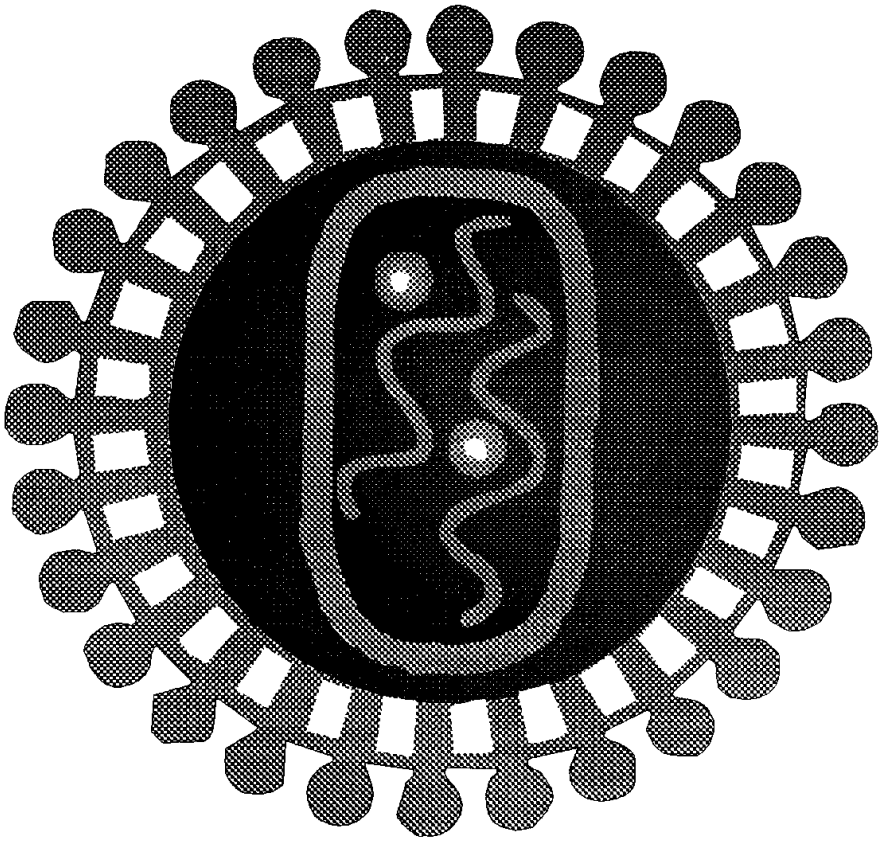
Results of the 1999 Retroviral Testing Survey Questionnaire Sent to Laboratories Participating in the Model Performance Evaluation Program



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

CENTERS FOR DISEASE CONTROL AND PREVENTION

This report provides the results of a **1999 Retroviral Laboratory Questionnaire Survey** mailed to laboratories participating in the Model Performance Evaluation Program, Centers for Disease Control and Prevention (CDC). The purpose of this retroviral survey is to collect information about the basic characteristics and testing practices of laboratories that test for human immunodeficiency virus type 1 (HIV-1) antibody, HIV-1 ribonucleic acid, HIV-1 p24 antigen, and human T-lymphotropic virus types I and II (HTLV-I/II) antibody.

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Introductory Comments on the Model Performance Evaluation Program 1999 Retroviral Questionnaire Survey Results

The Model Performance Evaluation Program (MPEP) retroviral questionnaire survey was mailed March 15, 1999, to 989 laboratories of which 804 (81%) responded. Of these 989 laboratories receiving the questionnaire, 825 were laboratories located in the United States (US) or US territories and 701 (85%) responded. The remaining 164 laboratories were located outside the US and 103 (63%) returned completed surveys. Aggregate data are presented in the following graphs and tables. This questionnaire survey, unlike previous MPEP retroviral surveys, contained questions specifically focused on testing for HIV-1 RNA (questions 25 - 33) and HIV-1 p24 antigen (questions 34 - 42). Additionally, responses regarding turn around time for testing (questions 22, 30, 39 and 51) and approximate fee charged for testing (questions 23, 32, 41 and 52) have been added to this survey.

The "N =" and numbers appearing on each graph or table are the total number of laboratories responding to specific questions. For questions permitting multiple responses, the total number of responses may exceed the number of laboratories reporting.

On pages 2 and 3, the number of laboratories enrolled in the MPEP by country, including the United States and US Territories, reflects the enrollment as of June 7, 1999 and does not necessarily reflect the MPEP enrollment at the time this survey was mailed.

All parts of questions 5 and 6 were designed to reflect current regulatory requirements related to the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as published in Code of Federal Regulations, Title 42, Part 493. These questions address the amendments related to the education and certification requirements of the laboratory director and supervisor. Questions 19, 27, 36 and 48 were designed to reflect the frequency with which external quality control samples are used and are also related to CLIA-88 regulations.

For questions 14a, 14b, and 43 responses reflecting routine testing combinations associated with algorithms are reported in a table format. Although many laboratories described common algorithms, many laboratories continue to have unique testing combinations for detecting HIV and HTLV antibody. These various unique testing combinations are grouped as "Other Algorithms" in these tables and represent 23.4%, 34.9% and 19.2% of the total responses to questions 14a, 14b, and 43, respectively.

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In questions 15, 34 and 44 the first column reflects a range of years (or employees) while the remaining columns reflect the number of laboratories performing specific tests for the range of years, or with the number of employees, indicated in the first column. Similarly, in questions 21, 29, 38 and 50, the first column reflects ranges of the number of tests performed while the remaining columns reflect the number of laboratories reporting tests performed and reactive tests within each range for each test type.

Number of MPEP Laboratories by Country

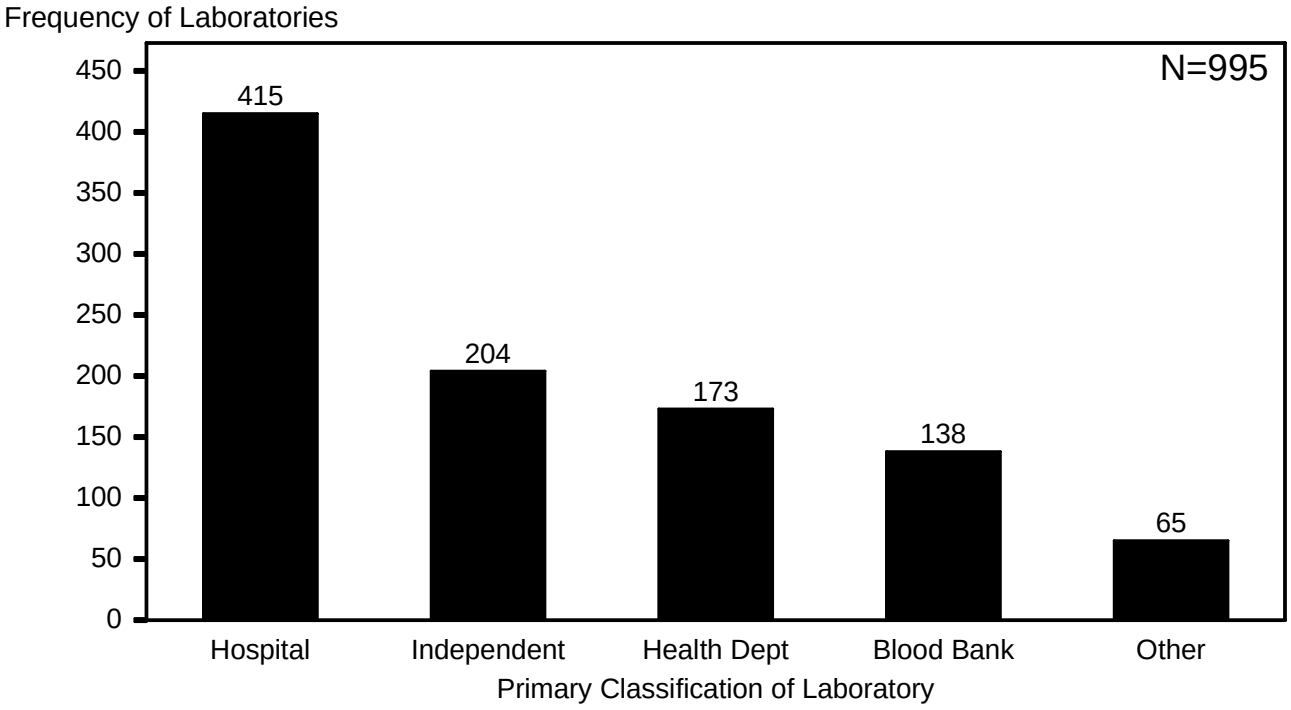
N = 995

Country	Number of Laboratories	Country	Number of Laboratories	Country	Number of Laboratories
Argentina	2	Honduras	2	Saudi Arabia	3
Australia	6	Hong Kong	2	Scotland	1
Austria	3	Hungary	1	Slovakia	1
Bahamas	1	India	4	Slovenia (Yugoslavia)	1
Barbados	1	Ireland	1	South Africa	3
Belgium	3	Israel	6	South Korea	3
Bolivia	1	Italy	2	Spain	3
Brazil	3	Jamaica	1	Sri Lanka	1
Burkina Faso	1	Japan	2	St. Kitts/Nevis	1
Canada	23	Kenya	1	Suriname	2
Central African Republic	1	Malaysia	2	Switzerland	2
Chile	1	Mali, West Africa	1	Taiwan	2
Colombia	1	Malta	1	Tanzania	2
Costa Rica	2	Mexico	1	Thailand	7
Cote d'Ivoire	3	Morocco	1	Trinidad	2
Croatia	2	Myanmar (Burma)	1	Turkey	1
Curacao, Netherlands Antilles	1	New Zealand	1	US Territory	27
Denmark	3	Nicaragua	1	Uganda, East Africa	2
Dominican Republic	3	Nigeria	1	Ukraine	1
Ecuador	1	Norway	1	United Arab Emirates	3
Egypt	1	Panama	1	United States	799
El Salvador	1	Paraguay	1	Uruguay	1
England	4	Peru	2	Venezuela	3
Ethiopia	2	Philippines	2	Vietnam	1
France	1	Portugal	1	Western Samoa	1
Germany	4	Republic of Singapore	1	Zambia	1
Ghana	2	Romania	1		
Guatemala	1	Russia	1		

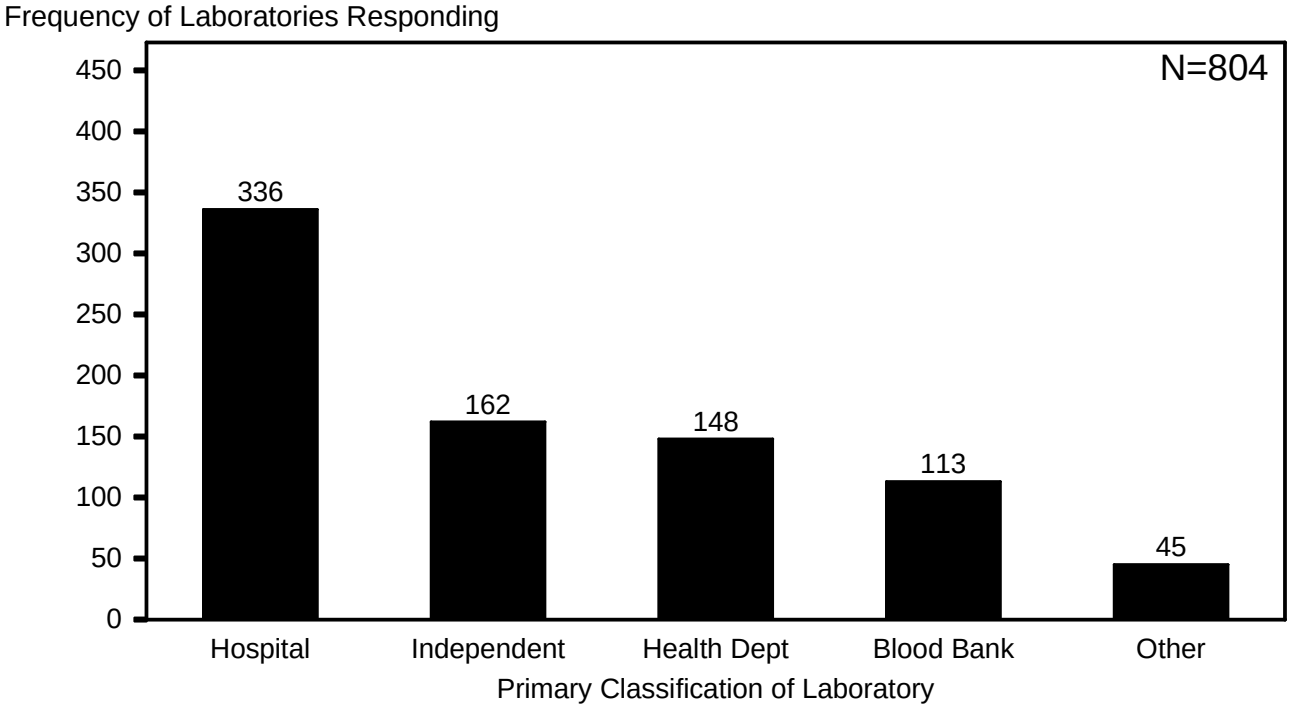
Number of MPEP Retroviral Laboratories in the United States and Territories

Primary Classification of MPEP Laboratories in Regard to Retroviral Testing

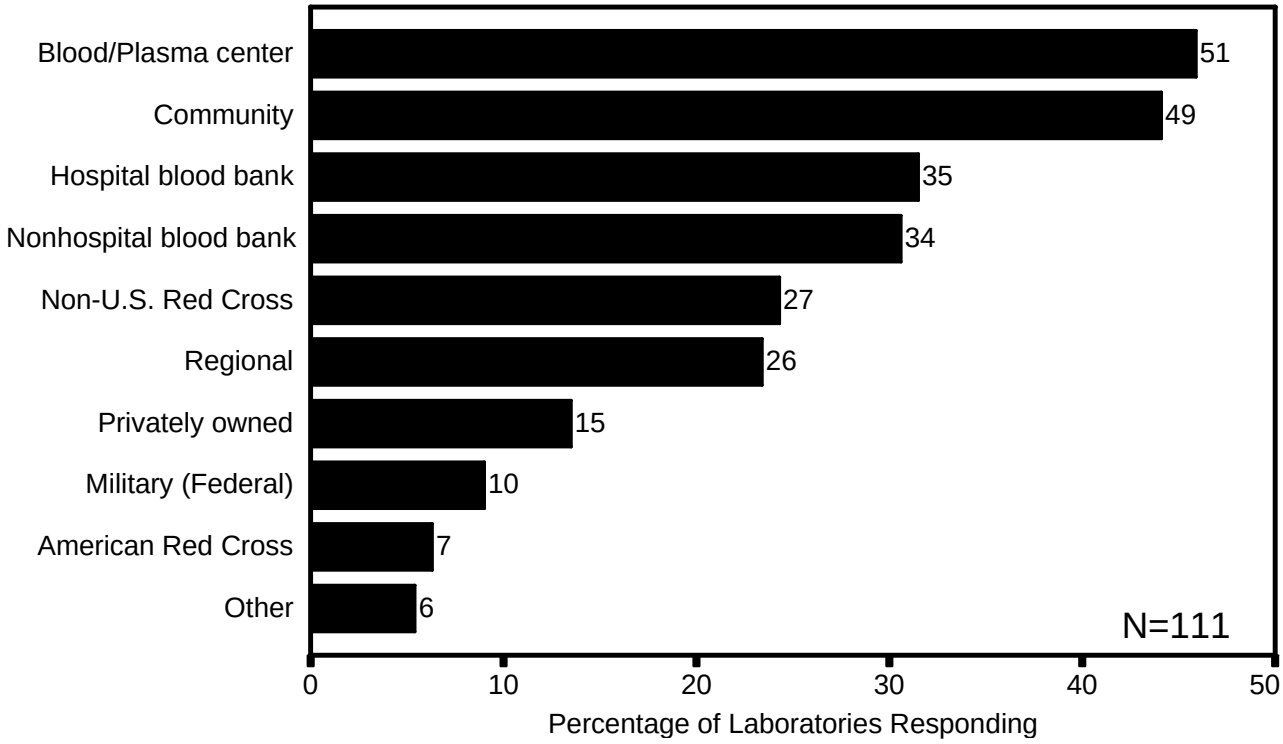
Total Number of Laboratories Enrolled in the Retroviral Program



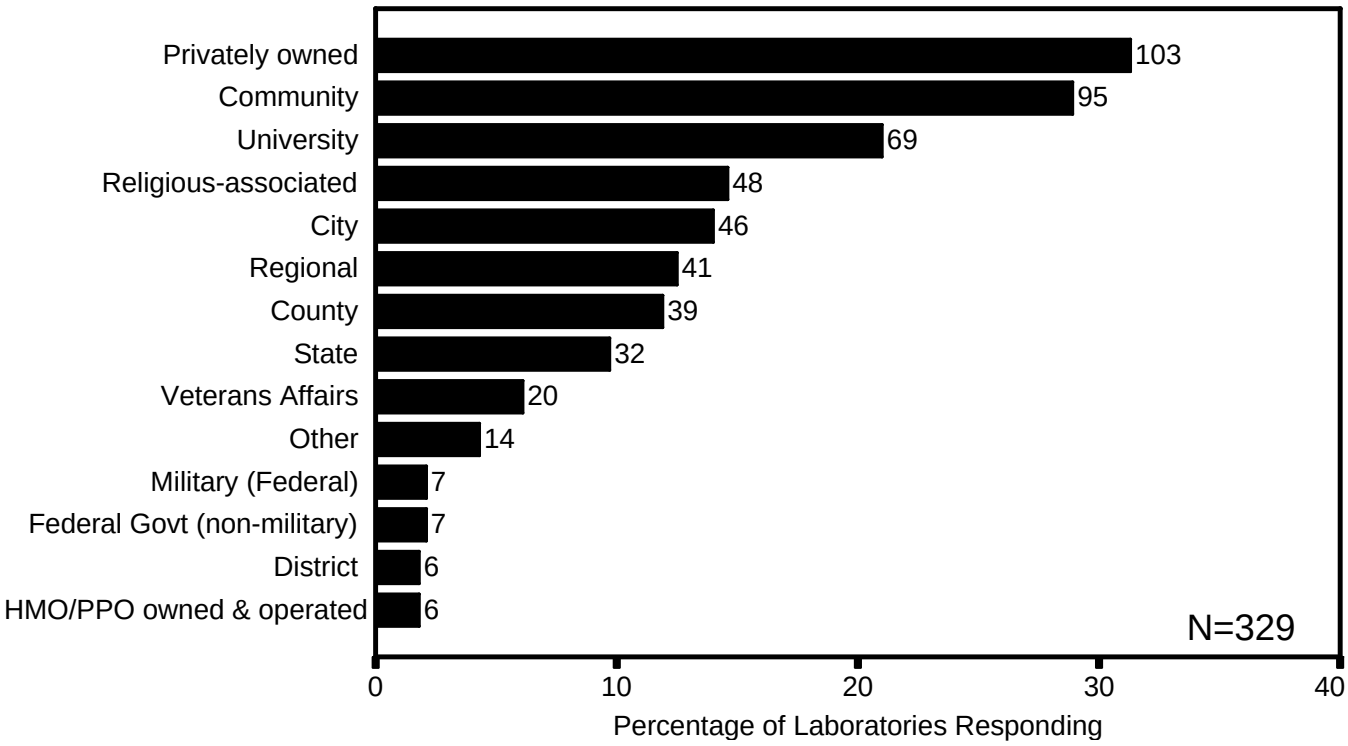
Classification of Laboratories Responding to Questionnaire Survey



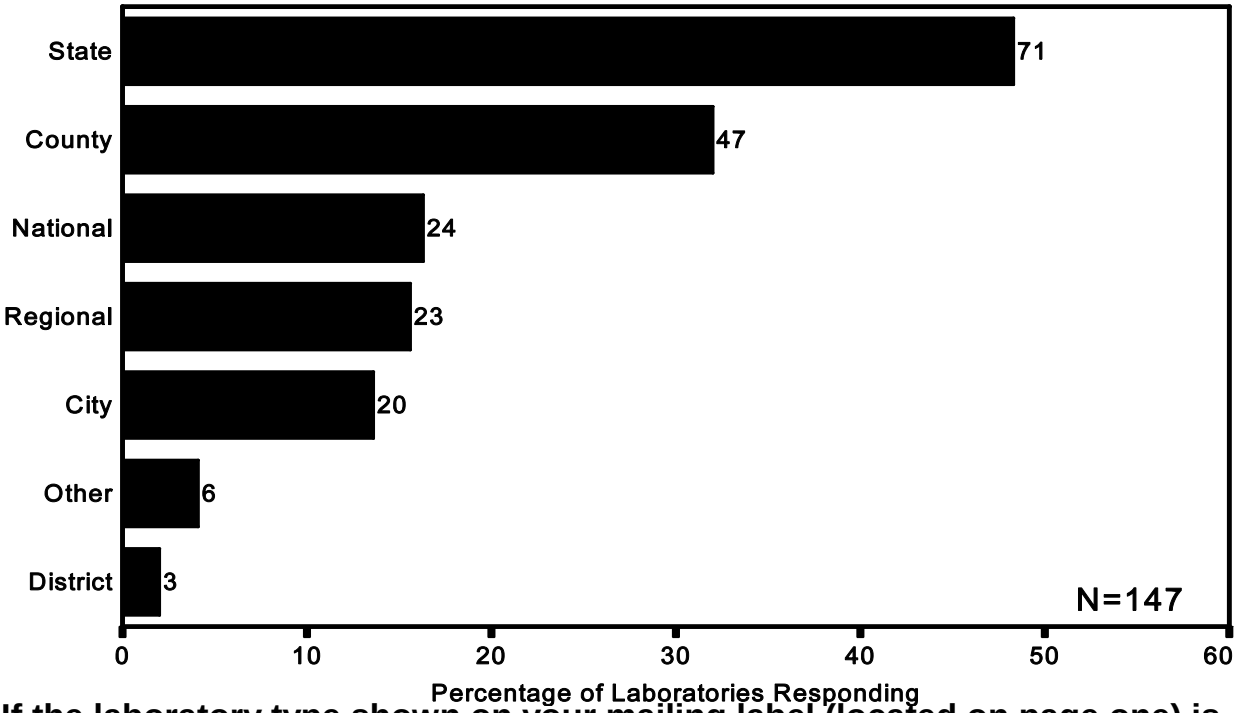
3.(a) If the laboratory type shown on your mailing label (located on page one) is BLOOD BANK, please <u>further describe</u> your retroviral testing laboratory (Check <u>all</u> that apply within your Blood Bank laboratory classification.):



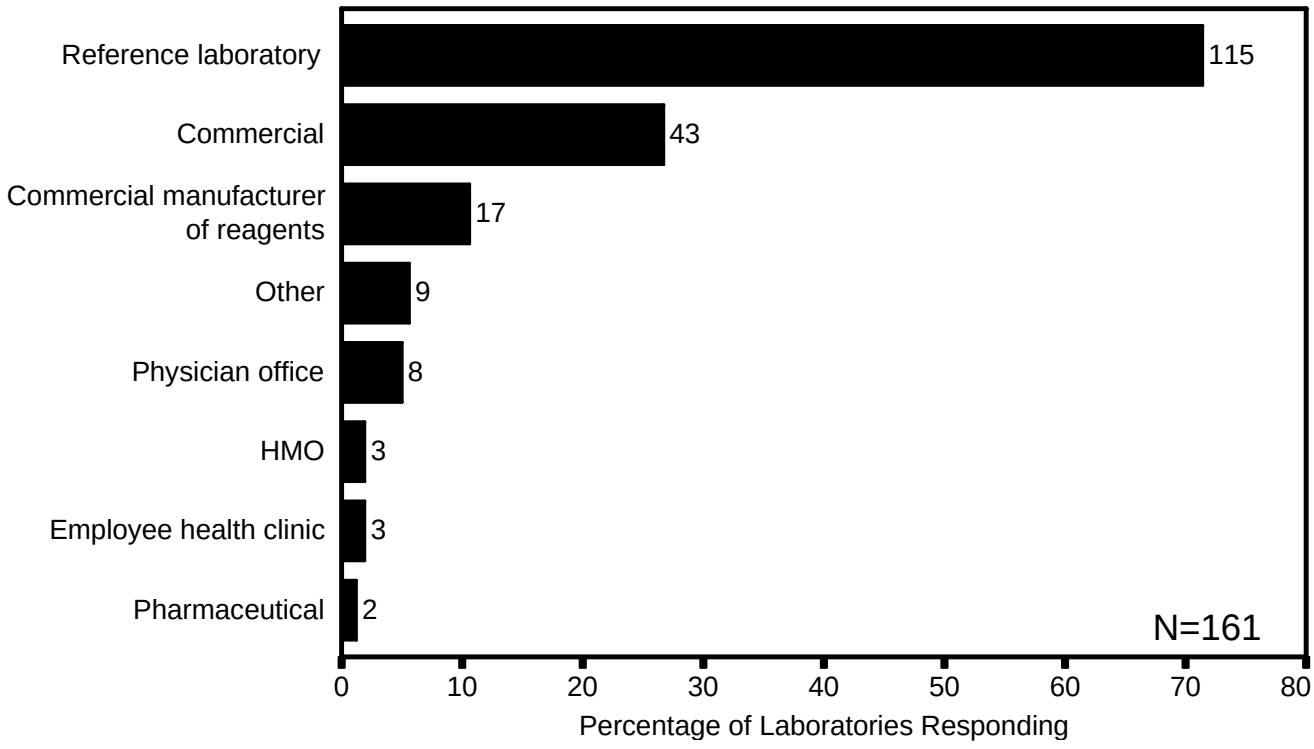
3.(b) If the laboratory type shown on your mailing label (located on page one) is HOSPITAL, please <u>further describe</u> your retroviral testing laboratory (Check <u>all</u> that apply within your Hospital laboratory classification.):



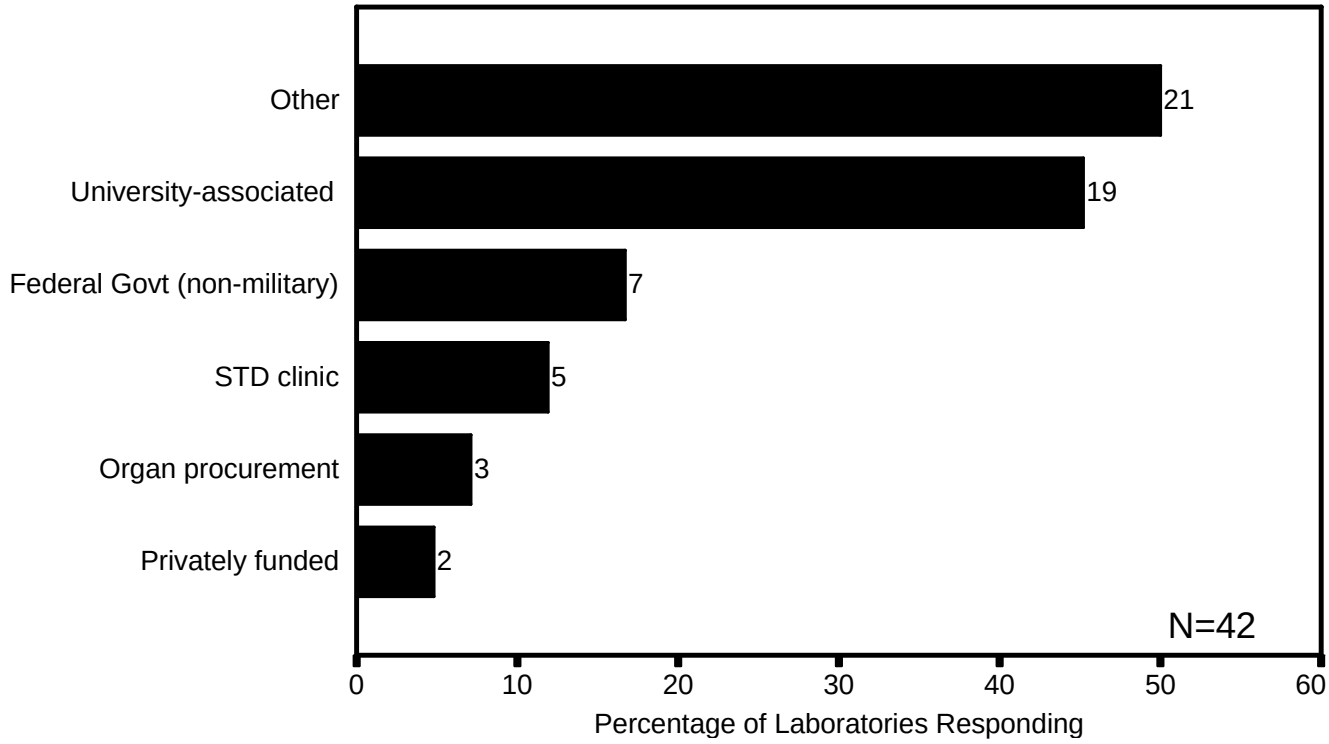
3.(c) If the laboratory type shown on your mailing label (located on page one) is HEALTH DEPARTMENT (or Government Health System as indicated in some countries outside the United States), please <u>further describe</u> your retroviral testing laboratory (Check <u>all</u> that apply within your Health Department laboratory classification.):



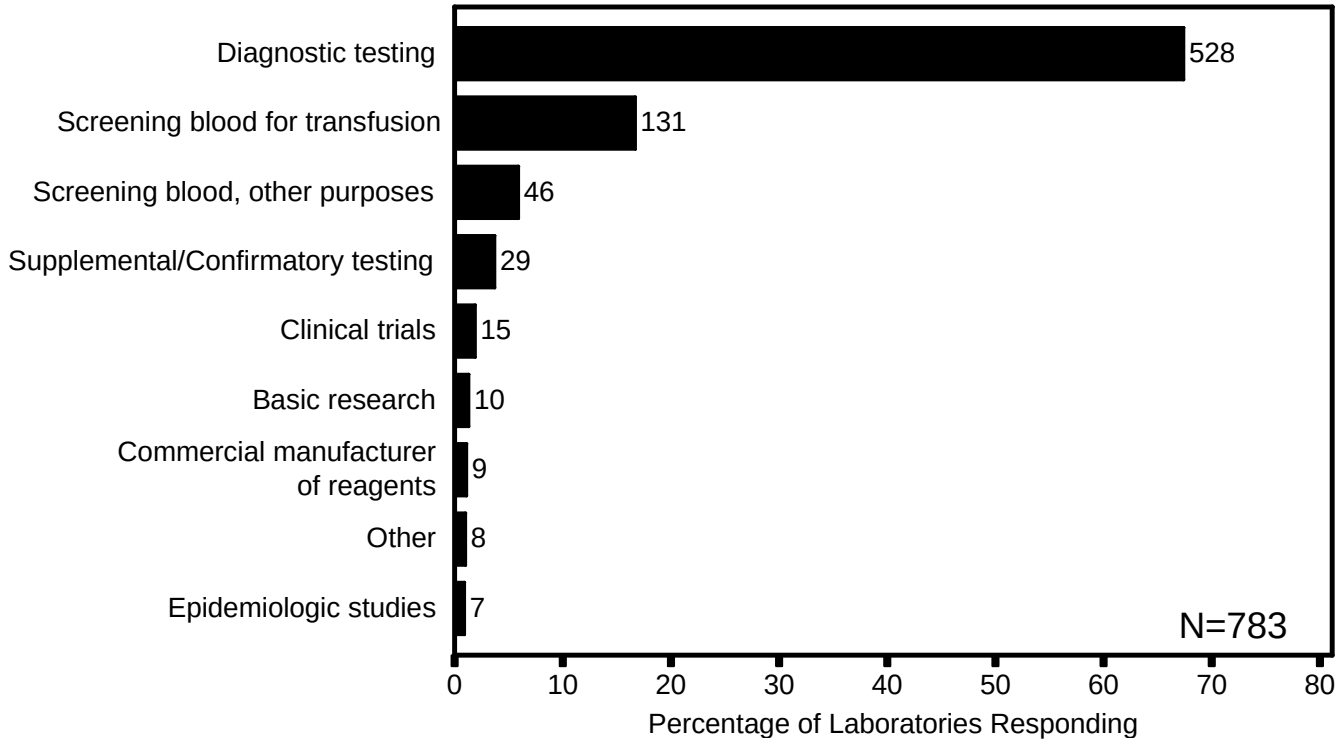
3.(d) If the laboratory type shown on your mailing label (located on page one) is INDEPENDENT, please <u>further describe</u> your retroviral testing laboratory (Check <u>all</u> that apply within your Independent laboratory classification.):



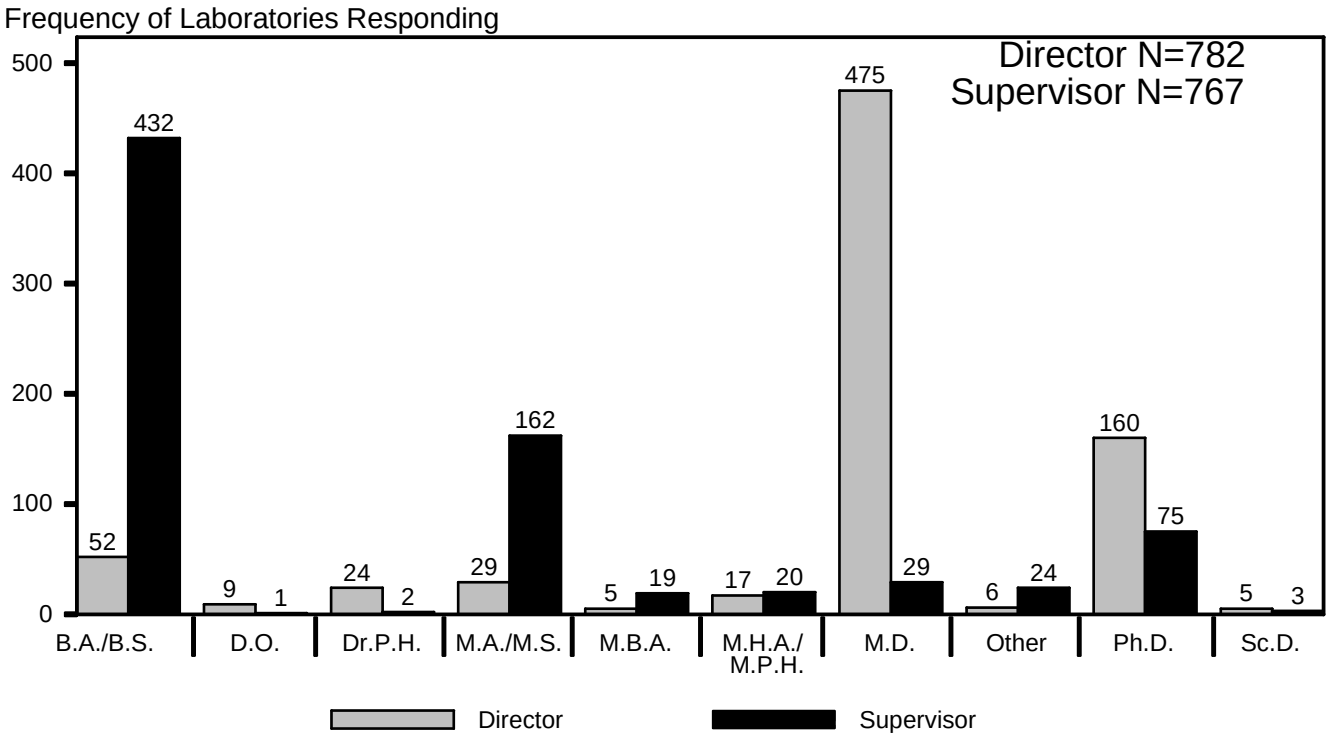
3.(e) If the laboratory type shown on your mailing label (located on page one) is OTHER, please <u>further describe</u> your retroviral testing laboratory (Check <u>all</u> that apply within your Other laboratory classification.):



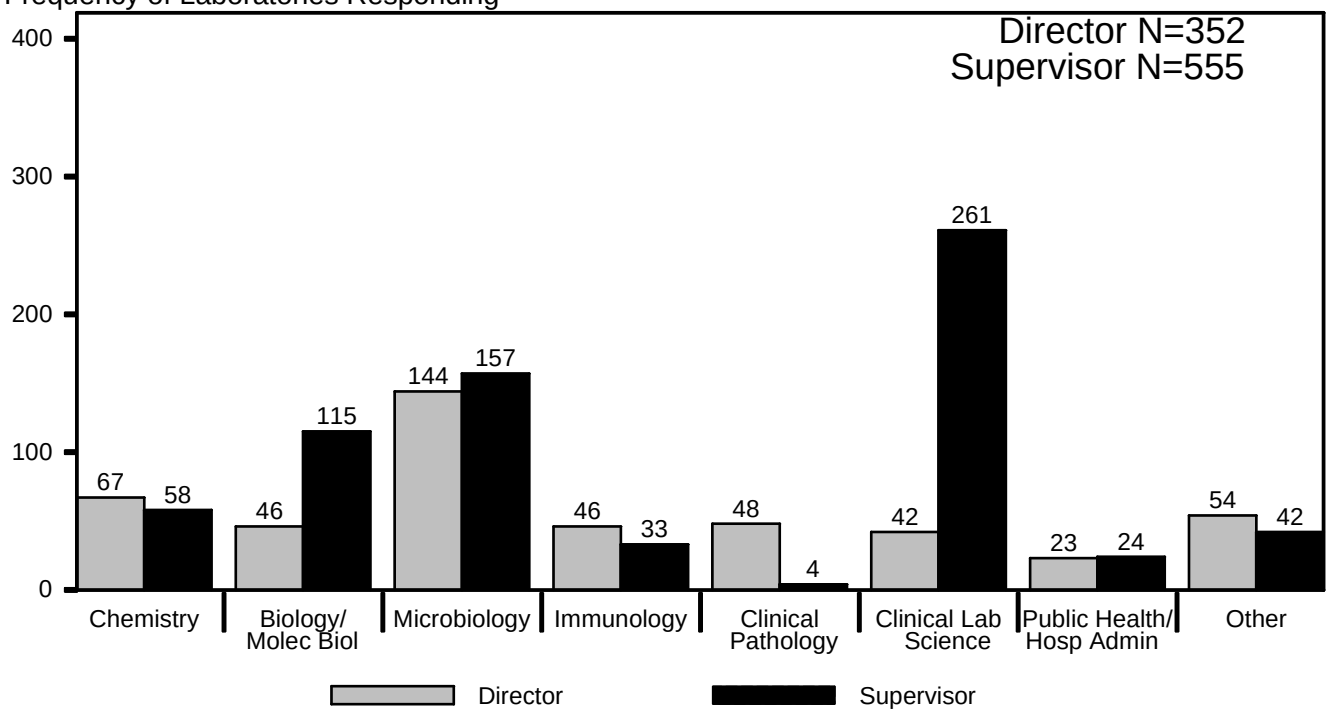
4. What is the *<u>primary purpose</u>*** of your retroviral testing operation? (Choose only <u>one</u>.)**



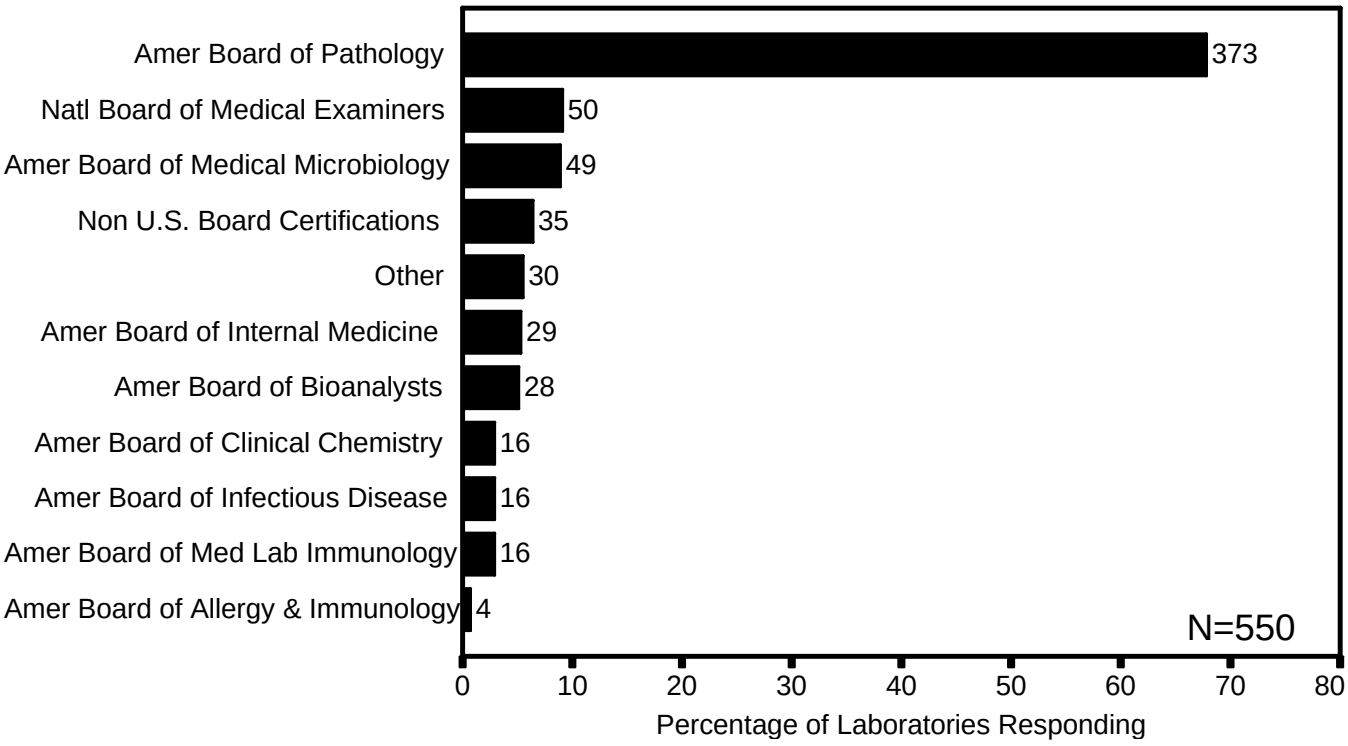
5.(a) Please choose the *highest academic degree* that has been awarded to your *Laboratory Director* and *Laboratory Supervisor* (Choose only one degree for each person.) Note: MT(ASCP) is not an academic degree.



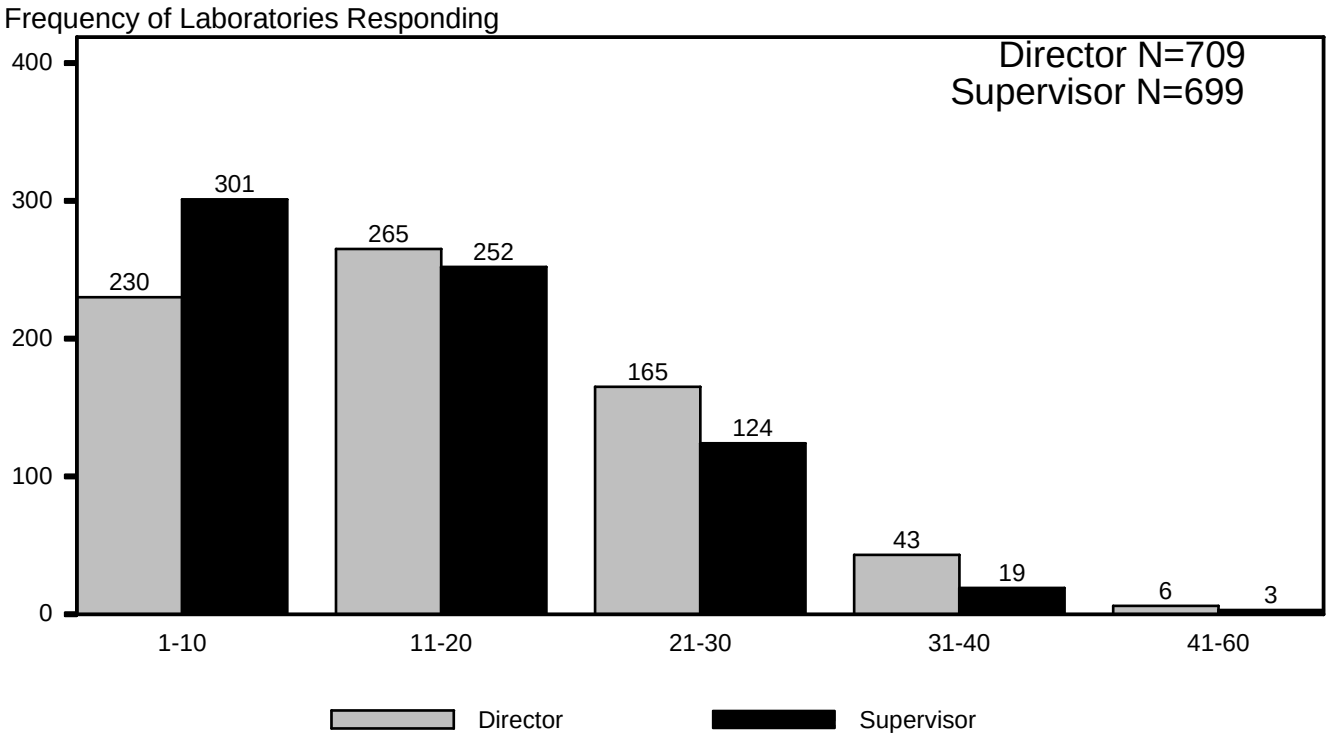
5.(b) If your Laboratory Director or Laboratory Supervisor has a degree other than M.D. or D.O., please indicate the academic discipline in which the degree was awarded (Check all that apply.):



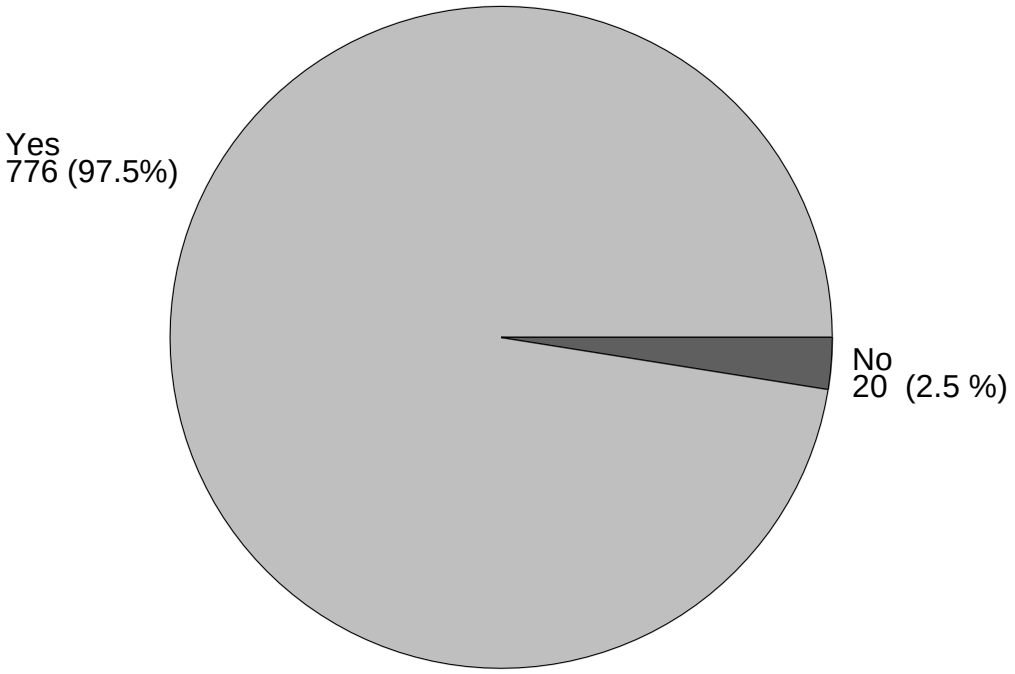
5.(c) What board certifications have been awarded to your Laboratory Director? (Check all that apply.):



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

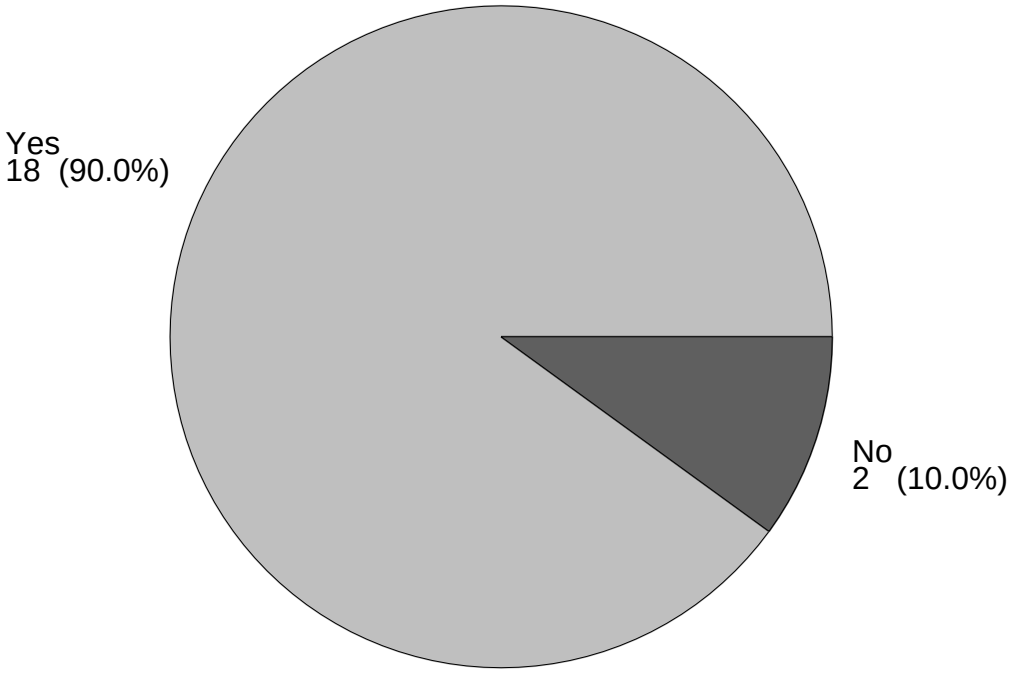


5.(e) Is your <u>Laboratory Supervisor</u> available to provide supervision on-site?



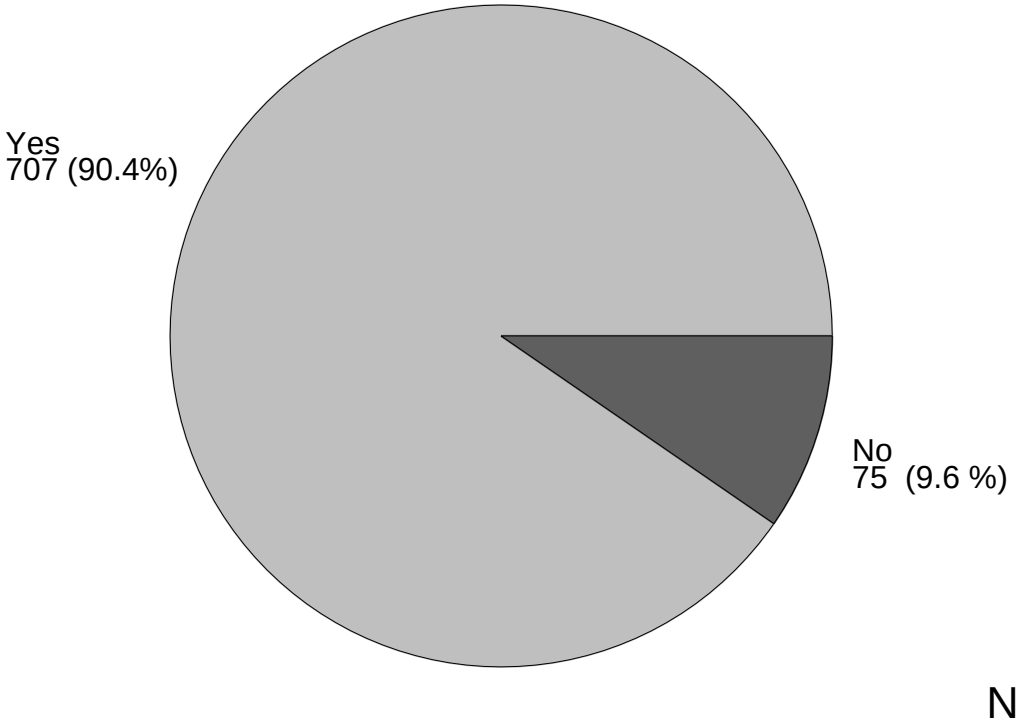
N=796

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

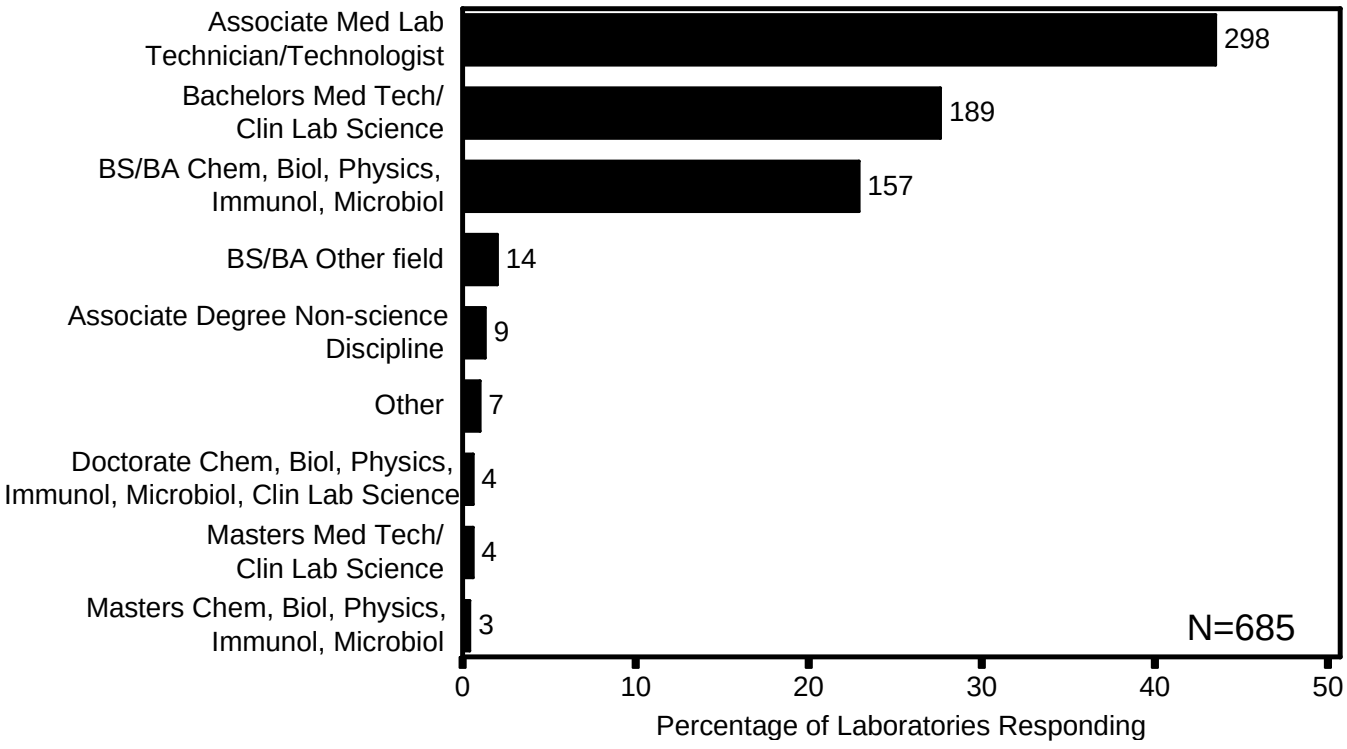


N=20

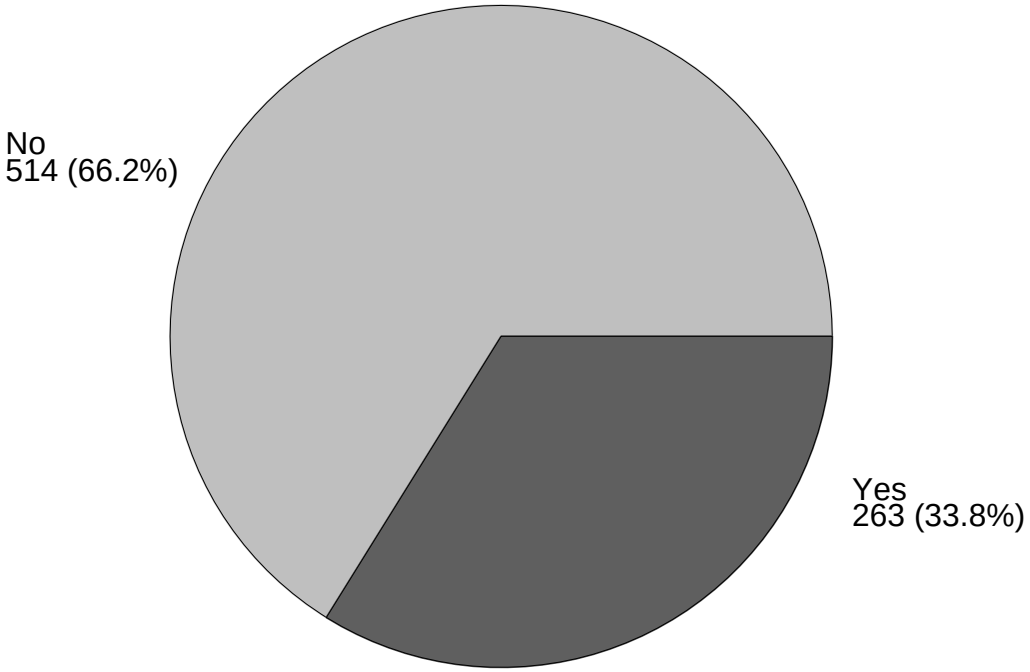
6.(a) Does your laboratory require that your *retroviral testing personnel* have a *minimum educational degree*?



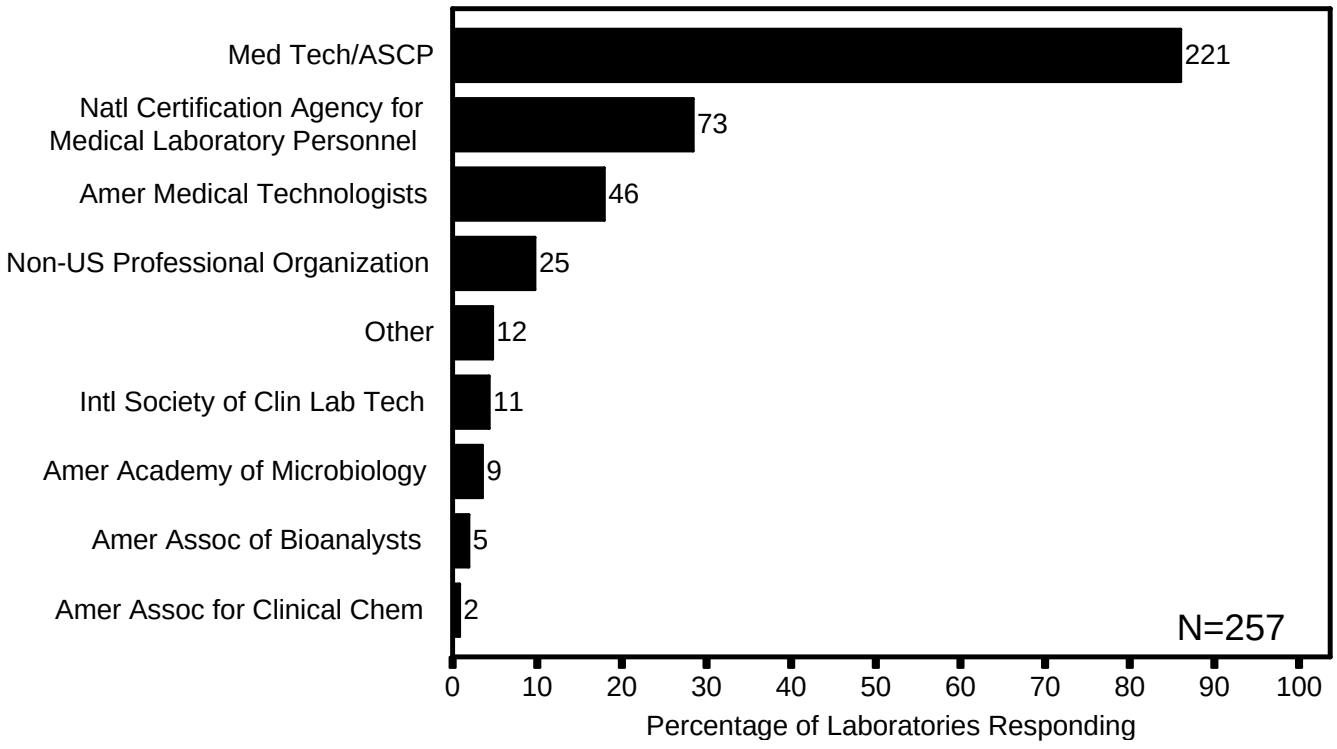
6.(b) If yes from question 6(a), what minimum educational degree is required of personnel performing retroviral testing in your laboratory? (Choose only one.)



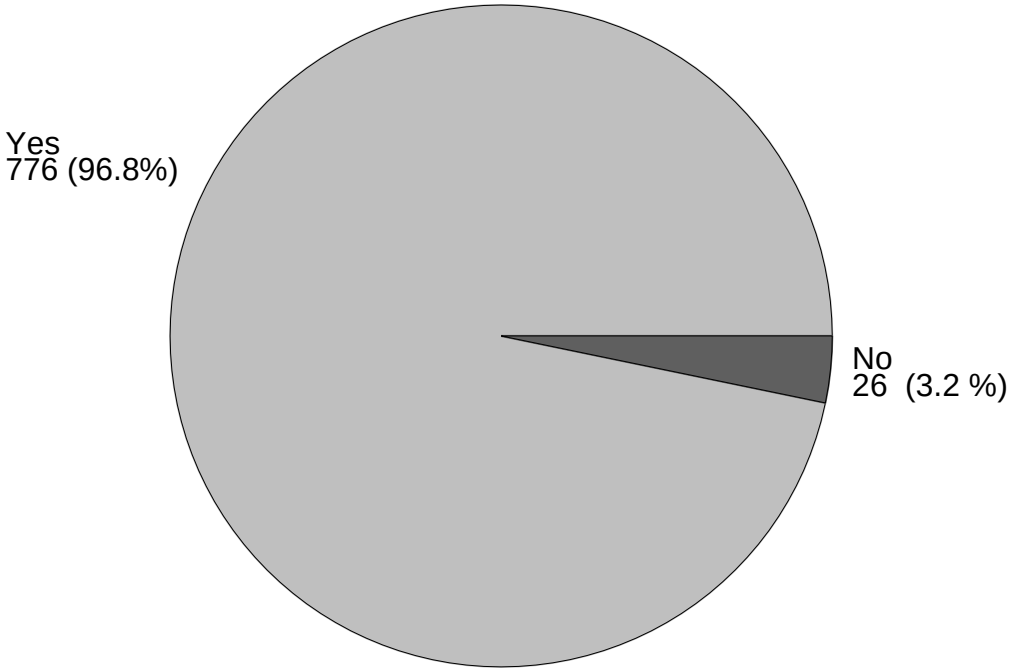
6.(c) Does your laboratory require that your retroviral testing personnel have certification by a professional organization? (Do not include certification or licensing by city, state, or country.)



6.(d) If Yes, please check the *professional organizations* that have awarded the required *certification* to your *retroviral testing personnel* (Check all that apply.):

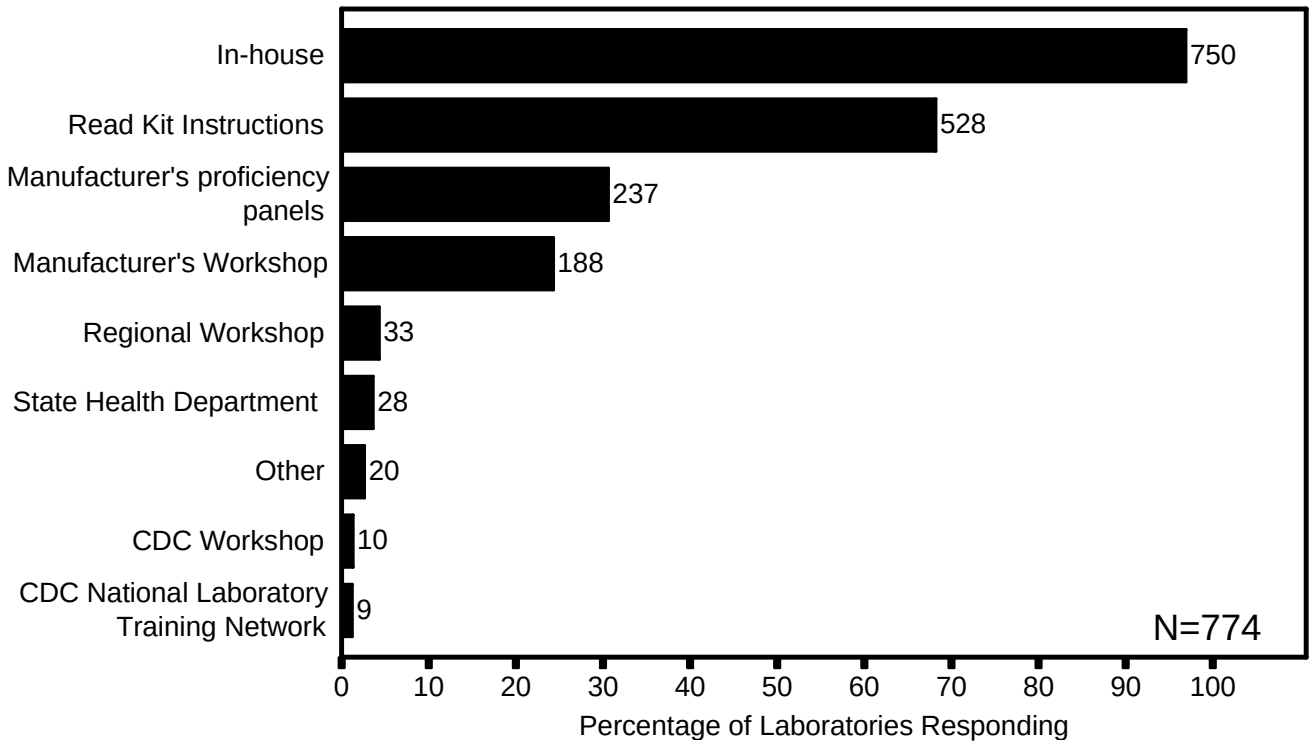


7.(a) Does your laboratory require personnel to have retroviral-specific training in testing before they are considered qualified to perform tests?

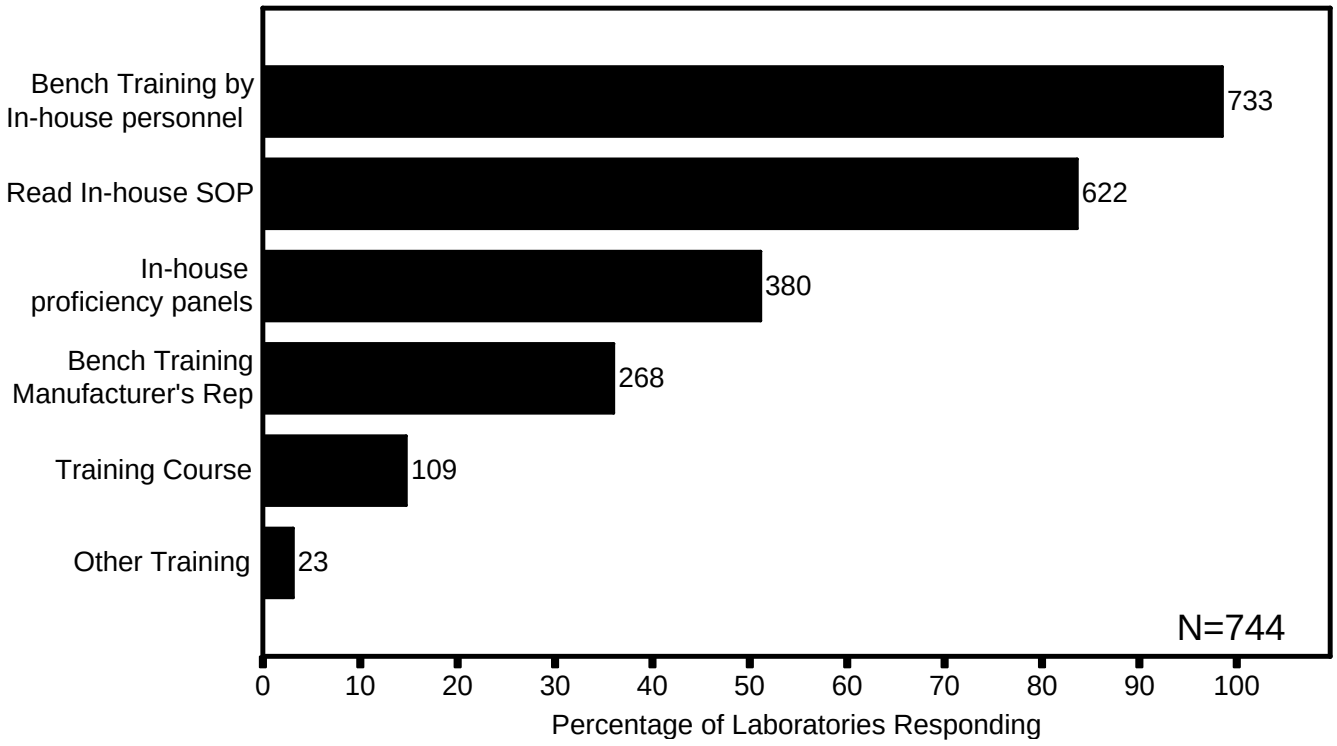


N=802

7.(b) If Yes, what training must your personnel complete before they are considered qualified to perform retroviral testing? (Check <u>all</u> that apply.):



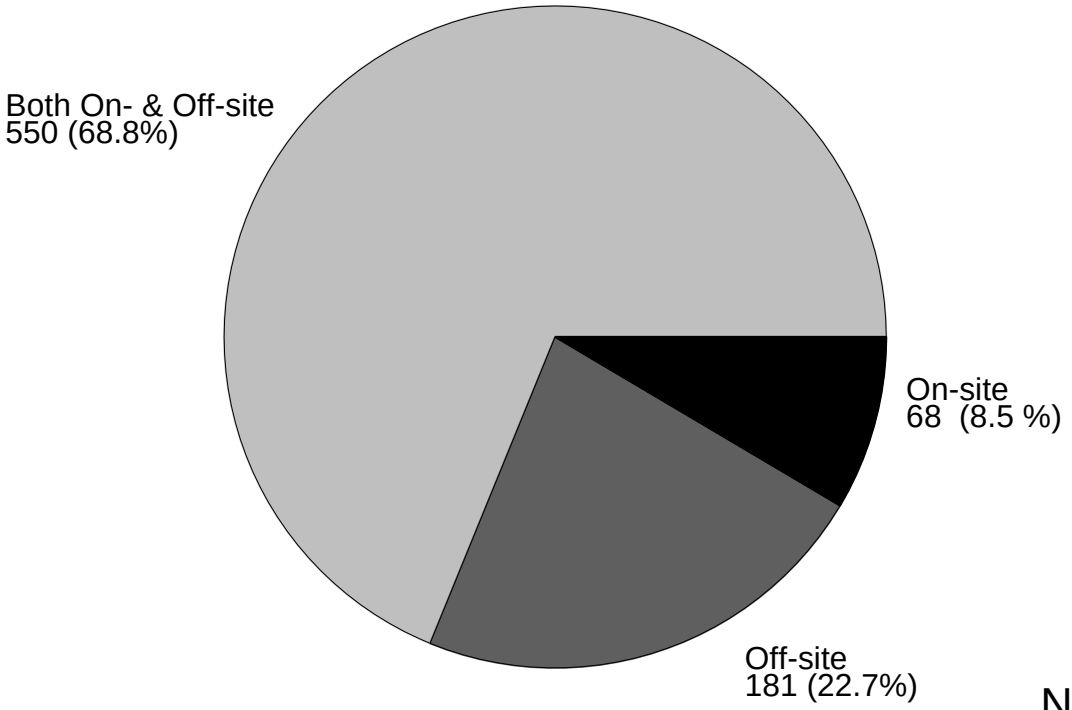
7.(c) If you selected "In-house" from question 7(b), please indicate the type of in-house training (Check <u>all</u> that apply.):



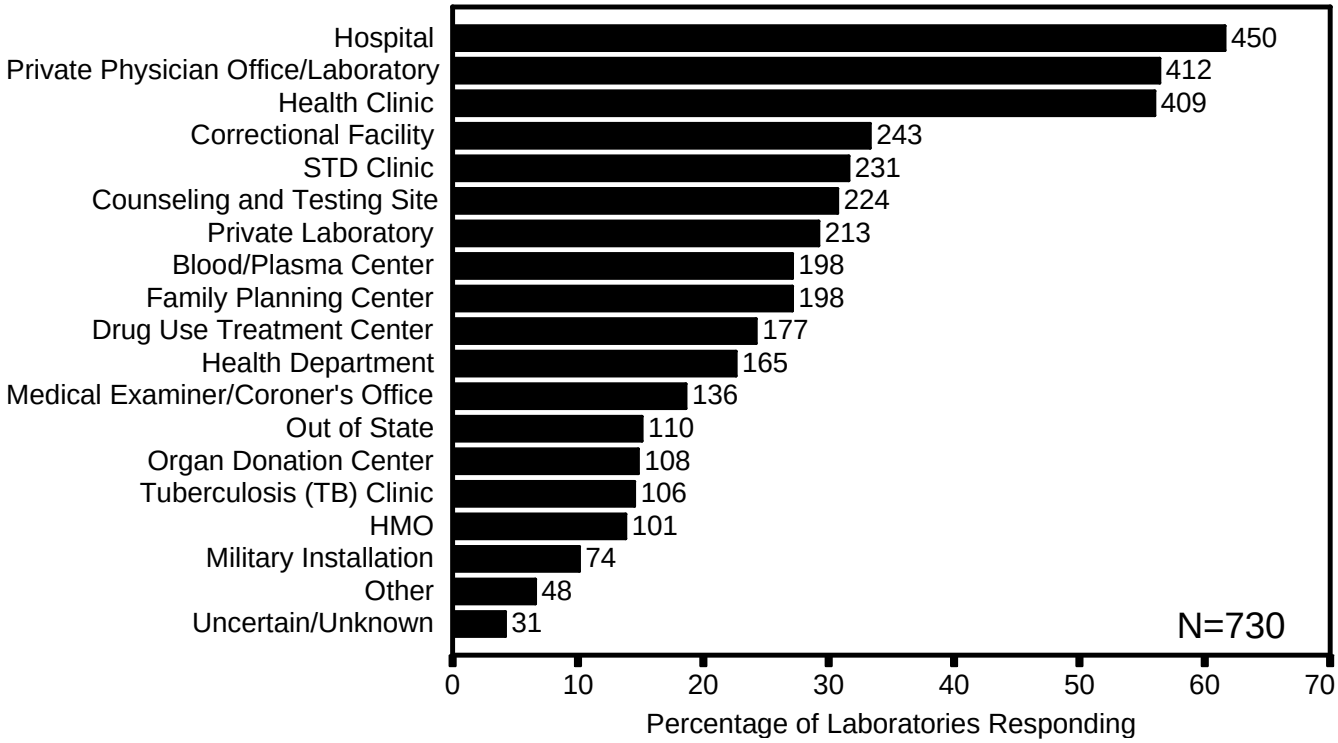
8. If written instructions are provided to collection site personnel for collecting, labeling, and transporting retroviral specimens, who provides these instructions? (Check <u>all</u> that apply.)

Type of Instruction	Instructions NOT Provided	Testing Laboratory	Associated Institution	Person Ordering Test	Other	N=
Collecting	20 (2.6%)	673 (88.8%)	82 (10.8%)	28 (3.7%)	27 (3.6%)	758
Labeling	19 (2.5%)	674 (89.0%)	83 (11.0%)	25 (3.3%)	28 (3.7%)	757
Transporting	24 (3.2%)	672 (89.2%)	78 (10.4%)	25 (3.3%)	27 (3.6%)	753

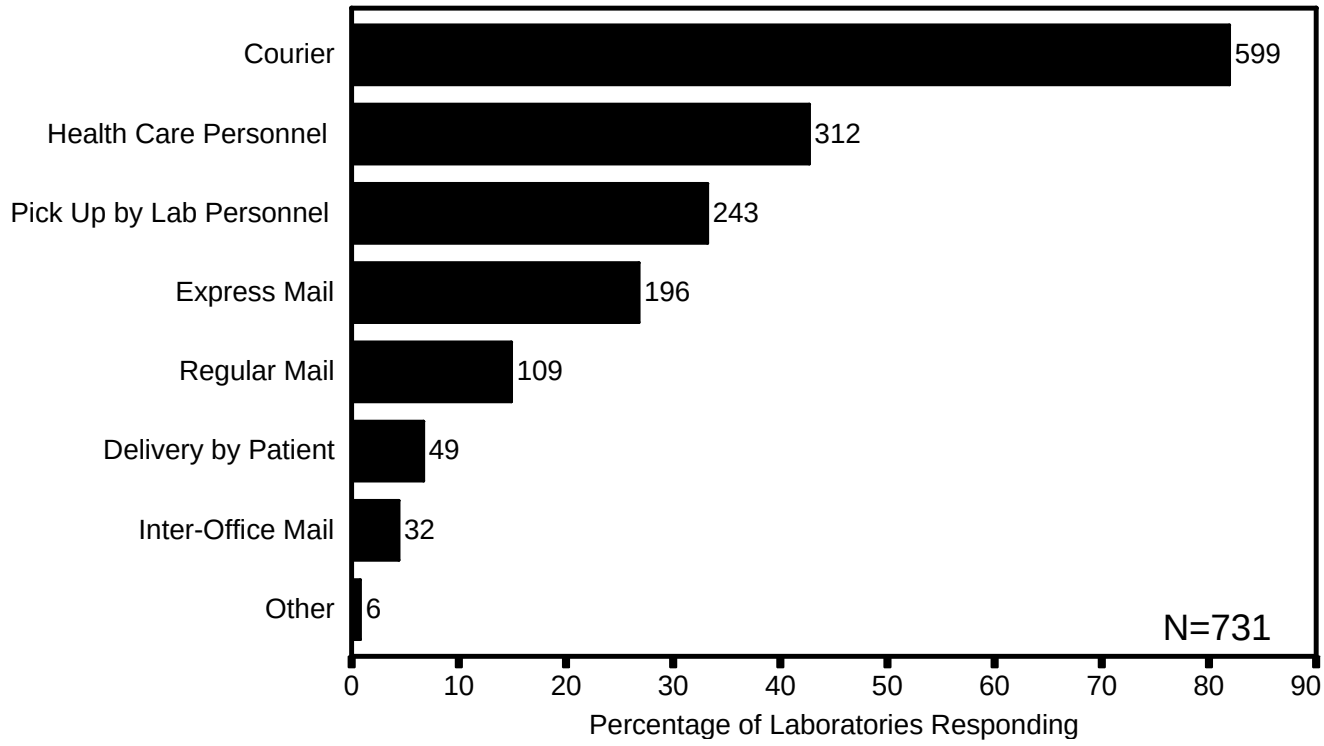
9.(a) Where are the specimens collected for retroviral testing performed in your laboratory? Please include <u>all</u> specimens tested (e.g., blood donor, diagnostic, serosurvey, neonatal dried blood spots, child-bearing women surveys). (Choose only <u>one</u>.)



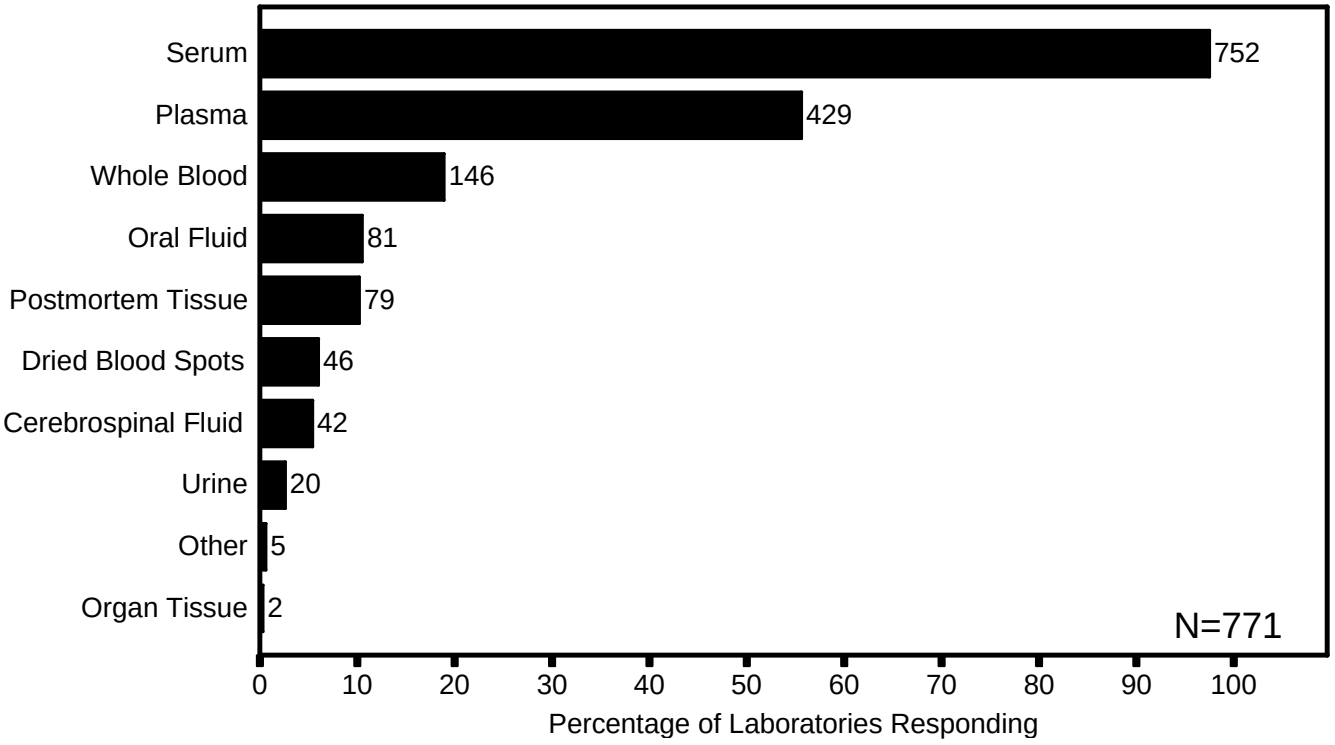
9.(b) If you test specimens <u>collected off-site</u>, please indicate where they are collected (Check <u>all</u> that apply.):



9.(c) How are the specimens <u>collected off-site</u> delivered to your laboratory? (Check <u>all</u> that apply.):



10. What types of specimens does your laboratory test for retroviral *<u>antibody</u>*****? Please include <u>all</u> specimens tested (e.g., blood donor, diagnostic, serosurvey, neonatal dried blood spots, child-bearing women surveys). (Check <u>all</u> that apply.):**



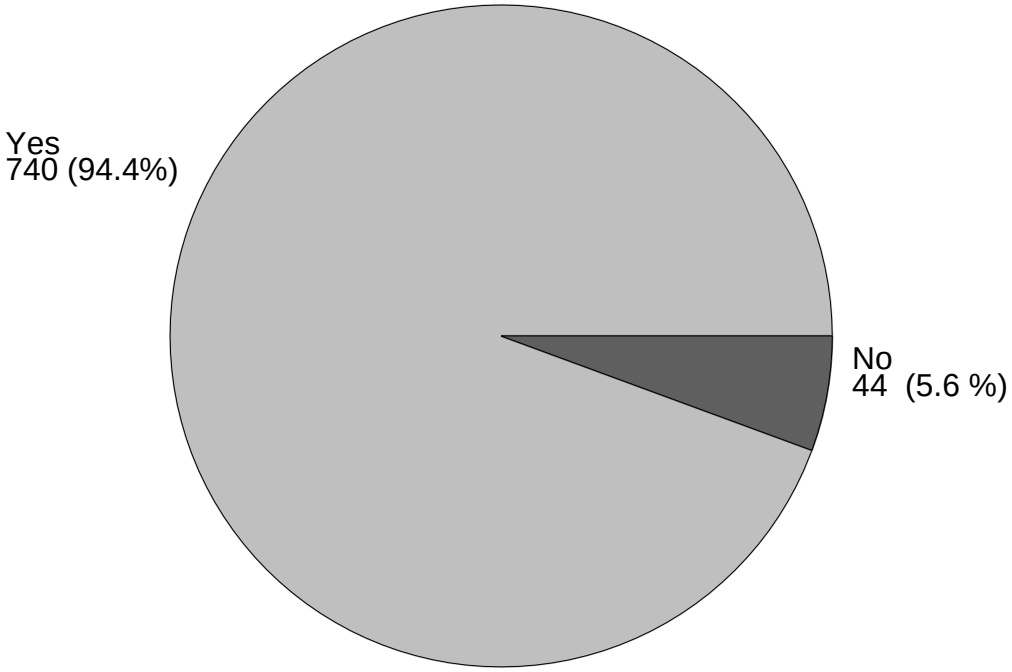
11. Please indicate which of the following procedures your laboratory routinely performs on a specimen before performing retroviral tests (Check <u>all</u> that apply.):

N=780

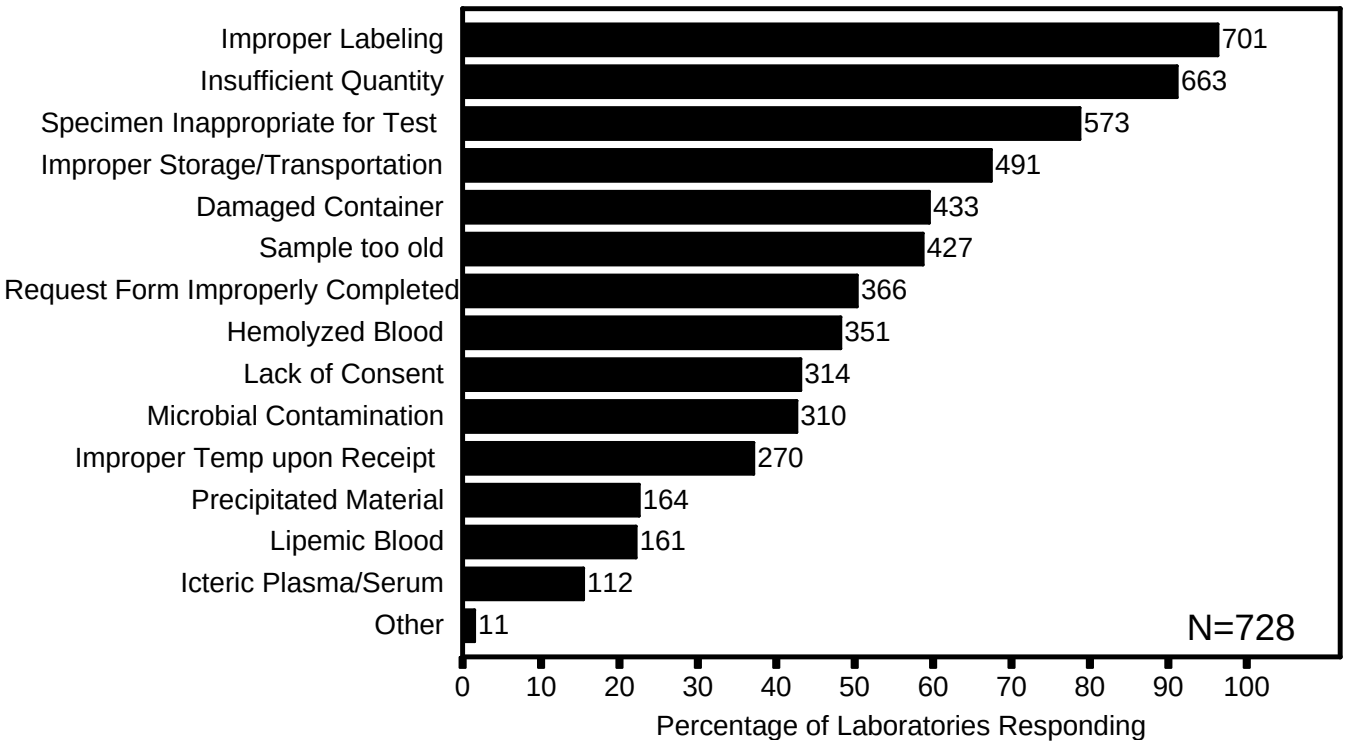
	Frequency of Laboratories Responding*		
Type of Specimen	Heat Inactivation	Clarification by Centrifugation or Filter	No Pretreatment
Whole Blood	4	147	68
Plasma	10	168	310
Serum	15	234	491
Oral Fluid	0	43	45
Urine	0	8	27
Postmortem	0	41	37
Dried Blood Spots	1	4	38
Organ Tissue	0	4	15
Cerebrospinal Fluid	0	14	41
Other	0	2	8

* The numbers in each column represent the frequency of laboratories that indicated the associated type of specimen.

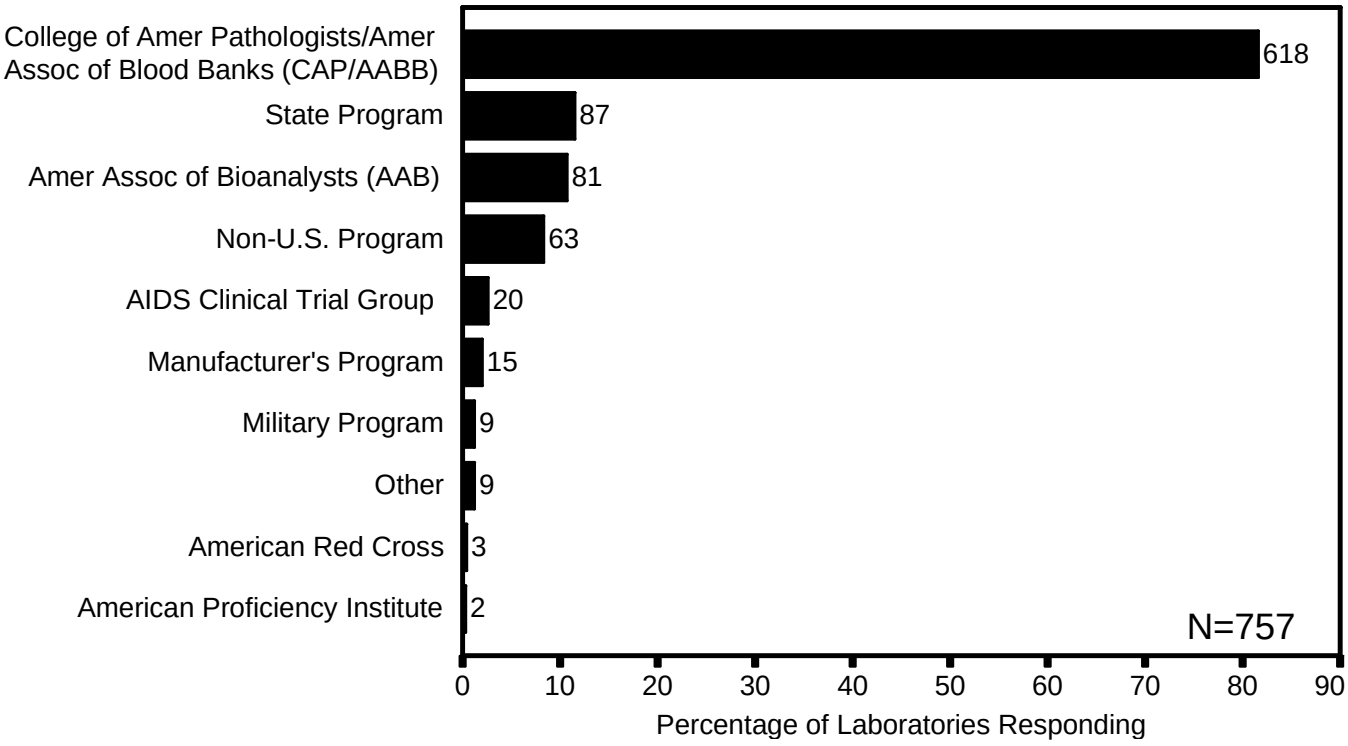
12.(a) Does your laboratory have <u>written</u> pre-test criteria for identifying specimens that are unsatisfactory for retroviral testing?



12.(b) Based upon your written pre-test criteria, please indicate which of the following conditions would exclude a specimen from retroviral testing in your laboratory (Check <u>all</u> that apply.):



13. If your laboratory participates in an <u>external</u> proficiency testing program for retroviral testing, please identify that program. Please <u>exclude</u> the CDC Model Performance Evaluation Program, which is *<u>not</u>*** designed for proficiency testing (Check <u>all</u> that apply.):**



14.(a) Many laboratories perform a series of tests to detect the presence of HIV-1 antibodies. Mark an "x" in the appropriate boxes in the table below to indicate: (1) the type(s) of tests routinely performed in your laboratory, (2) the order in which they are performed (1st step, 2nd step, etc.), (3) whether an EIA is performed singly or in duplicate, and (4) whether the EIA method used is manual or nonmanual:

N=441

	Step 1	Step 2	Step 3	Step 4	Step 5	Number of Laboratories	Percentage of Laboratories
Algorithm*	EIA-S**	EIA-D**	A			116	26.3
	EIA-S	EIA-D	WB			108	24.5
	EIA-S	EIA-D				25	5.7
	EIA-S	EIA-D	WB	A		20	4.5
	EIA-S	A				12	2.7
	EIA-S	EIA-S	WB			9	2.0
	EIA-D	WB				7	1.6
	EIA-S	EIA-D	WB	O		6	1.4
	EIA-S	EIA-S	A			6	1.4
	EIA-D	A				5	1.1
	EIA-S					5	1.1
	EIA-S	EIA-D	WB	O	A	5	1.1
	EIA-S	EIA-D	WB/A			5	1.1
	EIA-S	WB				5	1.1
	EIA-S	EIA-D	IIF	A		4	0.9
Other Algorithms						103	23.4

Labels

Test
EIA-S = HIV-1 Enzyme Immunoassay (EIA) Singly
EIA-D = HIV-1 EIA in duplicate
WB = HIV-1 Western Blot (WB)
IIF = HIV-1 Indirect Immunofluorescence (IIF)
O = test Other than HIV-1 EIA, IIF or WB
A = refer for Additional testing

Footnotes

* A total of 94 unique algorithms were reported
** EIA data in this table includes both manual and non-manual procedures

14.(b) Many laboratories perform a series of tests when performing HIV-1/HIV-2 antibody testing. Mark an "x" in the appropriate boxes in the table below to indicate: (1) the type(s) of tests routinely performed in your laboratory, (2) the order in which they are performed (1st step, 2nd step, etc.), (3) whether an EIA is performed singly or in duplicate, and (4) whether the EIA method used is manual or nonmanual:

N=435

	Step 1	Step 2	Step 3	Step 4	Number of Laboratories	Percentage of Laboratories
Algorithm*	EIA 1/2-S**	EIA 1/2-D**	A		157	36.1
	EIA 1/2-S	EIA 1/2-D			46	10.6
	EIA 1/2-S	EIA 1/2-D	WB-1		36	8.3
	EIA 1/2-S	EIA 1/2-D	WB-1	A	17	3.9
	EIA 1/2-S	EIA 1/2-D	WB-1/A		6	1.4
	EIA 1/2-S	EIA 1/2-D/A			6	1.4
	EIA 1/2-S	A			5	1.1
	EIA 1/2-S	EIA 1/2-D	WB-1	WB-2	5	1.1
	EIA 1/2-S	EIA 1/2-S	A		5	1.1
Other Algorithms					152	34.9

Labels

Test

EIA 1/2-S = HIV-1/HIV-2 Enzyme Immunoassay(EIA) singly
EIA 1/2-D = HIV-1/HIV-2 EIA in duplicate
EIA 2-S = HIV-2 EIA singly (2)
EIA 2-D = HIV -2 EIA in duplicate (2)
WB-1 = HIV-1 Western Blot (WB)
WB-2 = HIV-2 WB
IIF = HIV -1 Indirect Immunofluorescence
O = test Other than HIV -1/HIV-2 EIA, IIF or WB
A = refer for Additional HIV-1/HIV-2 testing

Footnotes

* A total of 135 unique algorithms were reported
** EIA data in this table includes both manual and non-manual procedures

15. Please indicate the number of years your laboratory has been performing these specific HIV tests. (Round off to the nearest year. If less than one year, round off to one year.)

N=696

	Frequency of Laboratories Responding*									
Number of Years	EIA	WB	IIF	HIV-1 RNA	HIV-1 DNA	Particle Agglutination	HIV-1 p24 Antigen	HIV-1 Rapid Test	Viral Culture	Other
1 - 3	39	21	5	111	18	3	102	75	3	5
4 - 6	64	25	13	25	28	1	23	21	4	2
7 - 9	73	39	5	3	15	5	17	6	1	6
10 - 12	174	96	14	1	7	7	37	8	10	2
13 - 15	285	65	12	0	0	3	7	3	7	3
>15	17	8	2	0	0	0	0	1	1	0

* The numbers in each column represent the frequency of laboratories that indicated the associated range.

15. Please indicate the number of different employees in your laboratory that perform these specific HIV tests.

N=702

	Frequency of Laboratories Responding*									
Number of Employees	EIA	WB	IIF	HIV-1 RNA	HIV-1 DNA	Particle Agglutination	HIV-1 p24 Antigen	HIV-1 Rapid Test	Viral Culture	Other
1 - 2	158	96	20	53	36	11	43	18	15	9
3 - 4	204	81	15	63	19	4	44	15	8	7
5 - 6	137	42	3	16	9	2	38	18	3	2
7 - 8	68	11	5	3	2	2	19	12	0	1
9 -10	41	9	0	2	0	0	14	11	0	0
>10	50	11	1	3	0	0	30	38	0	1

* The numbers in each column represent the frequency of laboratories that indicated the associated range.

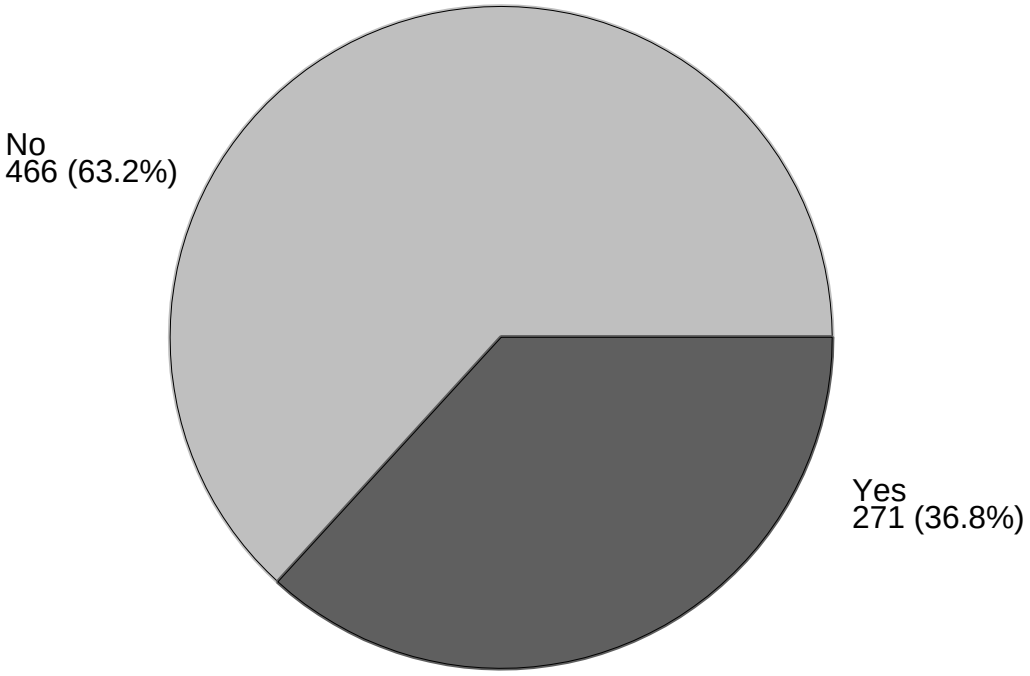
16. Please identify the source of written procedure(s) your laboratory follows for performing the following HIV-1 tests? (Check all that apply only for the procedures performed in your laboratory.)

N=734

	Frequency of Laboratories Responding*			
Source of procedure	EIA	WB	IIF	Other
No Written Procedures	2	4	3	1
In-house Written Protocol	567	204	38	60
Manufacturer's Insert	631	231	33	62
Provided by State Health Department	22	11	2	0
Other Sources	19	13	2	3

* The numbers in each column represents the frequency of laboratories that indicated the associated source of procedure.

17.(a) Does your laboratory perform HIV-1 Western blot testing?



N=737

17.(b) Which of the following WB band patterns does your laboratory routinely use to classify a specimen as HIV-1 antibody reactive? (Choose only one.)

N=266

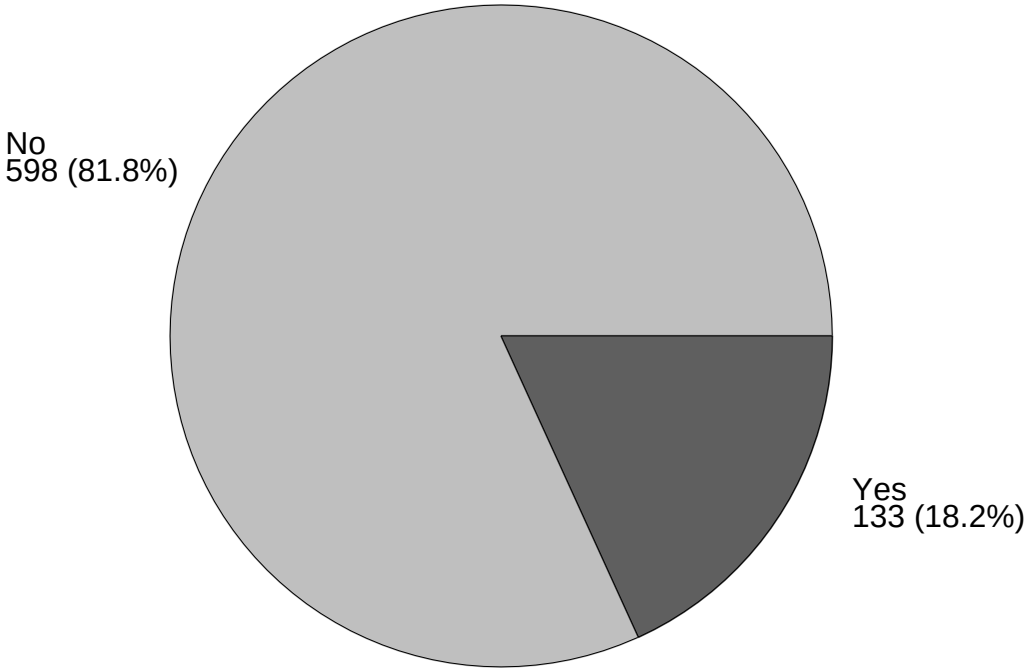
Band Patterns	Number of Laboratories	Percentage of Laboratories
Any two of p24, gp41, gp120/gp160	225	84.6
One protein from each: gag (p17/18, p24, p55), and env (gp41, gp120, gp160), and pol (p31, p51, p65/66)	11	4.1
Other	11	4.1
Two env bands w/ or w/o gag or pol bands	10	3.8
p24 or p31, and gp41 or gp120/gp160	7	2.6
p24 plus p31, and either gp41 or gp120/gp160)	2	0.8

17.(c) Which of the following is required for your laboratory to interpret an HIV-1 WB result as *negative*? (Choose only one.)

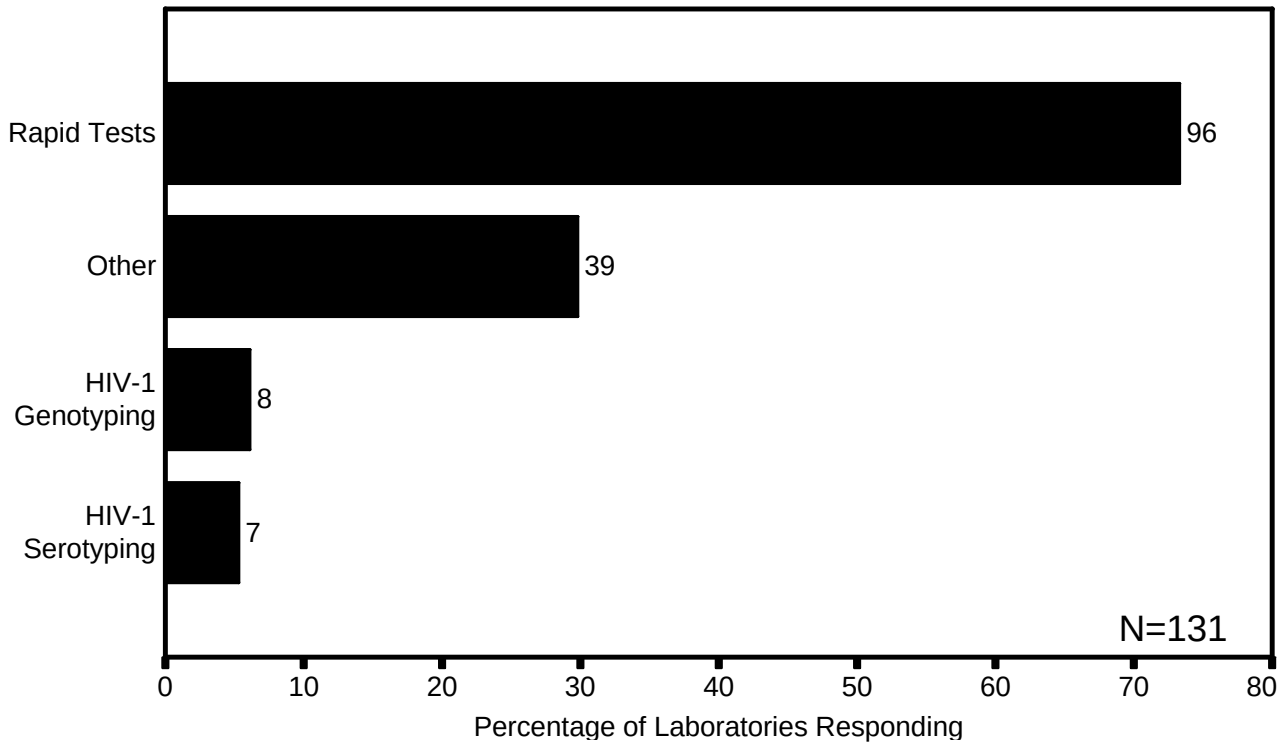
N=266

Band Patterns	Number of Laboratories	Percentage of Laboratories
No bands present	187	70.3
No HIV-1 specific protein band(s) (i.e., 17/18, 24, 31, 41, 51, 55, 65/66, 120, 106)	75	28.2
Other	4	1.5

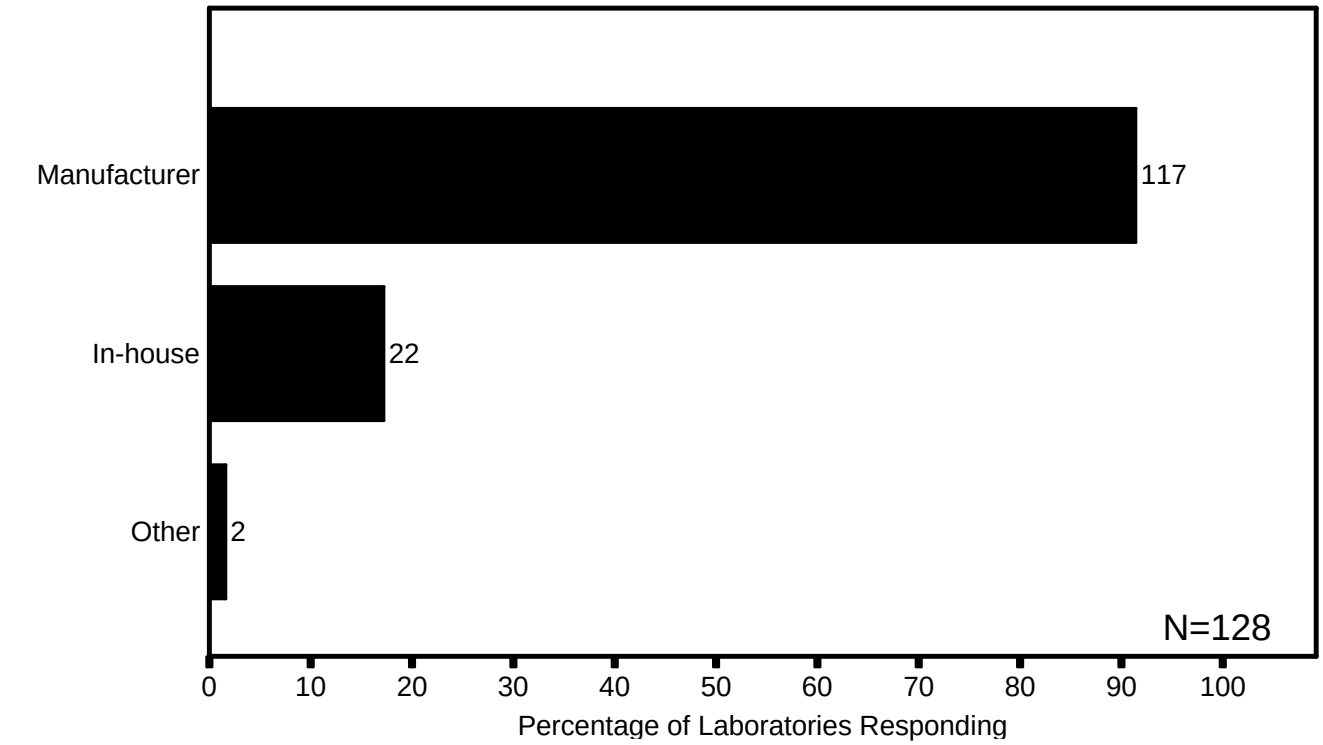
18.(a) Do you perform a test <u>other than</u> EIA antibody, WB, IIF, p24 Ag, or RNA <u>to detect HIV-1 infection</u>?



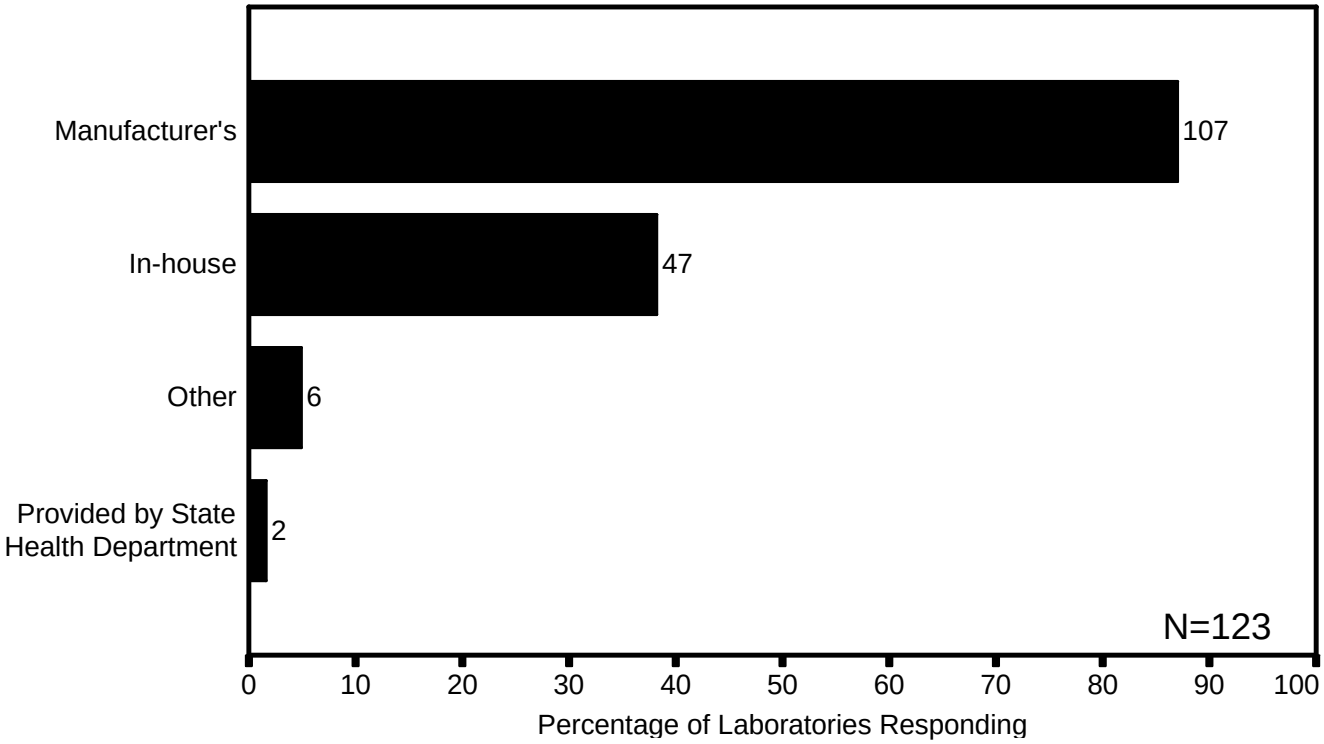
18.(b) If yes, indicate below the other HIV-1 tests performed in your laboratory (Check <u>all</u> that apply.):



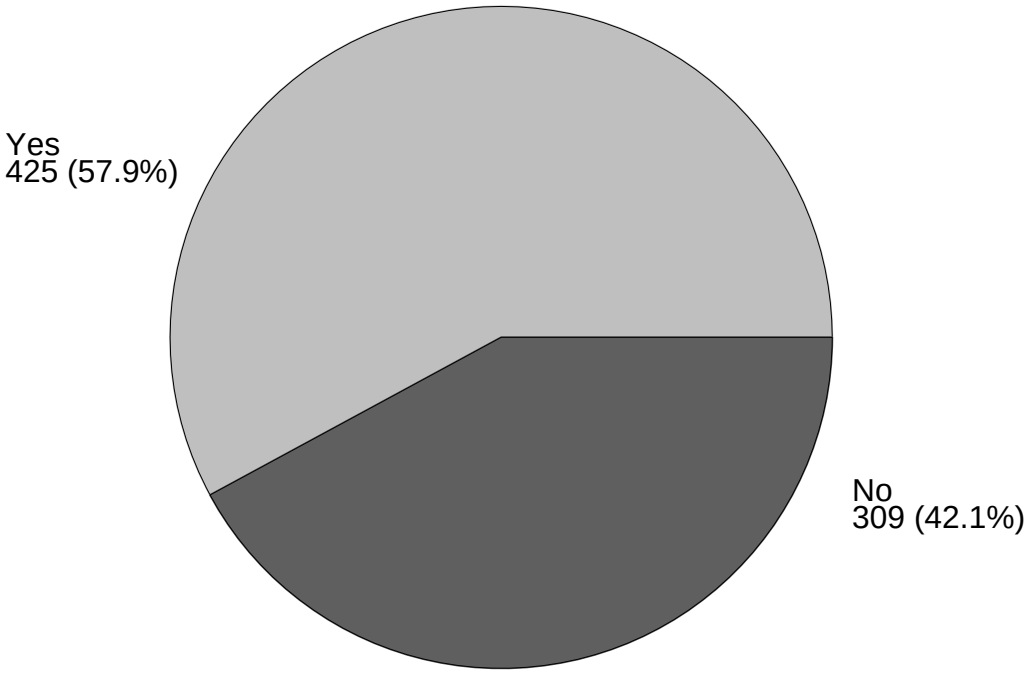
18.(c) Source of reagents for HIV-1 tests other than EIA antibody, WB, IIF, p24 Ag, and RNA as indicated in question 18(b). (Check <u>all</u> that apply.):



18.(d) What procedure does your laboratory follow for performing HIV-1 tests <u>other than</u> EIA antibody, WB, IIF, p24 Ag, and RNA? (Check <u>all</u> that apply.)



19.(a) Does your laboratory use controls other than kit manufacturer controls?



N=734

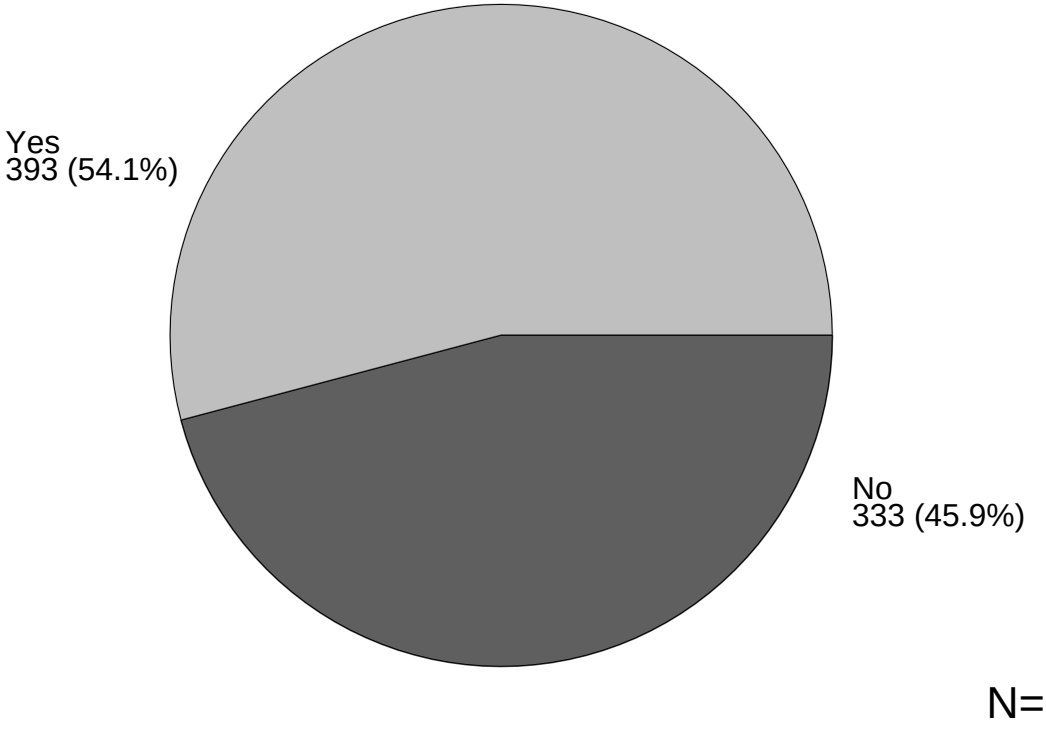
19.(b) If your laboratory uses controls other than kit manufacturer controls, please indicate the frequency with which your laboratory uses HIV-1 control sera/plasma for each of the test methods below (Check <u>all</u> that apply.):

N=422

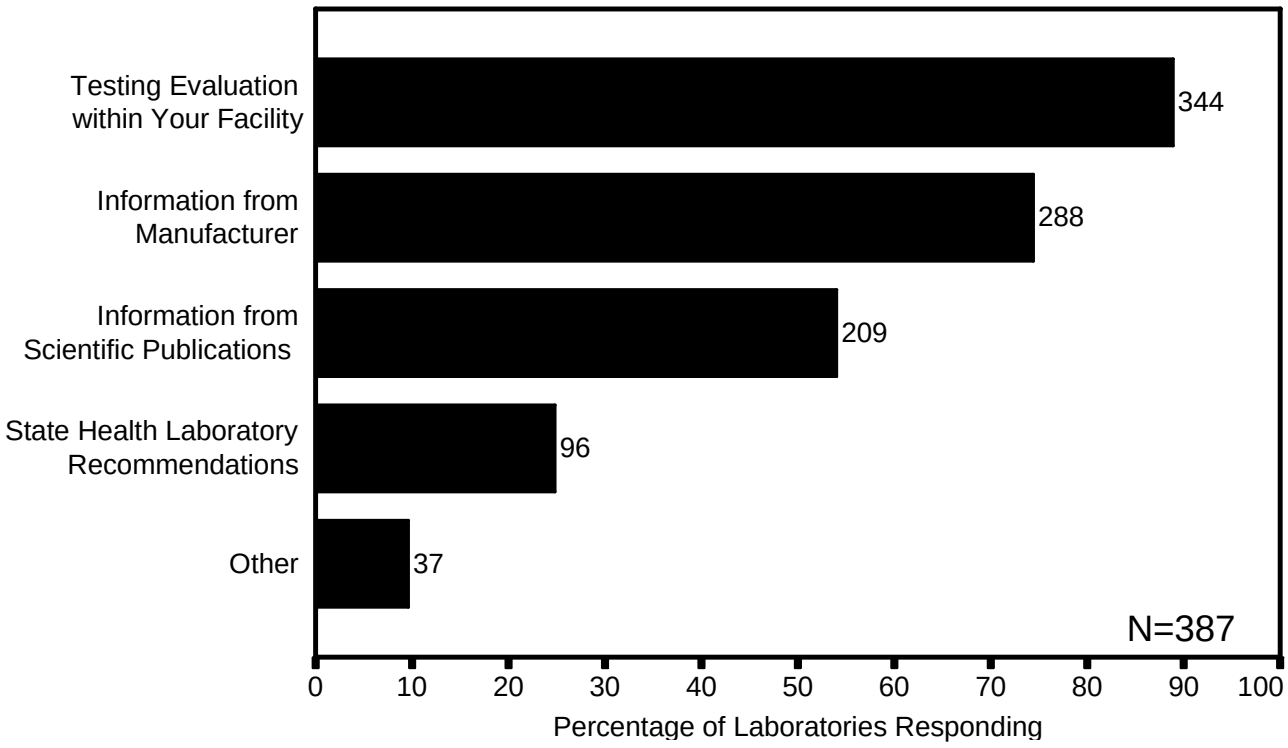
	Frequency of Laboratories Responding*				
Test Method	Each Test[a]	Each Set[b]	Two Each Day	Each Test Kit	Other Frequency
EIA	177	195	44	42	10
WB	4	70	6	31	2
IIF	3	15	1	4	1
Other	3	16	2	9	1

[a] An EIA plate, Western blot strip or IIF slide
[b] A set of EIA plates, Western blot strips or IIF slides
* The numbers in each column represent the frequency of laboratories that indicated the associated test method.

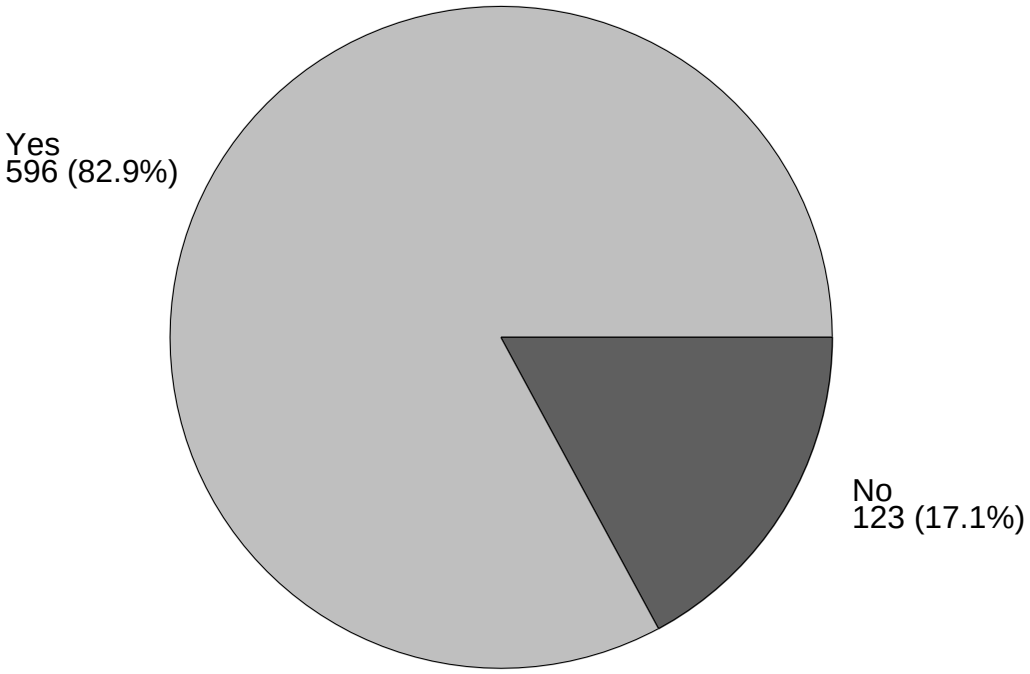
20.(a) Does your laboratory have *written criteria* for adopting a new test or a different manufacturer's test for HIV-1 testing?



20.(b) If Yes, please identify the methods used for establishing these written criteria (Check all that apply.):

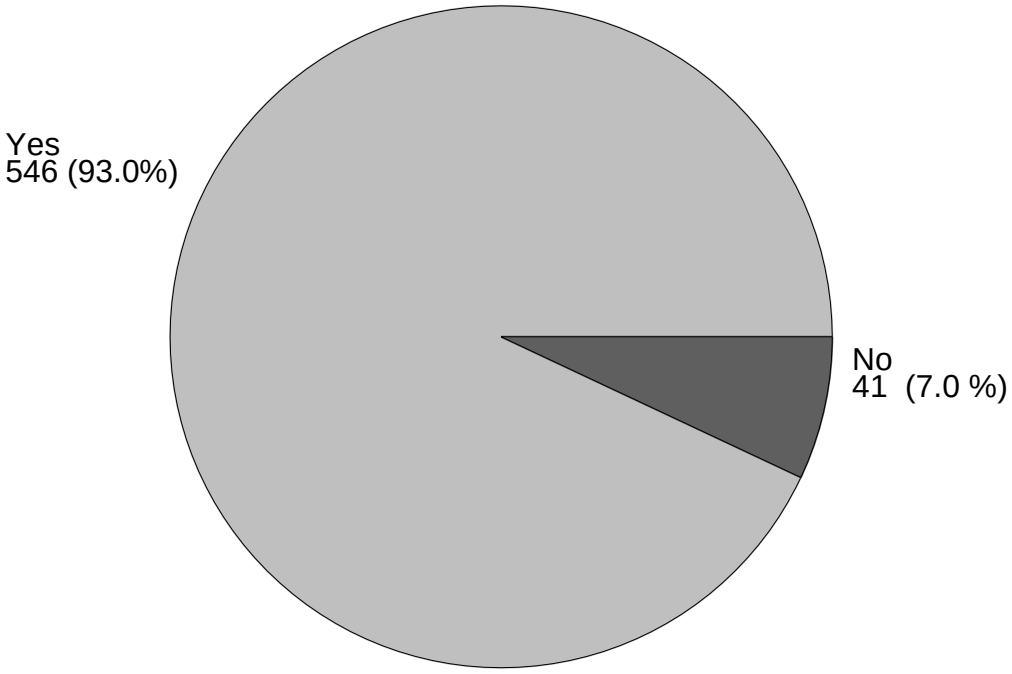


20.(c) Does your laboratory have a quality assurance plan for HIV-1 testing?



N=719

20.(d) Does your laboratory have written policies and/or procedures for monitoring an HIV-1 testing quality assurance plan?



N=587

21. This question refers to the volume of HIV-1 antibody testing performed in your laboratory. Responses should reflect the number of patient/donor specimens tested during the most recent representative month. (Round off to the nearest whole number.)

N=710

	Frequency of Laboratories Responding*			
Number During Most Recent Representative Month	Total Specimens Tested	Reactive by Screen	Tested by Suppl/Conf	Reactive by Suppl/Conf
<10	15	315	278	263
10-99	103	217	200	157
100-999	336	57	57	43
1,000-9,999	203	2	2	1
10,000-99,999	42	1	0	0
>99,999	5	0	0	0

* The numbers in each column represent the frequency of laboratories that indicated the associated range.

22. On average, how much time occurs for the following events in your laboratory? (Round off to nearest day, if less than one day, round off to one day.)

N=715

	Frequency of Laboratories Responding*		
Days Until →	Receipt in Laboratory	Specimen is Tested	Results are Reported
1	570	408	548
2-3	96	255	101
4-5	20	32	14
6-7	2	7	9
>7	5	3	5

* The numbers in each column represent the frequency of laboratories that indicated the associated range.

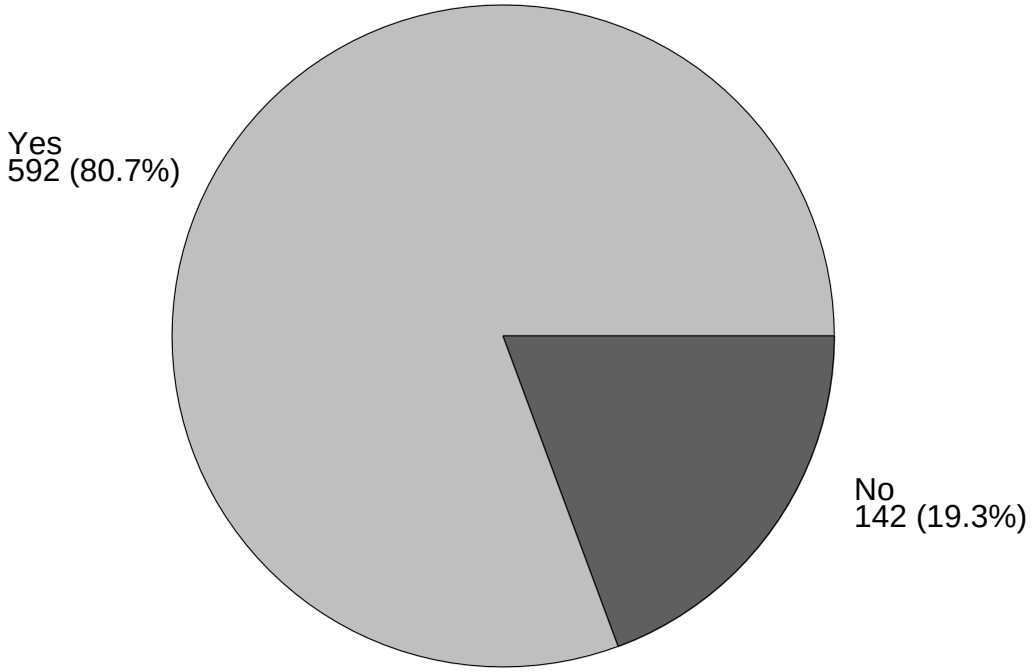
23. Approximately how much does your laboratory charge to perform the following tests? Please answer all areas applicable to your laboratory. (Round off to nearest U.S. dollar.)

N=507

	Frequency of Laboratories Responding*			
Approximate Charge by Laboratory	EIA	WB	IIF	Other
<$50	355	71	14	25
$50-$99	116	76	5	20
$100-$149	12	29	2	13
$150-$200	0	8	0	5
>$200	1	6	1	7

* The numbers in each column represent the frequency of laboratories that indicated the associated range.

24.(a) Does your laboratory refer HIV specimens to other laboratories for additional testing?



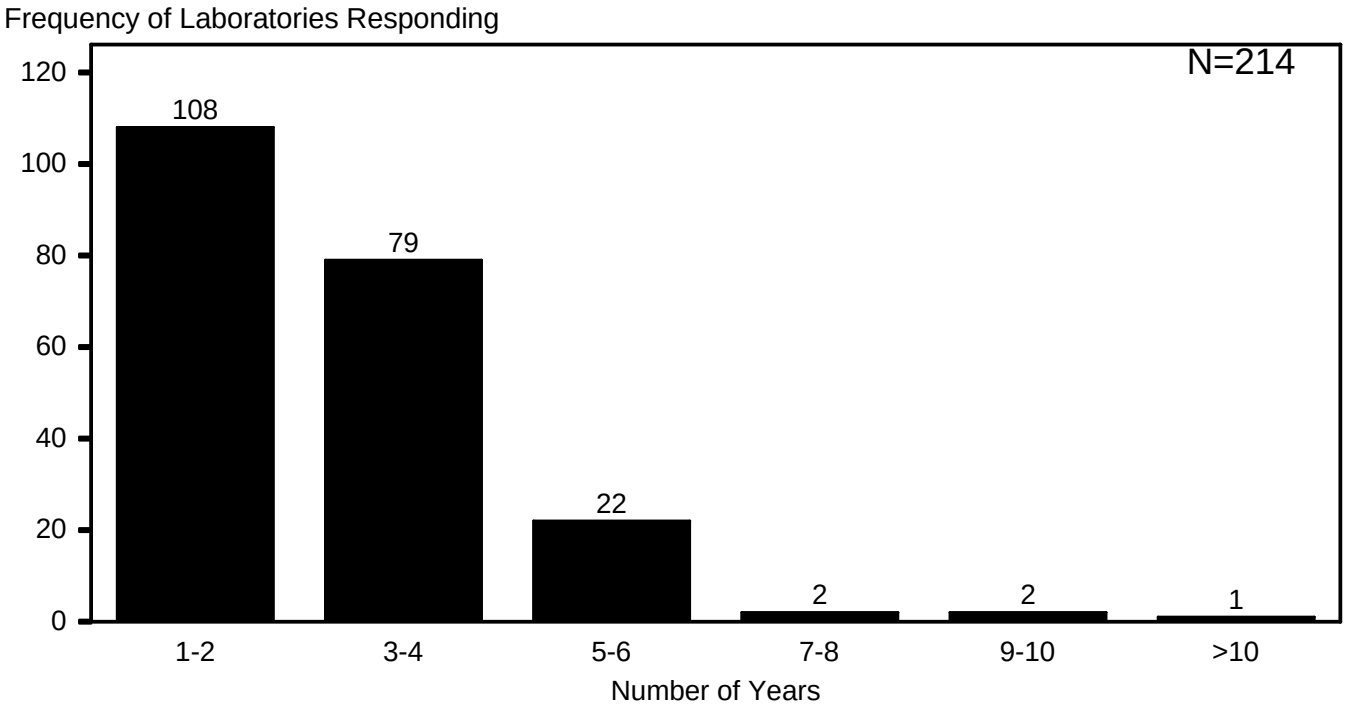
N=734

24.(b) Please indicate the additional testing requested by identifying the types of laboratories to which HIV specimens are referred for these additional tests (Check <u>all</u> that apply.):

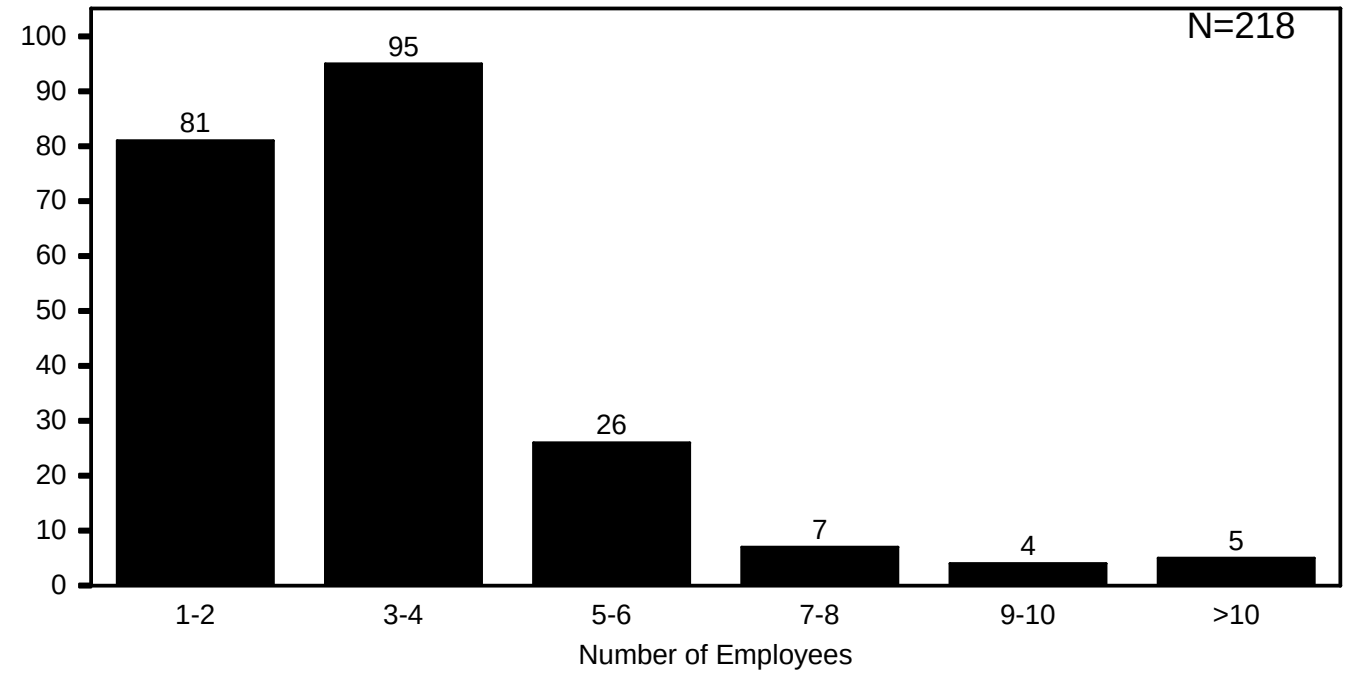
N=581

Test Type	Hospital	Health Department	Blood Bank	Independent	Other	Total
EIA HIV-1	4	31	2	33	8	78
EIA HIV-2	4	23	15	139	24	205
EIA HIV-1/HIV-2	8	13	7	64	10	102
WB HIV-1	24	78	23	302	13	440
WB HIV-2	6	42	10	219	34	311
IIF HIV-1	4	21	0	41	0	66
IIF HIV-2	2	4	0	36	1	43
Particle Agglutination	1	1	0	26	0	28
HIV-1 p24 Antigen	11	14	6	139	11	181
HIV-1 DNA	5	6	1	166	10	188
HIV-1 RNA	9	13	0	168	12	202
Viral Culture	4	8	0	63	3	78
Antiretroviral Resistance	5	3	0	97	2	107
Other	2	6	2	14	8	32

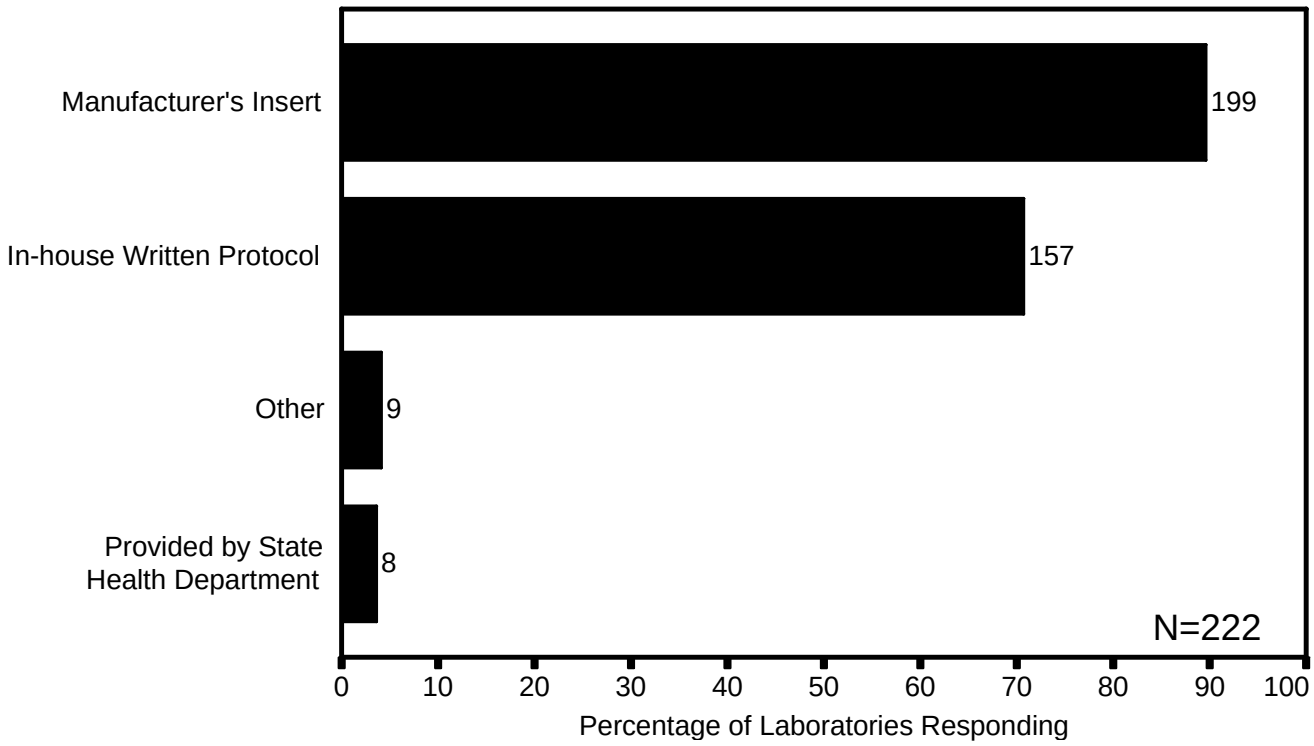
25. Please indicate the number of years your laboratory has been performing the HIV-1 RNA tests. (Round to the nearest year. If less than one year, round off to one year.)



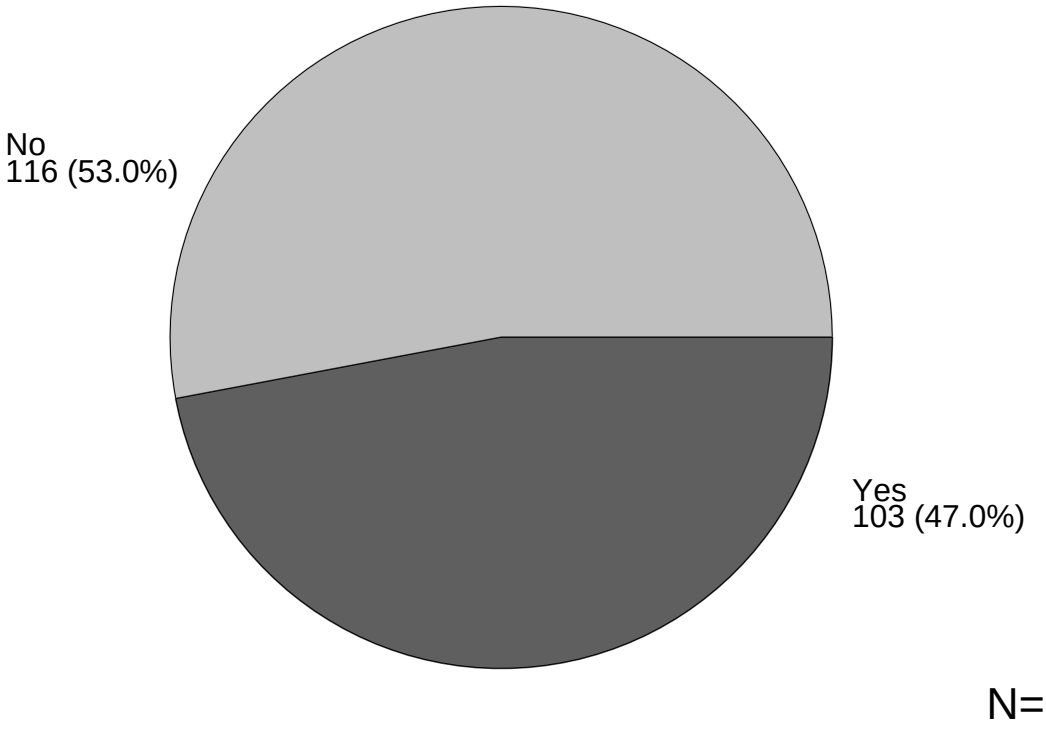
25. Please indicate the number of different employees in your laboratory that perform HIV-RNA testing.



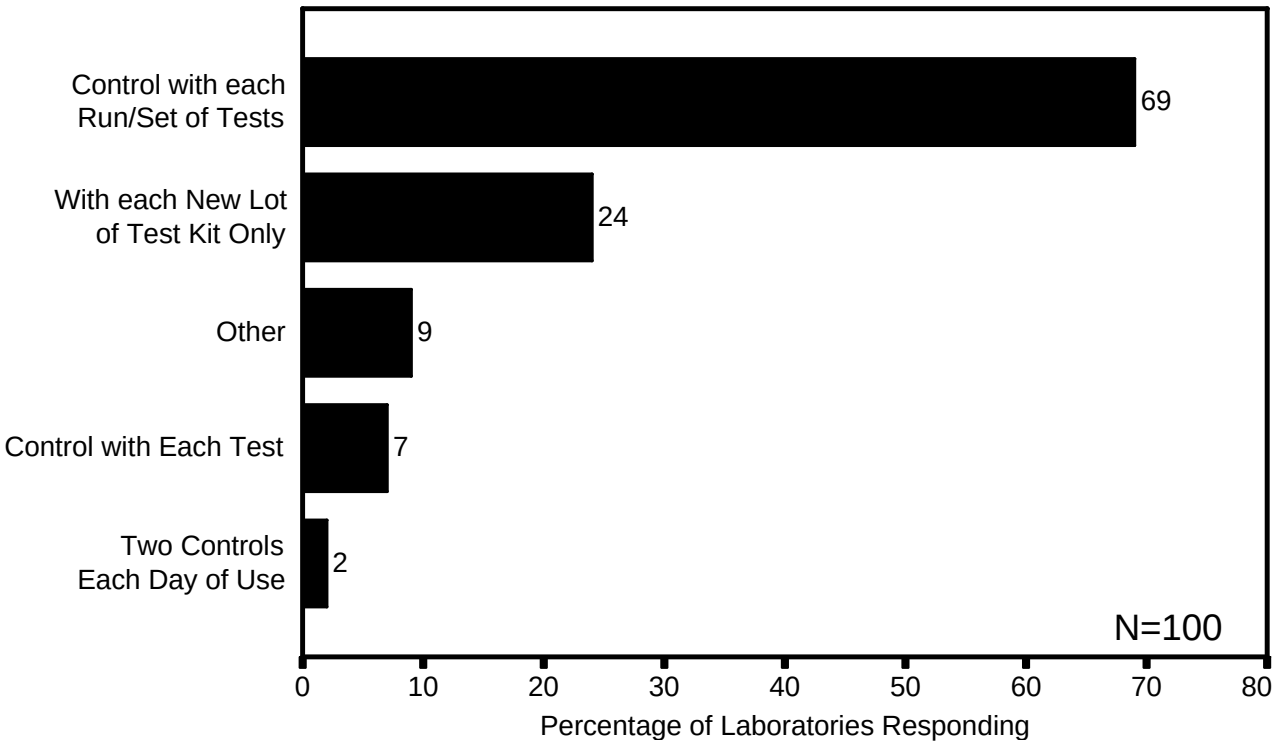
26. Please identify the source of written procedure(s) your laboratory follows for performing HIV-1 RNA tests? (Check all that apply.)



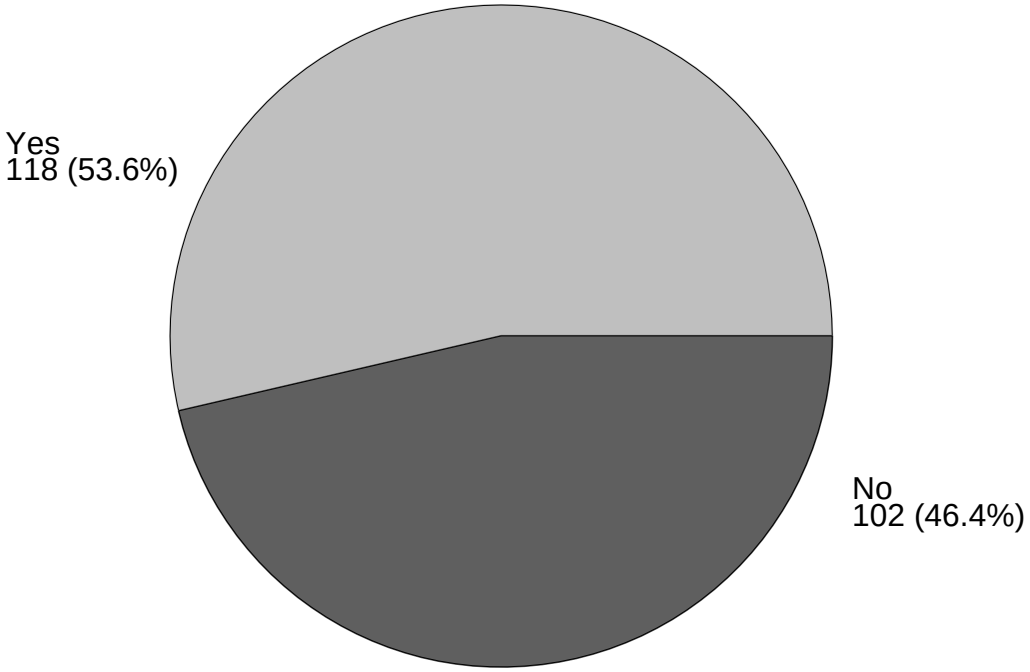
27.(a) Does your laboratory use controls other than kit manufacturer controls?



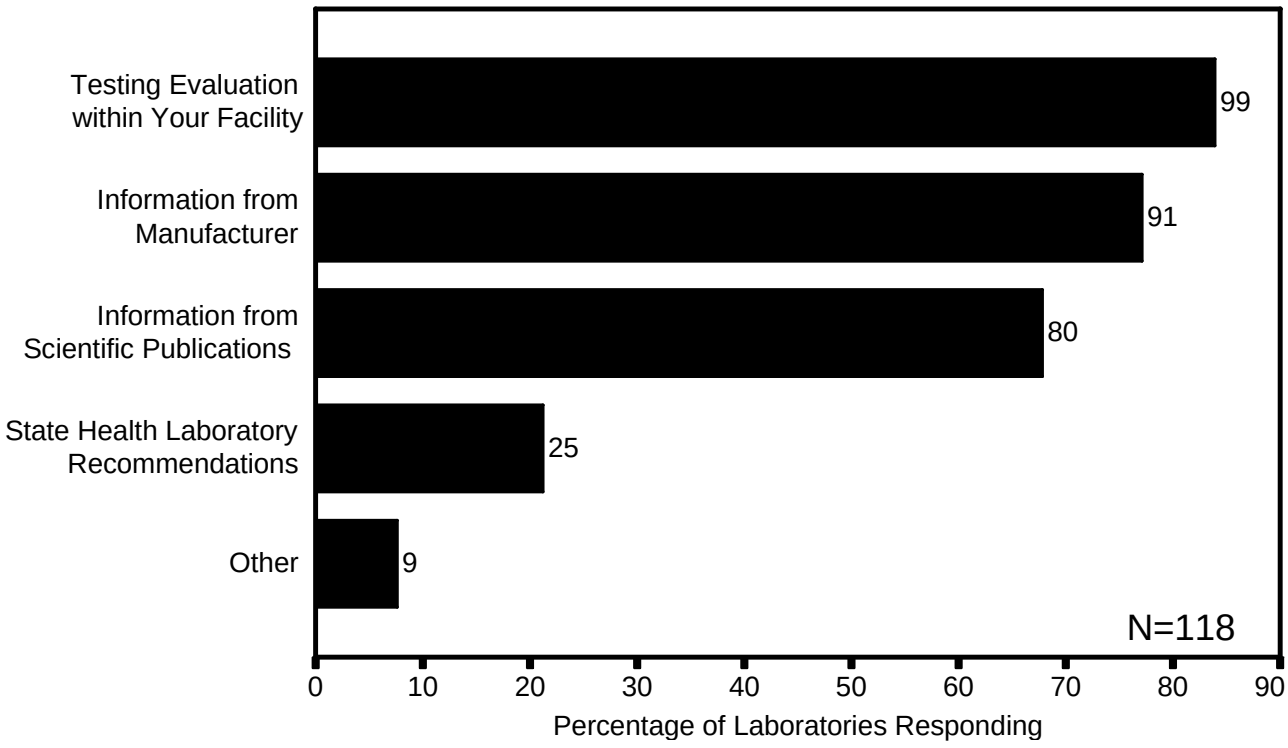
27.(b) If your laboratory uses controls other than kit manufacturer controls, please indicate the frequency with which your laboratory uses HIV control sera/plasma for your HIV-1 RNA testing (Check <u>all</u> that apply.):



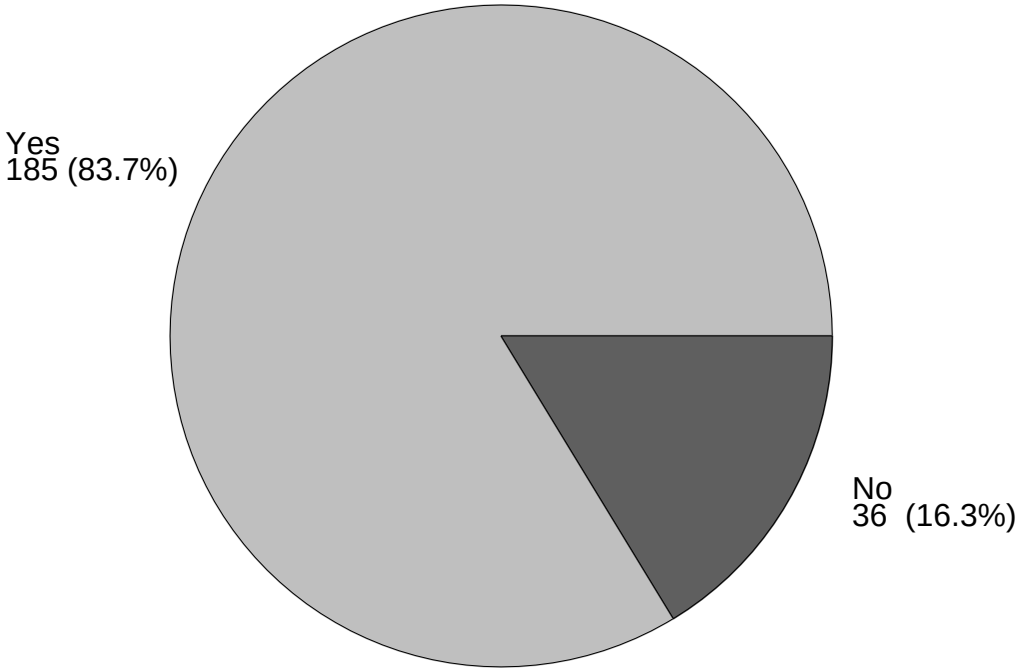
28.(a) Does your laboratory have *written criteria* for adopting a new test or a different manufacturer's test for HIV-1 RNA testing?



28.(b) If Yes, please identify the methods used for establishing these written criteria (Check all that apply.):

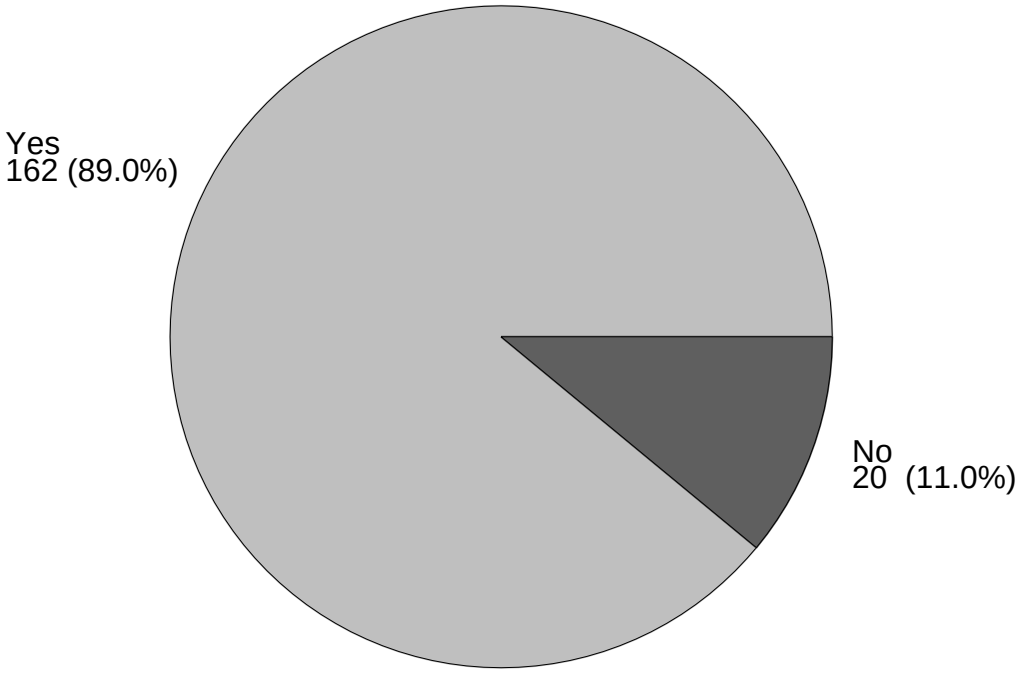


28.(c) Does your laboratory have a quality assurance plan for HIV-1 RNA determinations?



N=221

28.(d) Does your laboratory have written policies and/or procedures for monitoring an HIV-1 RNA testing quality assurance plan?



N=182

29. This question refers to the volume of HIV-1 RNA testing performed in your laboratory. Responses should reflect the number of patient/donor specimens tested during the most recent representative month. (Round off to the nearest whole number.)

N=210

	Frequency of Laboratories Responding*	
Number During Most Recent Representative Month	Total Specimens Tested	Specimens with RNA Detected
<10	6	8
10-99	66	77
100-999	113	99
1,000-9,999	21	9
10,000-99,999	4	0

* The numbers in each column represent the frequency of laboratories that indicated the associated range.

30. On average, how much time occurs for the following events in your laboratory? (Round off to nearest day, if less than one day, round off to one day.)

N=213

	Frequency of Laboratories Responding*		
Days Until →	Receipt in Laboratory	Specimen is Tested	Results are Reported
1	176	36	141
2-3	22	85	34
4-5	5	49	14
6-7	0	28	8
>7	5	13	4

* The numbers in each column represent the frequency of laboratories that indicated the associated range.

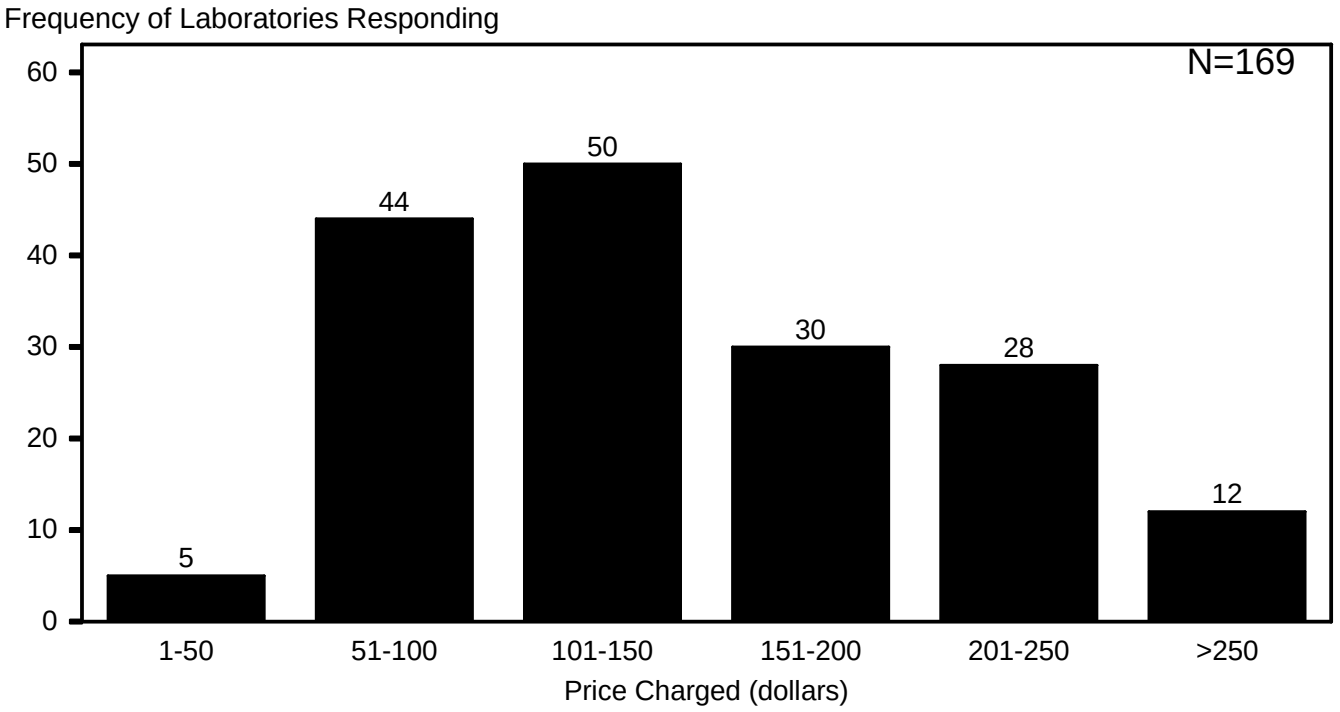
31. What is the temperature of specimens received by your laboratory? (Check all that apply to HIV-1 RNA specimens received only in your laboratory.)

N=219

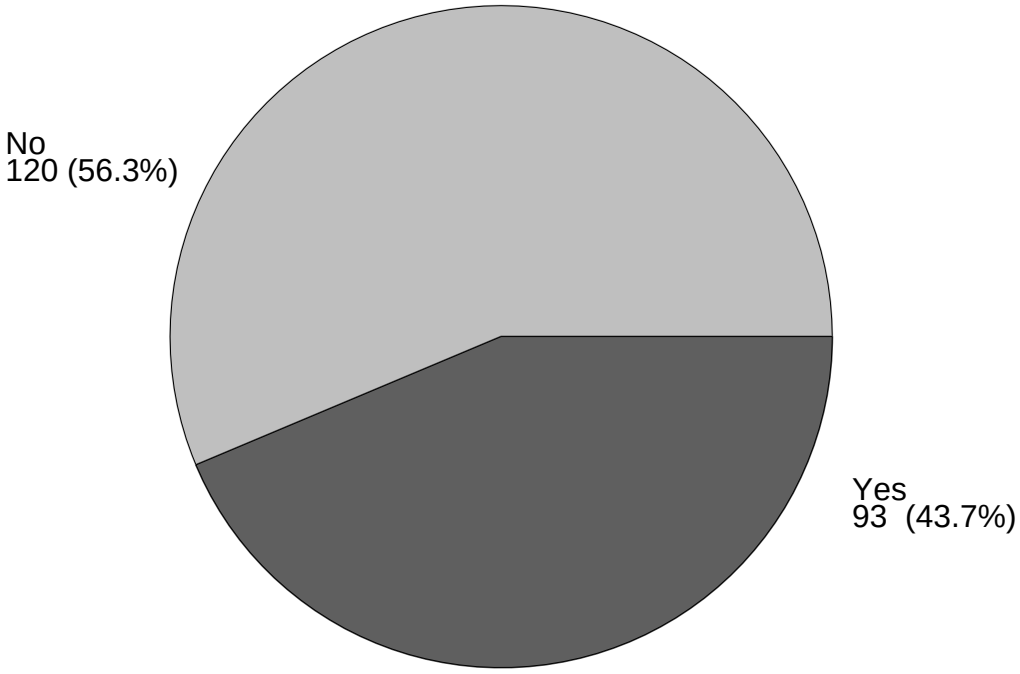
	Frequency of Laboratories Responding*		
Type of Specimen	Ambient	2-4 □C(refrigerated)	Frozen
Plasma	69	59	141
Serum	12	7	24
Whole Blood	89	14	0
Dried Blood Spots	2	1	1
Other	10	5	9

* The numbers in each column represent the frequency of laboratories that indicated the associated type of specimen.

32. Approximately how much does your laboratory charge to perform an HIV-1 RNA determination? (Round off to nearest U.S. dollar.)



33.(a) Does your laboratory refer HIV specimens to other laboratories outside your institution for additional testing?



N=213

33.(b) Please indicate the additional testing requested and identify the types of laboratories outside your institution to which HIV specimens are referred for these additional tests (Check <u>all</u> that apply.):

N=87

Test Type	Hospital	Health Department	Blood Bank	Independent	Other	Total
EIA HIV-1	3	5	0	6	0	14
EIA HIV-2	1	4	0	24	3	32
EIA HIV-1/HIV-2	1	3	0	5	2	11
WB HIV-1	3	13	0	16	2	34
WB HIV-2	1	8	0	27	1	37
IIF HIV-1	2	4	0	2	0	8
IIF HIV-2	1	2	0	3	0	6
Particle Agglutination	0	0	0	2	0	2
HIV-1 p24 Antigen	2	5	0	17	1	25
HIV-1 DNA	5	5	0	32	1	43
Viral Culture	4	4	0	10	0	18
Antiretroviral Resistance	4	3	0	36	3	46
Other	1	1	0	2	3	7

34. Please indicate the number of years your laboratory has been performing these specific HIV-1 p24 antigen tests. (Round to the nearest year. If less than one year, round off to one year.)

N=221

	Frequency of Laboratories Responding*		
Number of Years	p24 Qualitative	p24 Neutralization	p24 Quantitative
1-3	126	51	2
4-6	26	13	7
7-9	19	11	8
10-12	37	25	18
13-15	6	5	4

* The numbers in each column represent the frequency of laboratories that indicated the associated range.

34. Please indicate the number of different employees in your laboratory that perform these specific HIV-1 p24 antigen tests.

N=220

	Frequency of Laboratories Responding*		
Number of Employees	p24 Qualitative	p24 Neutralization	p24 Quantitative
1-2	50	39	16
3-4	58	29	14
5-6	38	17	8
7-8	24	6	1
9-10	16	8	0
>10	28	6	1

* The numbers in each column represent the frequency of laboratories that indicated the associated range.

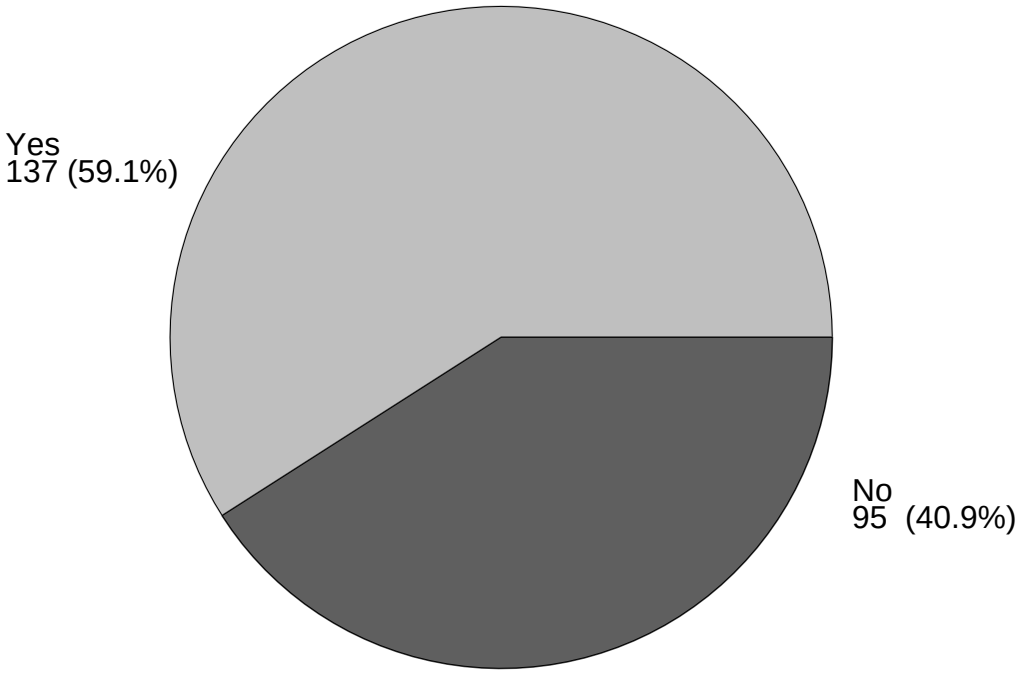
35. Please identify the source of written procedure(s) your laboratory follows for performing the following HIV-1 p24 antigen tests? (Check all that apply only for the procedures performed in your laboratory.)

N=232

	Frequency of Laboratories Responding*		
Source of procedure	p24 Qualitative	p24 Neutralization	p24 Quantitative
No Written Procedures	0	1	1
In-house Written Protocol	173	89	28
Manufacturer's Insert	205	102	36
Provided by State Health Department	4	3	0
Other Sources	11	5	5

* The numbers in each column represent the frequency of laboratories that indicated the associated source of procedure.

36.(a) Does your laboratory use controls other than kit manufacturer controls?



N=232

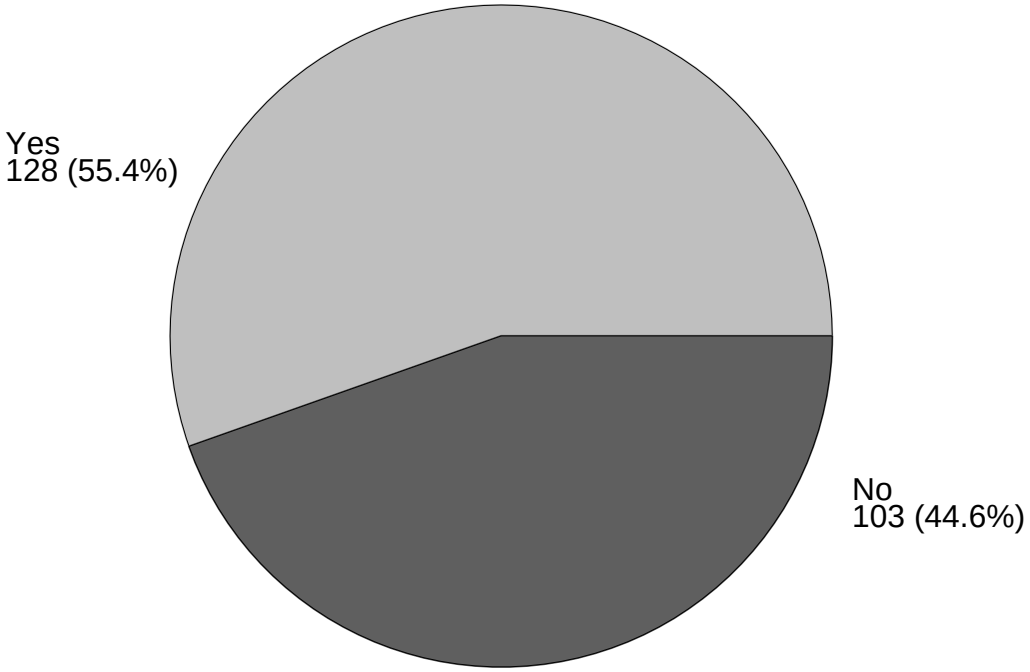
36.(b) If your laboratory uses controls other than the kit manufacturer controls, please indicate the frequency with which your laboratory uses HIV control sera/plasma for each of the HIV-1 p24 antigen tests below (Check <u>all</u> that apply.):

N=136

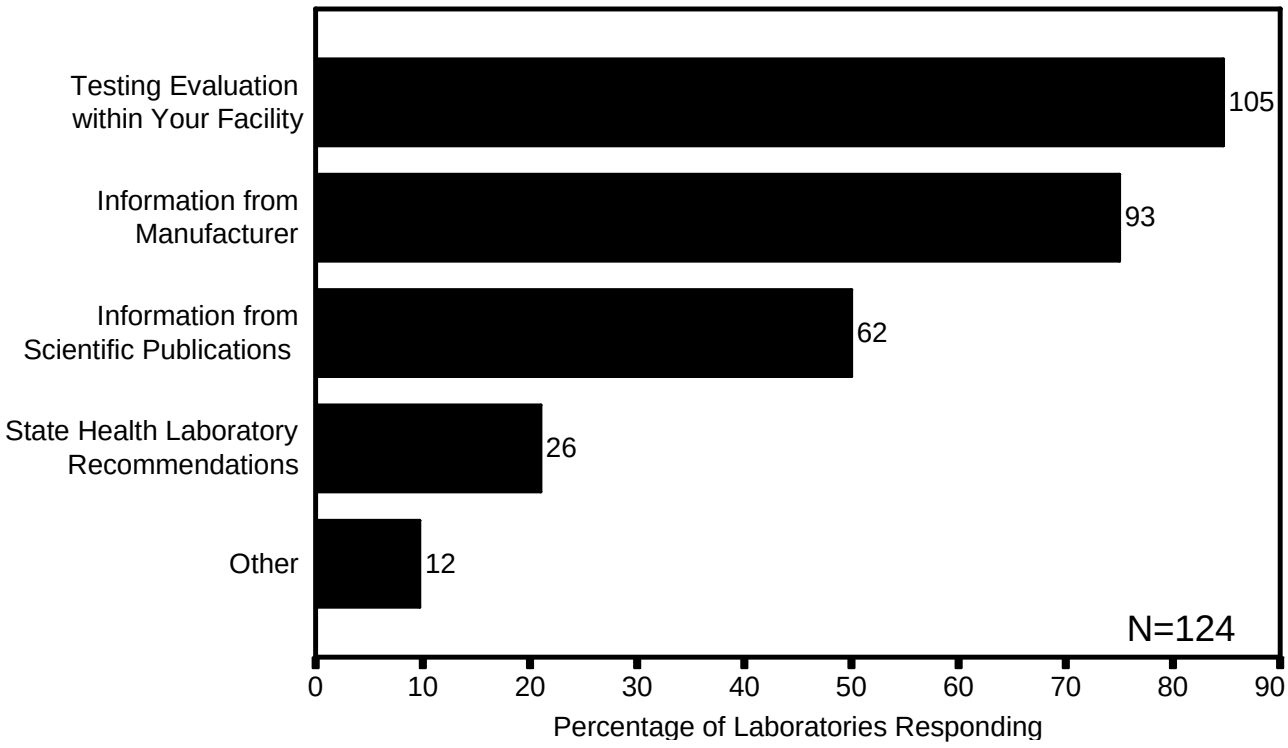
	Frequency of Laboratories Responding*				
Test Method	Each Test[a]	Each Set[b]	Two Each Day	Each Test Kit	Other Frequency
Qualitative	49	72	5	11	2
Neutralization	17	17	0	1	1
Quantitative	7	9	0	0	1

[a] An EIA plate, Western blot stip or IIF slide
[b] A set of EIA plates, Western blot strips or IIF slides
* The numbers in each column represent the frequency of laboratories that indicated the associated test method.

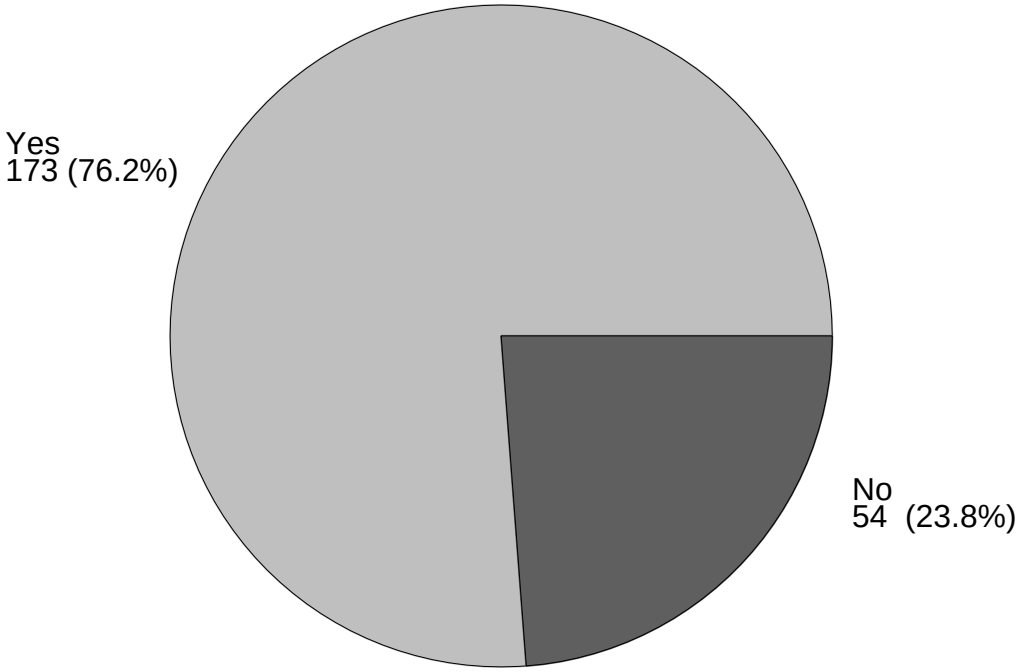
37.(a) Does your laboratory have *written criteria* for adopting a new test or a different manufacturer's test for HIV-1 p24 antigen testing?



37.(b) If Yes, please identify the methods used for establishing these written criteria (Check all that apply.):

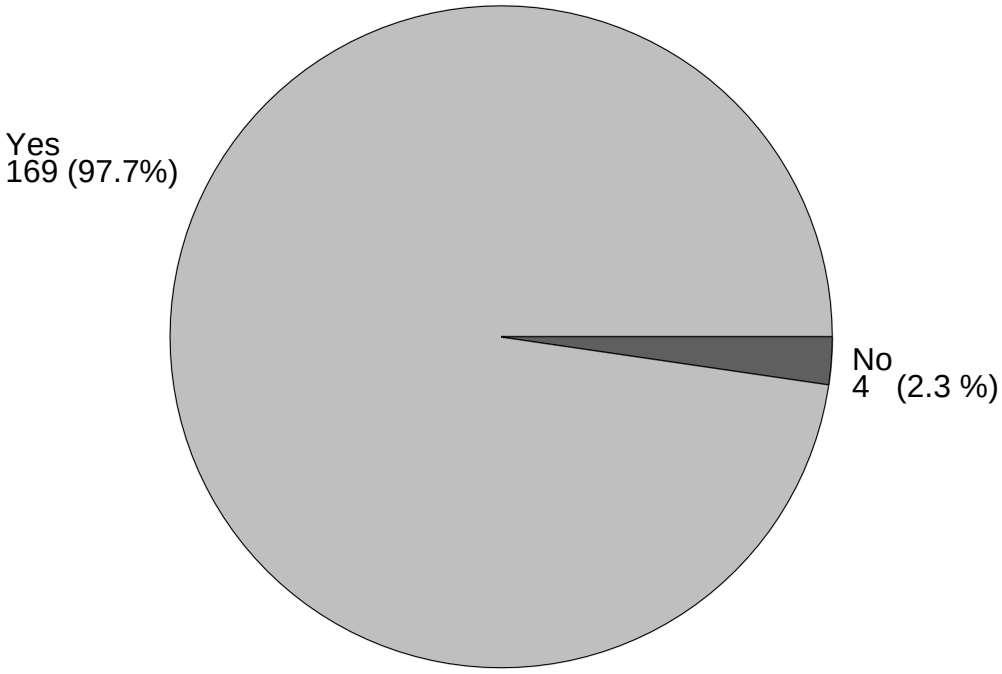


37.(c) Does your laboratory have a quality assurance plan for HIV-1 p24 antigen testing?



N=227

37.(d) Does your laboratory have written policies and/or procedures for monitoring an HIV-1 p24 antigen testing quality assurance plan?



N=173

38. This question refers to the volume of HIV-1 p24 antigen testing performed in your laboratory. Responses should reflect the number of patient/donor specimens tested during the most recent representative month. (Round off to the nearest whole number.)

N=222

	Frequency of Laboratories Responding*			
Number During Most Recent Representative Month	Total Specimens Tested	Reactive by Qualitative Tests	Confirmed by Neutralization	p24 Antigen Quantitated
<10	21	74	46	18
10-99	66	20	9	8
100-999	62	2	1	2
1,000-9,999	53	0	0	0
10,000-99,999	17	0	0	0
>99,999	3	0	0	0

* The numbers in each column represent the frequency of laboratories that indicated the associated range.

39. On average, how much time occurs for the following events in your laboratory? (Round off to the nearest day, if less than one day, round off to one day.)

N=228

	Frequency of Laboratories Responding*		
Days Until →	Receipt in Laboratory	Specimen is Tested	Results are Reported
1	184	128	160
2-3	25	63	38
4-5	3	9	6
6-7	1	11	6
>7	4	11	6

* The numbers in each column represent the frequency of laboratories that indicated the associated range.

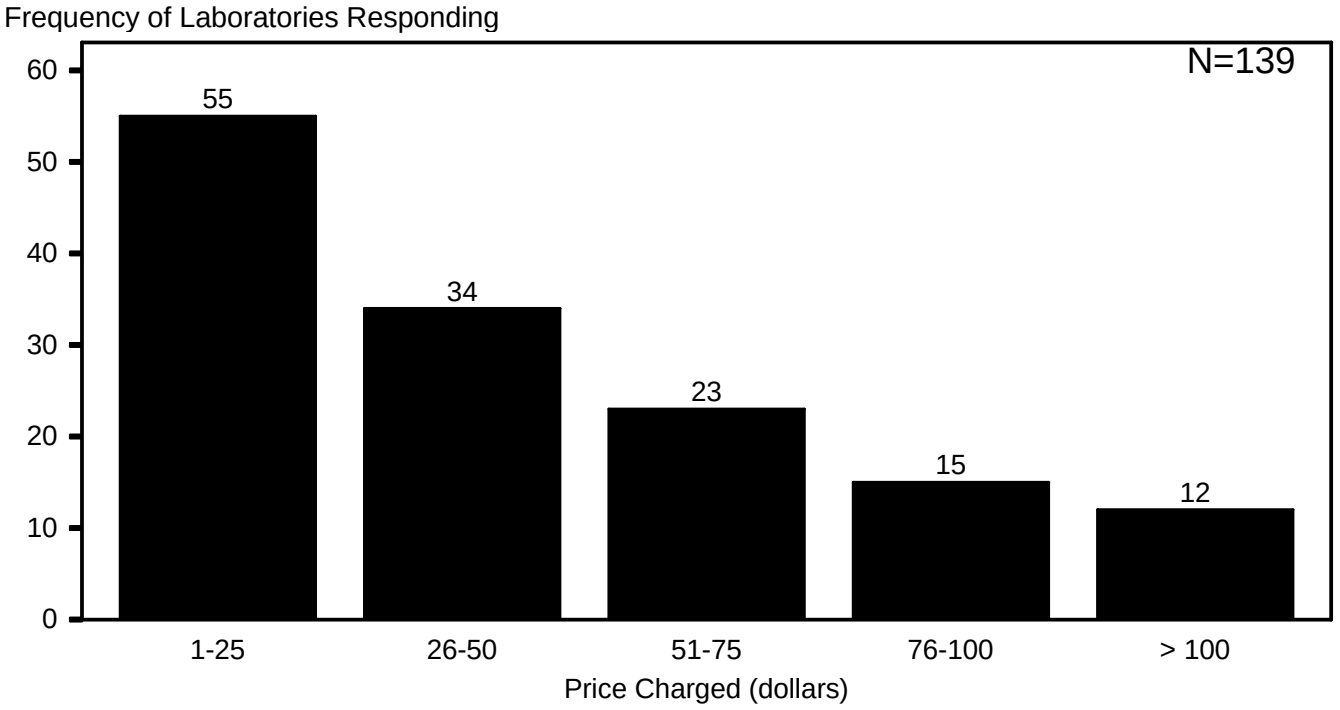
40. What is the usual temperature of specimens received by your laboratory? (Check all that apply to HIV-1 p24 antigen specimens received in your laboratory.)

N=227

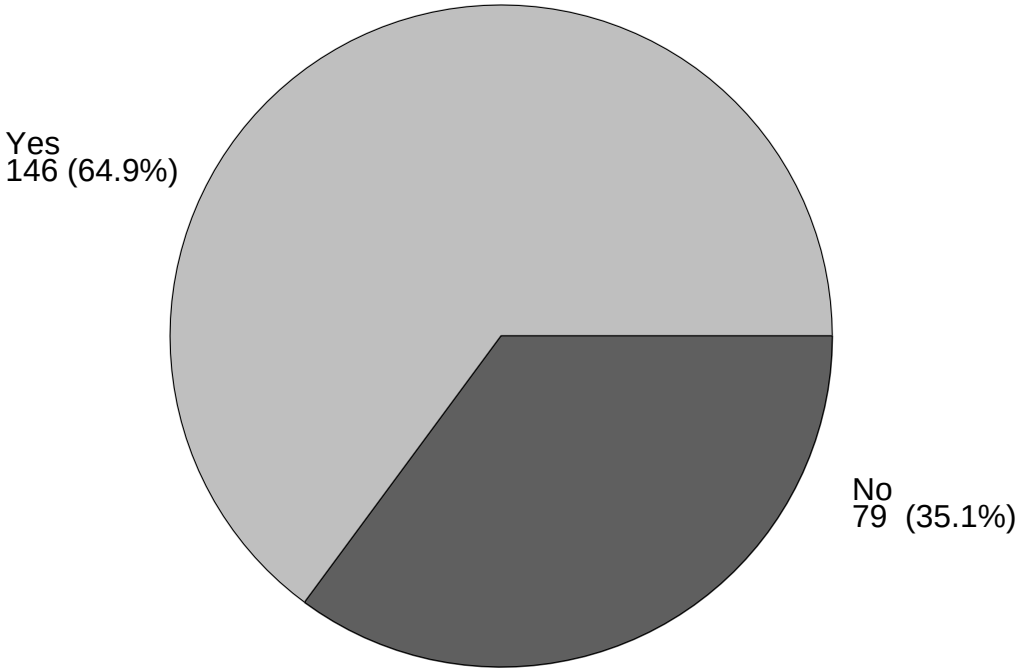
	Frequency of Laboratories Responding*		
Type of Specimen	Ambient	2-4 °C (refrigerated)	Frozen
Plasma	94	56	23
Serum	128	80	24
Whole Blood	79	27	2
Dried Blood Spots	2	0	0
Other	3	3	2

* The numbers in each column represent the frequency of laboratories that indicated the associated type of specimen.

41. Approximately how much does your laboratory charge to perform an HIV-1 p24 antigen test? (Round off to nearest U.S. dollar.)



42.(a) Does your laboratory refer HIV specimens to other laboratories for additional testing?



N=225

42.(b) Please indicate the additional testing requested and identify the types of laboratories outside your institution to which HIV specimens are referred for these additional tests (Check all that apply.):

N=141

Test Type	Hospital	Health Department	Blood Bank	Independent	Other	Total
EIA HIV-1	0	3	2	7	0	12
EIA HIV-2	0	3	7	39	0	49
EIA HIV-1/HIV-2	1	1	2	11	1	16
WB HIV-1	2	6	11	62	2	83
WB HIV-2	2	4	8	67	3	84
IIF HIV-1	0	3	0	2	0	5
IIF HIV-2	0	1	0	1	0	2
Particle Agglutination	0	0	0	0	0	0
HIV-1 DNA	2	4	0	28	1	35
HIV-1 RNA	2	1	2	22	1	28
Viral Culture	0	1	0	9	1	11
Antiretroviral Resistance	1	1	0	17	2	21
Other	1	1	11	20	1	34

43. Many laboratories perform a series of tests to detect the presence of HTLV antibodies. Mark an "x" in the appropriate boxes in the table below to indicate: (1) the type(s) of tests routinely performed in your laboratory, (2) the order in which they are performed (1st step, 2nd step, etc.), (3) whether an EIA is performed singly or in duplicate, and (4) whether the EIA method used is manual or nonmanual:

N=229

	Step 1	Step 2	Step 3	Step 4	Number of Laboratories	Percentage of Laboratories
Algorithm*	EIA-S**	EIA-D**			79	34.5
	EIA-S	EIA-D	A		64	27.9
	EIA-S	EIA-D	WB		36	15.7
	EIA-S	EIA-D	WB	A	3	1.3
	EIA-S	EIA-D	WB/A		3	1.3
Other Algorithms					44	19.2

Labels

Test
EIA-S = HTLV Enzyme Immunoassay (EIA) singly
EIA-D = HTLV EIA in duplicate
WB = HTLV Western Blot (WB)
O = test Other than HTLV EIA, IIF or WB
A = refer for Additional testing

Footnotes

* A total of 40 unique algorithms were reported
** EIA data in this table includes both manual and non-manual procedures

44. Please indicate the number of years your laboratory has been performing these specific HTLV-I/II tests. (Round off to the nearest year. If less than one year, round off to one year.)

N=222

	Frequency of Laboratories Responding*								
Number of Years	EIA	WB	IIF	PCR	PA	RIPA	HTLV-I/II Antigen Detection	Viral Culture	Other
1 - 3	71	9	1	3	0	0	2	0	3
4 - 6	30	12	2	9	1	0	4	1	1
7 - 9	19	5	1	2	1	0	1	1	0
10 - 12	80	11	1	2	3	0	2	1	0
13 - 15	7	0	0	0	0	0	0	0	0
>15	2	3	0	1	0	0	0	1	0

* The numbers in each column represent the frequency of laboratories that indicated the associated range.

44. Please indicate the number of different employees in your laboratory that perform these specific HTLV-I/II tests.

N=219

	Frequency of Laboratories Responding*								
Number of Employees	EIA	WB	IIF	PCR	PA	RIPA	HTLV-I/II Antigen Detection	Viral Culture	Other
1-2	40	16	5	11	3	0	2	3	2
3-4	49	17	1	2	1	0	5	1	2
5-6	47	6	0	1	1	0	1	0	0
7-8	24	1	0	0	0	0	2	0	0
9-10	17	0	0	0	0	0	0	0	0
>10	30	0	0	0	0	0	0	0	0

* The numbers in each column represent the frequency of laboratories that indicated the associated range.

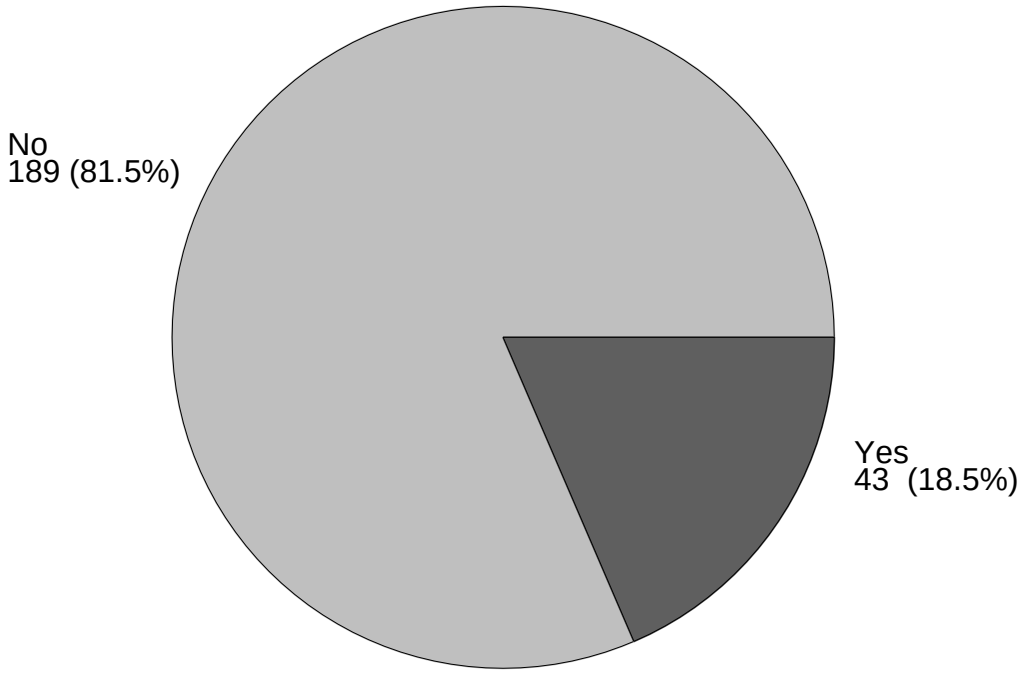
45. Please identify the source of written procedure(s) your laboratory follows for performing the following HTLV-I/II tests? (Check <u>all</u> that apply only for the procedures performed in your laboratory.)

N=234

	Frequency of Laboratories Responding*			
Source of procedure	EIA	WB	IIF	Other
No Written Procedures	1	1	1	0
In-house Written Protocol	184	32	5	12
Manufacturer's Insert	213	37	2	4
Provided by State Health Department	6	2	0	1
Other Sources	7	2	0	0

* The numbers in each column represent the frequency of laboratories that indicated the associated source of procedure.

46.(a) Does your laboratory perform HTLV-I/II Western blot testing?



N=232

46.(b) Which of the following WB band patterns does your laboratory routinely use to classify a specimen as HTLV-I/II antibody reactive? (Choose only <u>one</u>.)

N=39

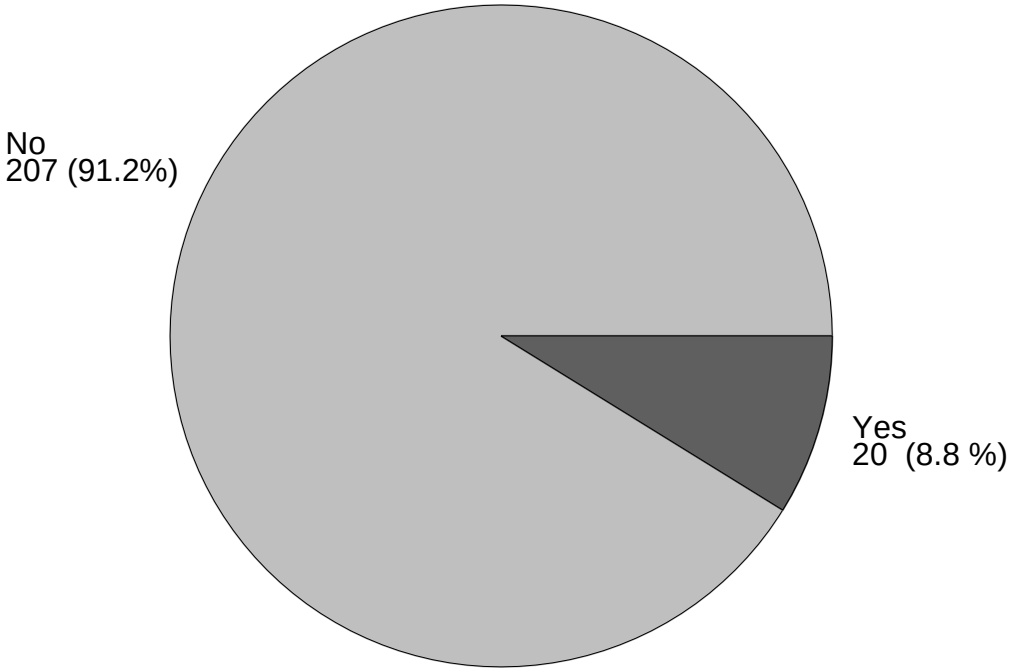
Band Patterns	Number of Laboratories	Percentage of Laboratories
Other	16	41.0
p24 and gp46 or r21e	9	23.1
One protein from each of the viral gene product groups: gag (19, p24) and env (gp21, gp 46, gp61/68)	8	20.5
p24 and gp46 or gp61/68	3	7.7
p19 or p24, and gp46 or gp61/68	2	5.1
Any HTLV-I/II specific protein bands	1	2.6

46.(c) Which of the following is required for your laboratory to interpret an HTLV-I/II WB result as ***negative***? (Choose only one.)

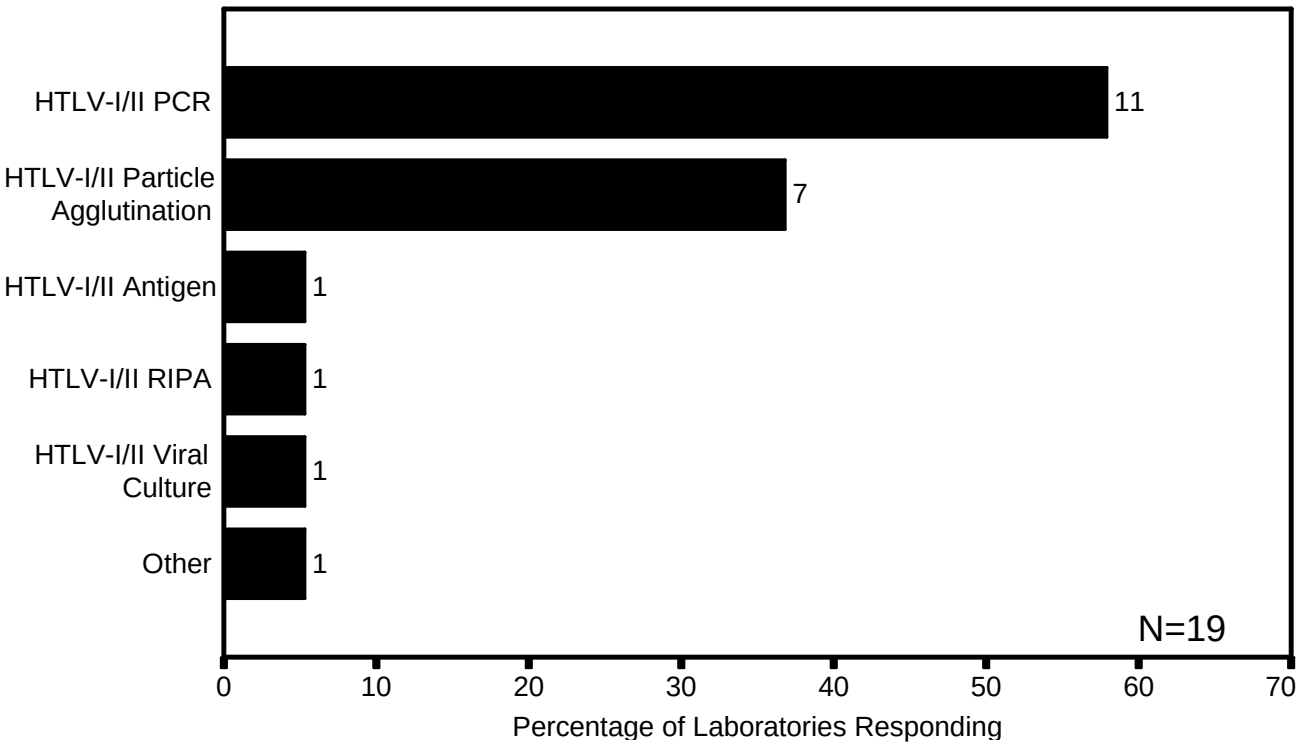
N=41

Band Patterns	Number of Laboratories	Percentage of Laboratories
No HTLV-I/II specific protein band(s) (i.e., 19, 21/22, 24, 26, 36, 46, 53/55, 61/68)	22	53.7
No bands present	15	36.6
Other	4	9.8

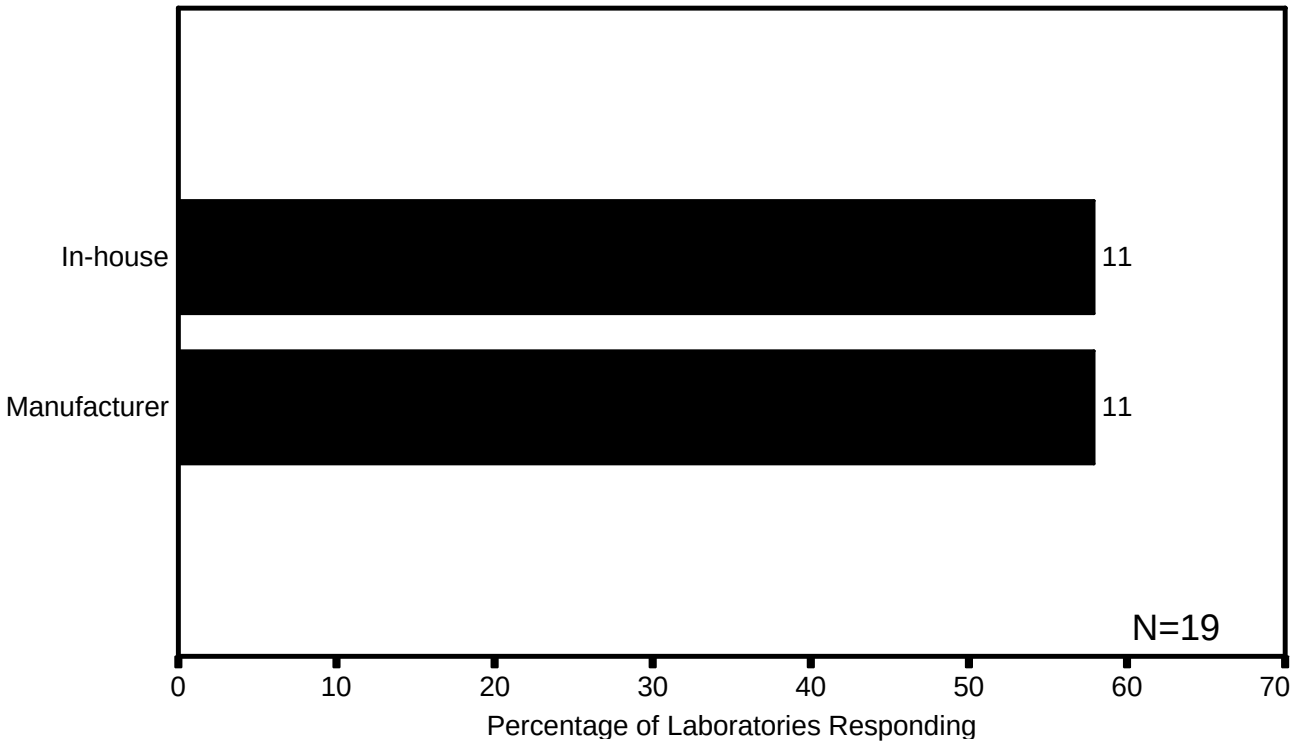
47.(a) Do you perform an HTLV-I/II antibody test <u>other than</u> EIA, WB, or IIF, <u>to detect HTLV-I/II infection</u>?



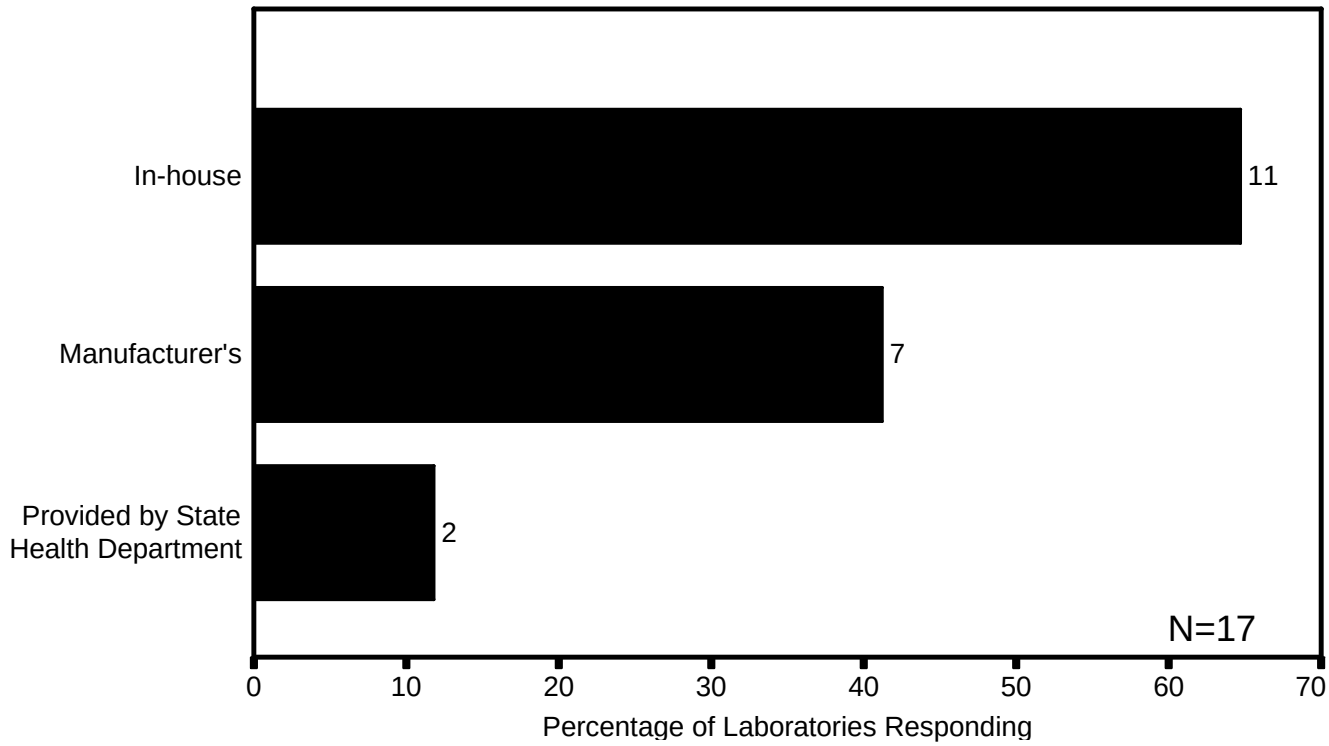
47.(b) If yes, indicate below the other tests performed in your laboratory (Check <u>all</u> that apply.):



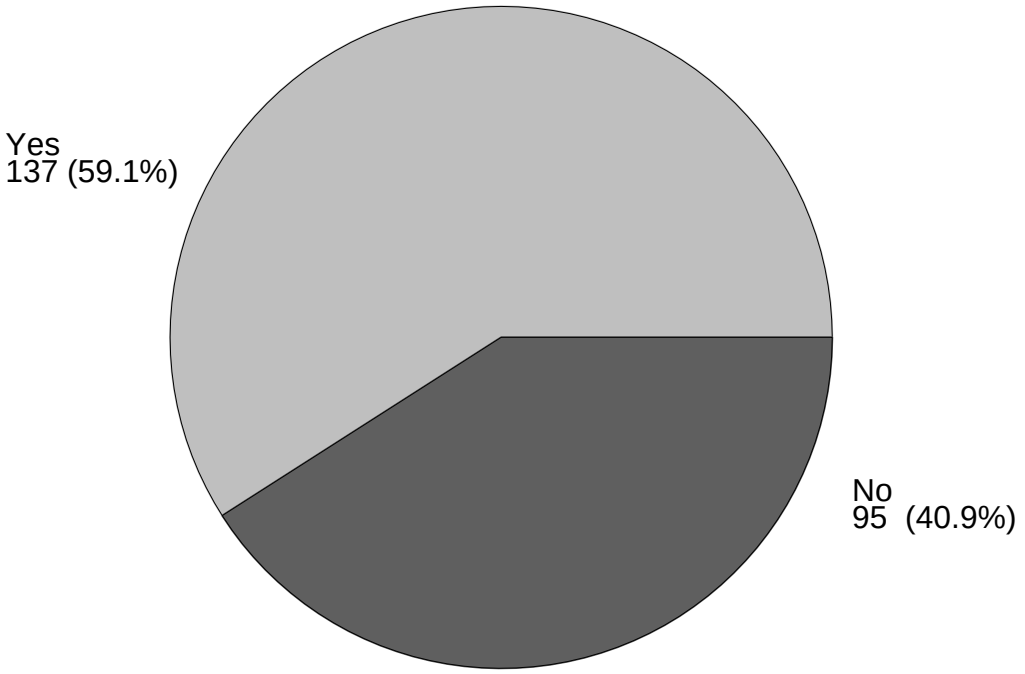
47.(c) Source of reagents for HTLV-I/II tests other than EIA, WB, and IIF as indicated in question 47(b) (Check <u>all</u> that apply.):



47.(d) What procedure does your laboratory follow for performing HTLV-I/II antibody tests <u>other than</u> EIA, WB, or IIF? (Check <u>all</u> that apply.)



48.(a) Does your laboratory use controls other than kit manufacturer controls?



N=232

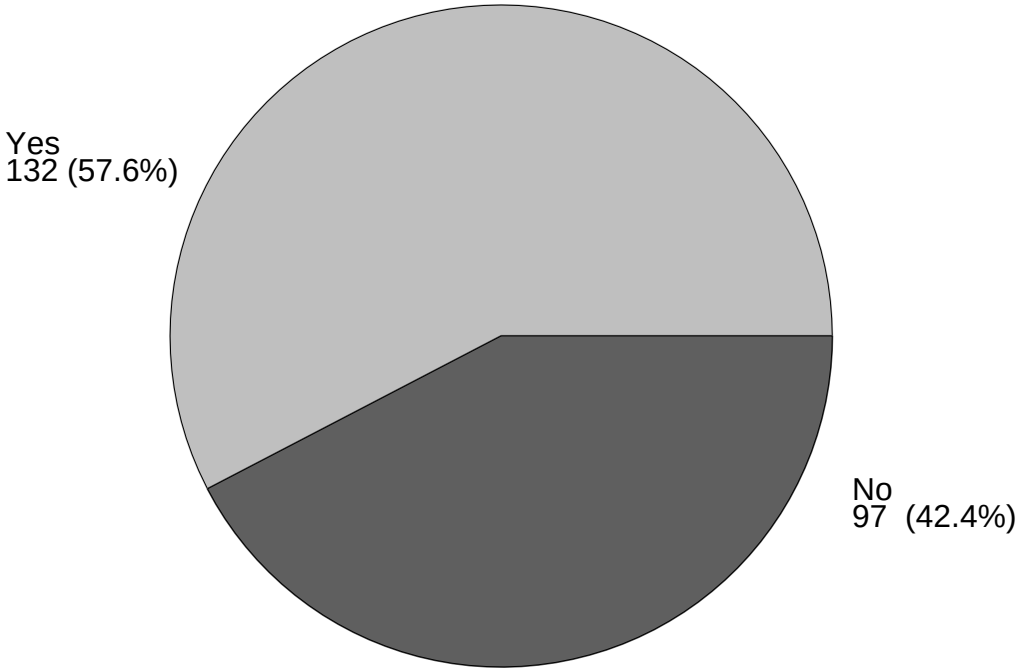
48.(b) If your laboratory uses controls other than the kit manufacturer controls, please indicate the frequency with which your laboratory uses HTLV-I/II control sera/plasma for each of the test methods below (Check <u>all</u> that apply.):

N=134

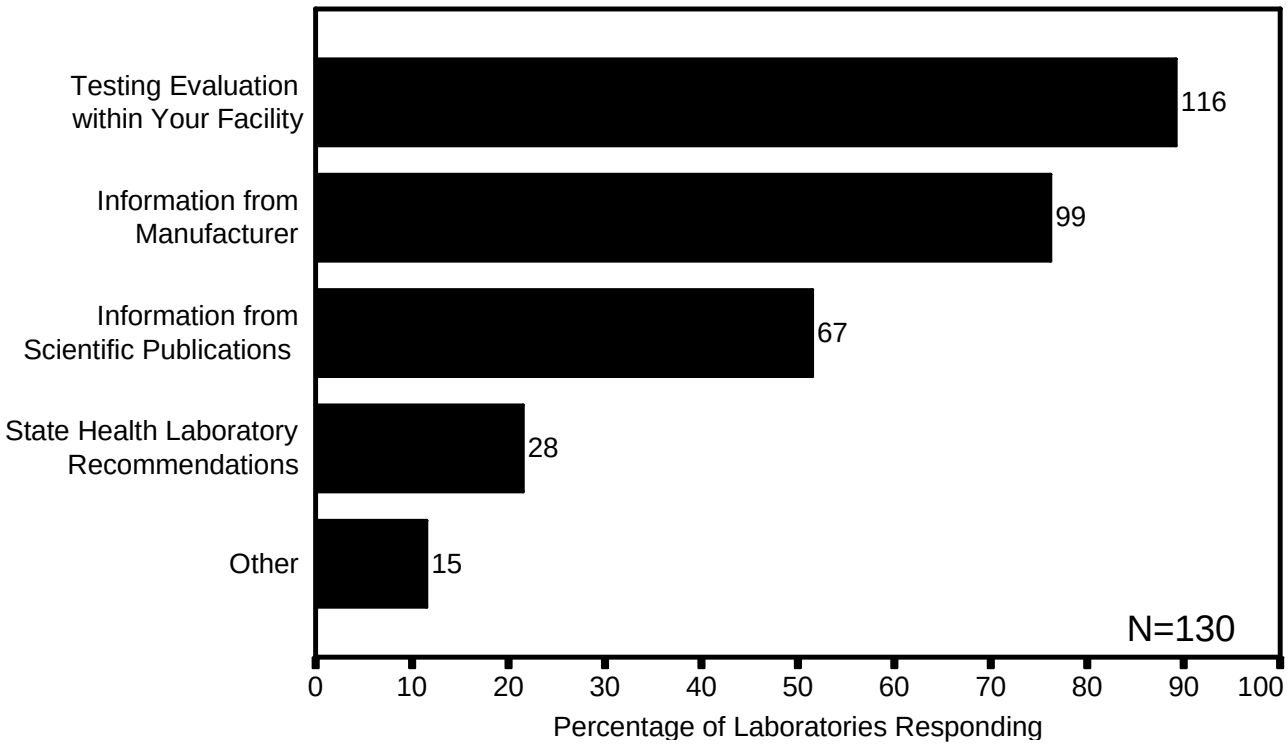
	Frequency of Laboratories Responding*				
Test Method	Each Test[a]	Each Set[b]	Two Each Day	Each Test Kit	Other Frequency
EIA	56	71	9	9	1
WB	1	12	1	3	1
IIF	0	4	0	0	0
Other	1	7	0	0	0

[a] An EIA plate, Western blot strip or IIF slide
[b] A set of EIA plates, Western blot strips or IIF slides
* The numbers in each column represent the frequency of laboratories that indicated the associated test method.

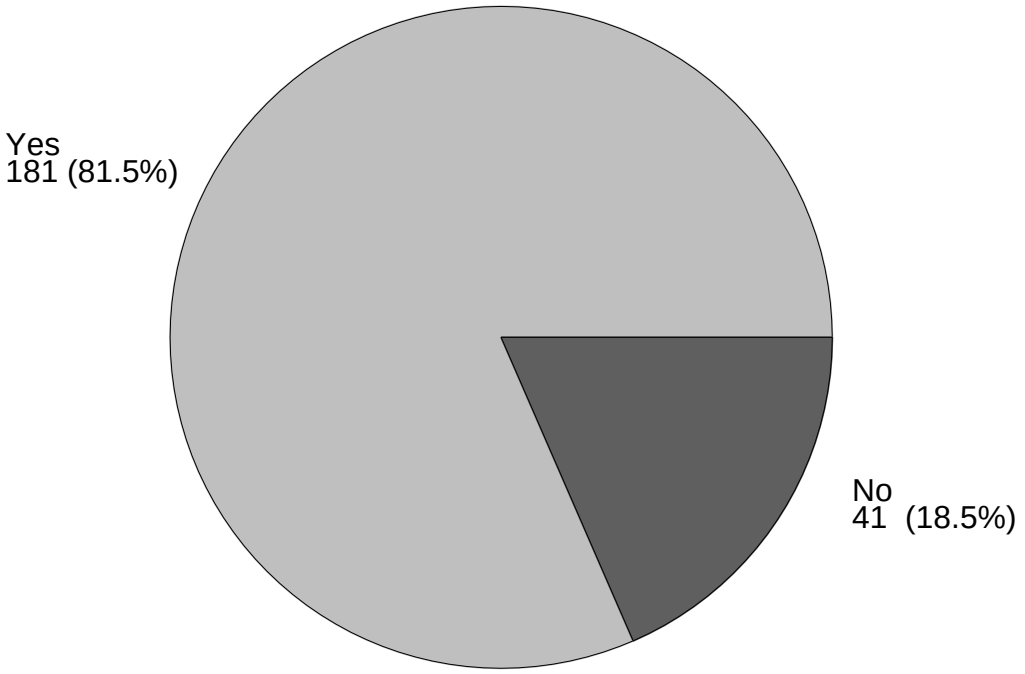
49.(a) Does your laboratory have *written criteria* for adopting a new test or a different manufacturer's test for HTLV-I/II testing?



49.(b) If Yes, please identify the methods used for establishing these written criteria (Check all that apply.):

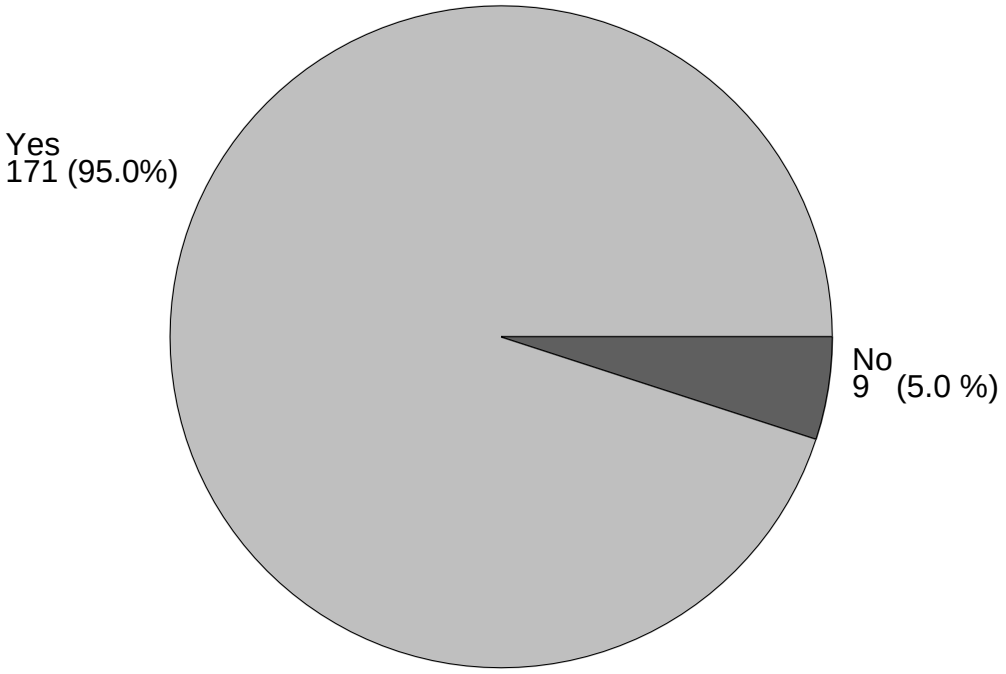


49.(c) Does your laboratory have an HTLV-I/II quality assurance plan?



N=222

49.(d) Does your laboratory have written policies and/or procedures for monitoring an HTLV-I/II testing quality assurance plan?



N=180

50. This question refers to the volume of HTLV-I/II antibody testing performed in your laboratory. Responses should reflect the number of patient/donor specimens tested during the most recent representative month. (Round off to the nearest whole number.)

N=230

	Frequency of Laboratories Responding*			
Number During Most Recent Representative Month	Total Specimens Tested	Reactive by Screen	Tested by Suppl/Conf	Reactive by Suppl/Conf
<10	15	98	76	51
10-99	64	40	23	9
100-999	76	7	8	2
1,000-9,999	53	0	0	0
10,000-99,999	20	0	0	0
>99,999	1	0	0	0

* The numbers in each column represent the frequency of laboratories that indicated the associated range.

51. On average, how much time occurs for the following events in your laboratory? (Round off to nearest day, if less than one day, round off to one day.)

N=220

	Frequency of Laboratories Responding*		
Days Until →	Receipt in Laboratory	Specimen is Tested	Results are Reported
1	181	124	164
2-3	19	60	33
4-5	4	21	5
6-7	0	8	3
>7	4	3	4

* The numbers in each column represent the frequency of laboratories that indicated the associated range.

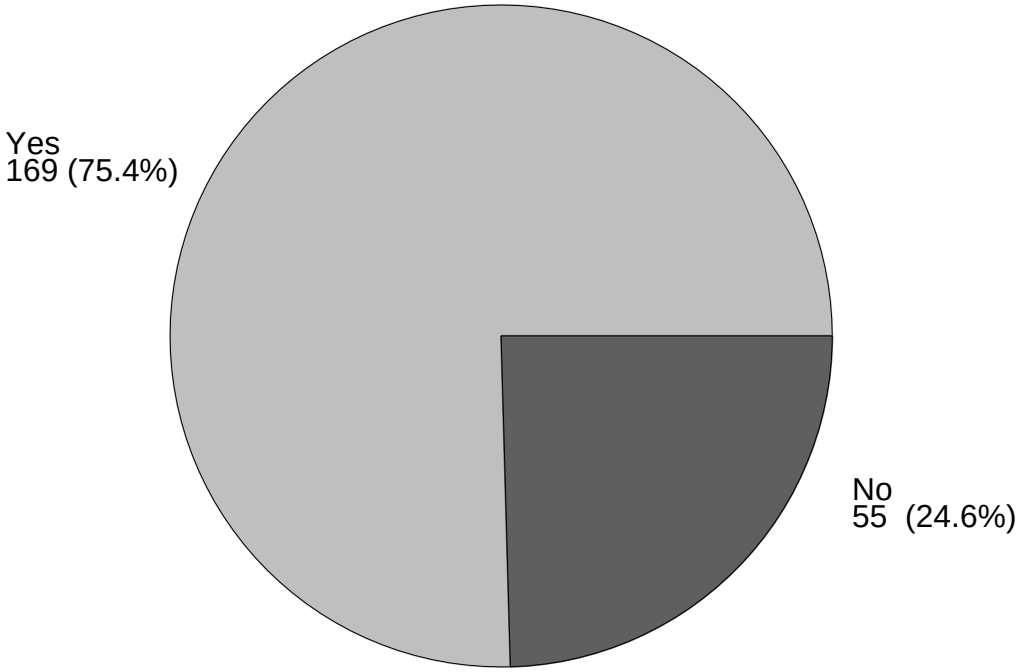
52. Approximately how much does your laboratory charge to perform an HTLV-I/II antibody? (Round off to nearest U.S. dollar.)

N=147

	Frequency of Laboratories Responding*			
Approximate Charge by Laboratory	EIA	WB	IIF	Other
<$50	102	7	4	0
$50-$99	35	8	0	2
$100-$149	7	10	0	3
$150-$200	1	1	0	0
>$200	2	1	1	2

* The numbers in each column represent the frequency of laboratories that indicated the associated range.

53.(a) Does your laboratory send HTLV-I/II specimens to other laboratories for additional testing?



N=224

53.(b) Please indicate the additional testing requested by identifying the types of laboratories to which HTLV-I/II specimens are referred for these additional tests (Check <u>all</u> that apply.):

N=169

Test Type	Hospital	Health Department	Blood Bank	Independent	Other	Total
EIA	1	6	10	21	1	39
WB	4	14	17	112	3	150
IIF	0	6	0	2	0	8
PA	0	0	0	2	0	2
RIPA	0	5	1	21	0	27
PCR	0	7	0	16	0	23
Viral Culture	0	0	0	2	0	2
Antigen	0	0	0	2	0	2
Other	0	0	0	2	0	2