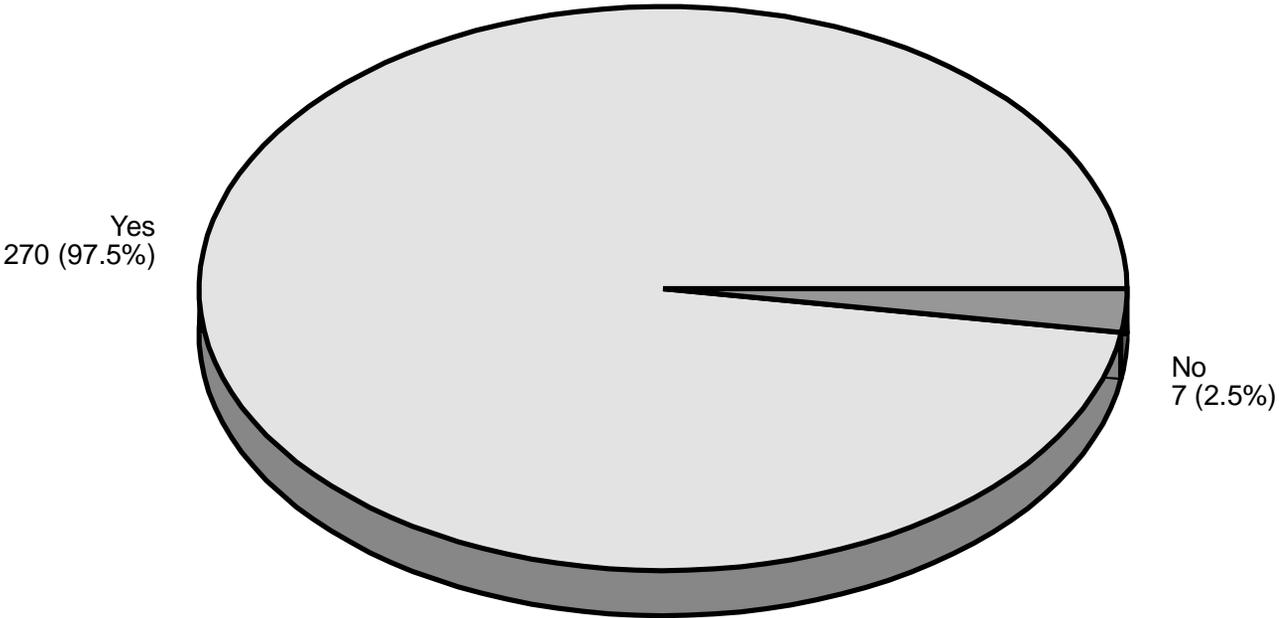
6.(c) What organization(s) have awarded board certification to your Laboratory Director ? (Check all that apply):



6.(d) Please indicate the years of experience your Laboratory Director has in directing or supervising laboratory testing.

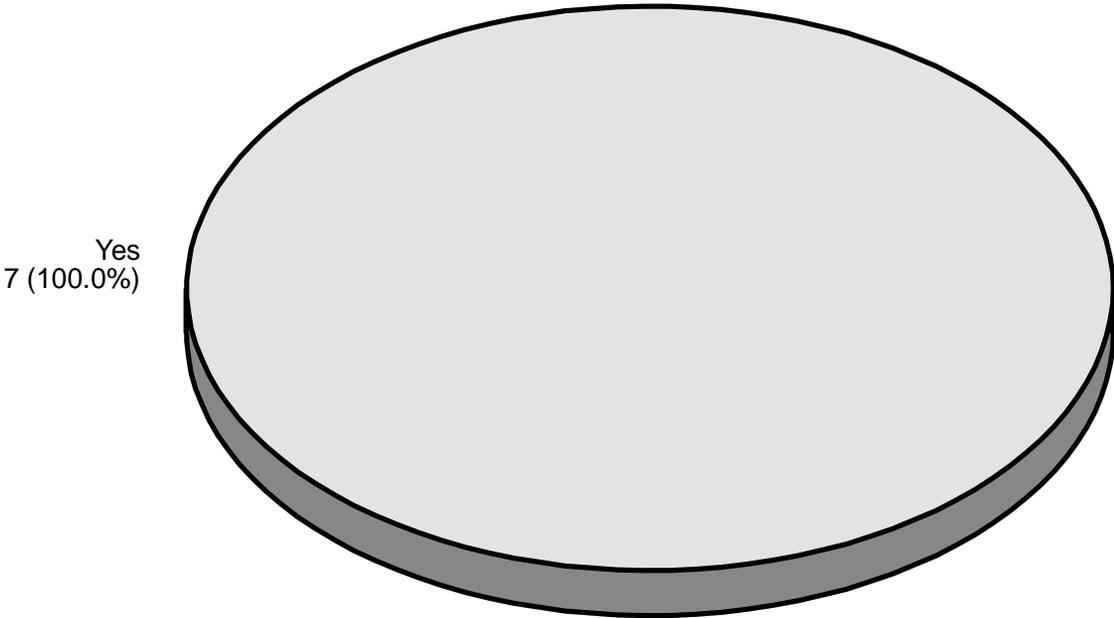


6.(e) Is your Laboratory Supervisor available to provide supervision on-site?



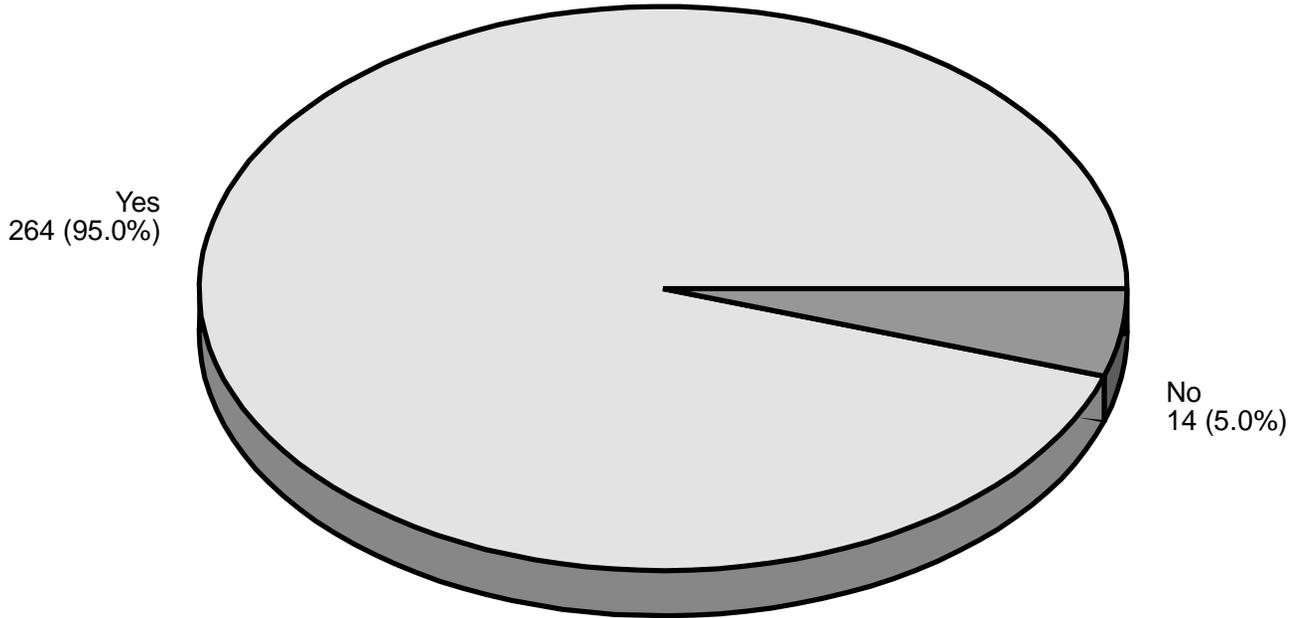
N=277

If no, is there another person on-site that has been assigned to provide supervision?



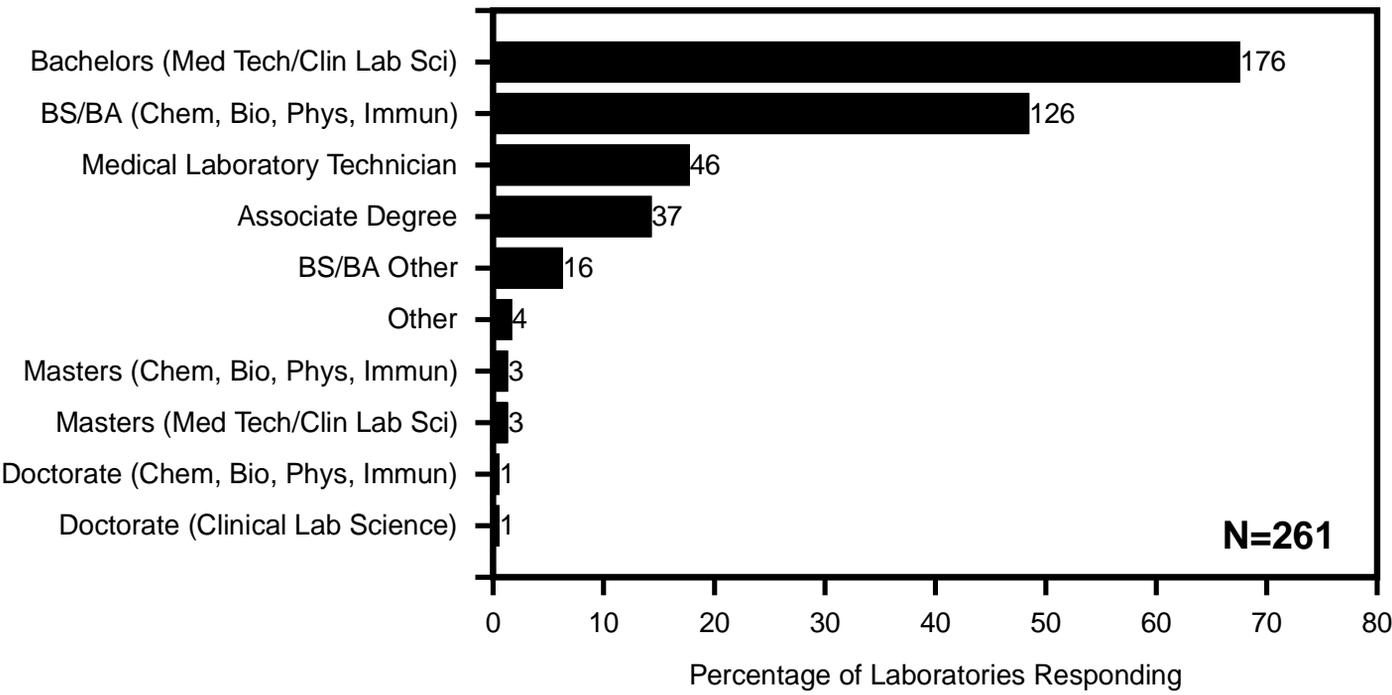
N=7

7.(a) Does your laboratory require that personnel who perform TLI (operate a flow cytometer and analyze resultant data) have a minimum degree?



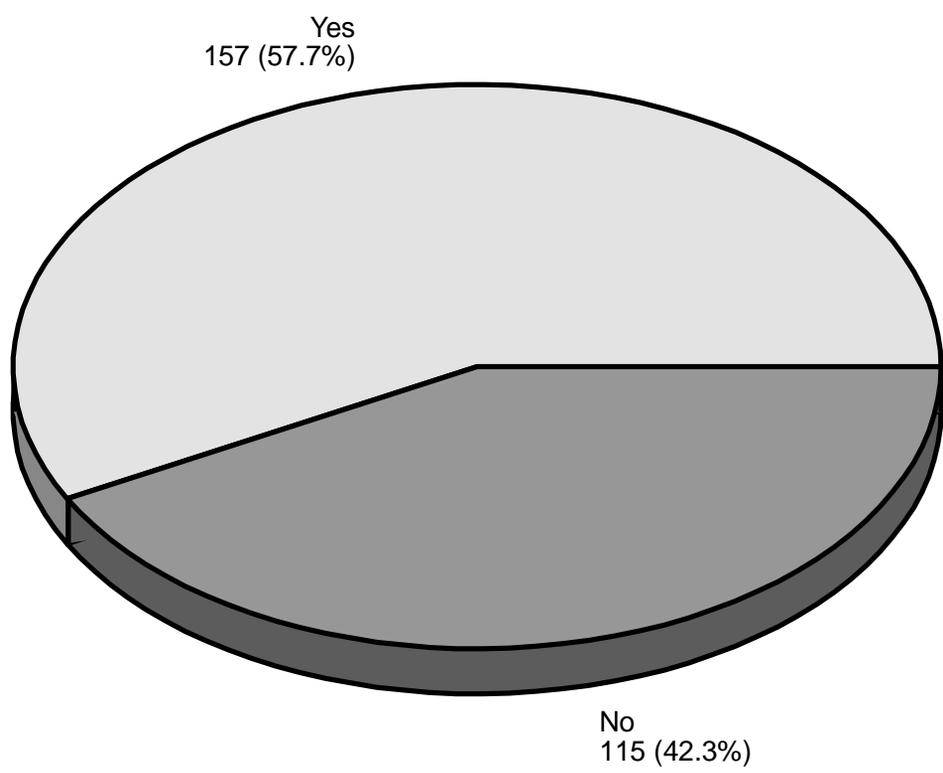
N=278

7.(b) What are the qualifications required of your TLI testing personnel? (Check all that apply.)



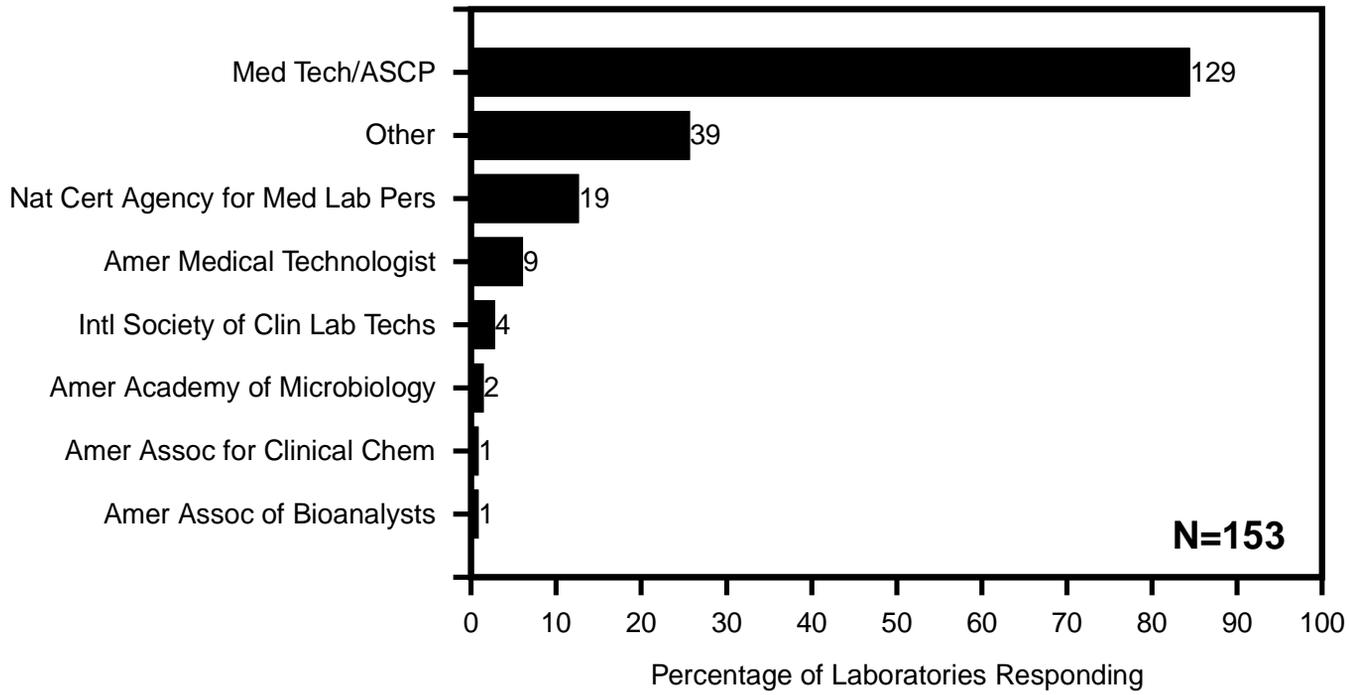
N=261

7.(c) Does your laboratory require that your TLI testing personnel have professional certification?



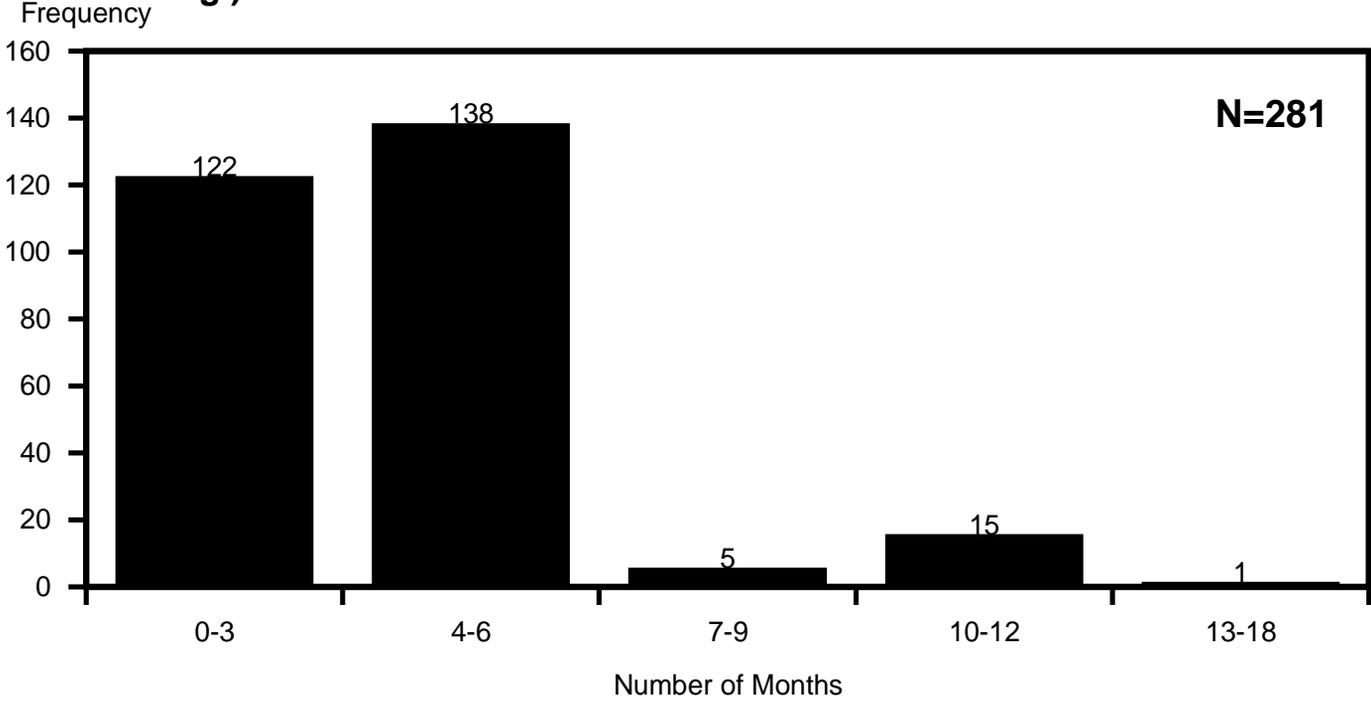
N=272

7.(d) Please check the professional organizations that have awarded the required certification to your TLI testing personnel. (Check all that apply.):

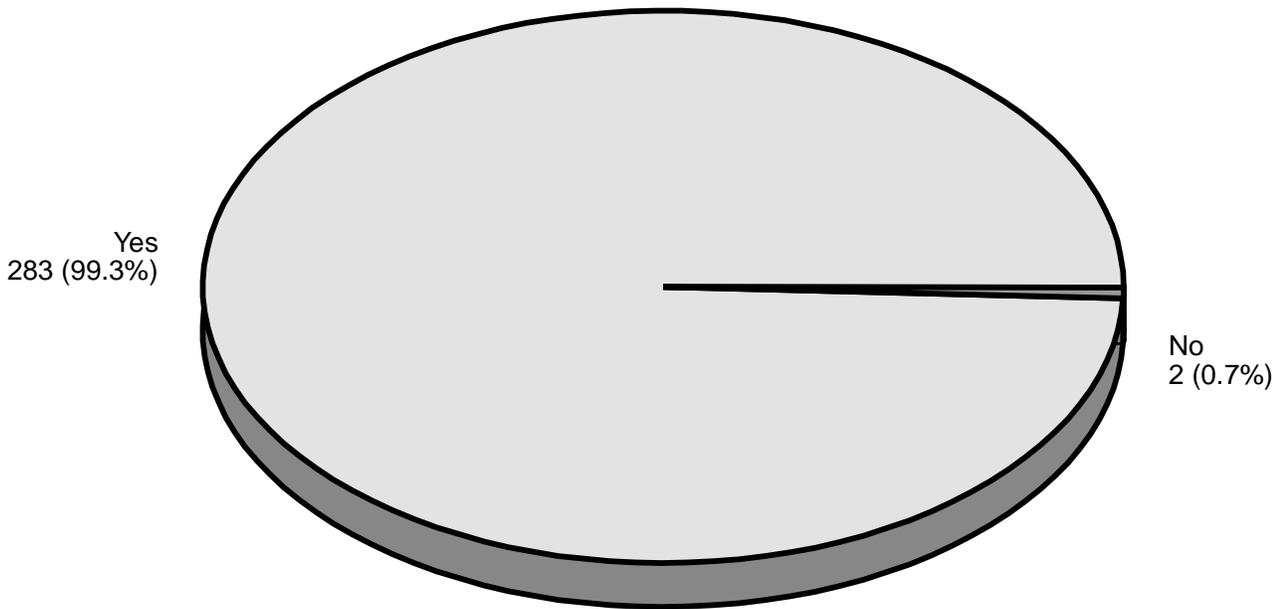


N=153

8. On average, how many months' experience do your laboratory's flow cytometer operators need to become proficient in operating a flow cytometer and analyzing the resultant data? (Indicate only experience needed to perform TLI, not other flow-cytometric functions, e.g., cell sorting.)

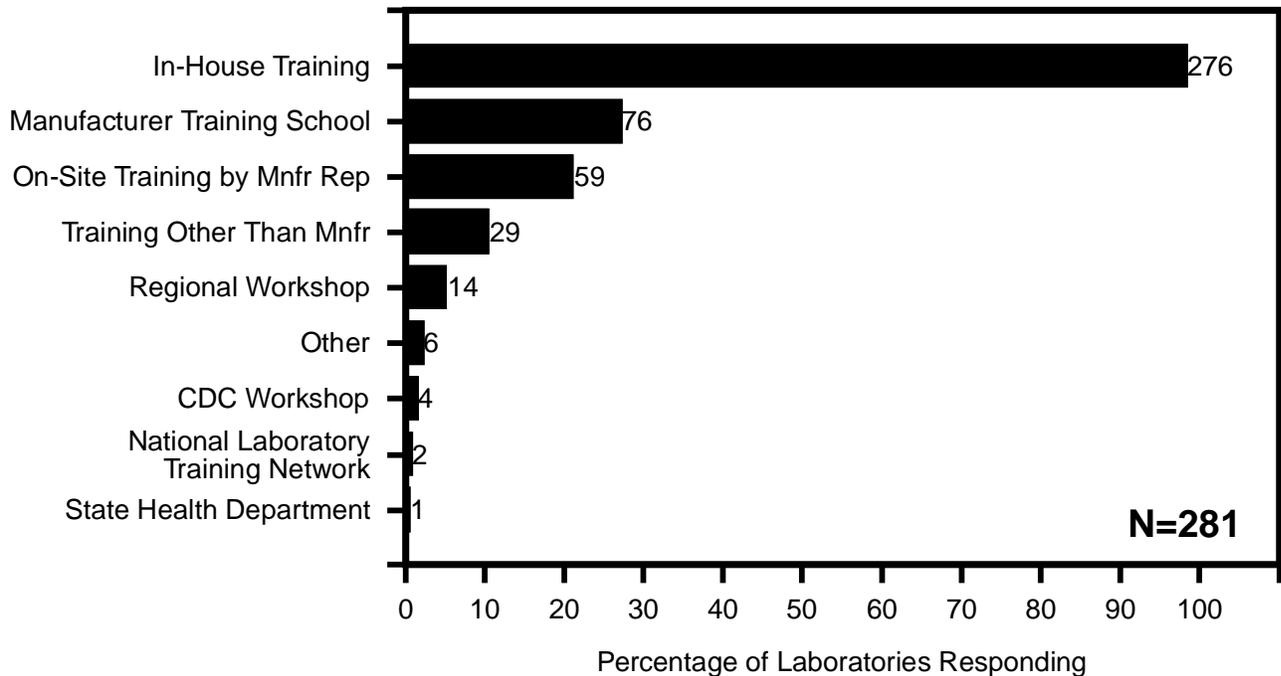


9.(a) Does your laboratory require that personnel who perform TLI (operate a flow cytometer and analyze resultant data) have training? (Choose only one.)



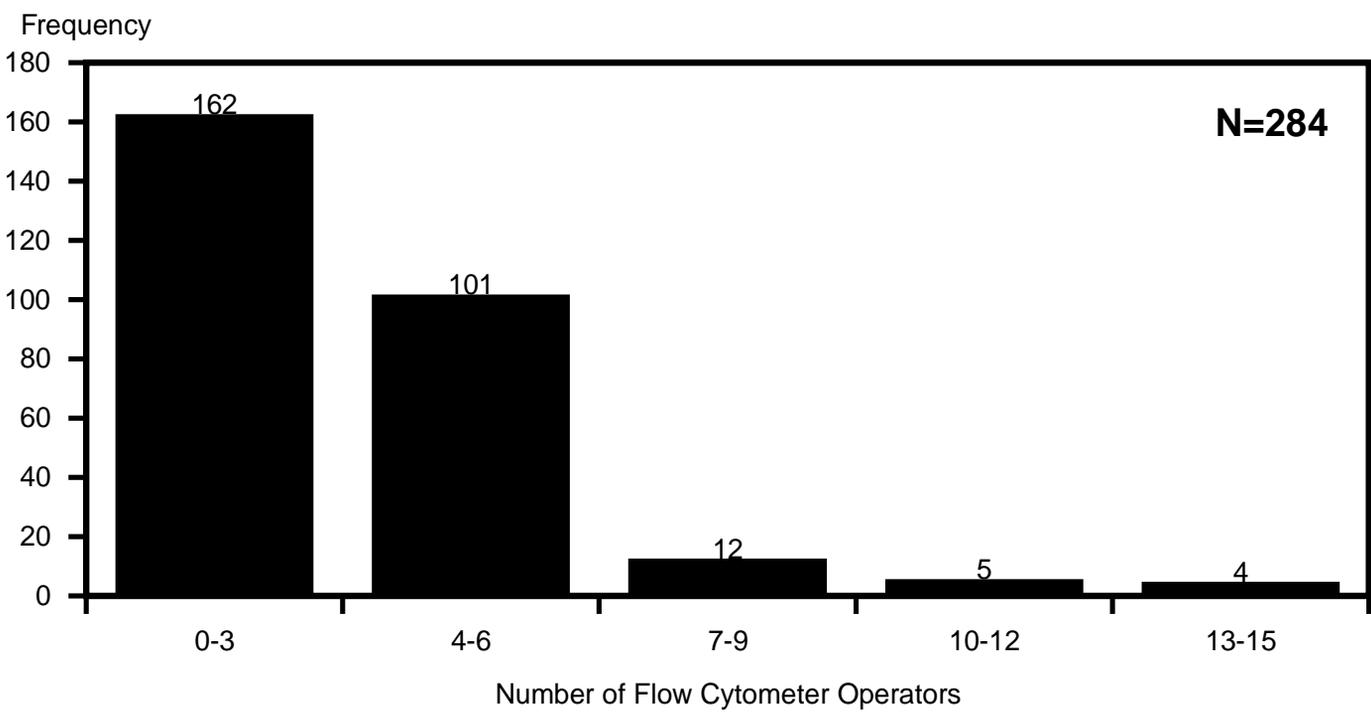
N=285

9.(b) What training must your laboratory personnel complete before they are considered qualified to perform TLI? (Check all that apply.)

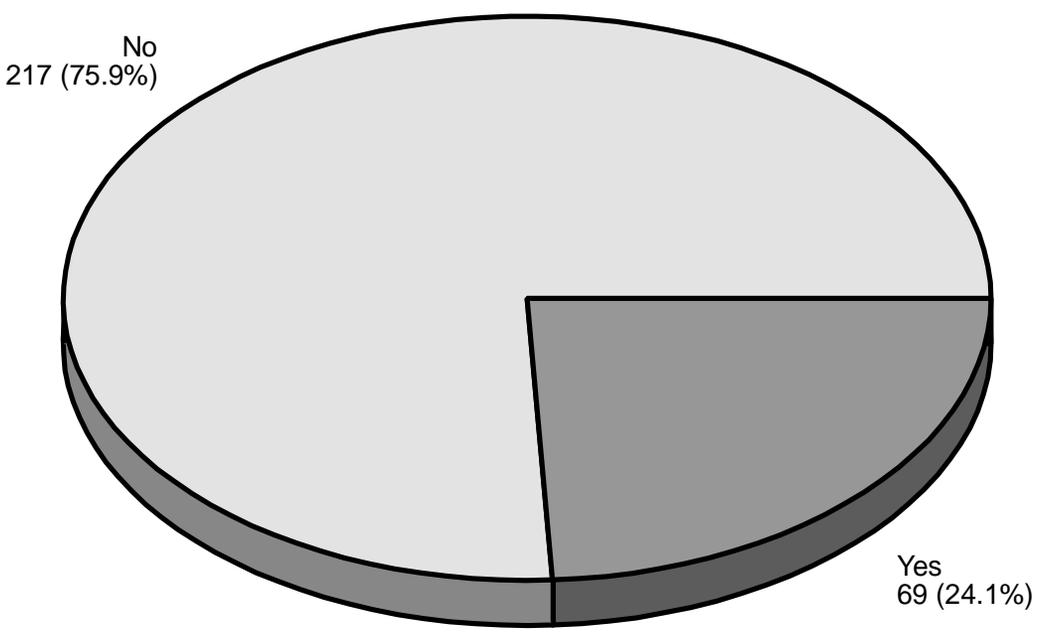


N=281

10.(a) How many different flow cytometer operators actually performed TLI in your laboratory over the last year?

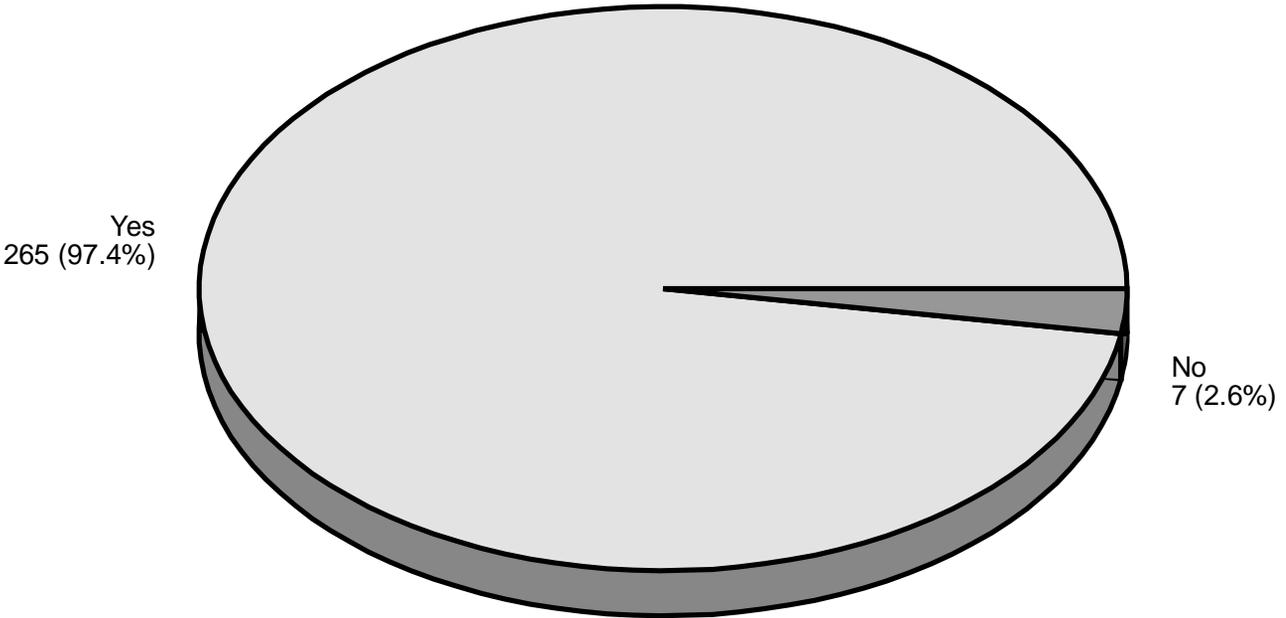


10.(b) Do any of your laboratory's flow cytometer operators routinely perform TLI on more than one flow cytometer?



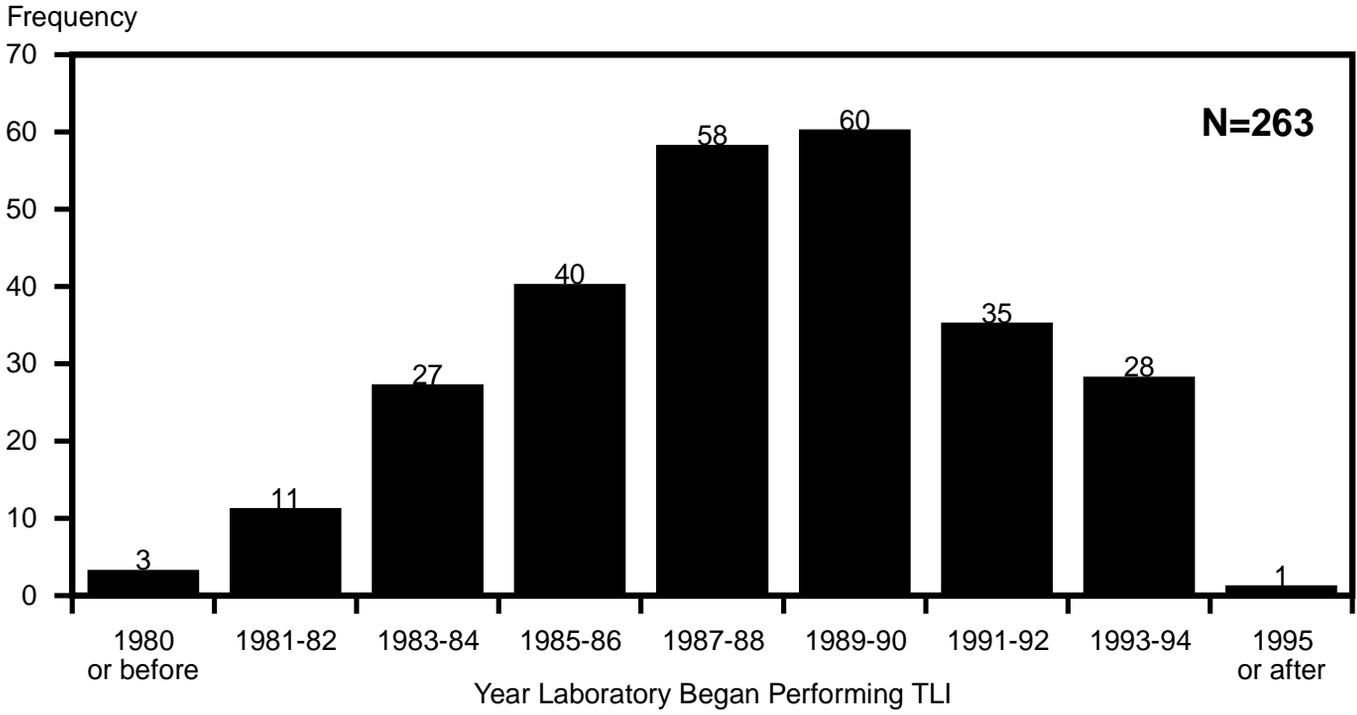
N=286

10.(c) Have your flow cytometer operators received training on all instruments operated?

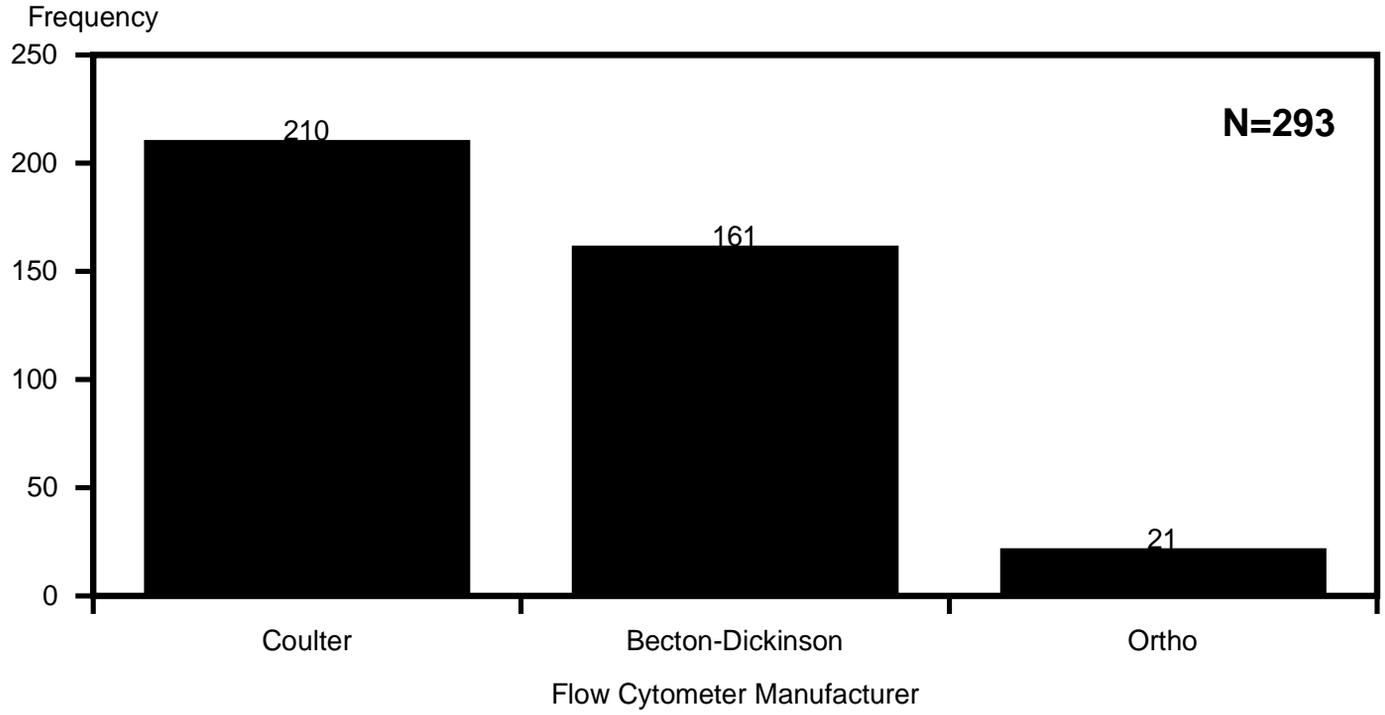


N=272

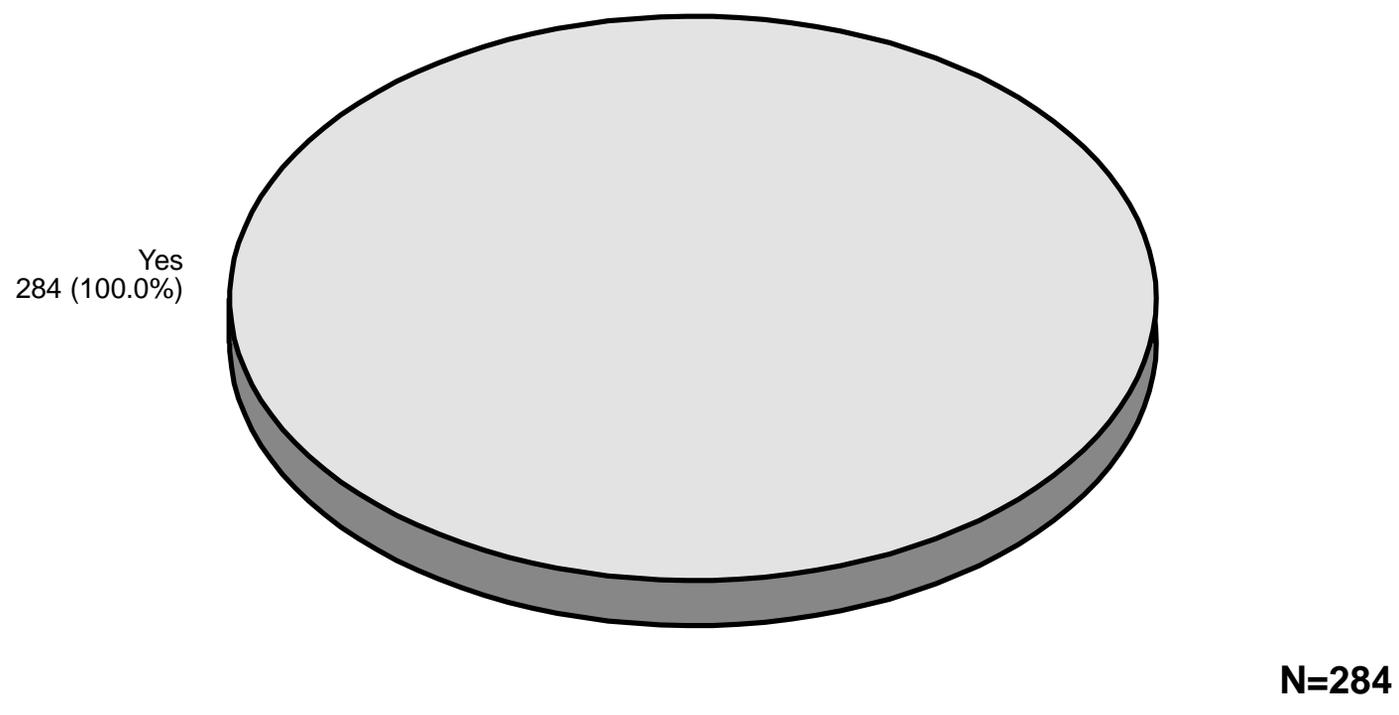
11. When did your laboratory begin performing TLI?



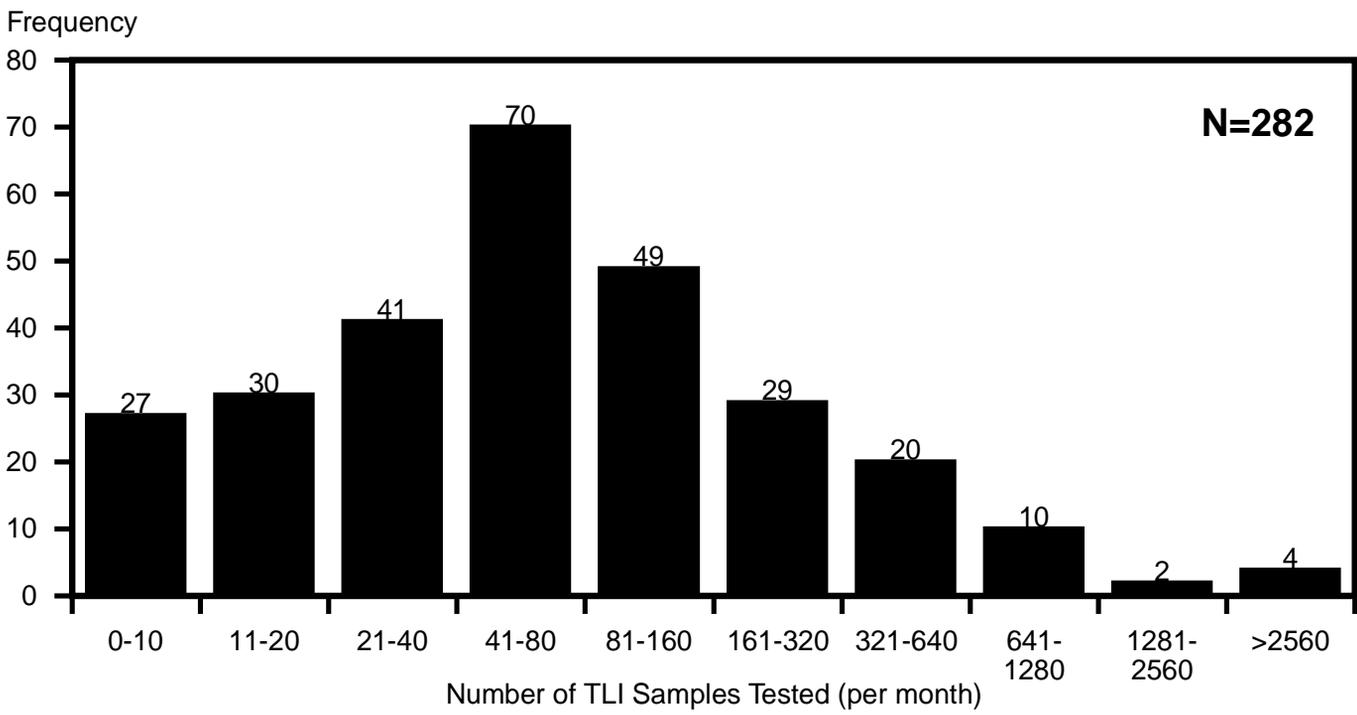
12. What are the quantities, manufacturers, models and ages (in years) of your laboratory's flow cytometers that are used for TLI?



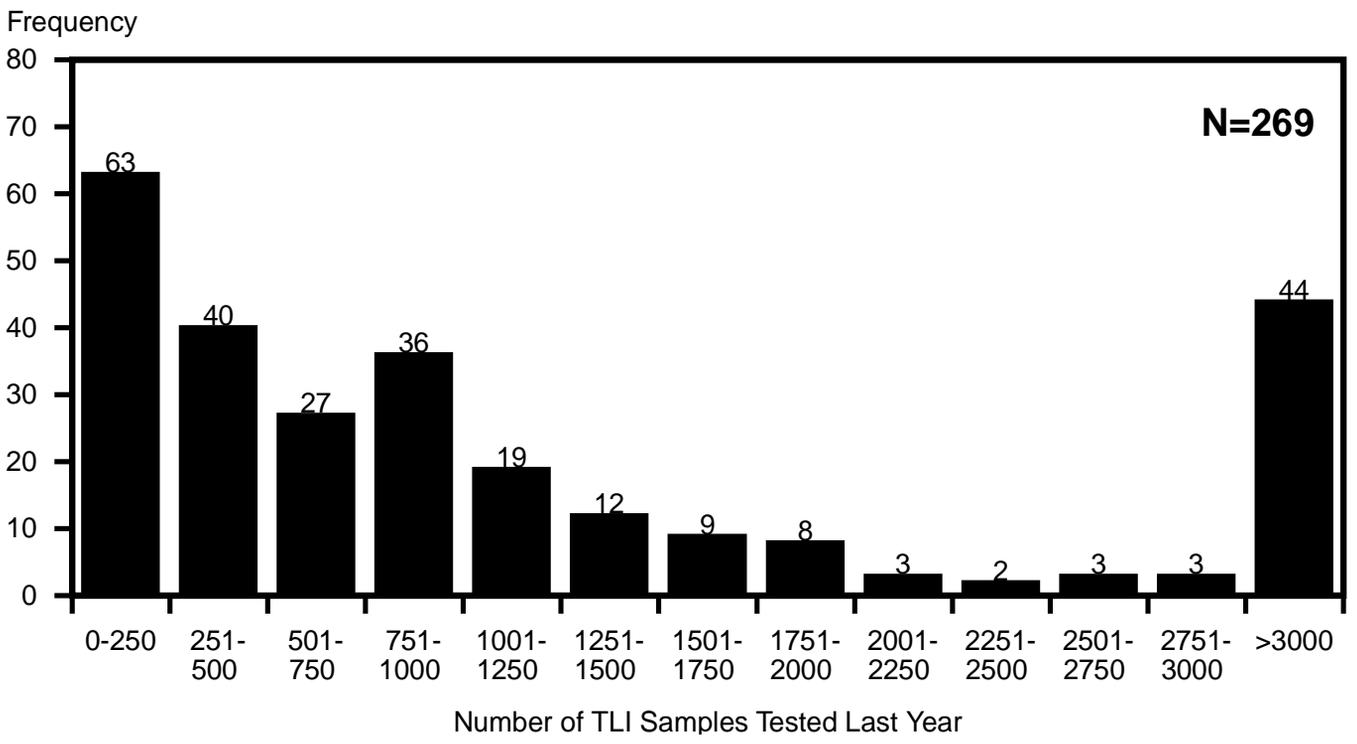
13. Can multicolor analysis techniques (two or more markers tagged with different color fluorochromes as a single test) be used to perform TLI on any of the instruments you indicated?



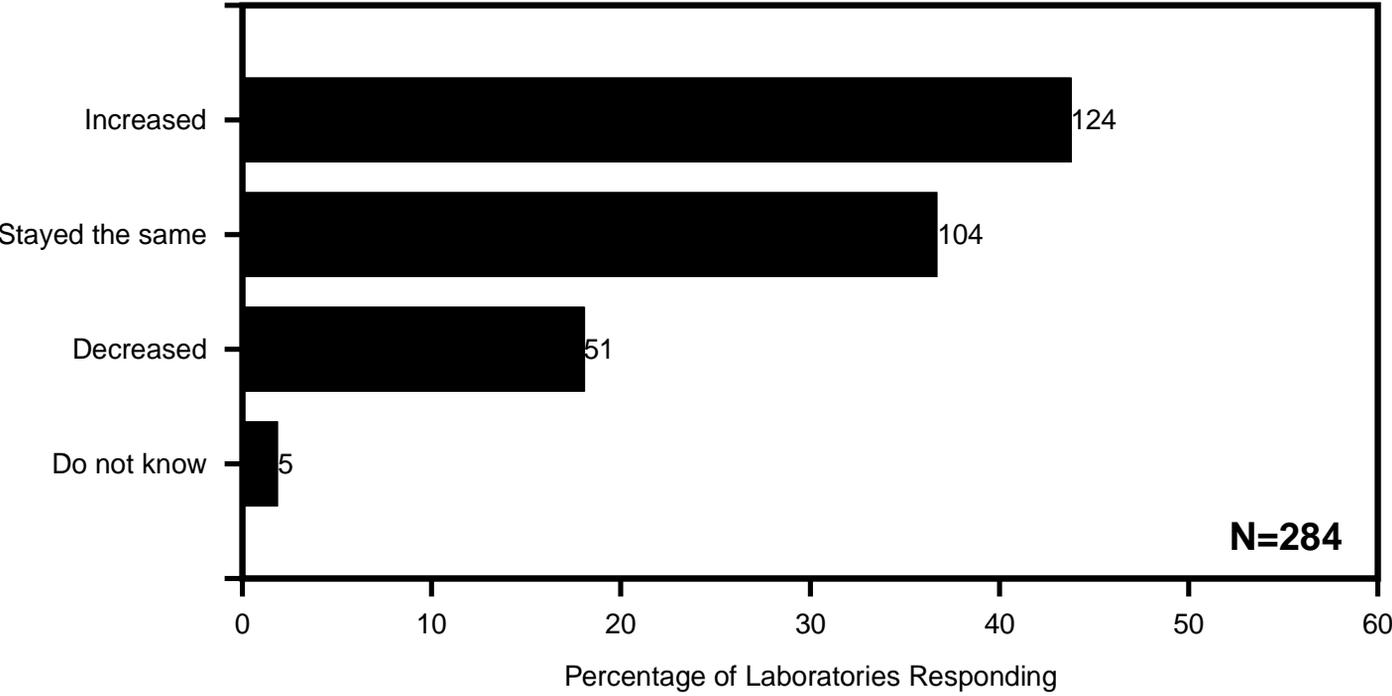
14.(a) On average, how many TLI samples are tested in your laboratory in a month? (Number of single patient and/or blood donor samples, not tests.)



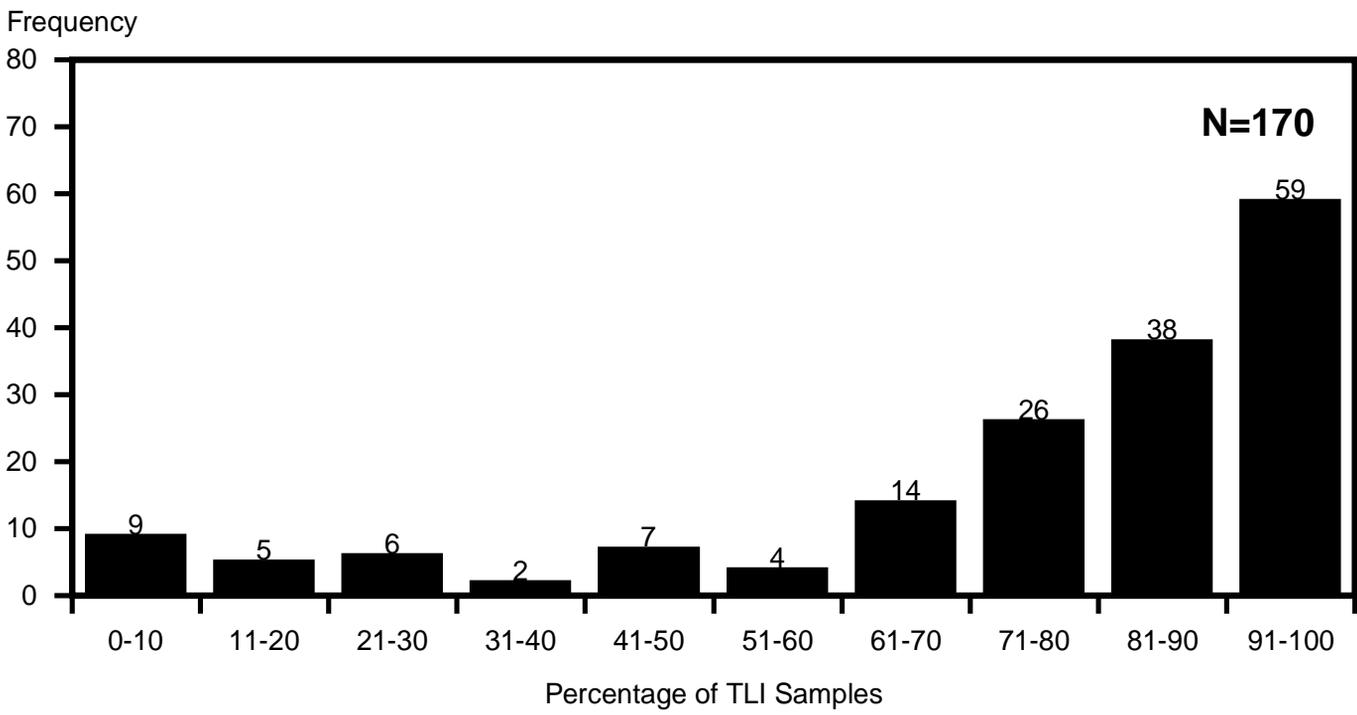
14.(b) How many TLI samples were tested in your laboratory in the last year? (Number of single patient and/or blood donor samples, not tests.)



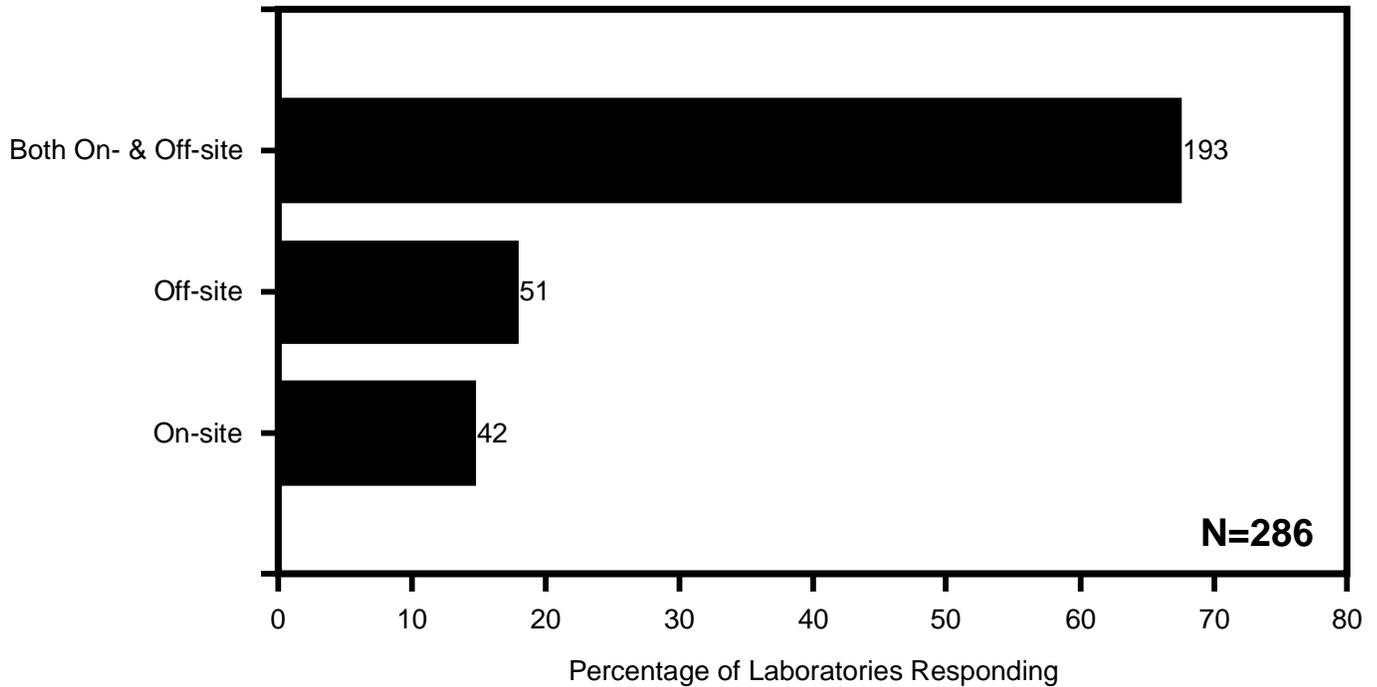
14.(c) Has the number of requests per month for TLI to be performed by your laboratory increased, decreased, or stayed the same compared to twelve months ago? (Choose only one.)



15. In the last year, what percentage of your TLI patient samples have come from patients known by your laboratory to be HIV-infected?



16.(a) Where are your specimens collected for TLI? (Choose only one.)



16.(b) Are written instructions provided to collection site personnel for collecting, labeling, and transporting TLI specimens?

	Yes	No	N=
Collecting	272	7	279
Labeling	268	12	280
Transporting	269	7	276

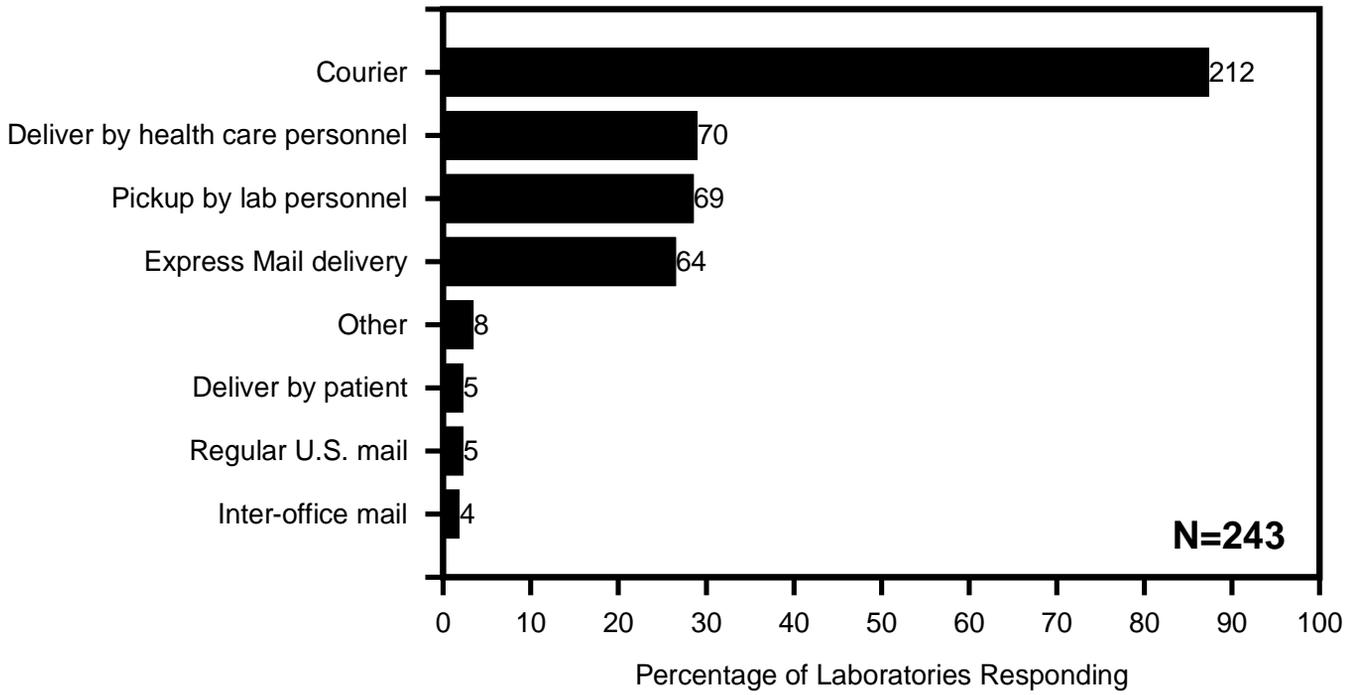
**If yes, who provides the written instructions for each activity?
(Check all that apply.)**

Instructions	Testing Laboratory	Associated Institution	Person Ordering the Test	Other	N=
Collecting	243	47	8	6	272
Labeling	233	54	10	6	268
Transporting	241	46	8	6	269

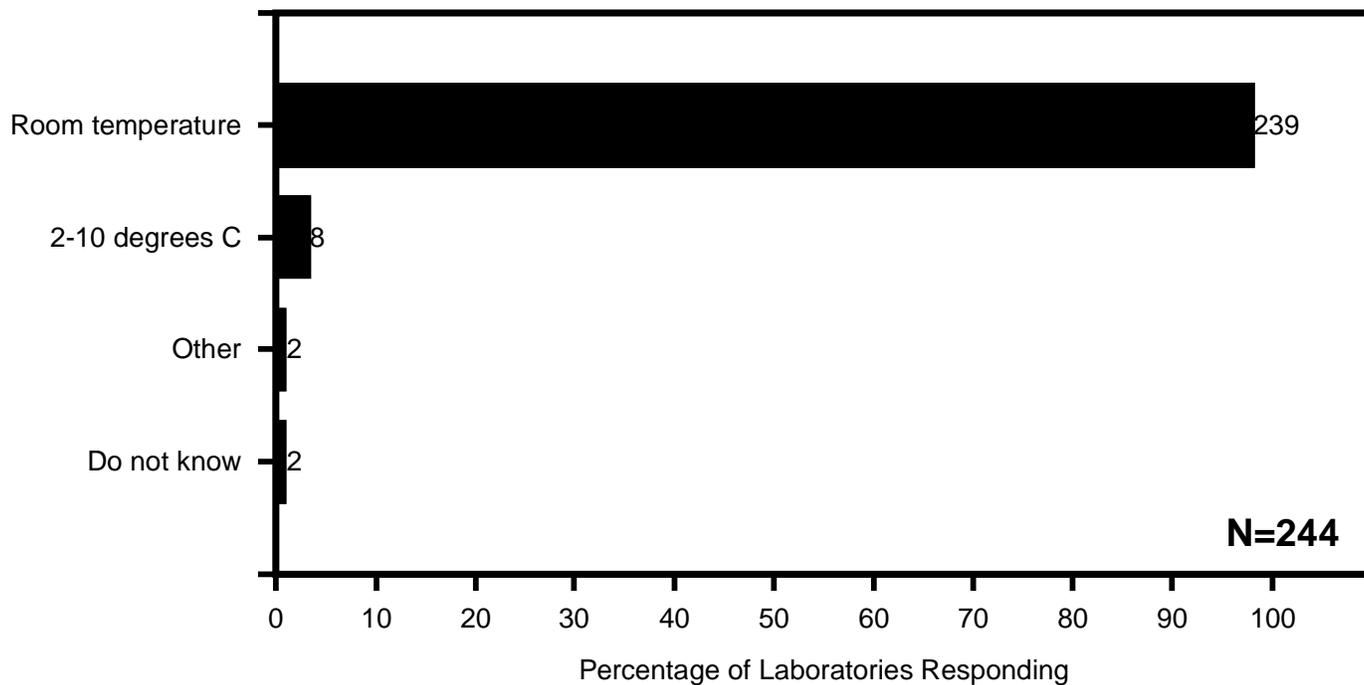
16.(c) When your laboratory tests TLI specimens that are collected off-site, where are the specimens collected? (Check all that apply.)

N=243 Location	Number of Laboratories	Percentage of Laboratories	Location	Number of Laboratories	Percentage of Laboratories
Hospital	176	72.4	Drug Abuse Treatment Facility	22	9.1
Private Physician Office	143	58.8	Other	21	8.6
Outpatient Health Clinic	131	53.9	City Health Department	17	7.0
HIV-1 Counseling and Testing Site	71	29.2	NIAID	15	6.2
HMO Facility	56	23.0	State Health Department	14	5.8
Correctional Facility	47	19.3	Military Installation	14	5.8
STD Clinic	40	16.5	Uncertain/do not know	9	3.7
Out of state	40	16.5	Organ Donation Center	5	2.1
Family Planning Clinic	30	12.3	Blood/plasma center	3	1.2
County Health Department	27	11.1			

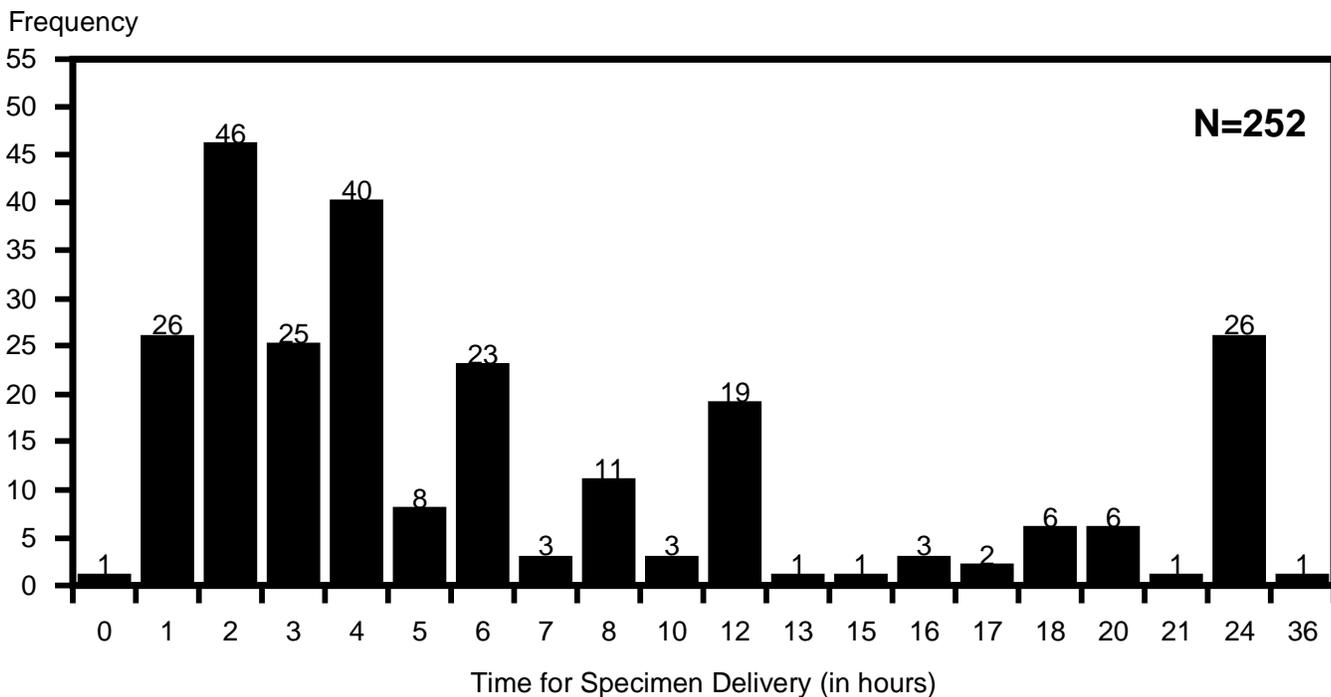
16.(d) How are the off-site TLI specimens delivered to your laboratory? (Check all that apply.)



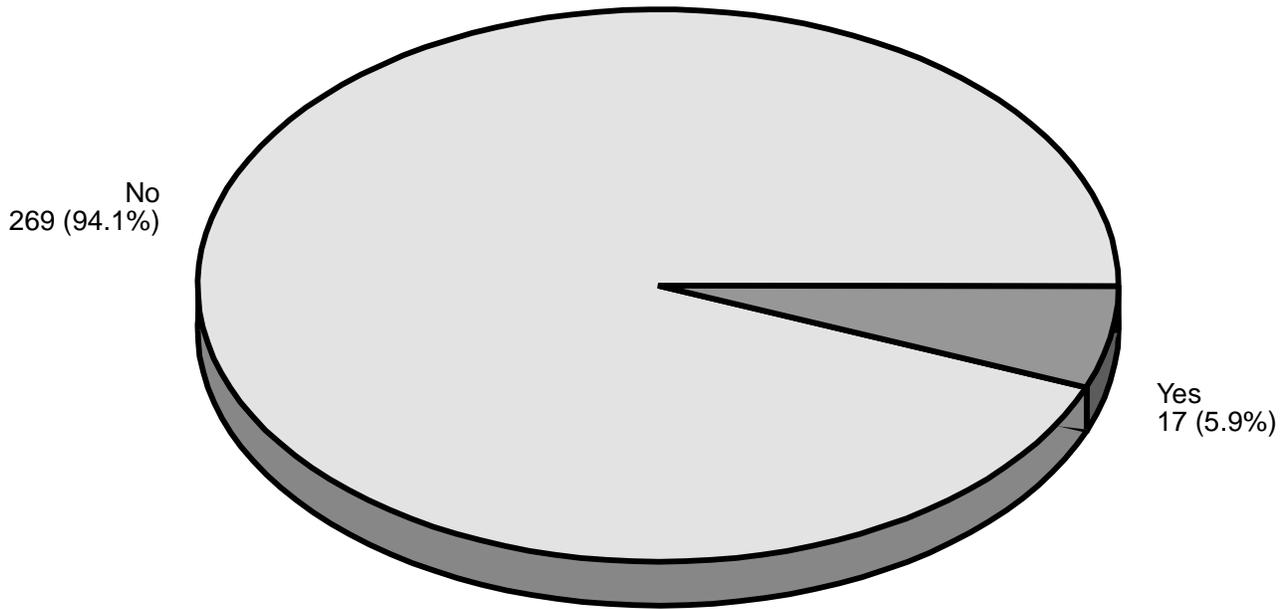
**16.(e) At what temperature are TLI specimens transported to your laboratory?
(Check all that apply.)**



17. On average, how many hours does it take from the time a TLI specimen is collected until the time it is delivered to your laboratory?

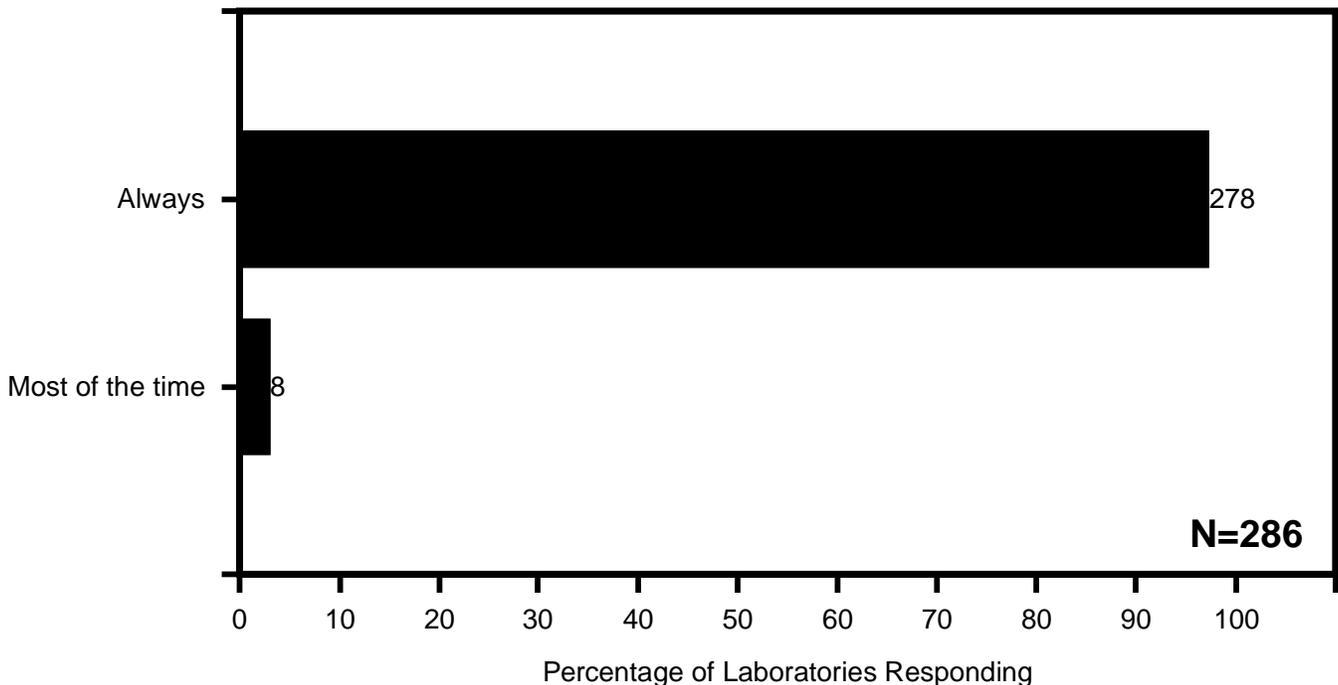


18.(a) Are the procedures your laboratory uses for labeling a suspected HIV-1-positive specimen different from the procedures you use for other specimens?



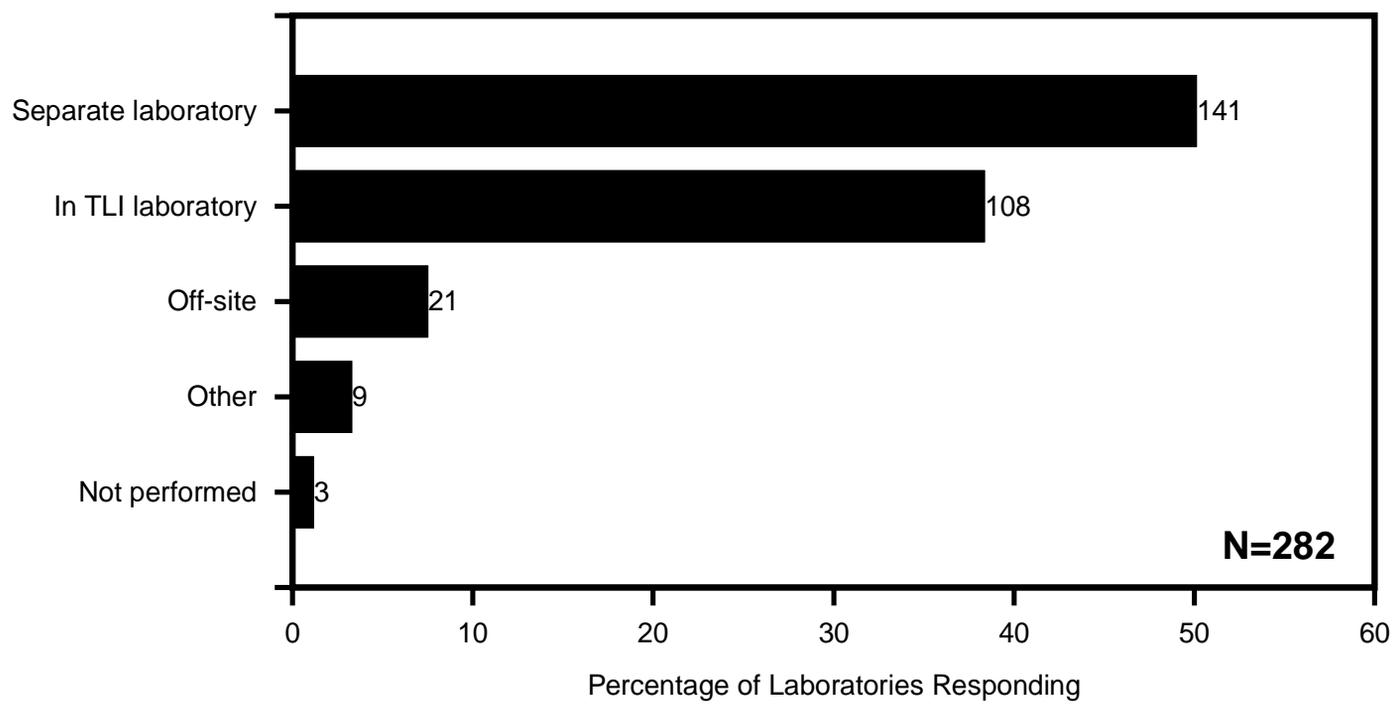
N=286

18.(b) Universal precautions assume that all blood and body fluids are potentially infectious for bloodborne pathogens. How often do your laboratory employees follow universal precautions when handling specimens for TLI? (Choose only one.)

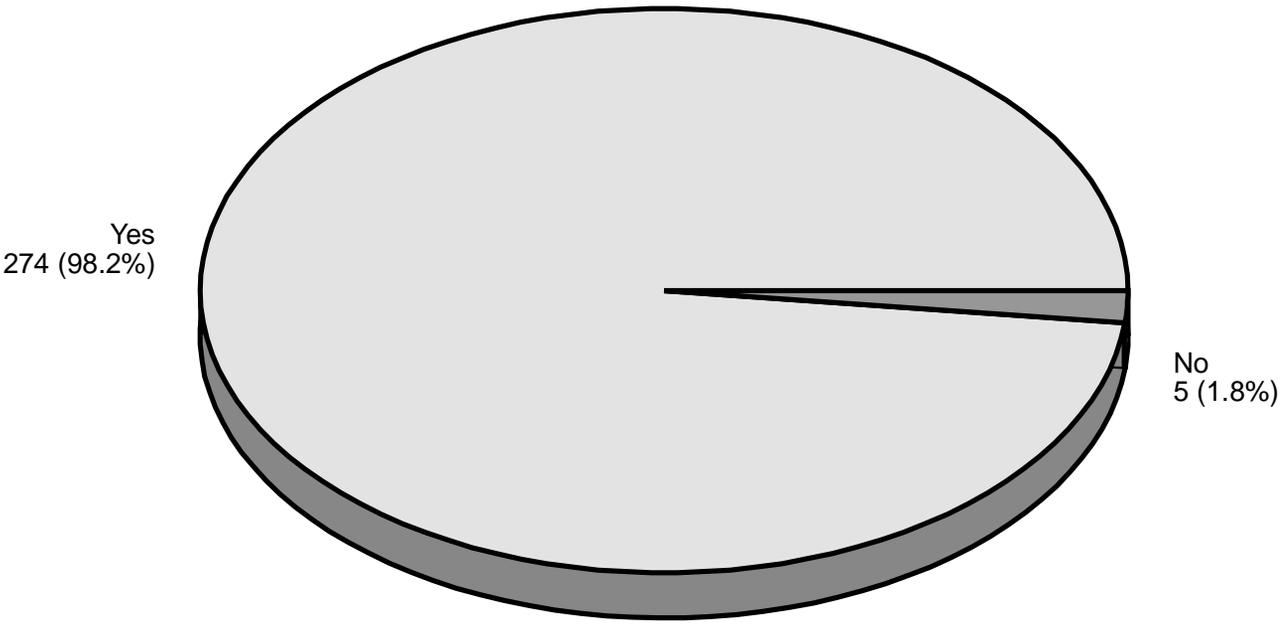


N=286

19. Where is the hematology testing, e.g., complete blood count (CBC), for your laboratory's TLI specimens, usually performed? (Choose only one.)



20.(a) Does your laboratory use TLI specimen collection criteria to determine whether or not a specimen is acceptable for TLI?

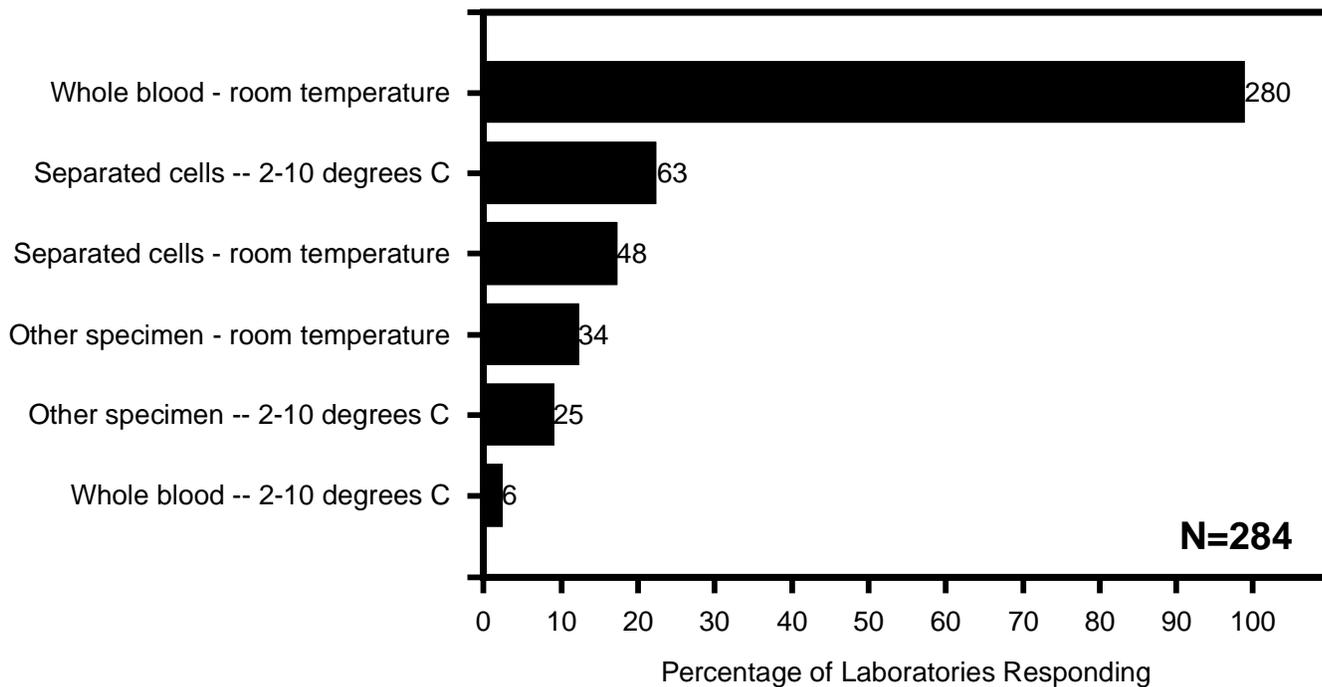


N=279

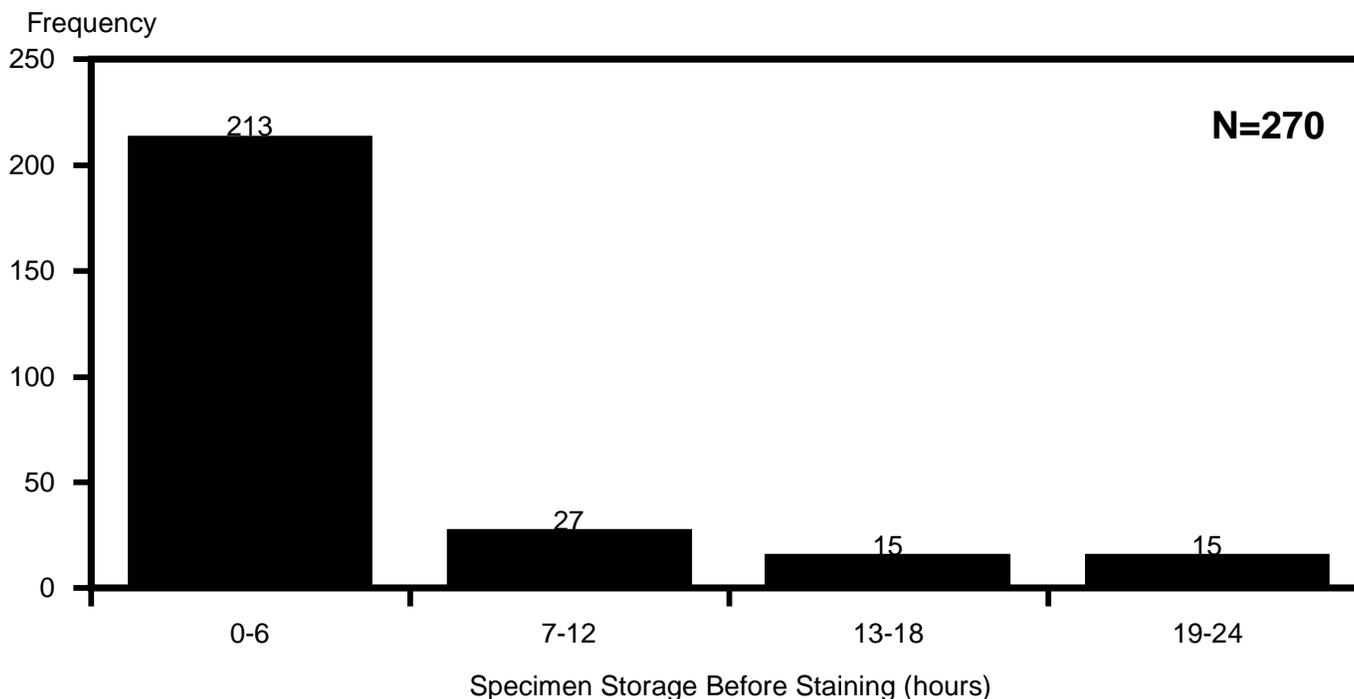
20.(b) What specimen collection criteria are used at your laboratory to determine whether or not a specimen is acceptable for TLI? (Check all that apply.)

N=272 Criteria	Number of Laboratories	Percentage of Laboratories	Location	Number of Laboratories	Percentage of Laboratories
Age of specimen	269	98.9	Improperly completed form	65	23.9
Clotted sample	252	92.6	Precipitated material	59	21.7
Improper labeling	241	88.6	Microbial contamination	56	20.6
Anticoagulant used	236	86.8	Time of day	47	17.3
Store/transport temperature	225	82.7	Lipemic blood	27	9.9
Insufficient quantity	211	77.6	Icteric blood	16	5.9
Storing temperature	196	72.1	Lack of consent	11	4.0
Hemolyzed blood	156	57.4	Patient's medication	7	2.6
Damaged container	140	51.5	Medium not used	5	1.8
Cell viability	104	38.2	Other	3	1.1
Incomplete filling of tube	71	26.1	Label for infectious agents	1	0.4

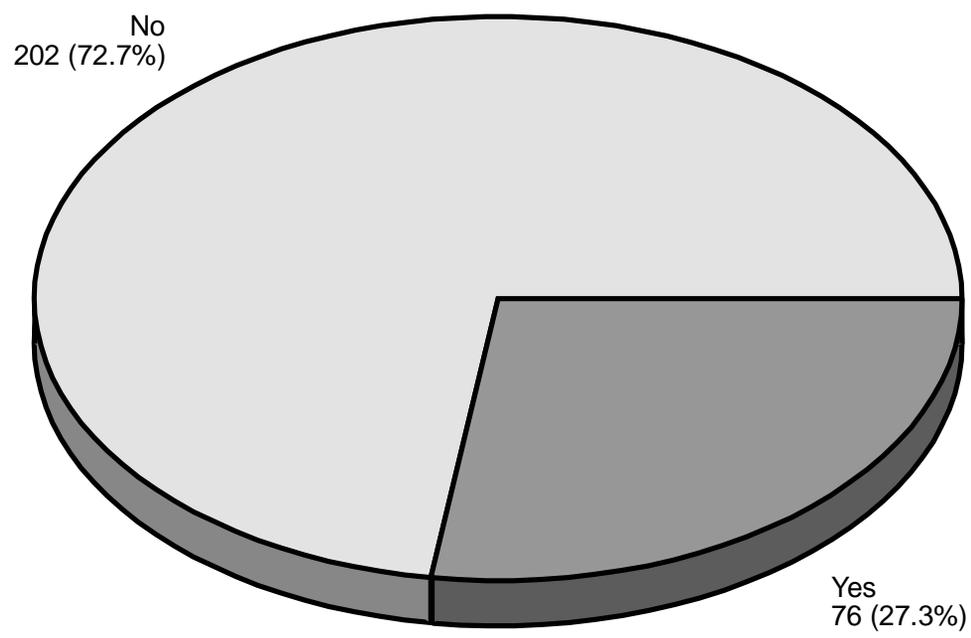
21.(a) At what temperatures does your laboratory store TLI specimens until they are stained? (Check all that apply.)



21.(b) On average, how many hours is a specimen stored at your laboratory before it is stained for TLI?

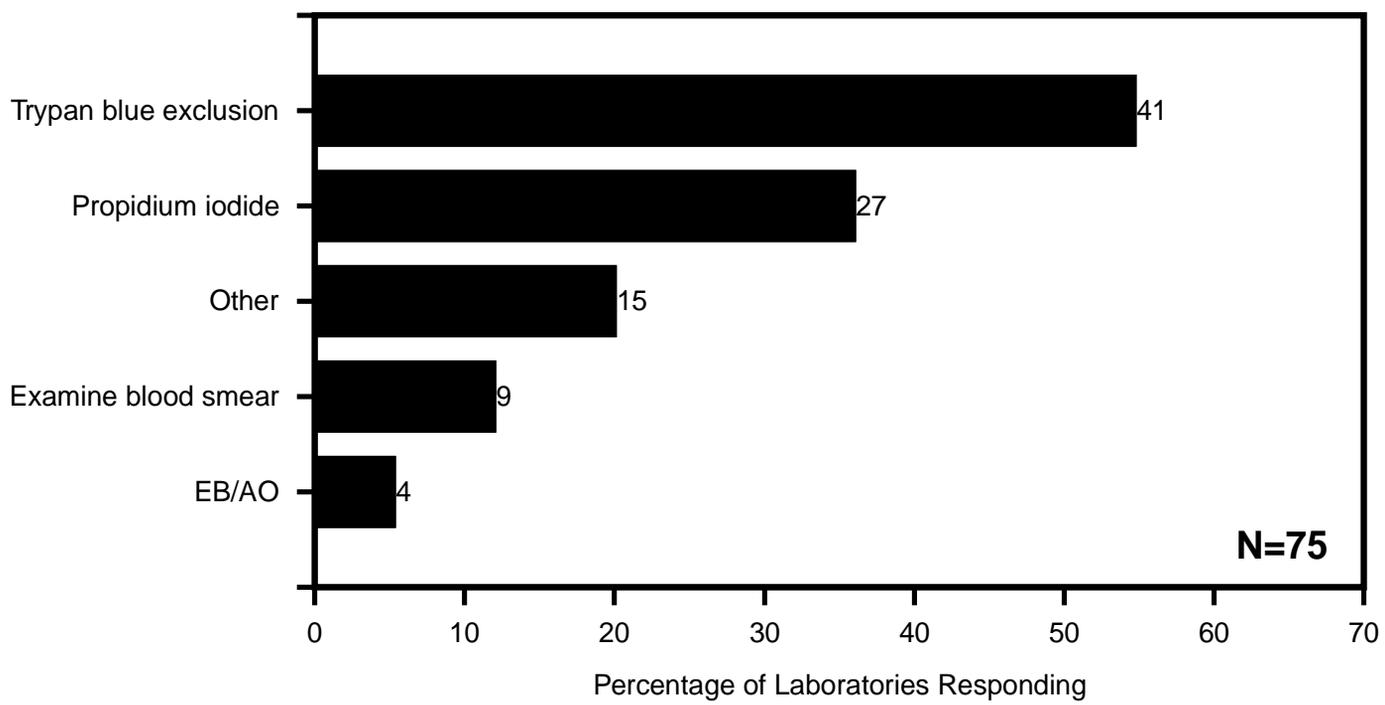


22.(a) Is testing for viability of TLI specimens performed by your laboratory?



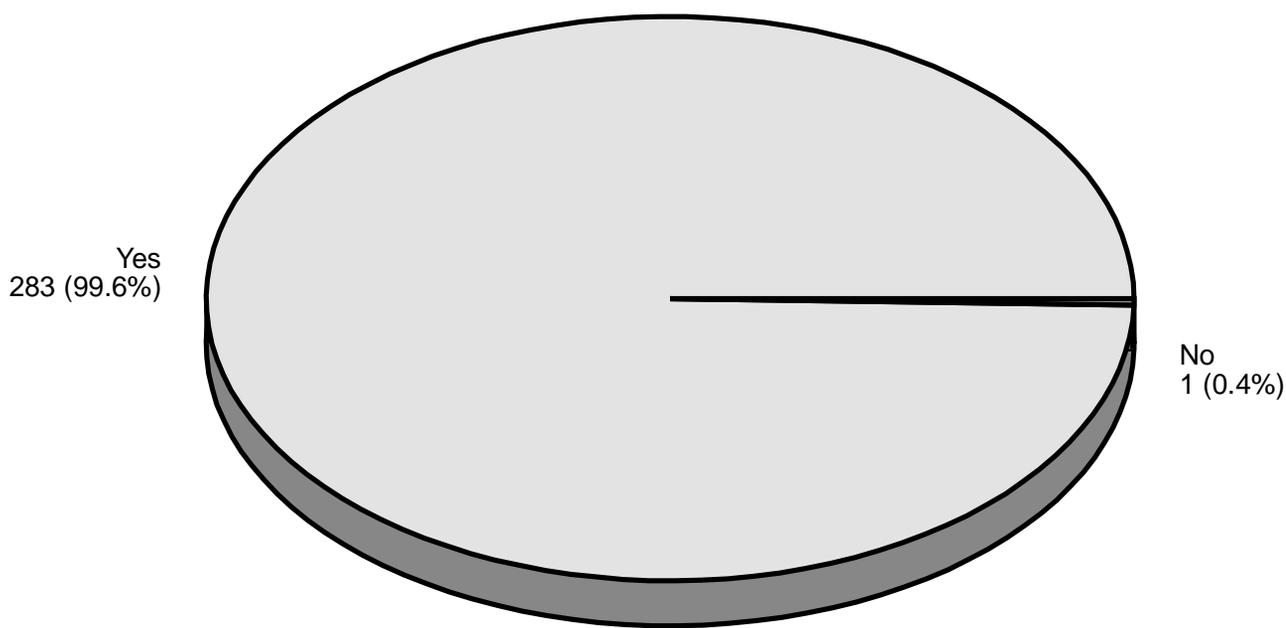
N=278

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



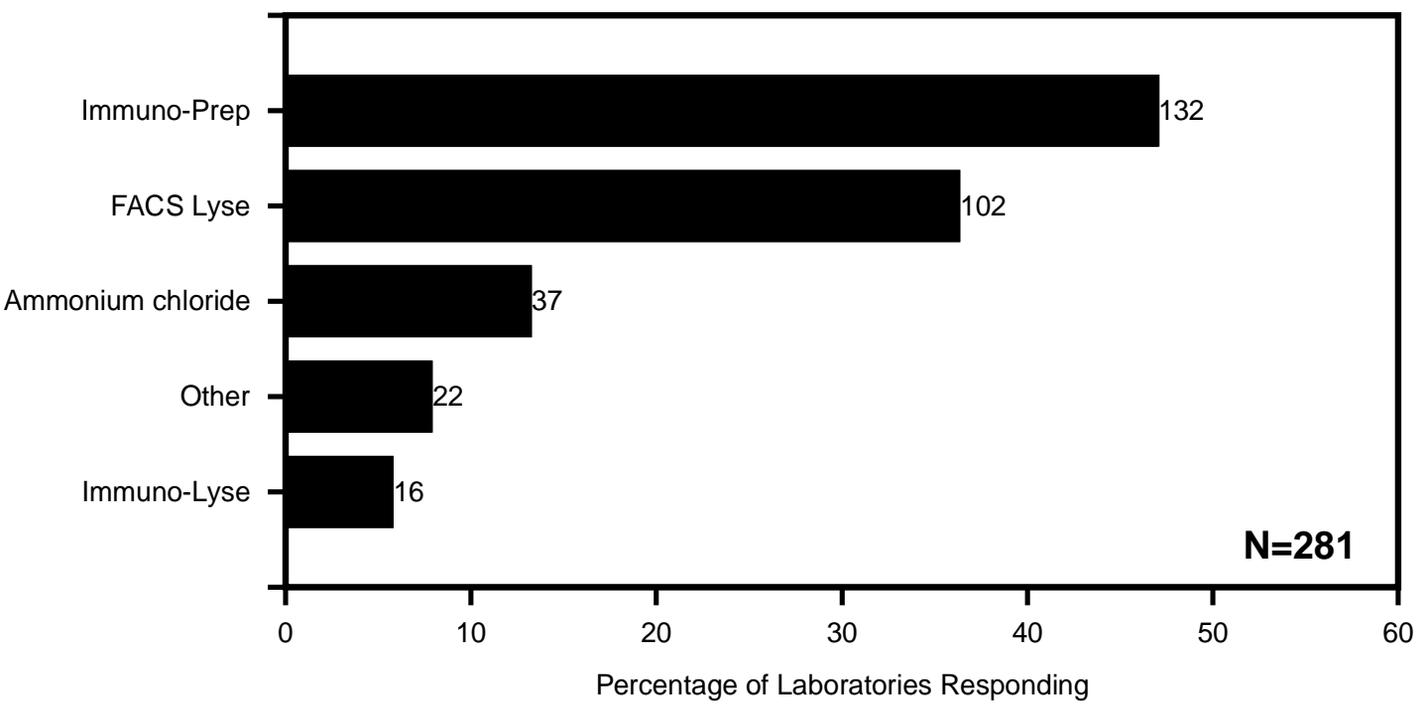
N=75

23.(a) Does your laboratory use a lysis method for staining TLI specimens?



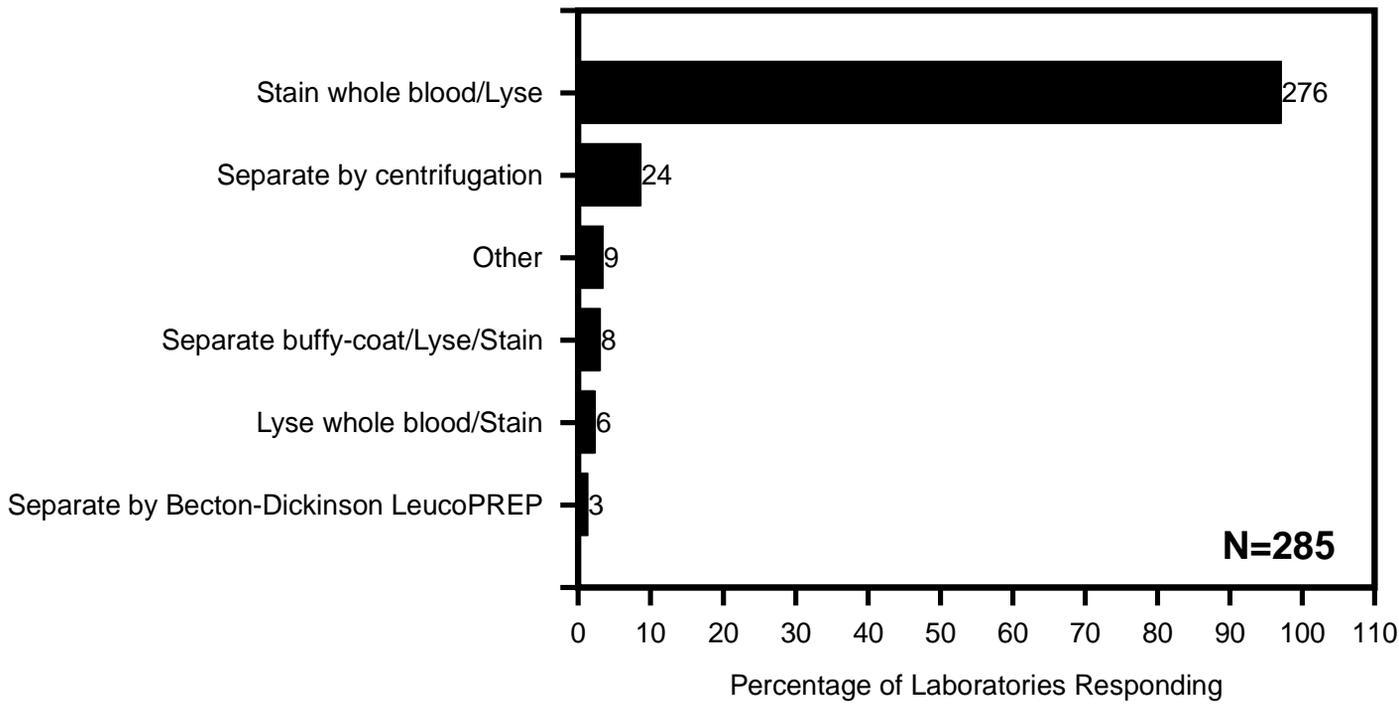
N=284

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

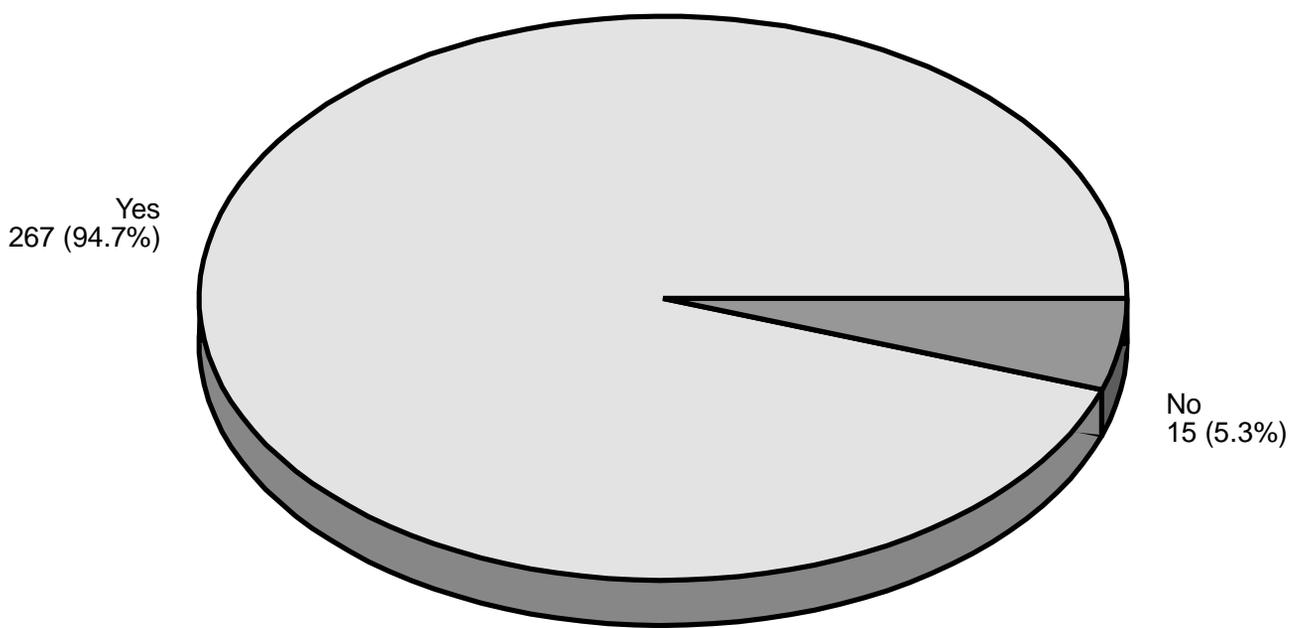


N=281

**23.(c) What sample staining procedure(s) does your laboratory use for TLI?
(Check all that apply.)**

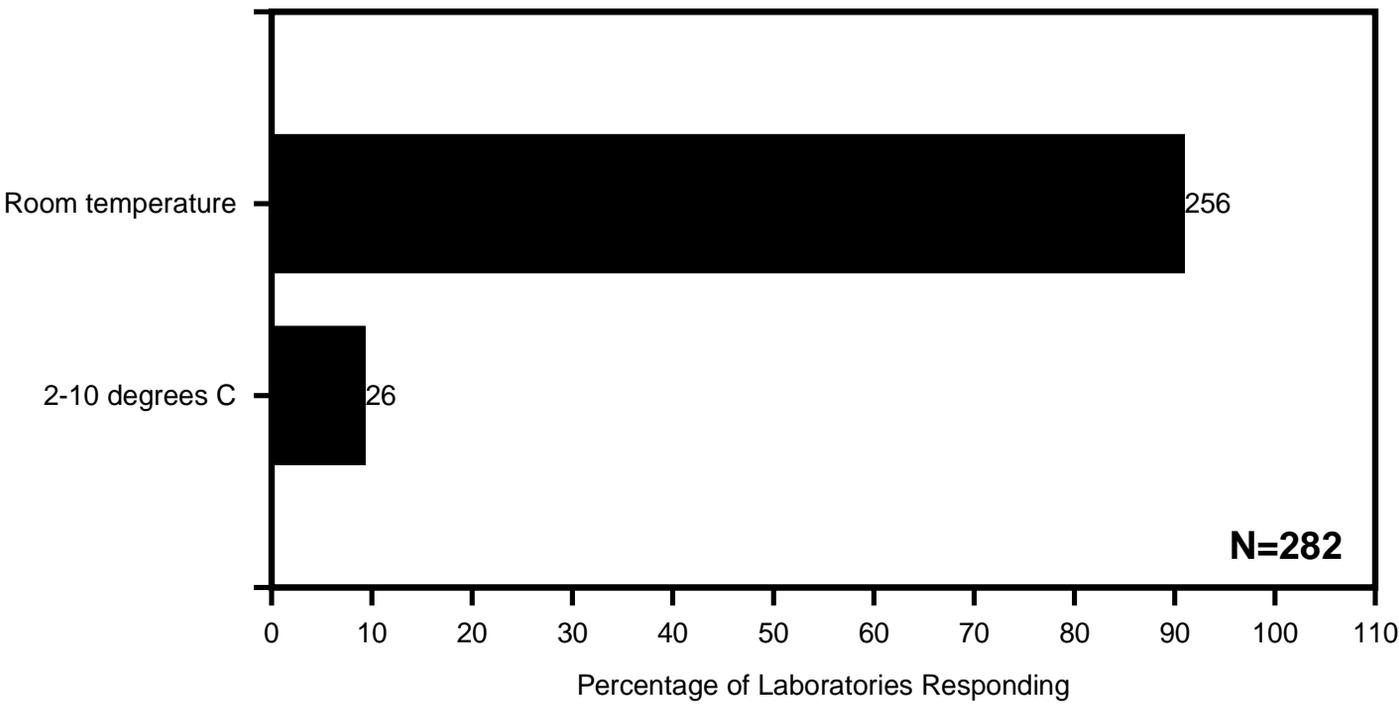


23.(d) Does your laboratory routinely use isotype controls as part of the staining procedure?

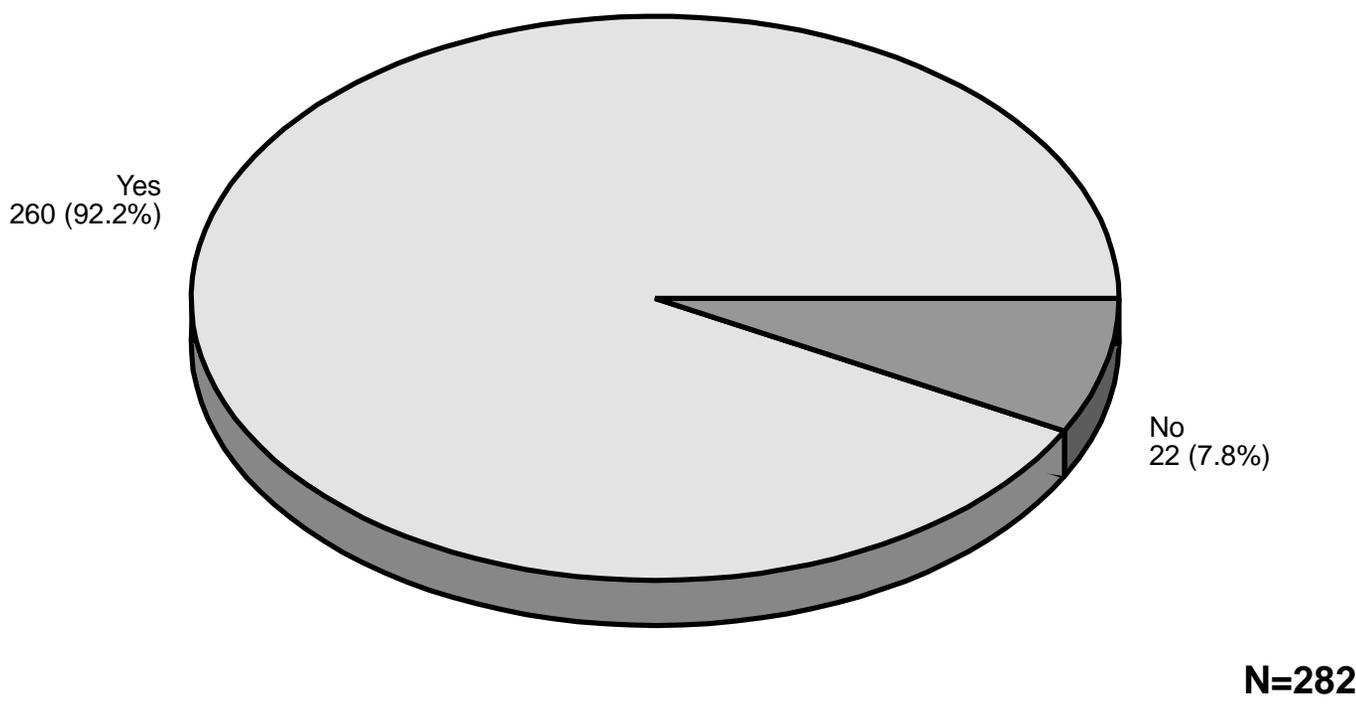


N=282

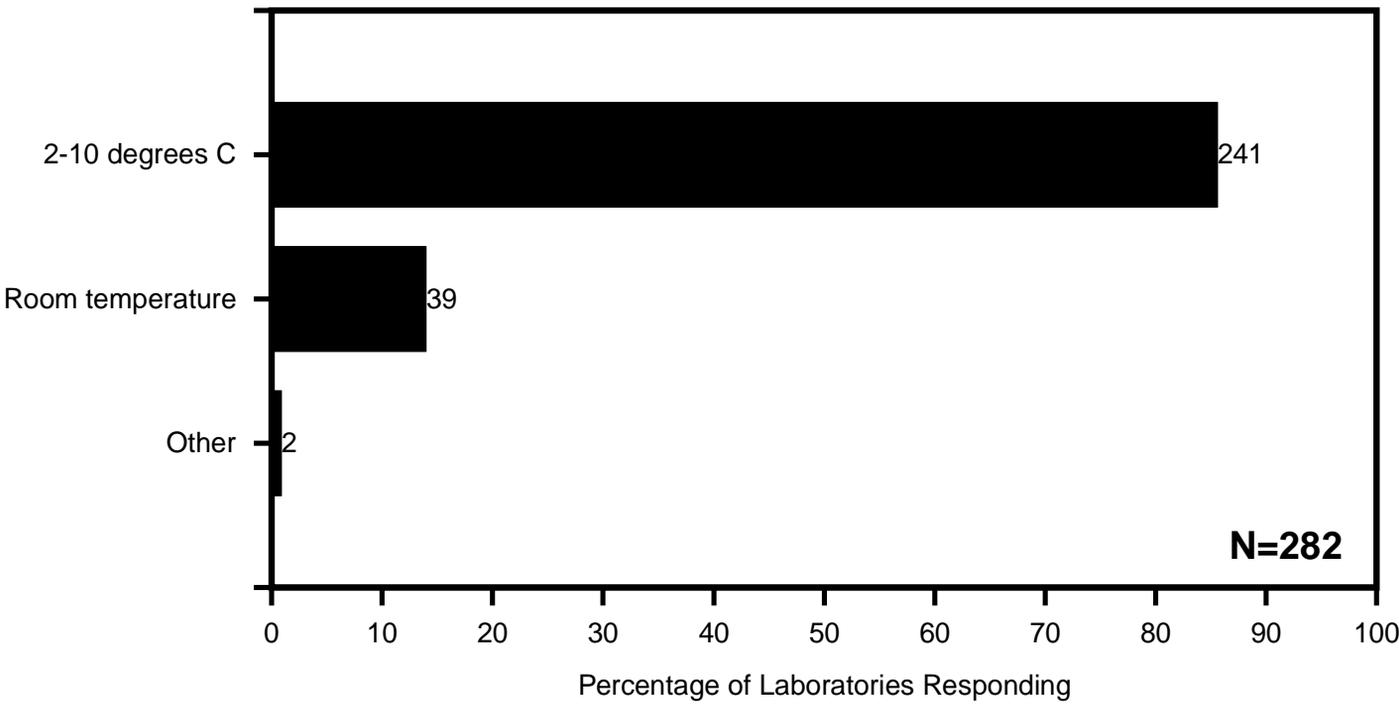
23.(e) At what temperature does your laboratory routinely perform the staining procedure? (Choose only one.)



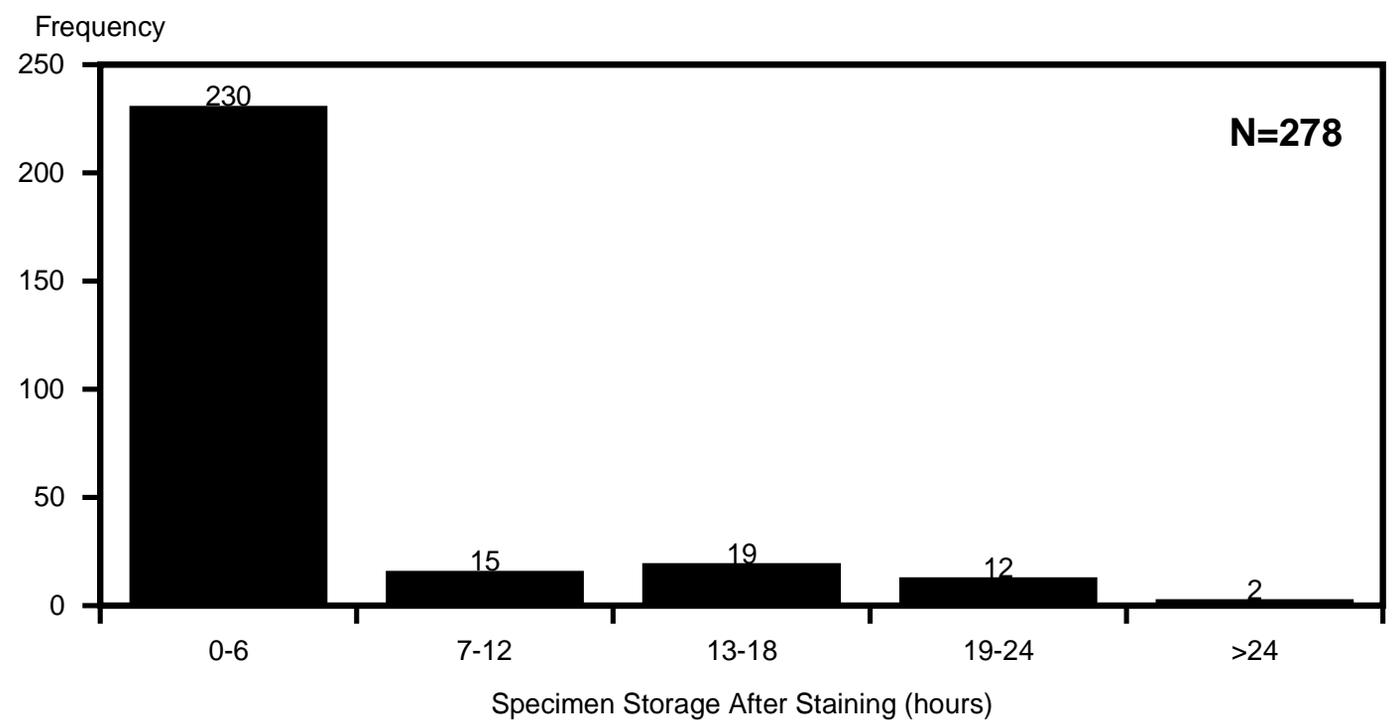
23.(f) Does your laboratory fix cells before TLI flow cytometry is performed?



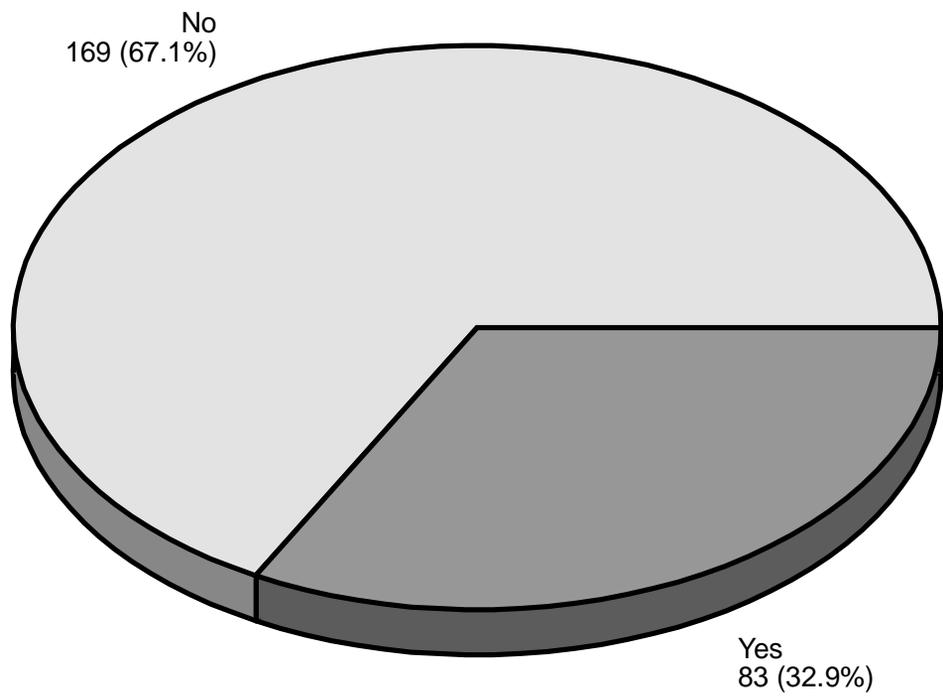
23.(g) At what temperature does your laboratory routinely store cells after staining? (Choose only one.)



23.(h) On average, how many hours is a specimen stored at your laboratory after staining before being analyzed?

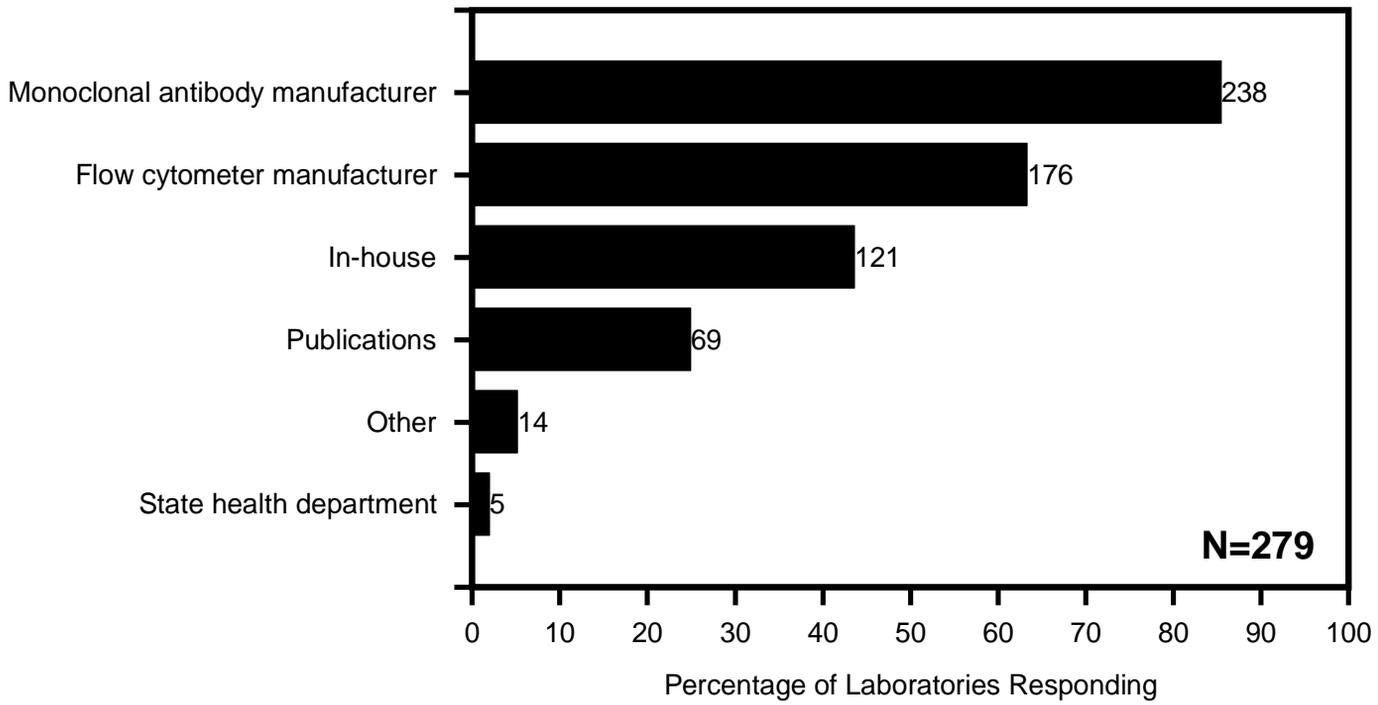


23.(i) Does your laboratory stain mononuclear cells?



N=252

24. From what source did your laboratory obtain its TLI staining procedure? (Check all that apply.)



N=279

25. Please complete the table on the following page, by choosing from the lists below, the monoclonal antibody manufacturer, type of stain, and fluorochrome associated with reagents for each of the cell marker combinations you routinely use for performing TLI. Complete only those sections of the table appropriate for the reagents routinely used in your laboratory.

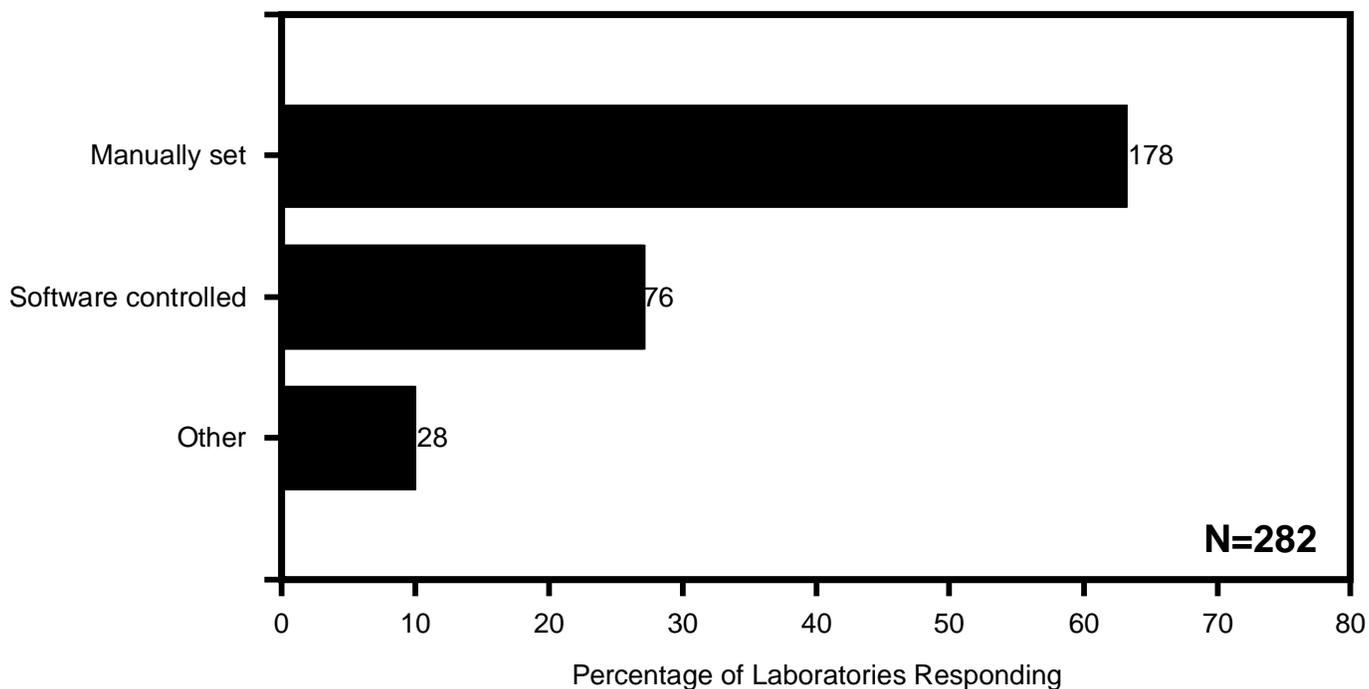
Monoclonal Antibody Manufacturer Combination

N=295 Population	B/ Ot																	
	A/A	B/B	B/C	C/A	C/B	C/C	C/G	D/C	D/D	G/B	G/G	G/Ot	Or/B	Or/Or	Ot/B	Ot/G	Ot/Ot	
CD45/CD14-	6	125	1	1	-	-	112	-	-	7	1	-	1	-	15	-	-	1
CD3+/CD4+	5	117	-	-	-	1	117	-	-	9	1	-	-	1	16	3	-	4
CD3+/CD8+	5	114	-	1	-	1	116	-	1	8	-	1	-	1	16	2	1	4
CD3-/CD16+	4	10	-	1	1	1	4	1	-	1	-	-	-	-	8	-	-	2
CD3-/CD56+	3	10	1	1	1	1	35	-	1	-	-	1	-	-	1	3	-	-
CD3-/CD56&16+	2	127	-	-	1	2	2	-	-	-	-	-	-	1	-	-	-	1
CD3-/CD19+	4	94	2	-	-	-	52	-	-	5	-	1	-	1	10	2	-	2
CD2+ alone	-	14	-	-	-	-	17	-	-	2	-	1	-	-	1	-	-	2
CD3+ alone	1	10	-	-	-	-	8	-	-	2	-	1	-	-	-	-	-	-
CD4+ alone	1	7	-	-	-	-	8	-	-	2	-	1	-	-	-	-	-	-
CD8+ alone	1	8	-	-	-	-	6	-	-	2	-	1	-	-	-	-	-	-
CD16+ alone	-	13	-	-	-	-	2	-	-	-	-	-	-	-	1	-	-	-
CD19+ alone	1	19	-	-	-	-	26	-	-	4	-	1	-	-	-	-	-	1
CD20+ alone	3	17	-	-	-	-	11	-	-	2	-	1	-	-	1	-	-	-
CD56+ alone	-	7	-	-	-	-	15	-	-	-	-	-	-	-	-	-	-	-
CD(56&16)+ alone	-	5	-	-	-	-	1	-	-	-	-	-	-	-	-	-	-	-

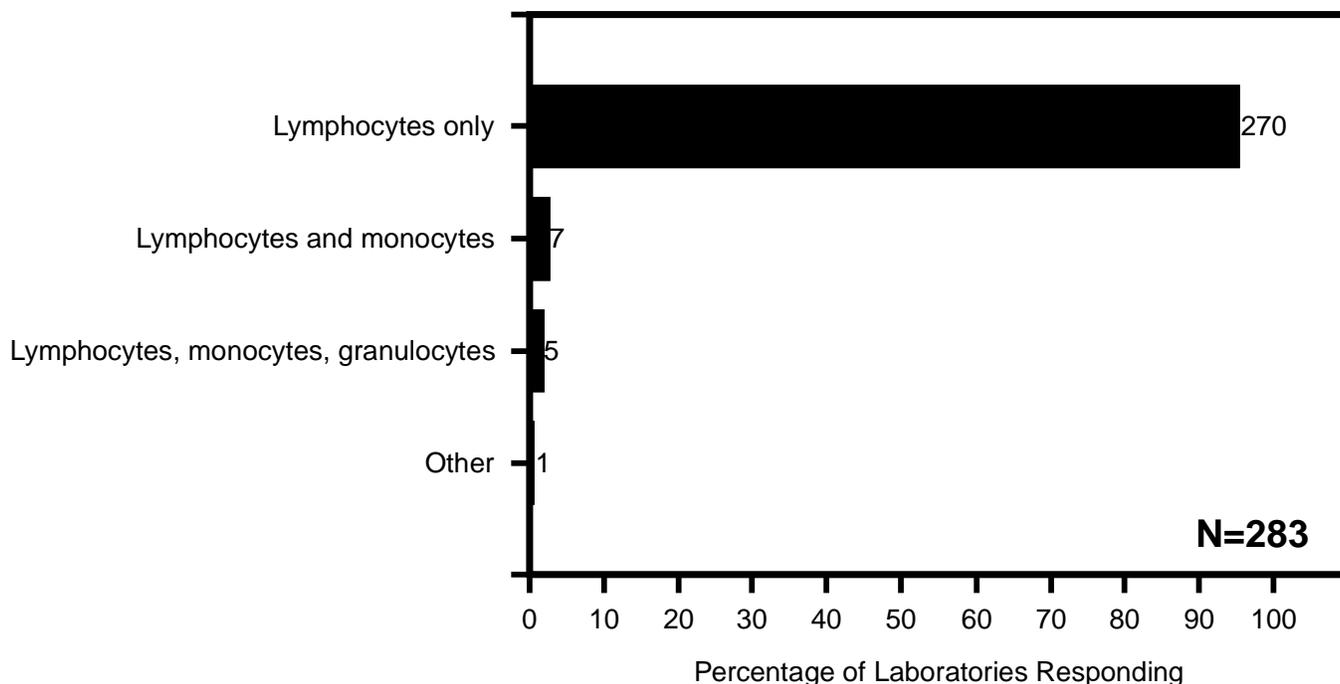
Manufacturer Key

A = AMAC
 B = Becton Dickinson
 C = Coulter
 D = Dako
 G = Gen Trak
 Or = Ortho
 Ot = Other

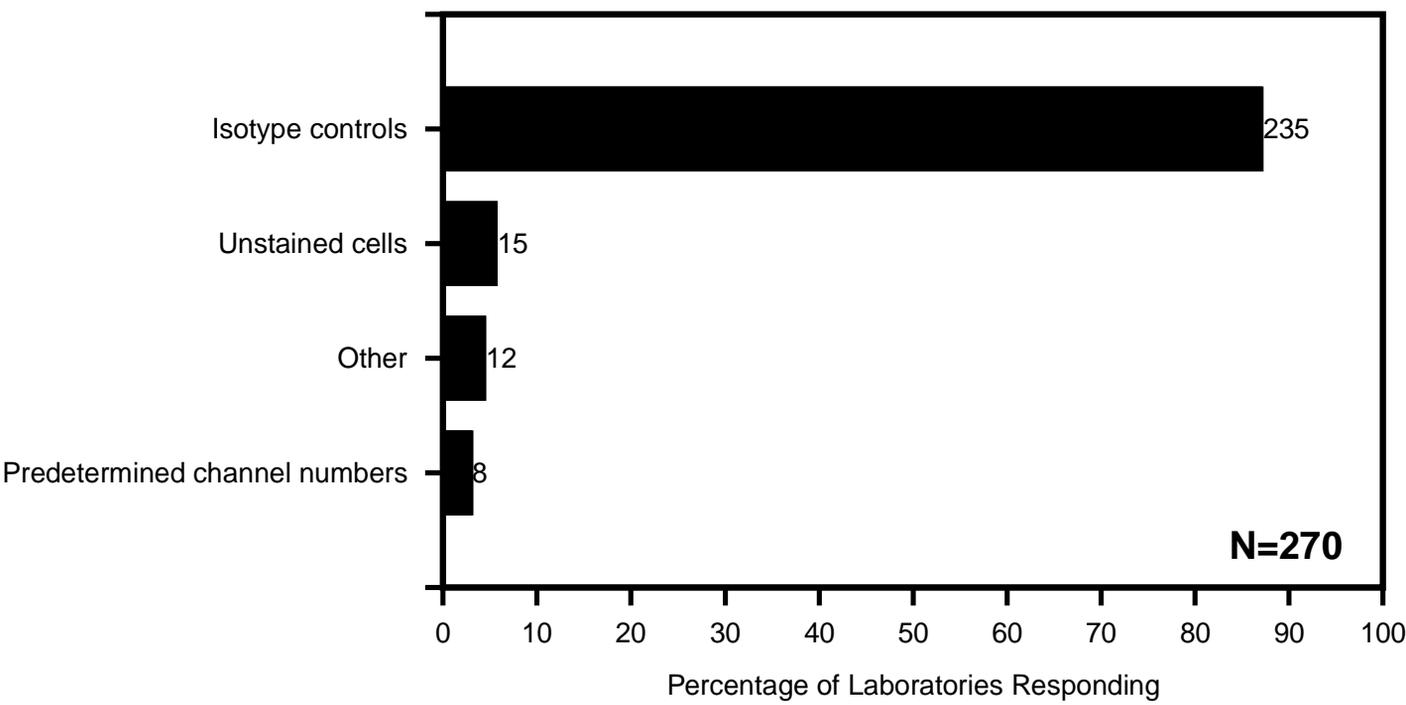
**26.(a) How is the gating set when performing TLI on your flow cytometers?
(Choose only one.)**



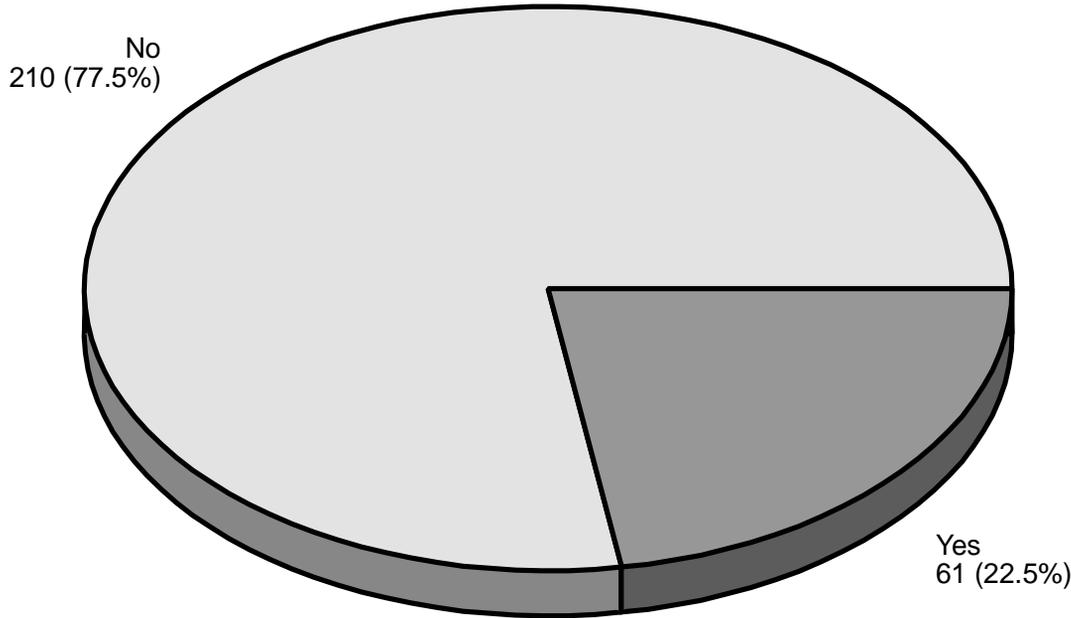
26.(b) Which cell populations are included in the gates for analyses of lymphocyte phenotypes? (Choose only one.)



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

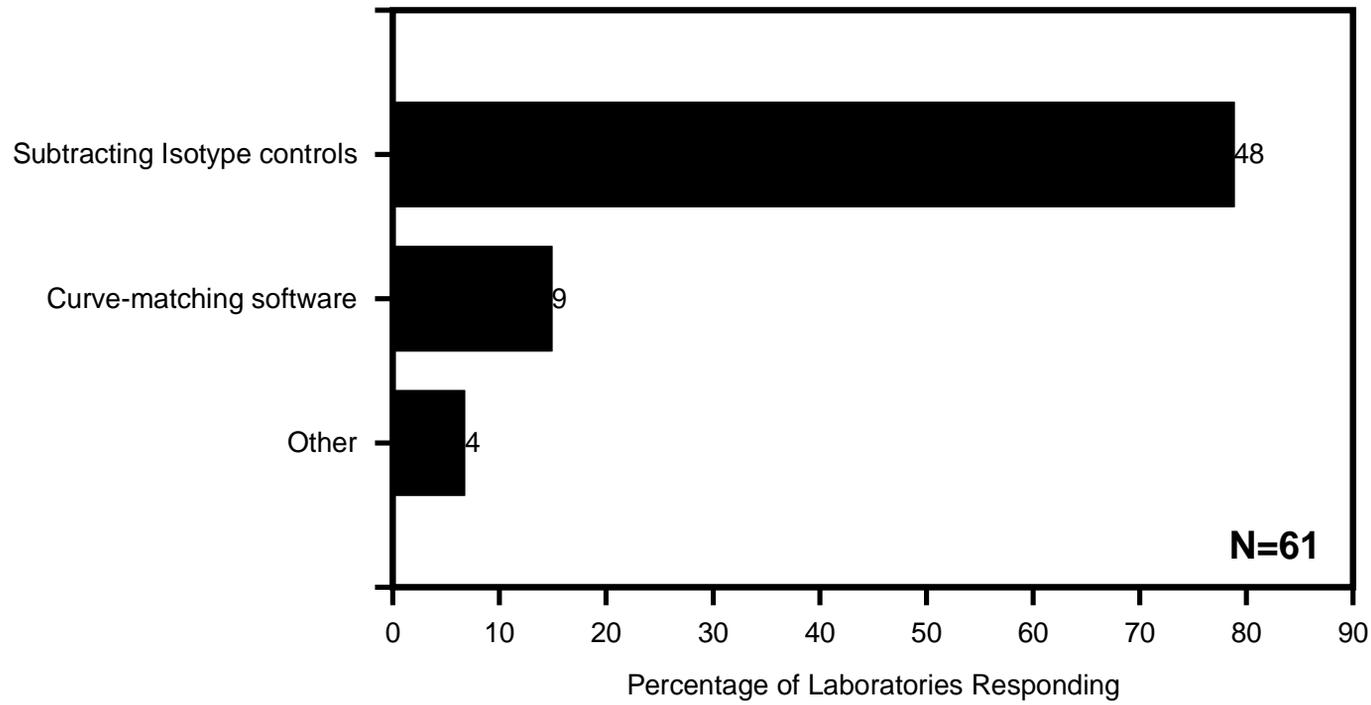


28.(a) Do you mathematically adjust your phenotype values for isotype control values?



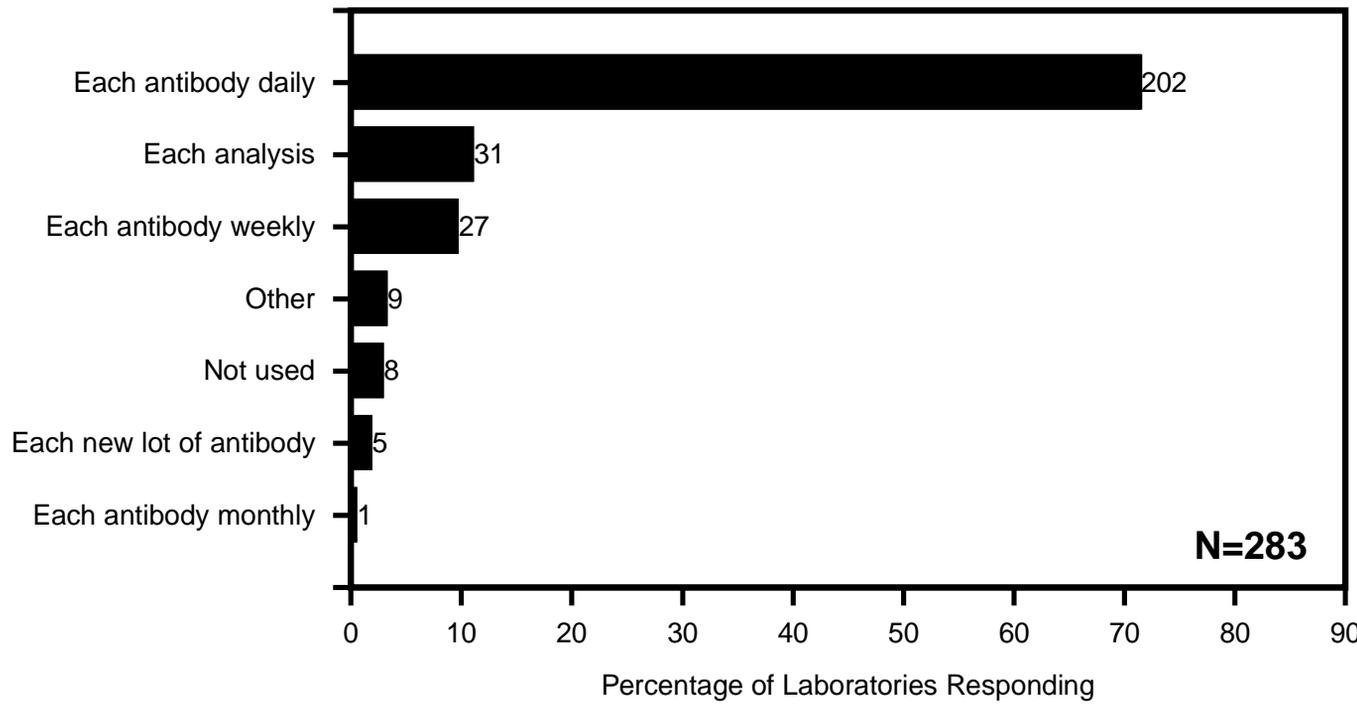
N=271

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

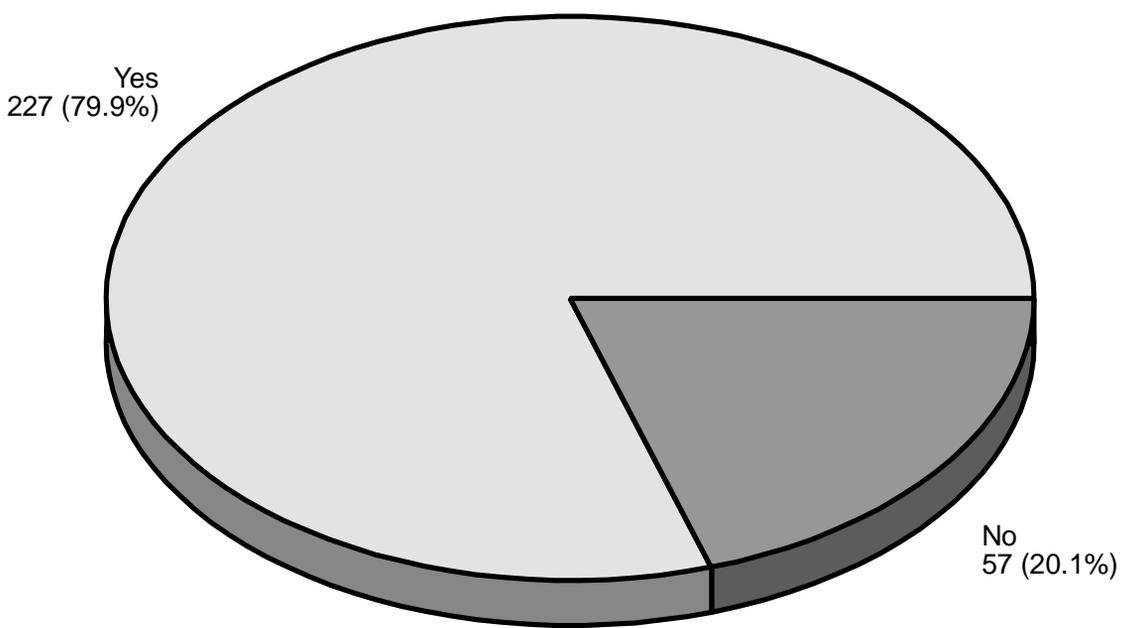


N=61

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

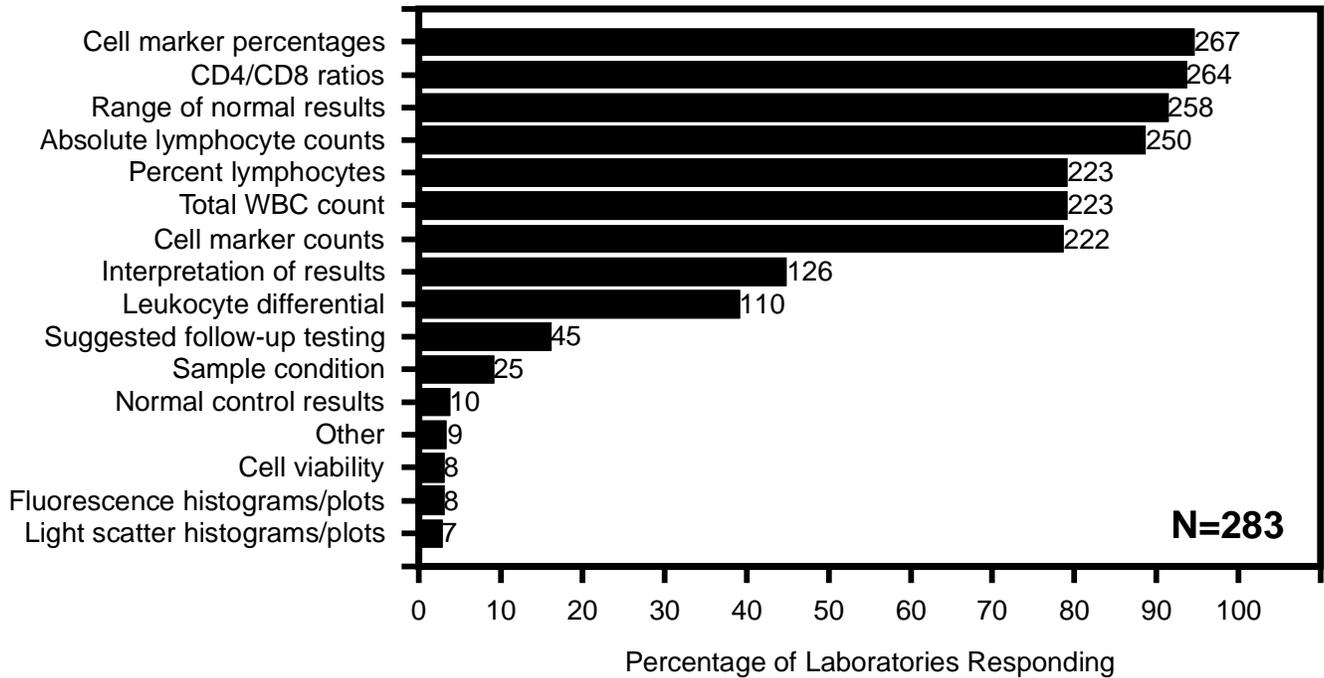


30. Before TLI results are reported, are they routinely reviewed by someone other than the person(s) who performed the tests?

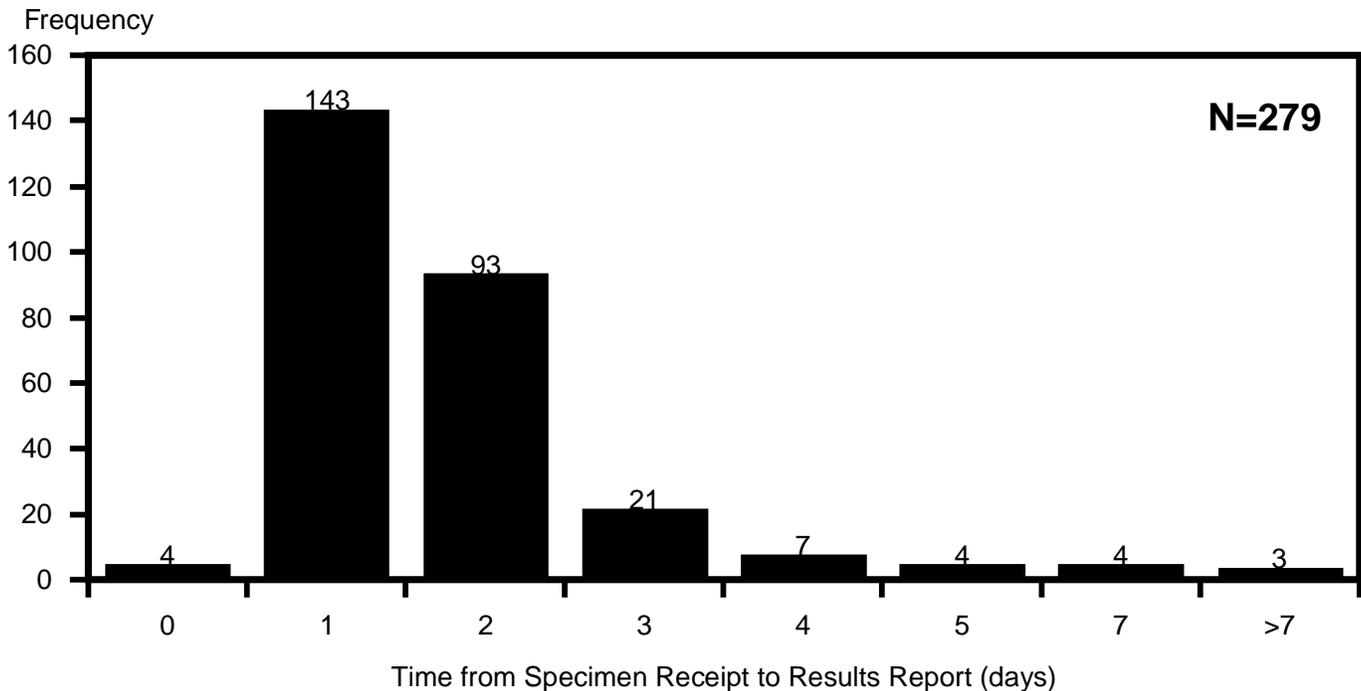


N=284

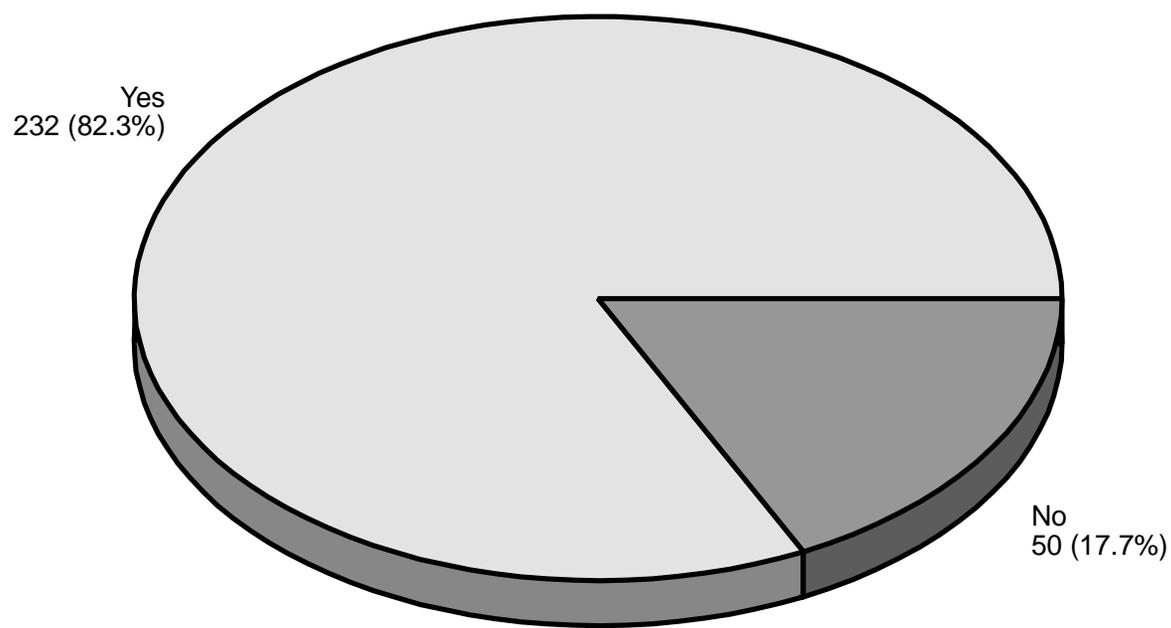
31. What information is included in the report returned to the person or institution initiating the request for TLI? (Check all that apply.)



32. 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 TLI?

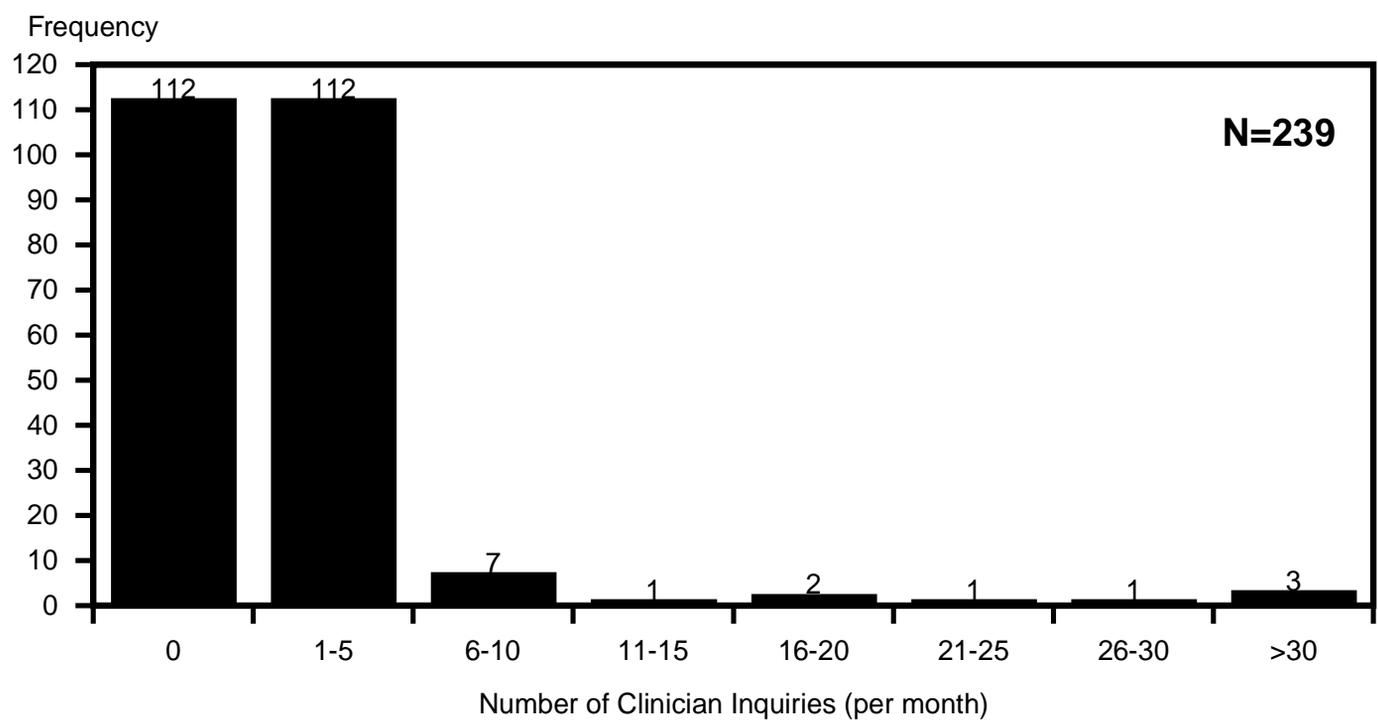


33. Does your laboratory have procedures for protecting the confidentiality of TLI results?

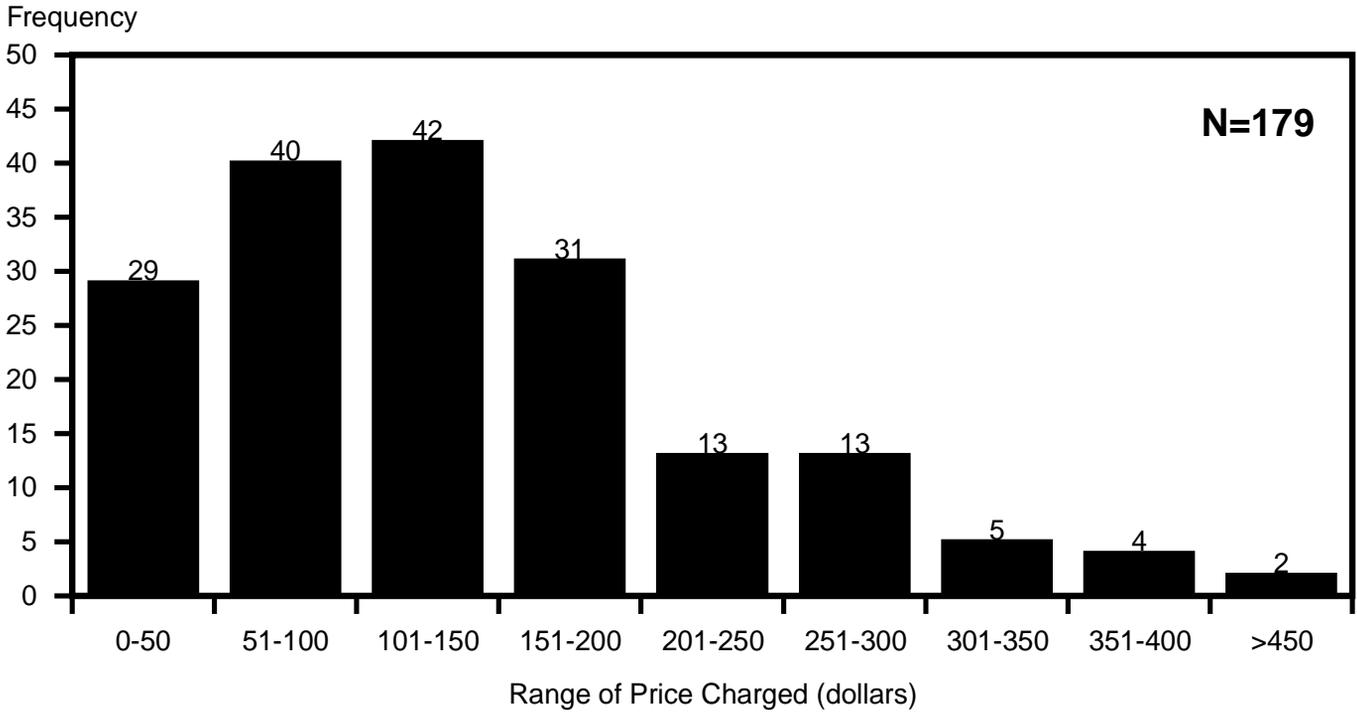


N=282

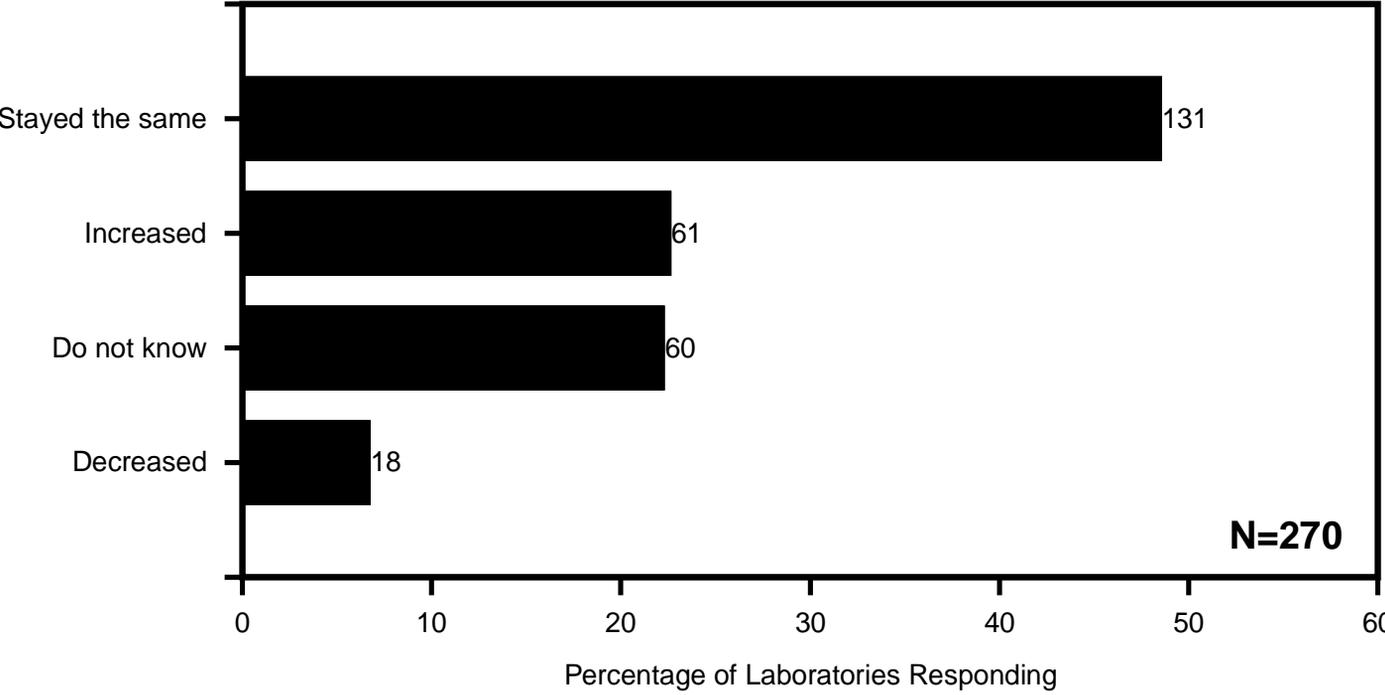
34. On average, how many times in a month does your laboratory receive inquiries from clinicians requesting interpretation of TLI results?



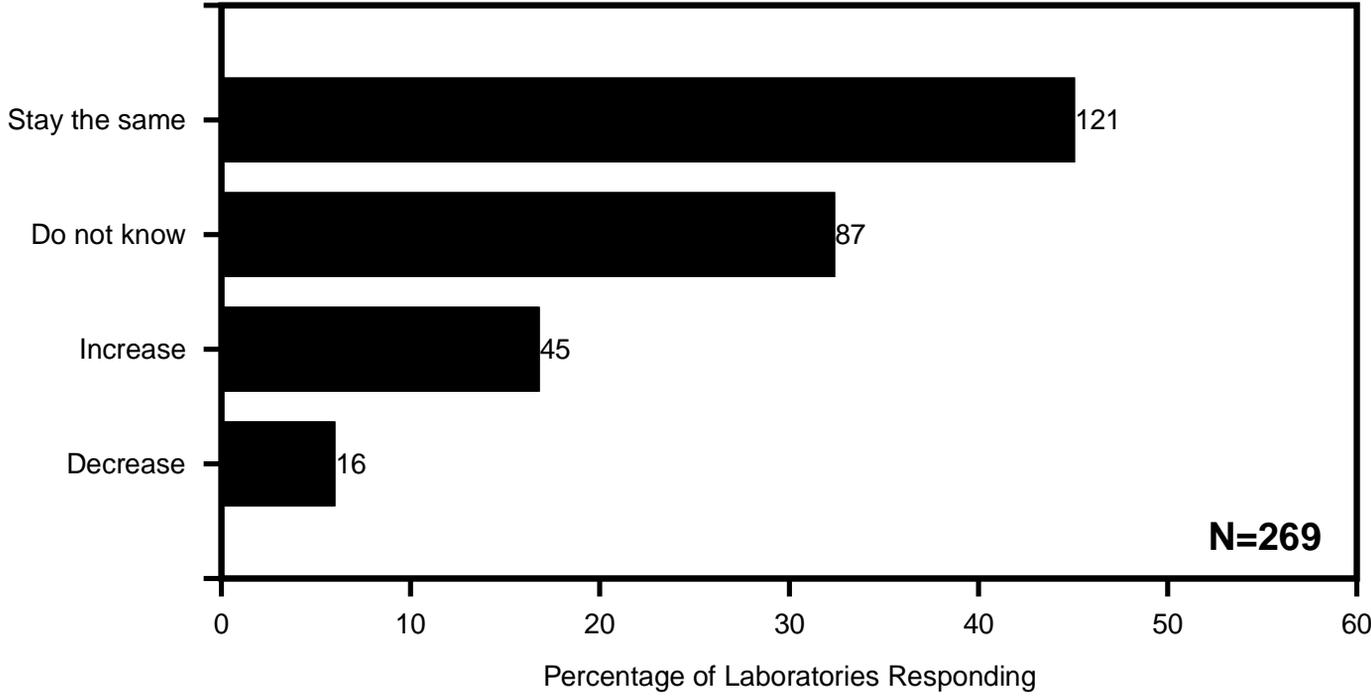
35.(a) What is the average full price currently charged by your laboratory for TLI for each patient/blood donor sample? (Round off to the nearest whole dollar.)



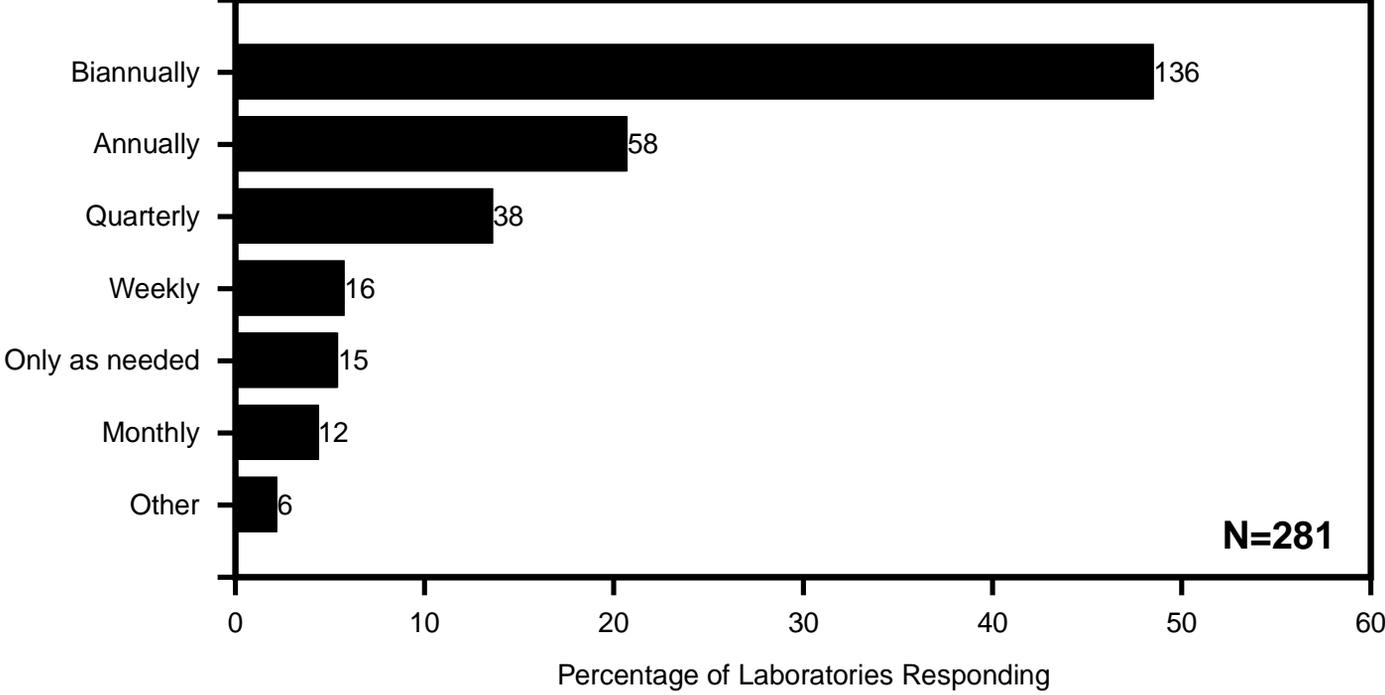
35.(b) Has the average full price that your laboratory charges for TLI for each patient/blood donor sample increased, decreased, or stayed the same compared to twelve months ago? (Choose only one.)



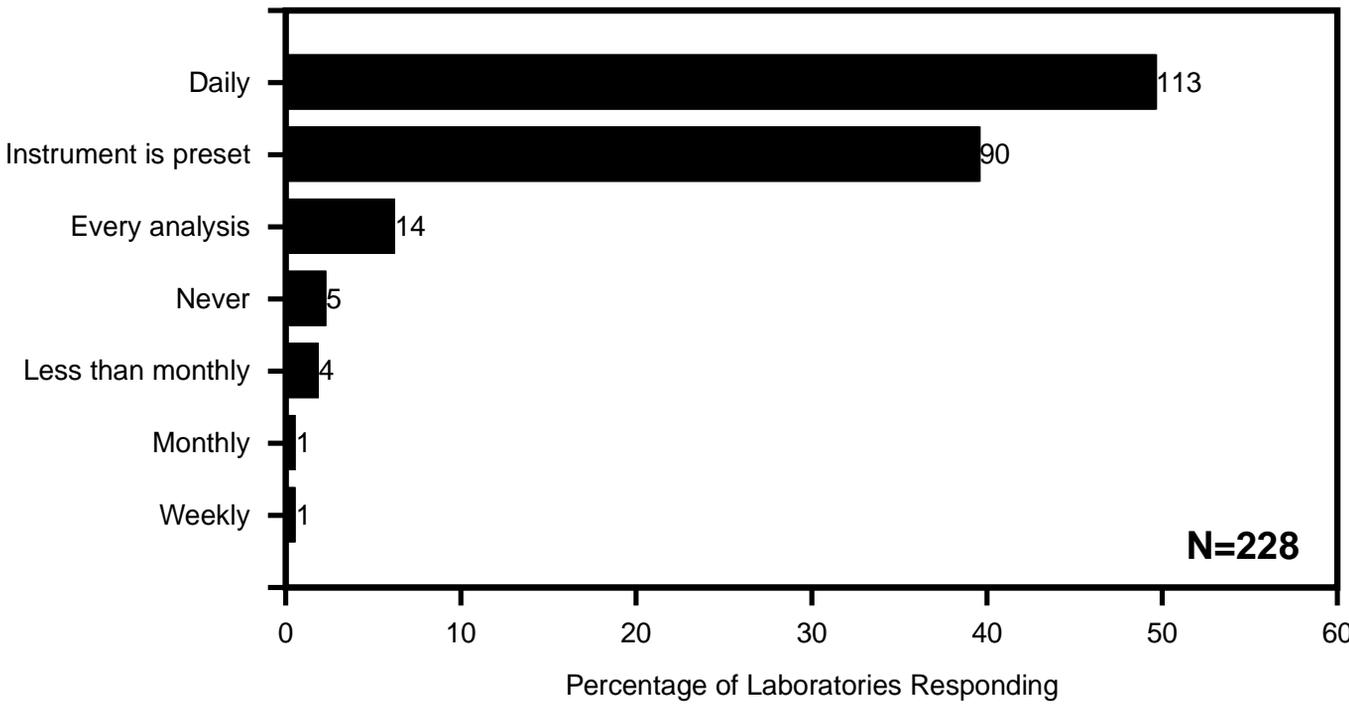
35.(c) Do you anticipate the price charged for TLI by your laboratory will increase, decrease, or stay the same in the next twelve months? (Choose only one.)



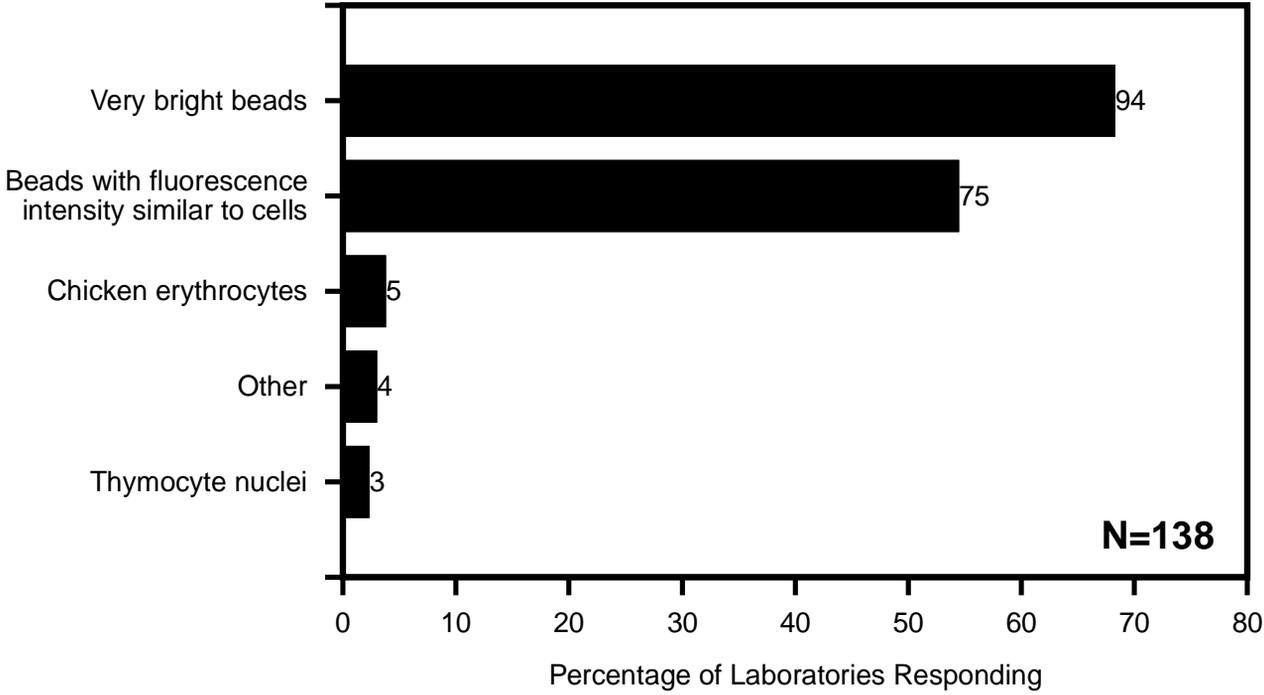
36. How often do your flow cytometer(s) receive preventive maintenance (e.g., cleaning of optical filters and lenses, and fluidics check)? (Choose only one.)



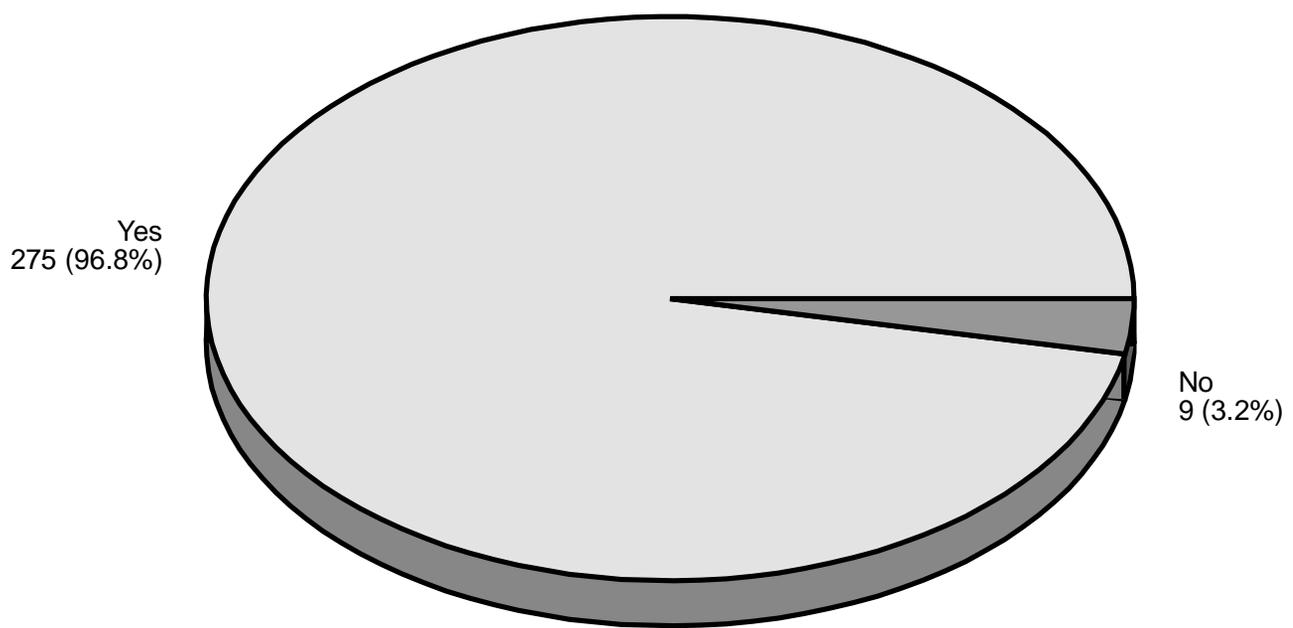
37.(a) How often does your laboratory optically align your flow cytometer(s)? (Choose only one.)



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

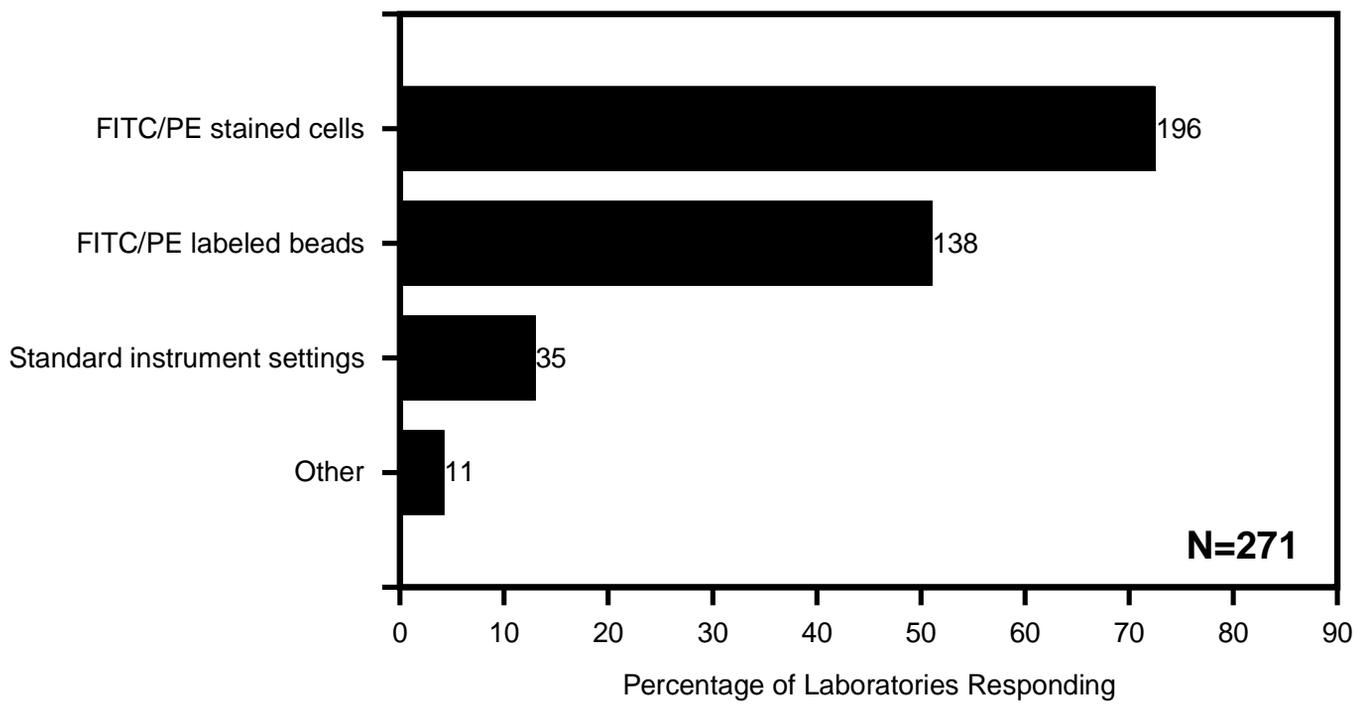


38.(a) Does your laboratory set fluorescence overlap compensation?



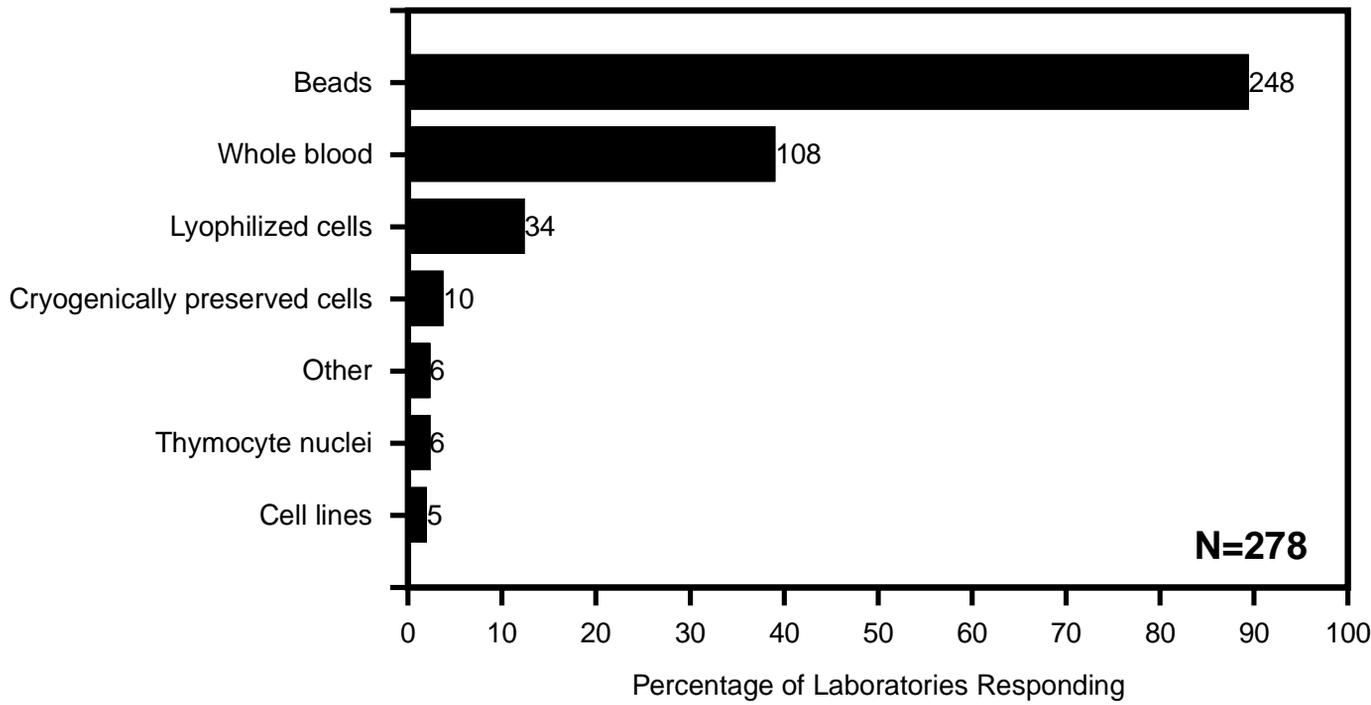
N=284

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

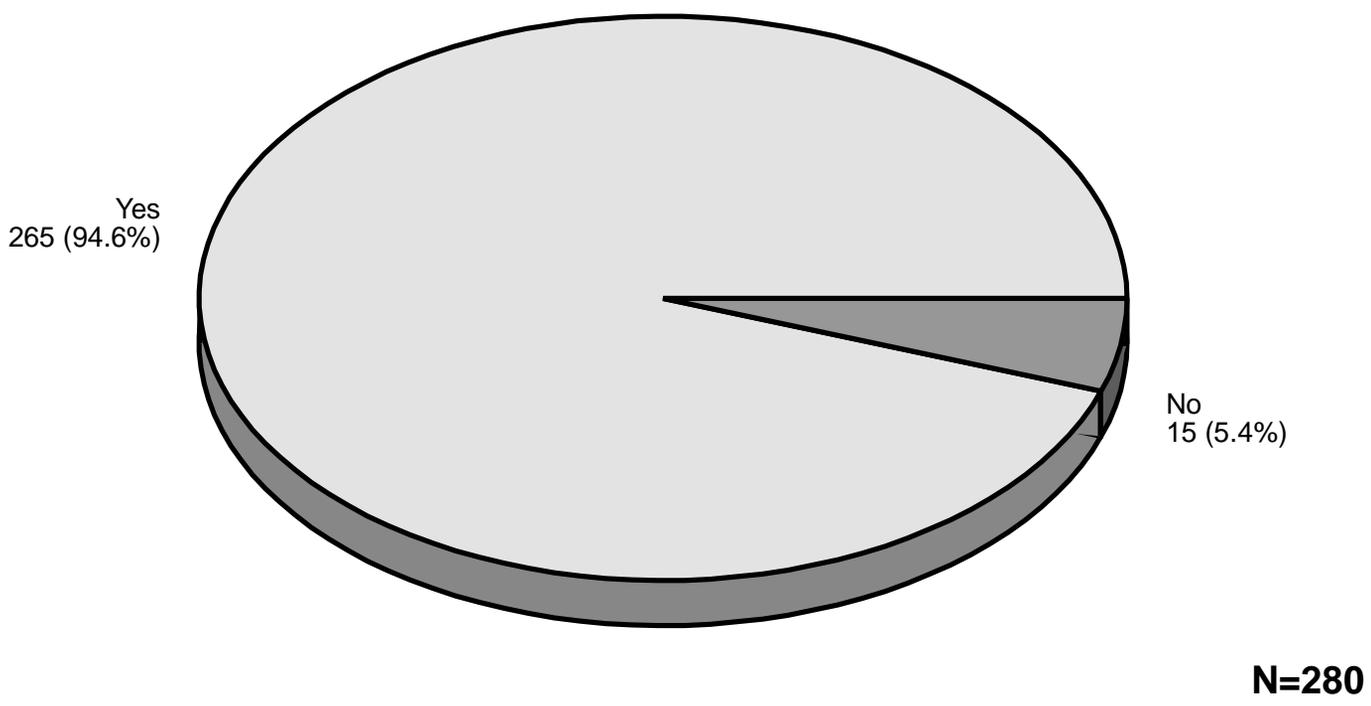


N=271

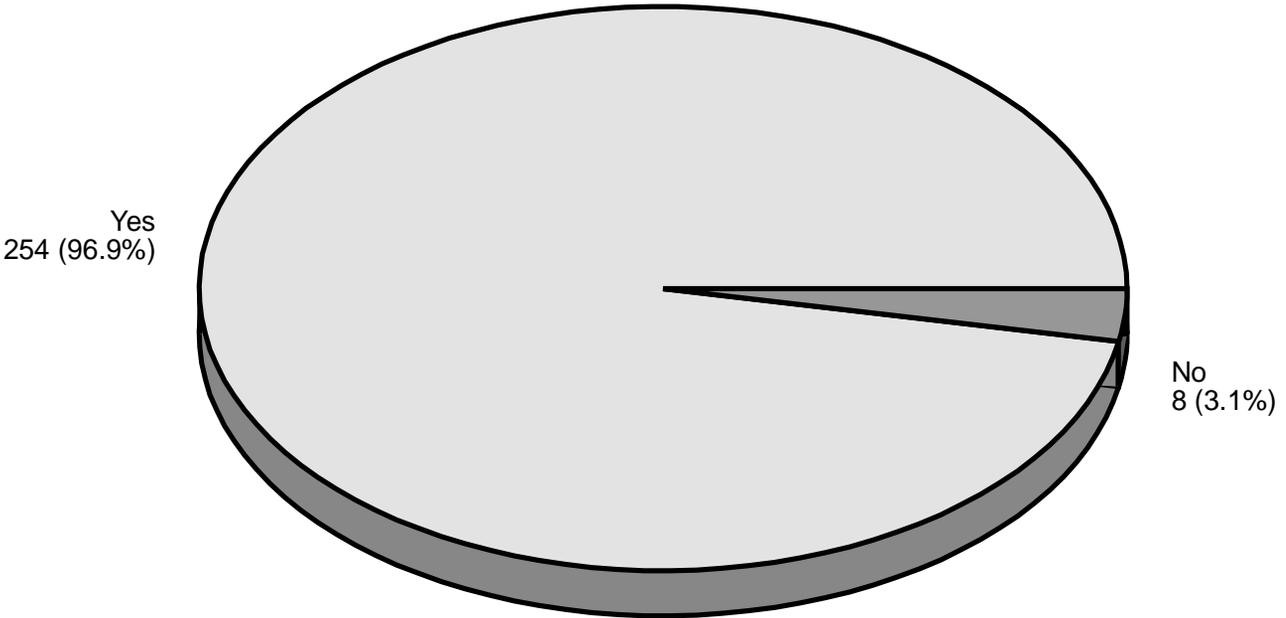
39.(a) What reference materials does your laboratory use to achieve the target conditions for forward angle light scatter (FALS) and fluorescence intensity (FI)? (Check all that apply.)



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

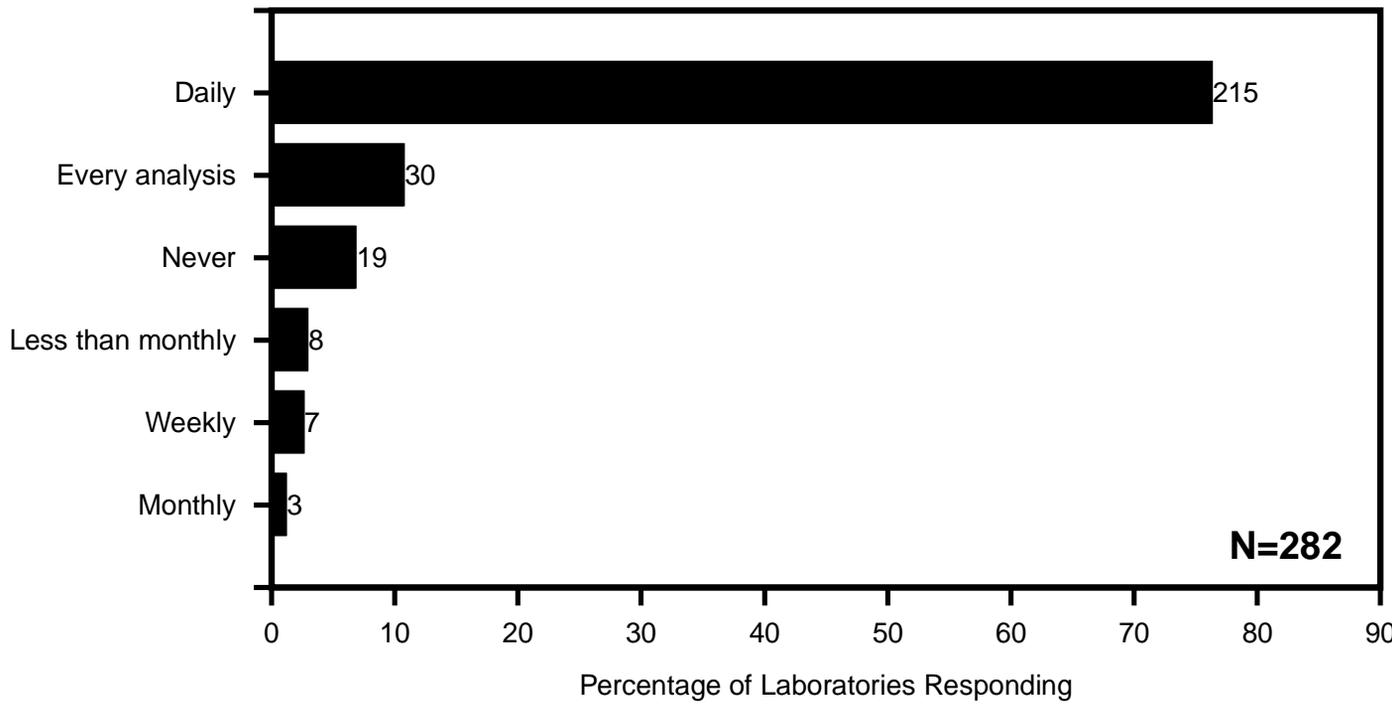


39.(c) Are these data analyzed to monitor trends or changes in instrument performance?

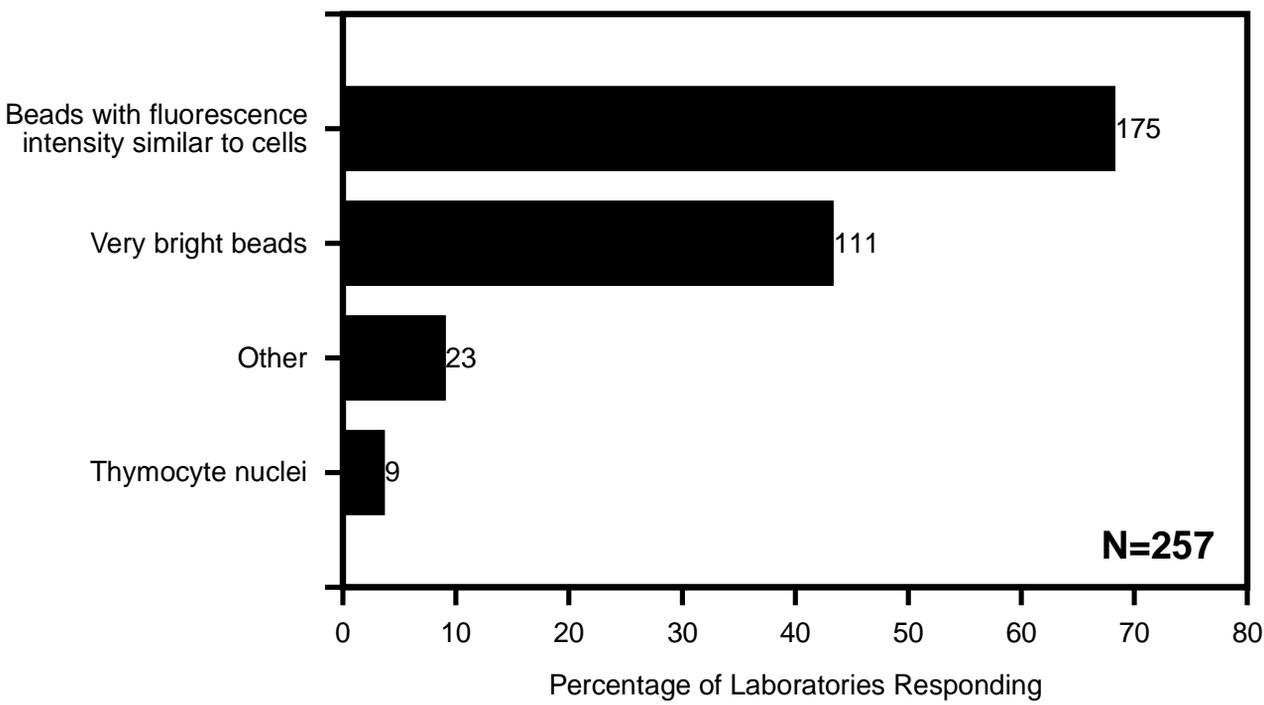


N=262

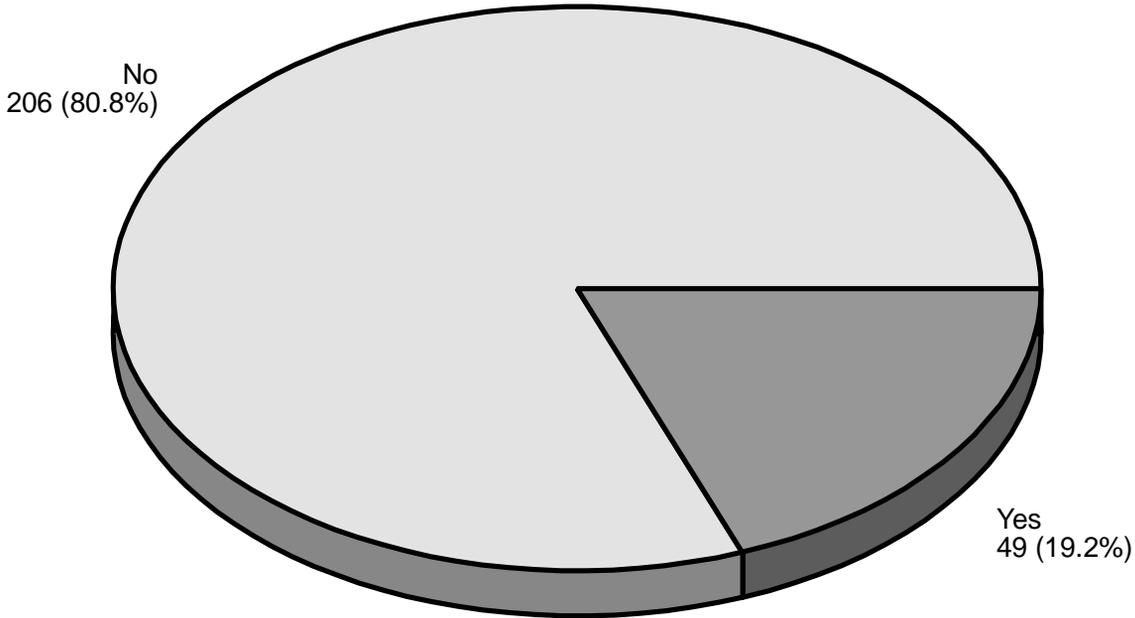
40.(a) How often does your laboratory standardize your flow cytometer(s)? (Choose only one.)



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

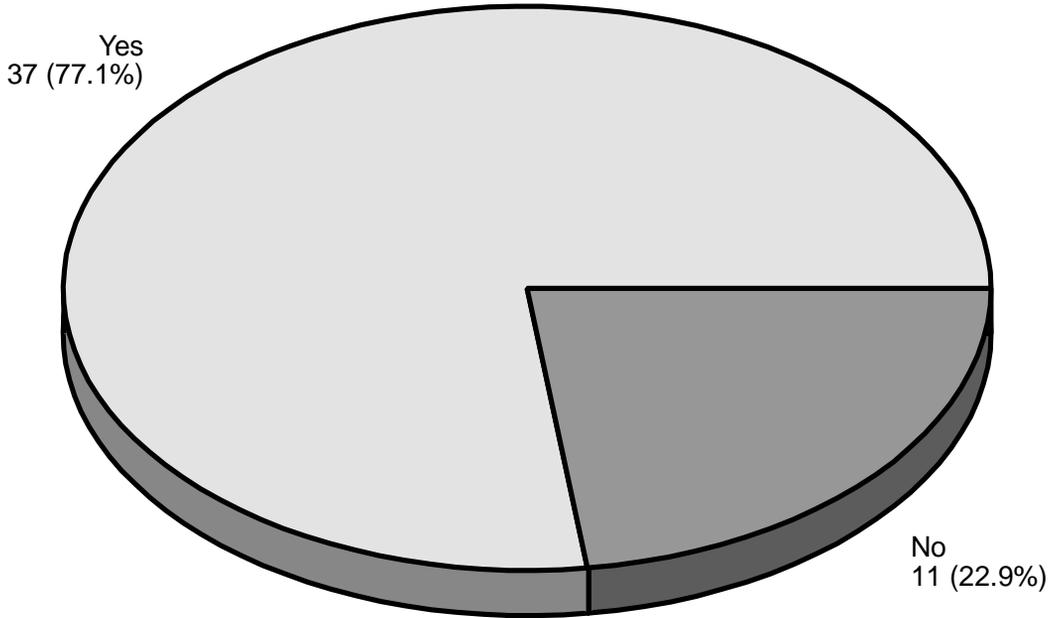


40.(c) Does your laboratory use reference standards to plot standard curves of mean channel fluorescence vs. molecules of equivalent soluble fluorochrome?



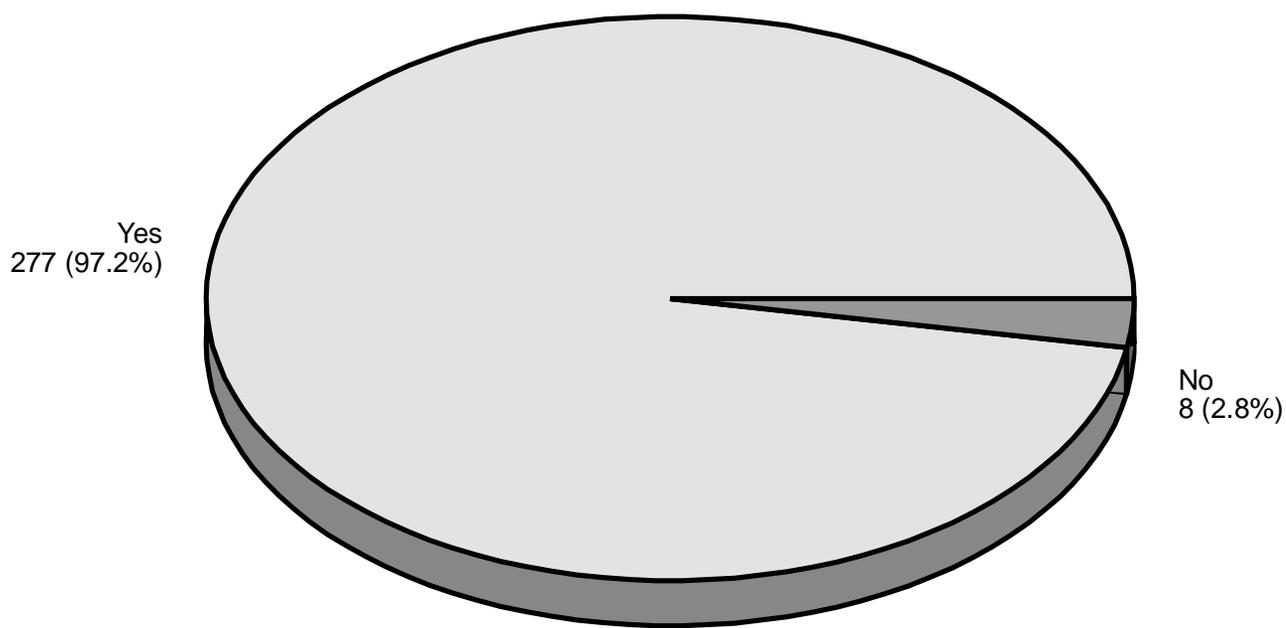
N=255

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



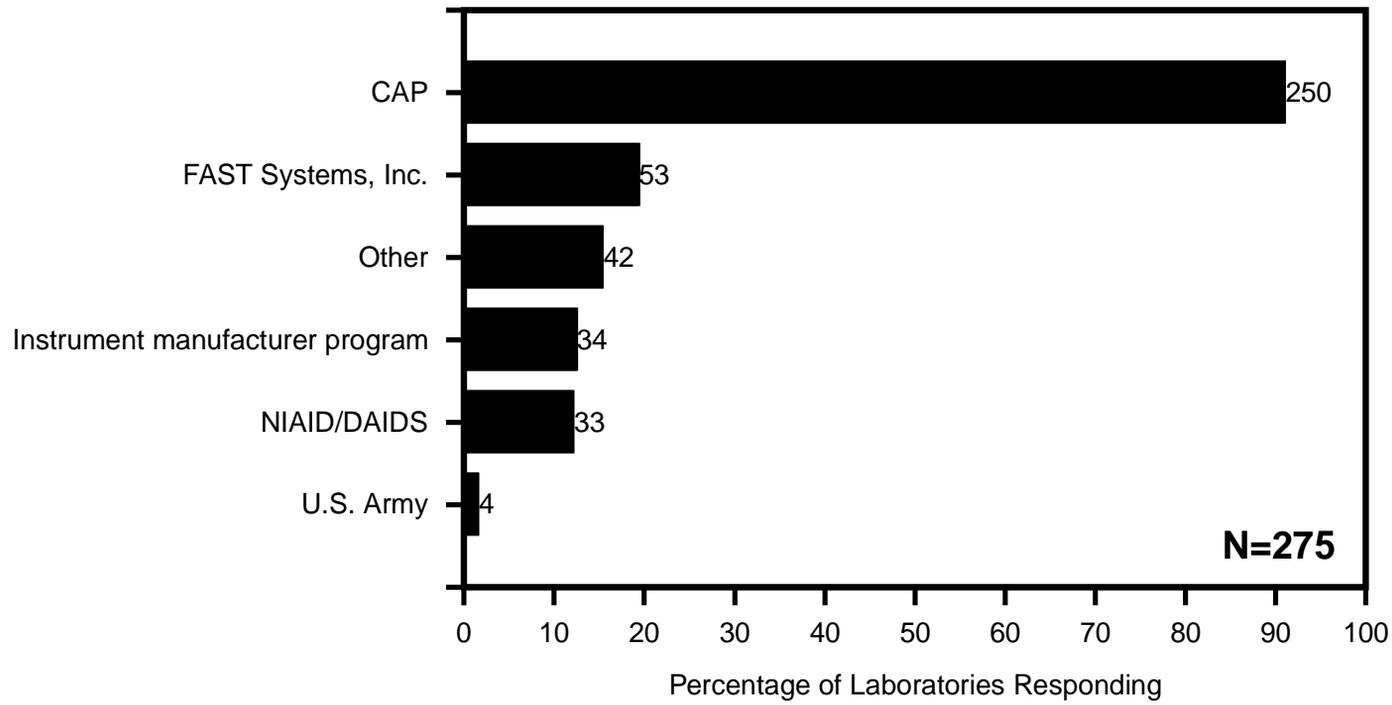
N=48

41.(a) Does your laboratory participate in an external TLI proficiency testing program?



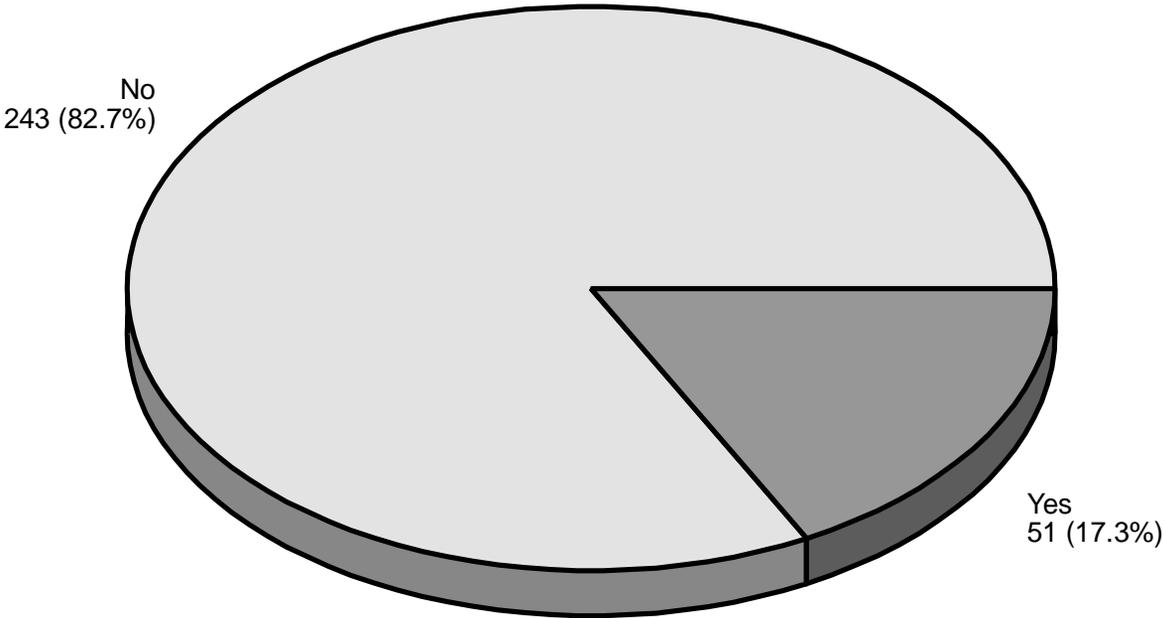
N=285

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



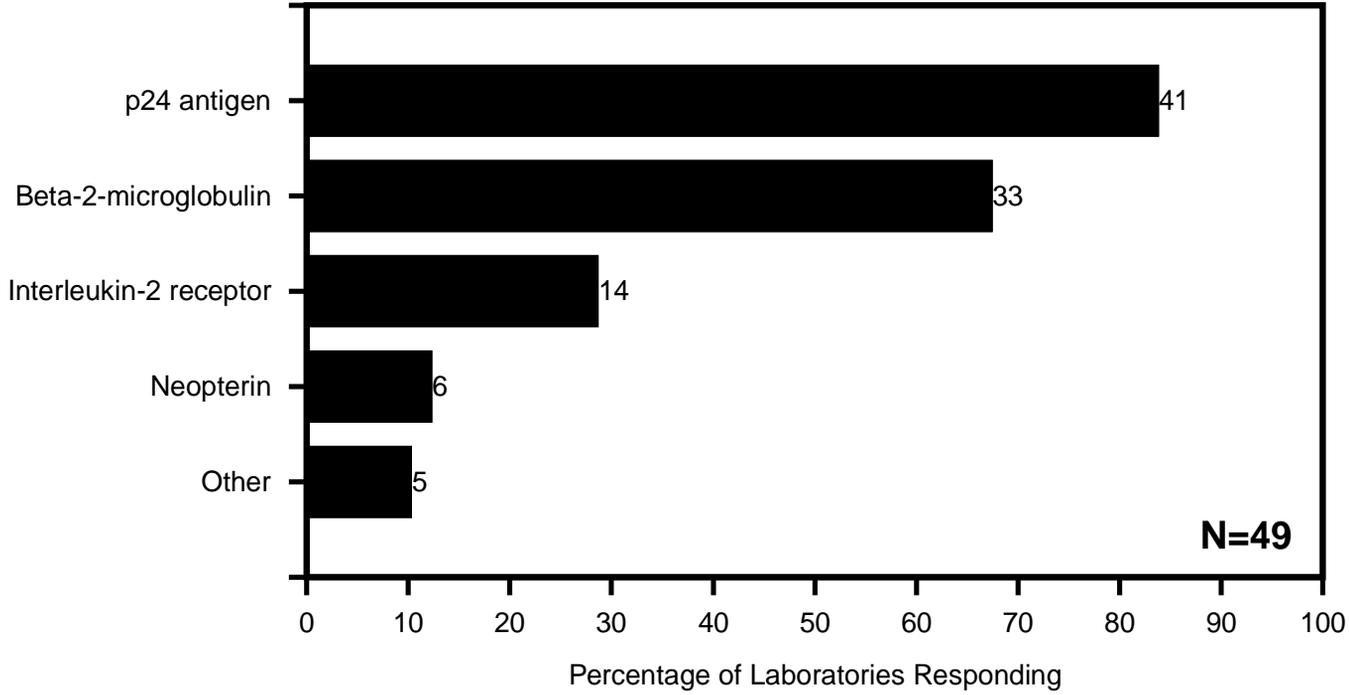
N=275

42.(a) In the last year, has your laboratory performed surrogate-marker tests for TLI in HIV-infected patients?



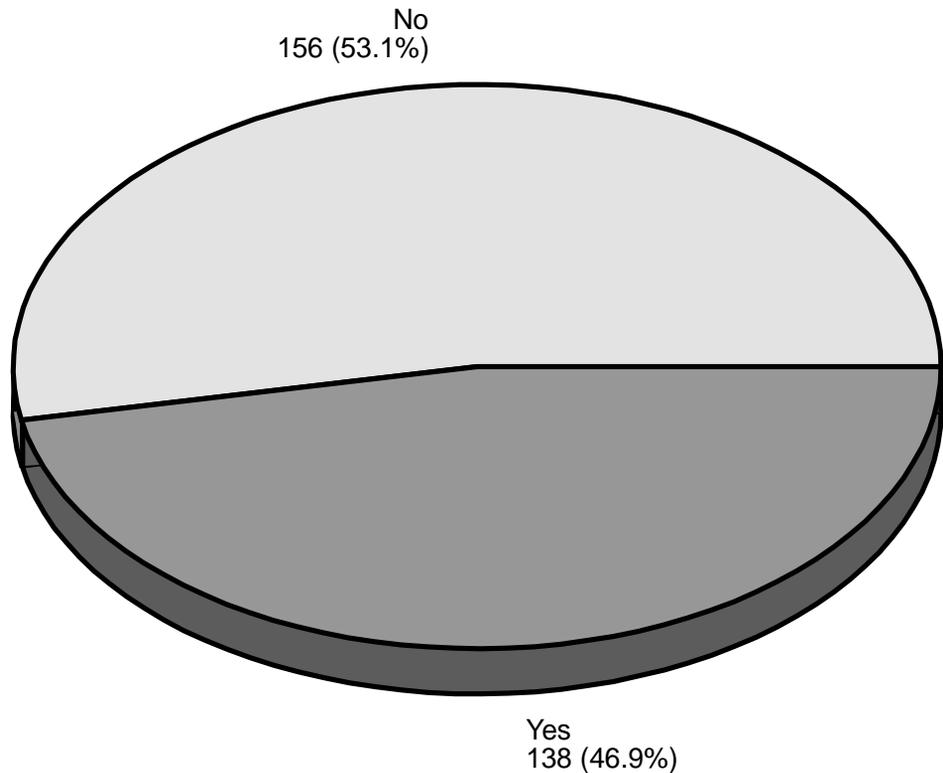
N=294

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



N=49

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



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

