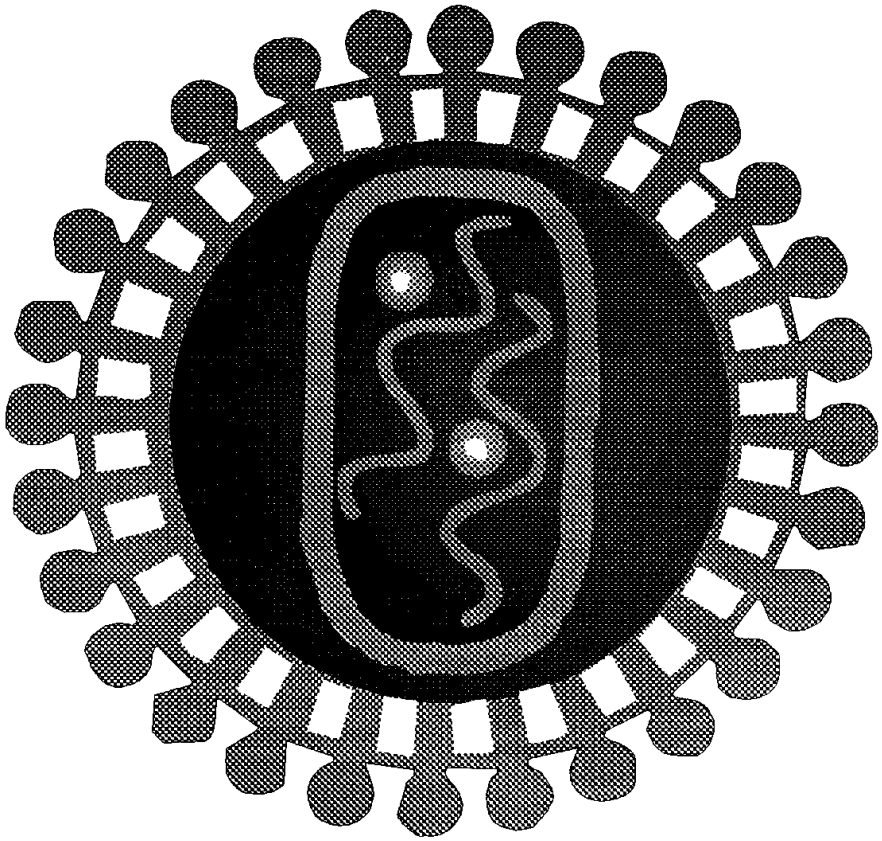
Results of the 2001 Retroviral Testing Survey Questionnaire Sent to Laboratories Participating in the Model Performance Evaluation Program



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

This report provides the results of a **2001 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
2001 Retroviral Questionnaire Survey Results

The Model Performance Evaluation Program (MPEP) retroviral questionnaire survey was mailed March 20, 2001, to 942 laboratories of which 690 (73%) returned completed surveys. Of these 942 laboratories receiving the questionnaire, 756 were laboratories located in the United States (US) or US territories and 562 (74%) responded. The remaining 186 laboratories were located outside the US and 129 (69%) returned completed surveys. Aggregate data are presented in the following graphs and tables.

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.

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 25.3%, 35.2% and 25.8% of the total responses to questions 14a, 14b, and 43, respectively.

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.

CDC Model Performance Evaluation Program
March 2001 Retroviral Survey

Number of MPEP Laboratories by Country

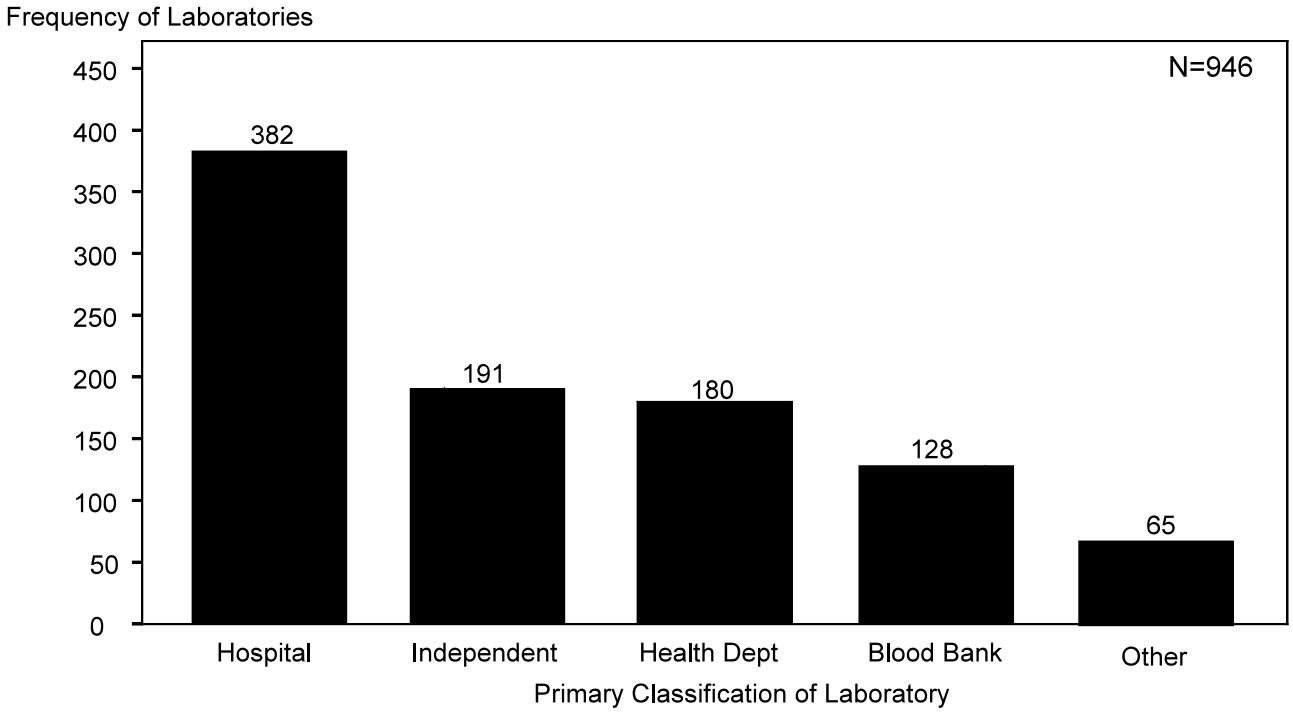
N = 946

Country	Number of Laboratories	Country	Number of Laboratories	Country	Number of Laboratories
Argentina	4	Guatemala	1	Russia	1
Australia	6	Honduras	1	Saudi Arabia	2
Austria	4	Hong Kong	2	Scotland	1
Bahamas	1	Hungary	1	Slovakia	1
Barbados	1	India	5	Slovenia (Yugoslavia)	2
Belgium	3	Ireland	1	South Africa	5
Bolivia	1	Israel	6	South Korea	2
Brazil	4	Italy	3	Spain	6
Burkina Faso	1	Jamaica	1	Sri Lanka	5
Cameroon	1	Japan	2	St. Kitts/Nevis	1
Canada	24	Kenya	1	Suriname	2
Central African Republic	1	Malaysia	2	Switzerland	1
Chile	1	Mali, West Africa	1	Taiwan	2
Colombia	1	Malta	1	Tanzania	2
Costa Rica	2	Mexico	1	Thailand	9
Cote d'Ivoire	3	Morocco	1	Trinidad	2
Croatia	2	Myanmar (Burma)	1	Turkey	1
Curacao, Netherlands Antilles	1	New Zealand	1	US Territory	24
Denmark	3	Nicaragua	1	Uganda, East Africa	3
Dominican Republic	3	Nigeria	1	Ukraine	4
Ecuador	1	Norway	1	United Arab Emirates	3
Egypt	1	Panama	1	United States	732
El Salvador	1	Paraguay	1	Uruguay	1
England	3	Peru	2	Venezuela	3
Ethiopia	2	Philippines	3	Vietnam	1
France	1	Portugal	1	Western Samoa	1
Germany	3	Republic of Singapore	1	Zambia	1
Ghana	3	Romania	1		

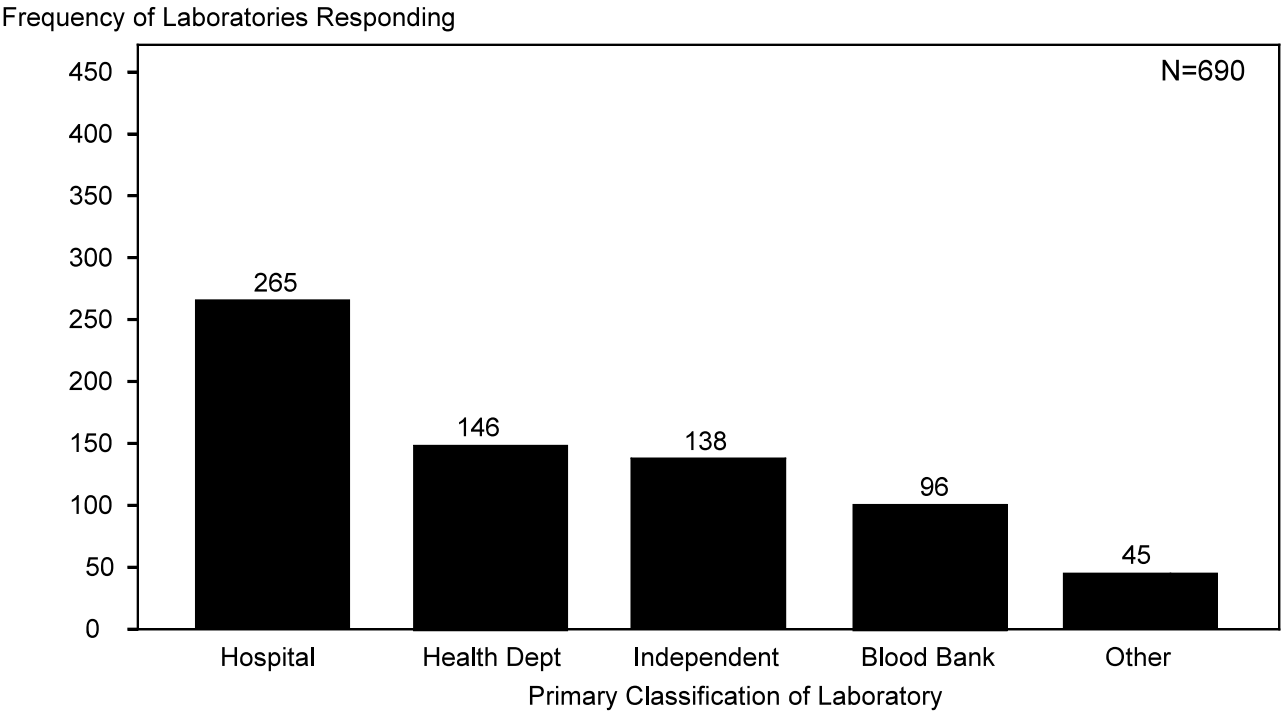
Number of MPEP Retroviral Laboratories in the United States and Territories

Primary Classification of MPEP Laboratories in Regard to Retroviral Testing

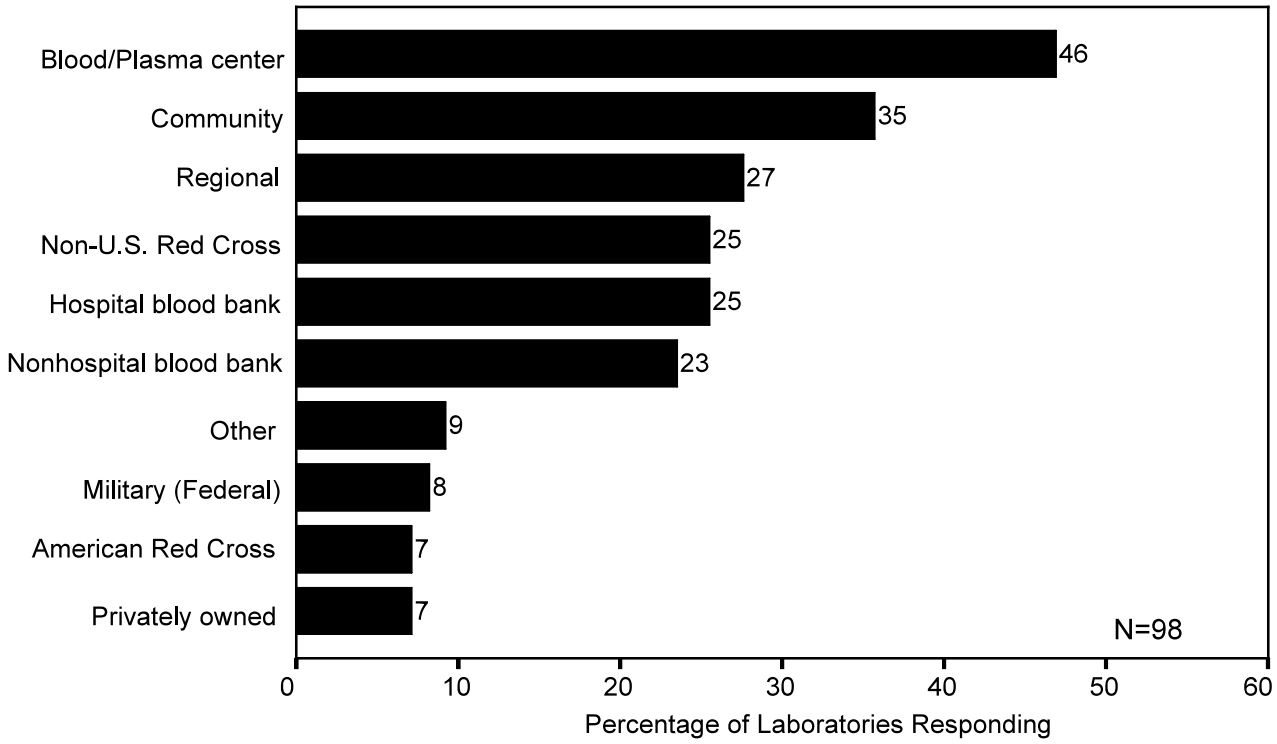
Total Number of Laboratories Enrolled in the Retroviral Program



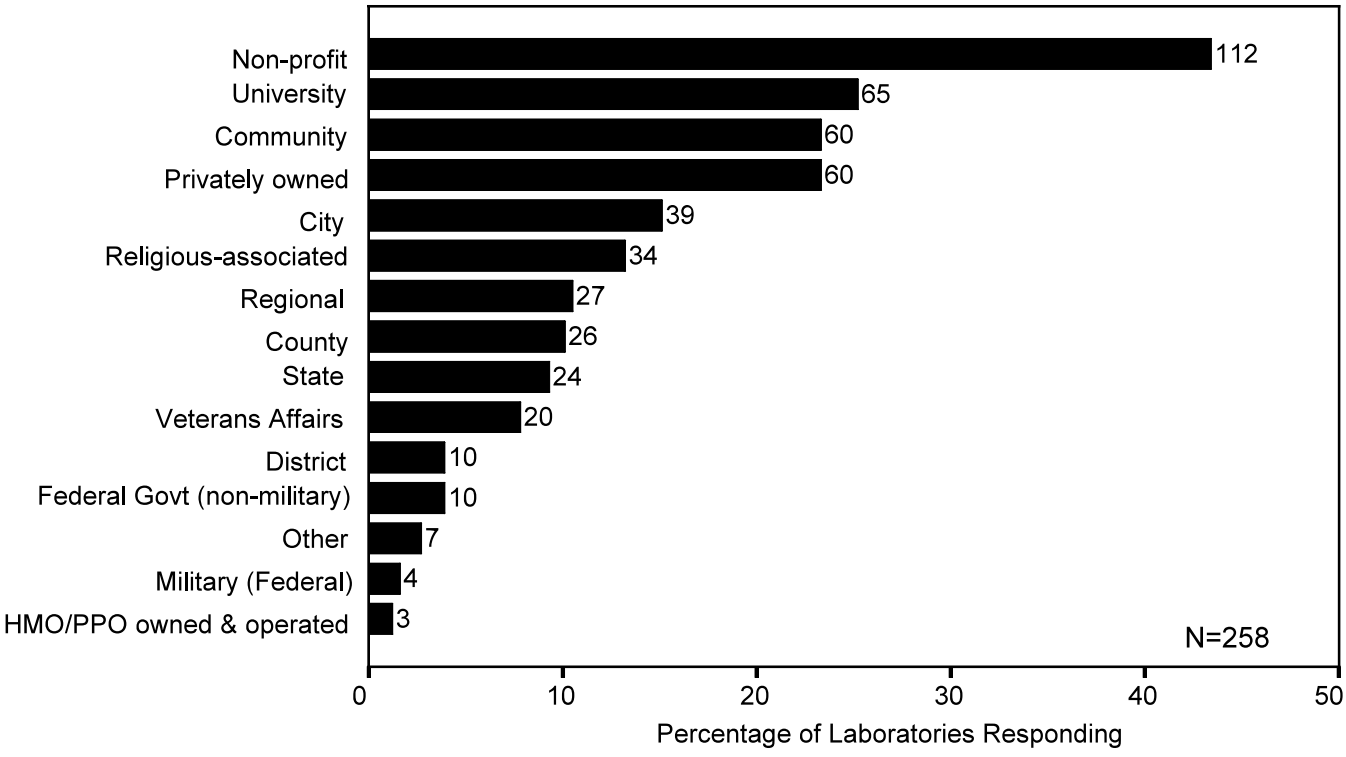
Classification of Laboratories Responding to Questionnaire Survey



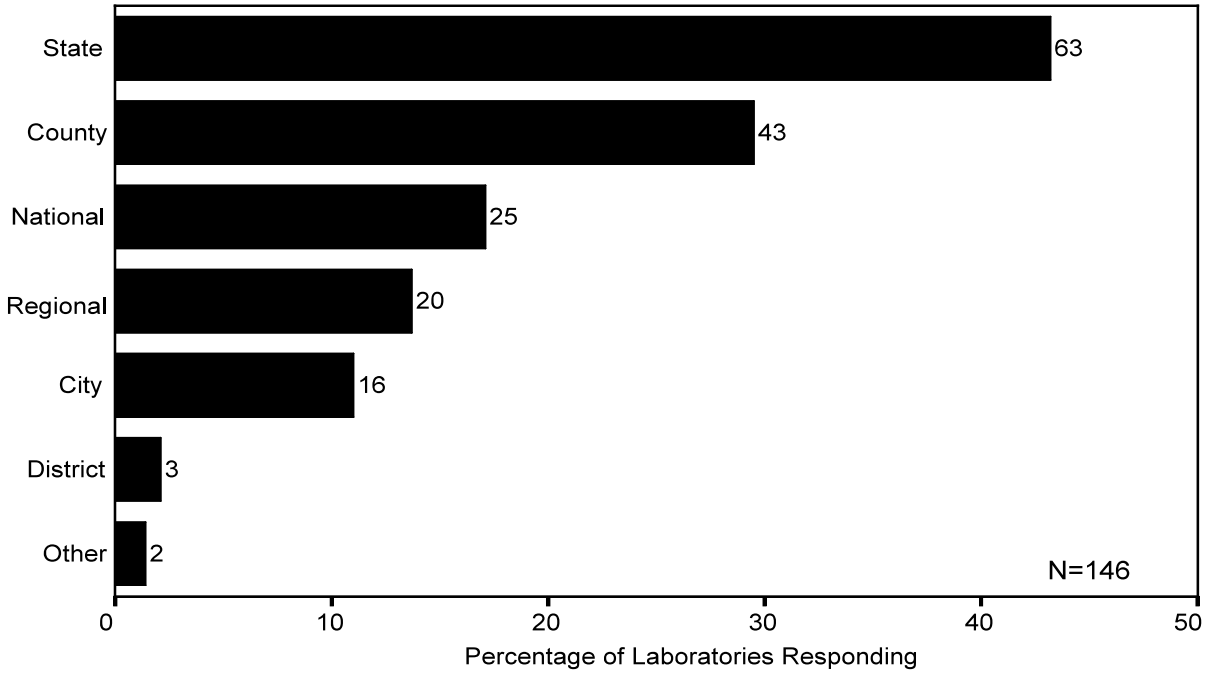
3.(a) If the laboratory type shown on your mailing label (located on page one) is BLOOD BANK, please <u>further describe</u> your retroviral testing laboratory (Check <u>all</u> that apply within your Blood Bank laboratory classification.):



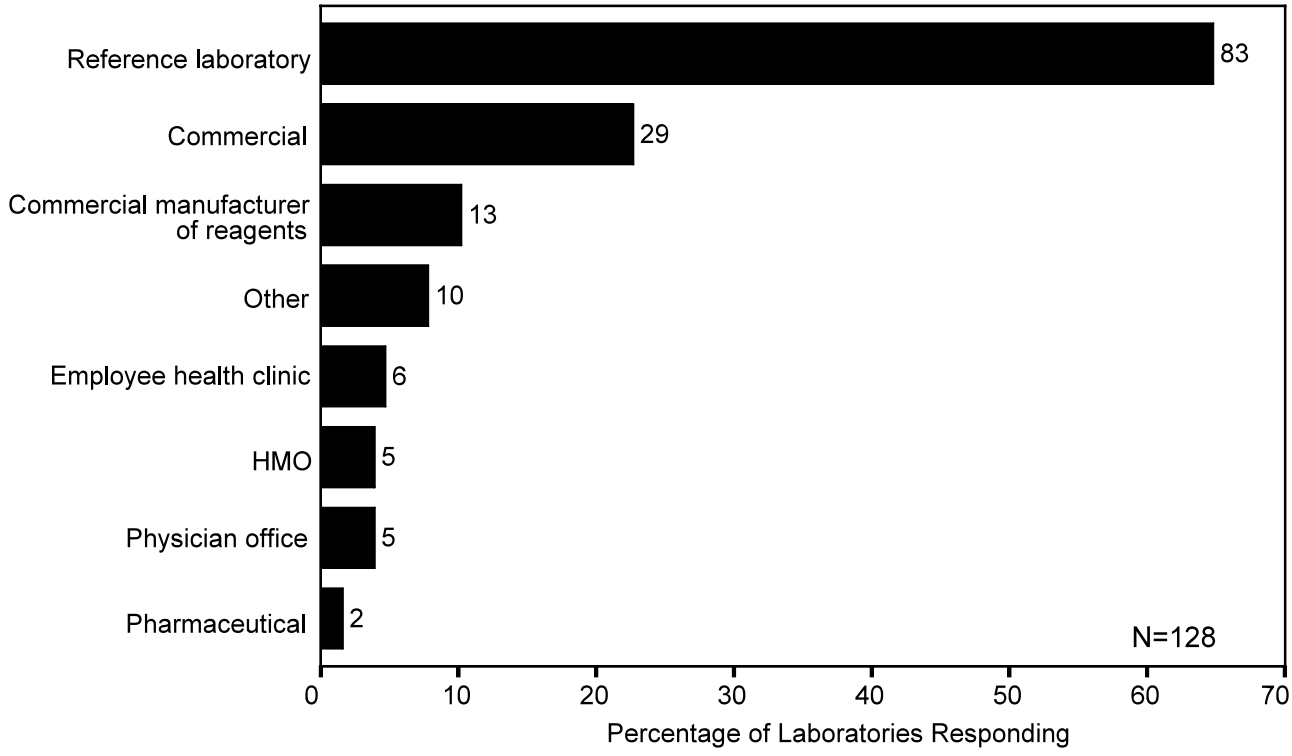
3.(b) If the laboratory type shown on your mailing label (located on page one) is HOSPITAL, please <u>further describe</u> your retroviral testing laboratory (Check <u>all</u> that apply within your Hospital laboratory classification.):



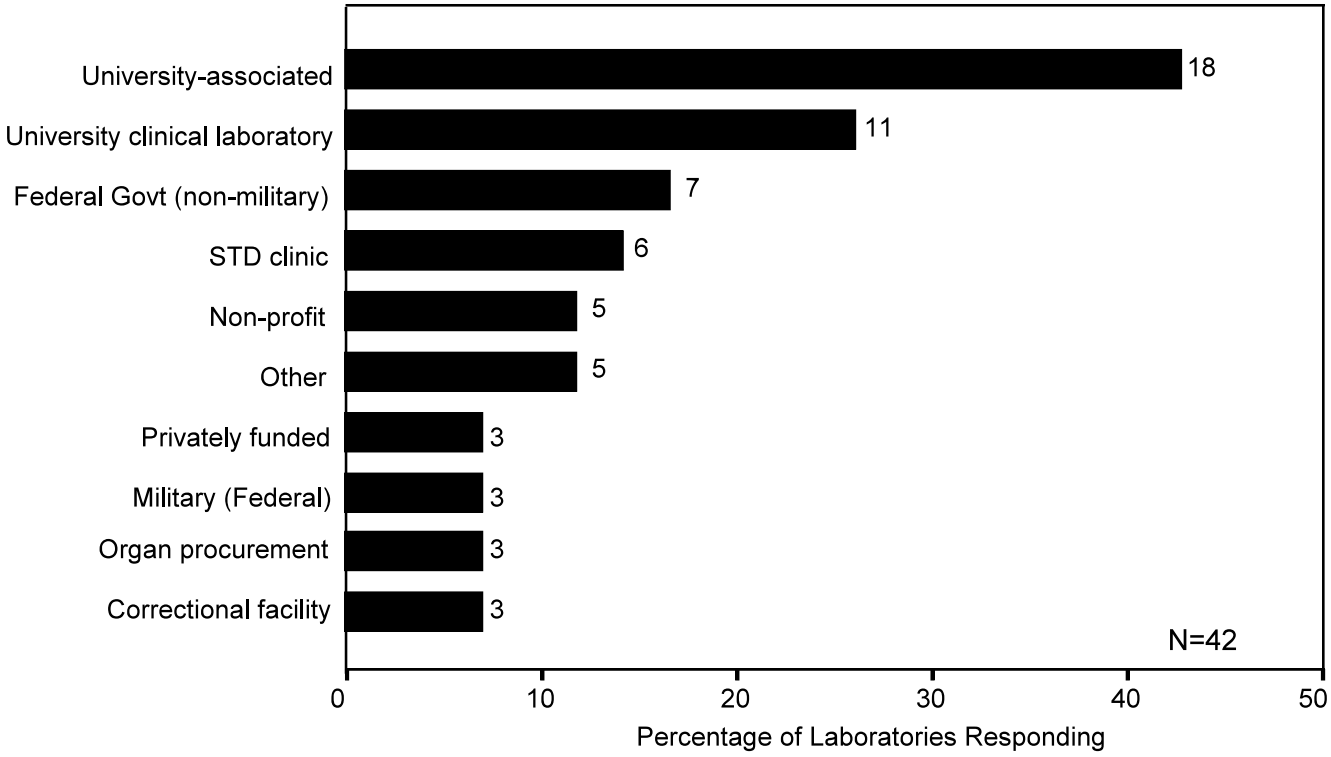
3.(c) **If the laboratory type shown on your mailing label (located on page one) is HEALTH DEPARTMENT (or Government Health System as indicated in some countries outside the United States), please <u>further describe</u> your retroviral testing laboratory (Check <u>all</u> that apply within your Health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



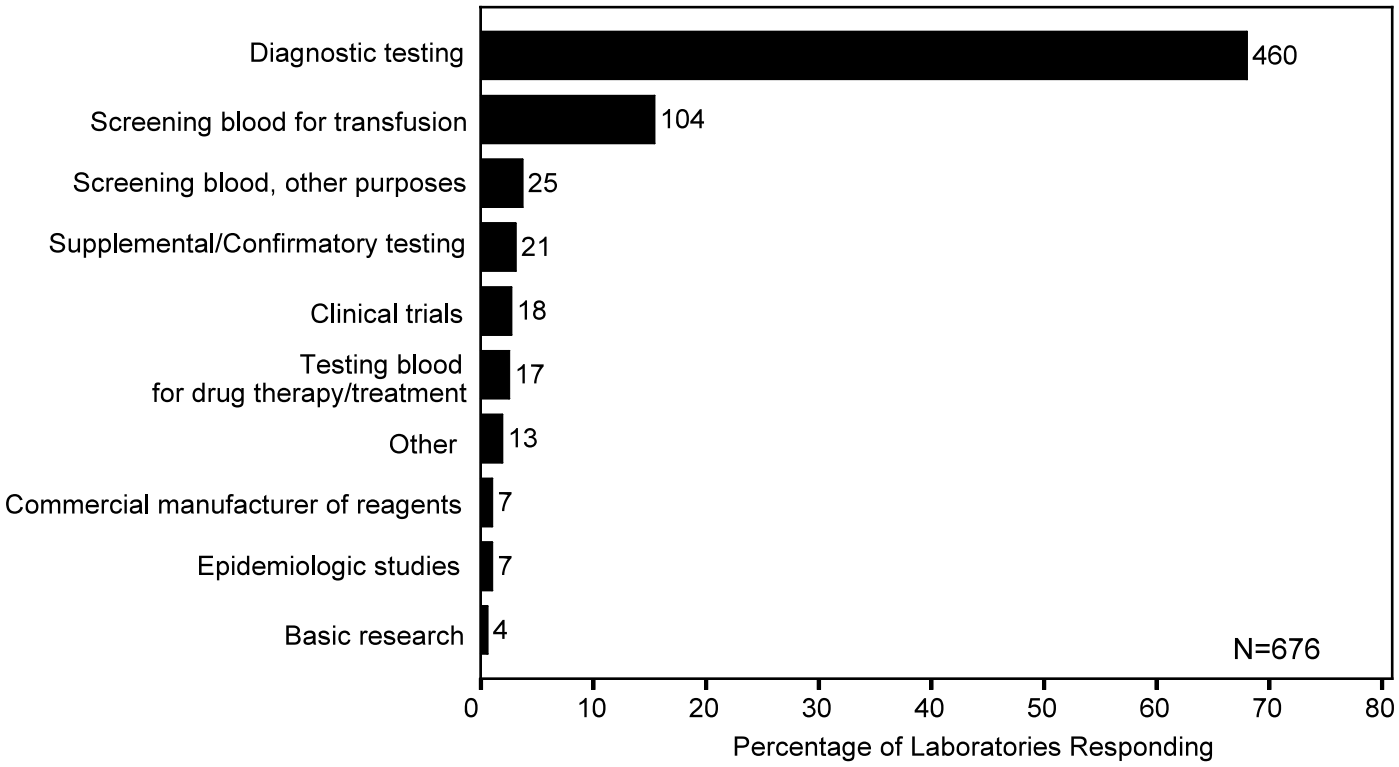
3.(d) **If the laboratory type shown on your mailing label (located on page one) is INDEPENDENT, please <u>further describe</u> your retroviral testing laboratory (Check <u>all</u> that apply within your Independent laboratory classification.):**



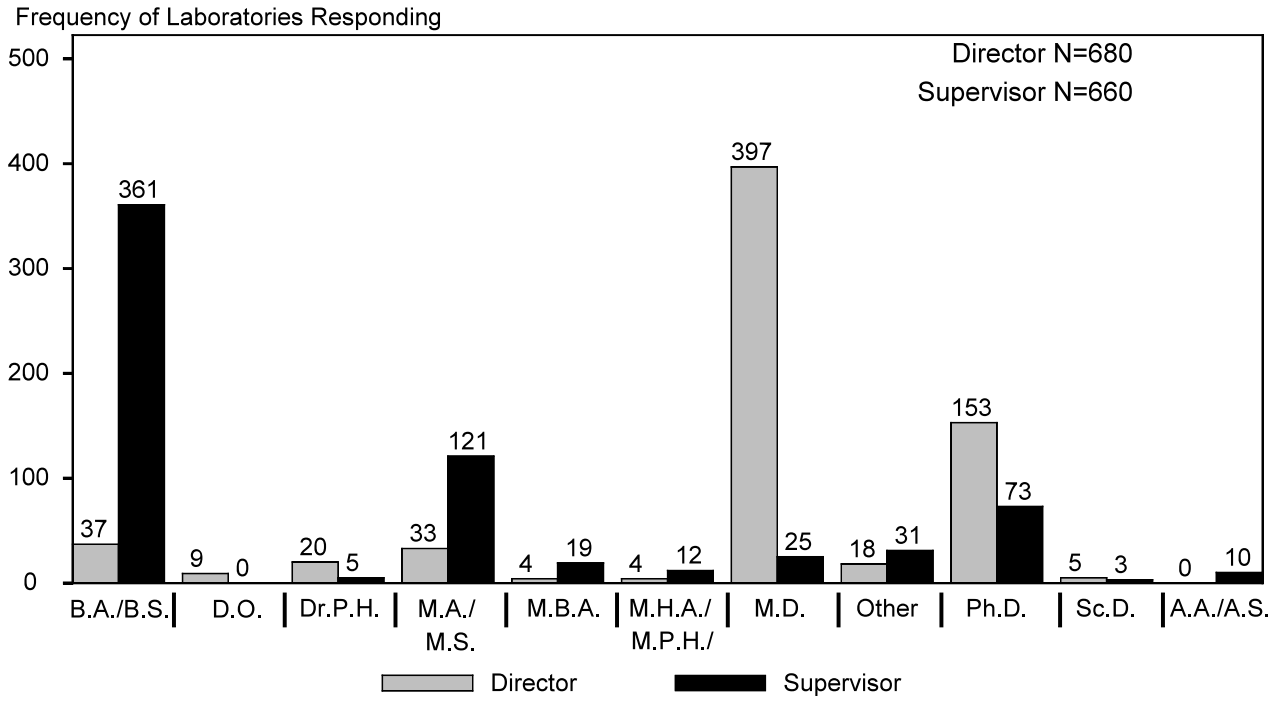
3.(e) If the laboratory type shown on your mailing label (located on page one) is OTHER, please <u>further describe</u> your retroviral testing laboratory (Check <u>all</u> that apply within your Other laboratory classification.):



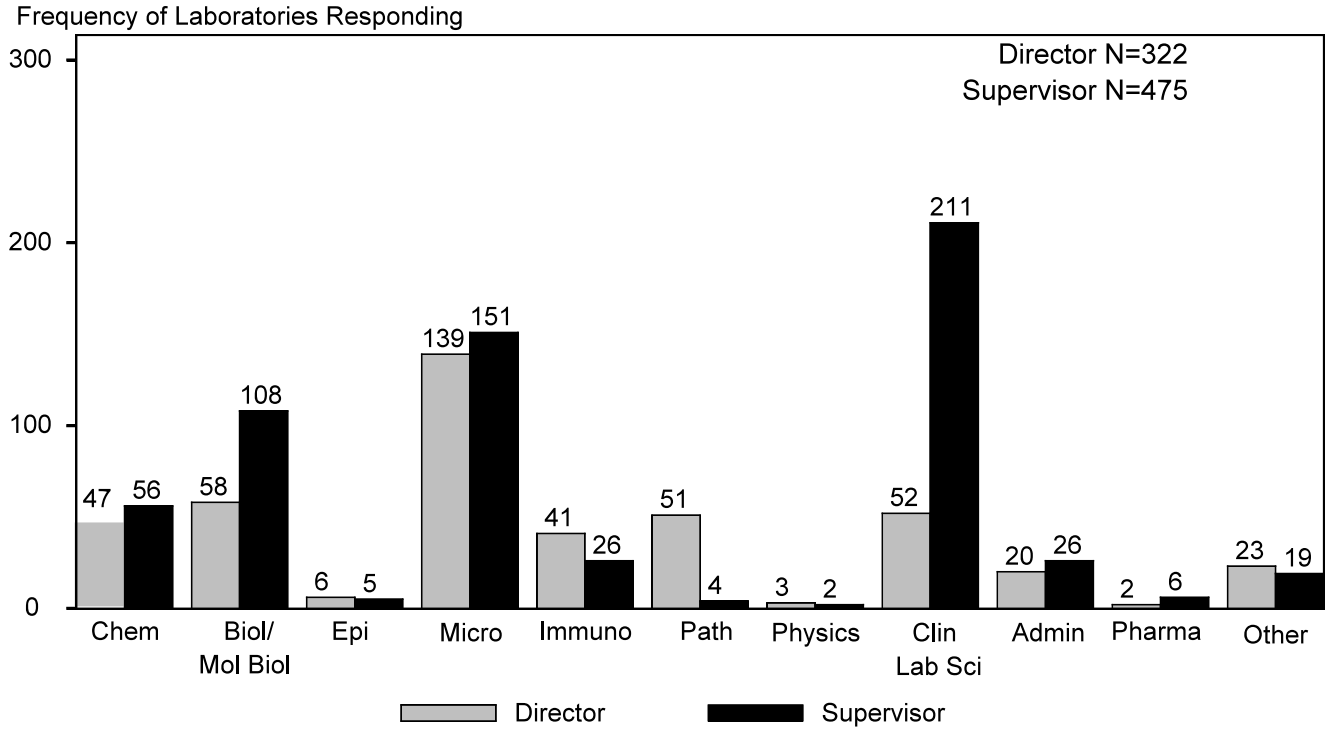
4. What is the *<u>primary purpose</u>*** of your retroviral testing operation? (Choose only <u>one</u>.)**



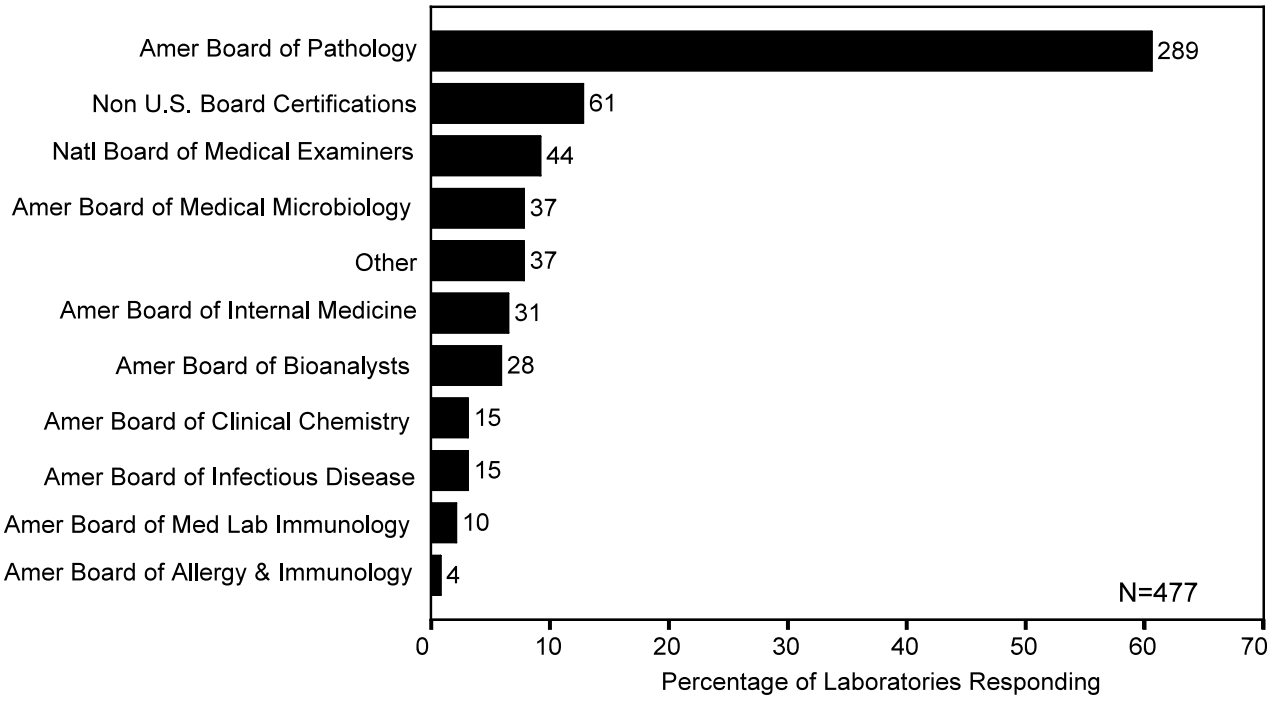
5.(a) Please choose the *highest academic degree* that has been awarded to your *Laboratory Director* and *Laboratory Supervisor* (Choose only one degree for each person.) Note: MT(ASCP) is not an academic degree.



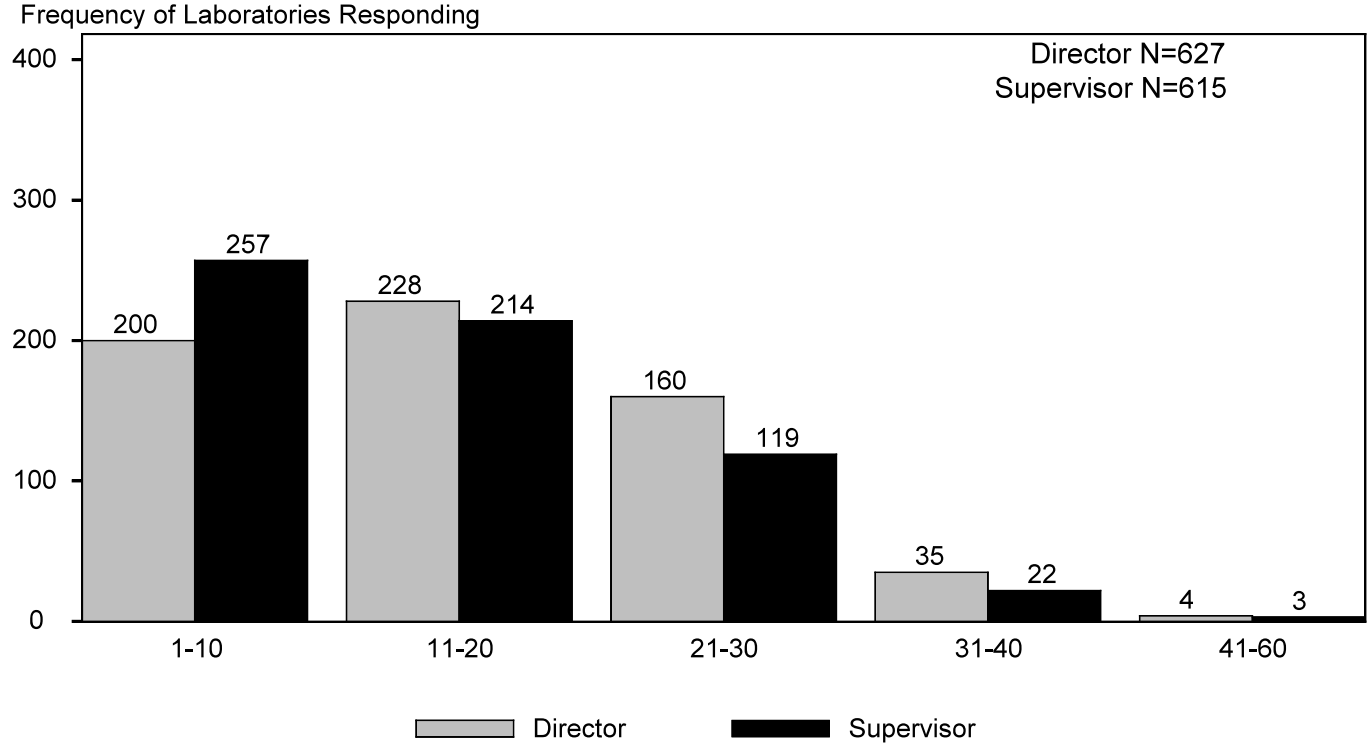
5.(b) If your Laboratory Director or Laboratory Supervisor has a degree other than M.D. or D.O., please indicate the academic discipline in which the degree was awarded (Check all that apply.):



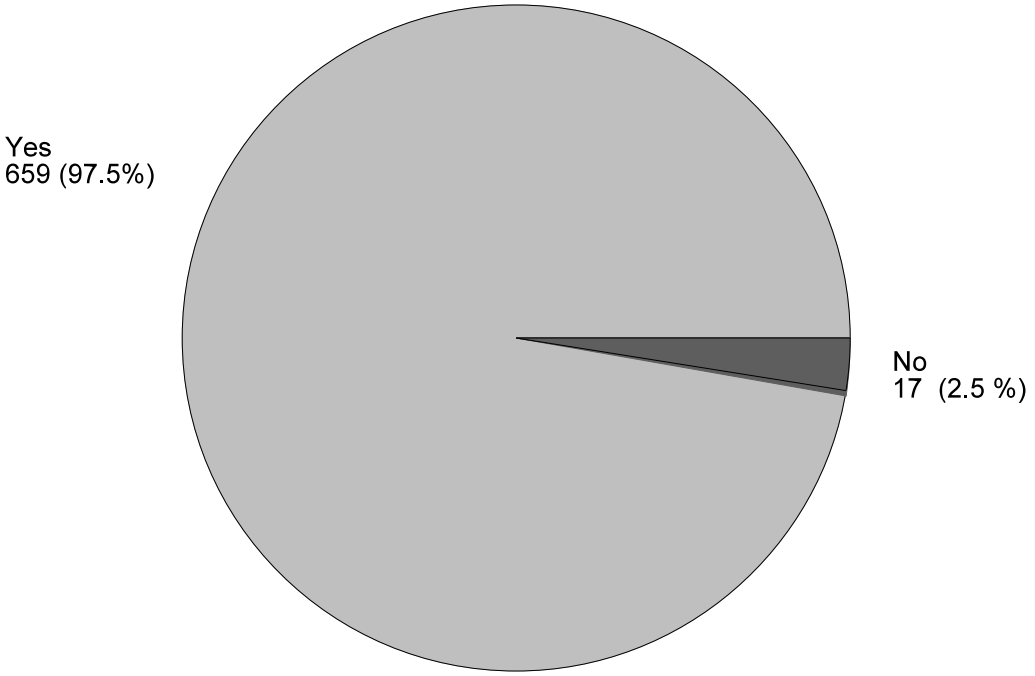
5.(c) What board certifications have been awarded to your Laboratory Director? (Check all that apply.):



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

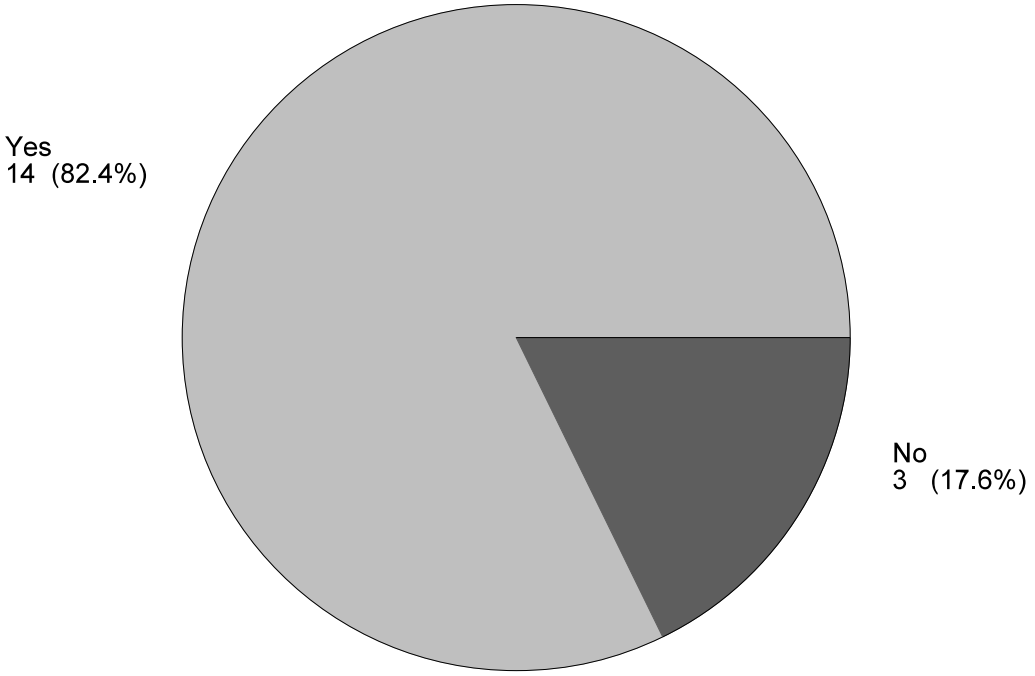


5.(e) Is your Laboratory Supervisor available to provide supervision on-site?



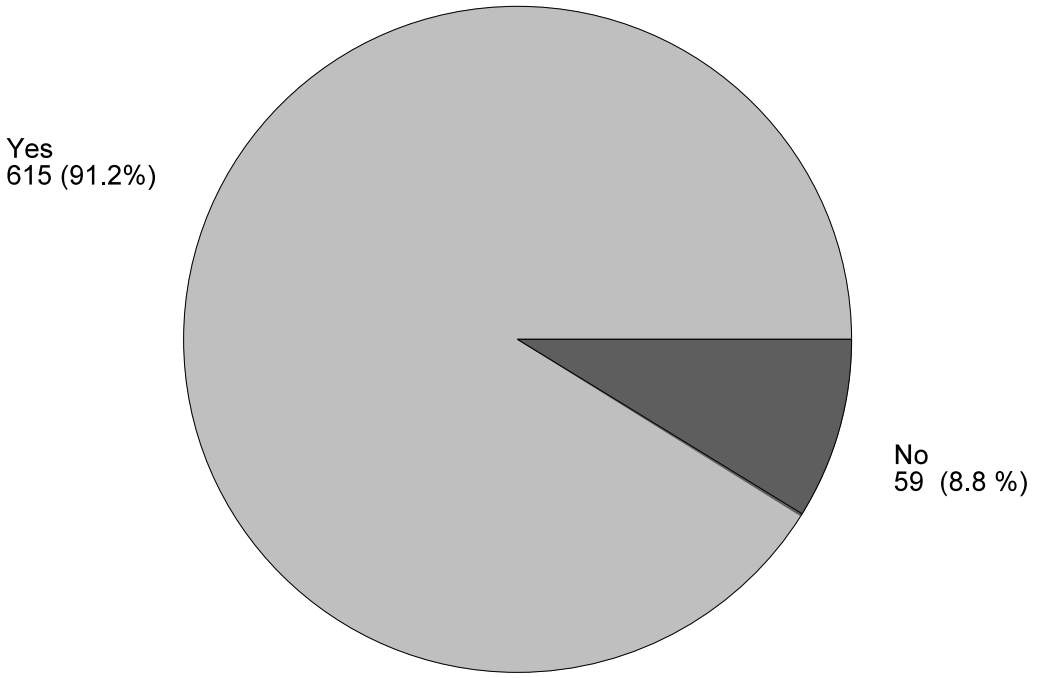
N=676

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



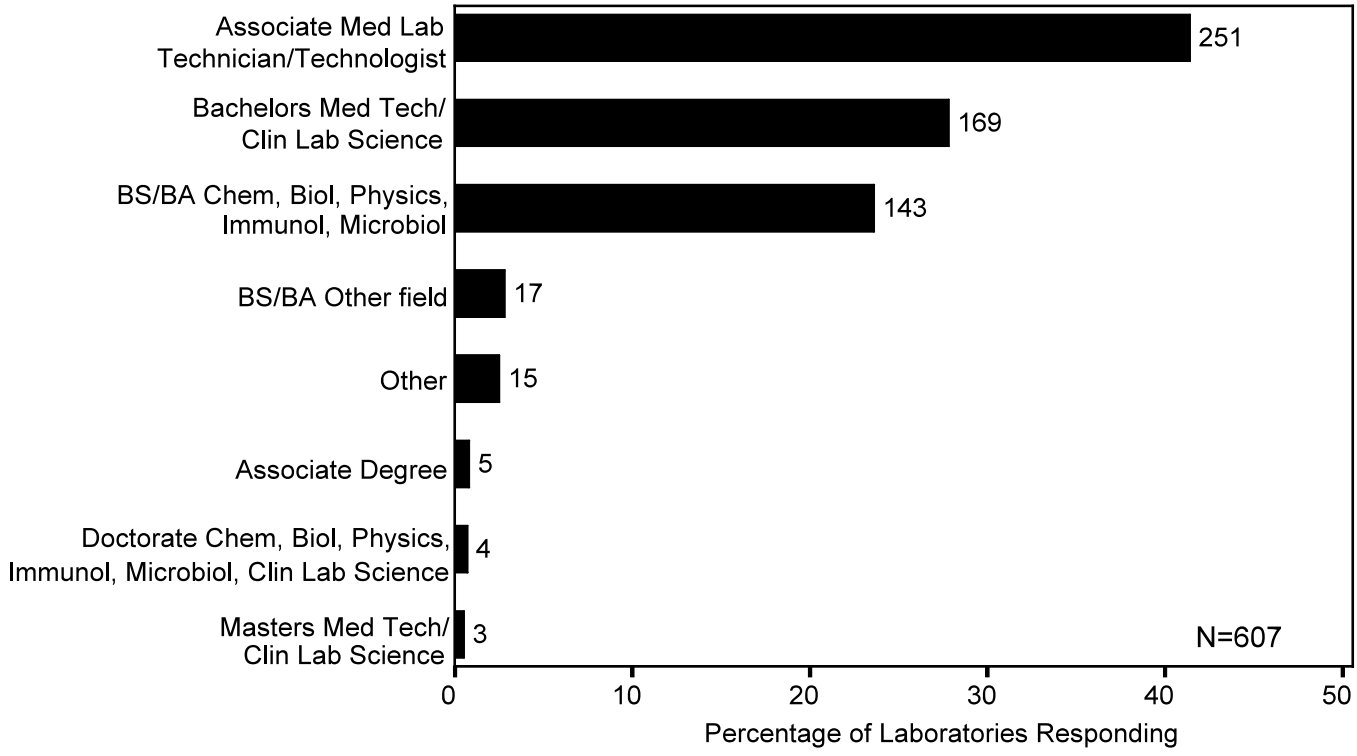
N=17

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

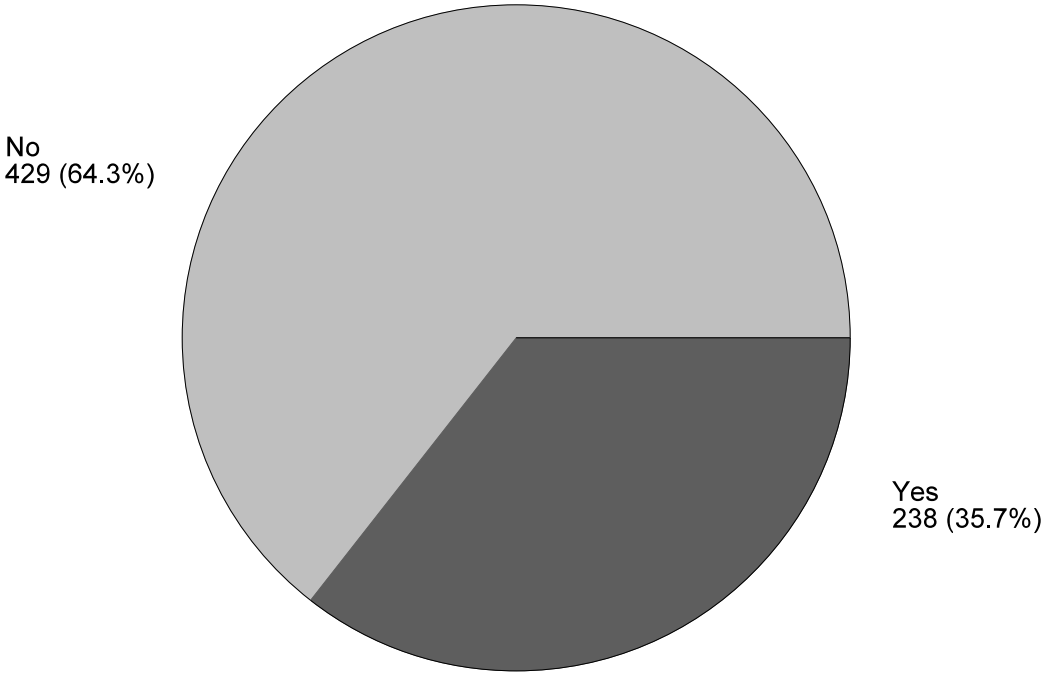


N=674

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.)

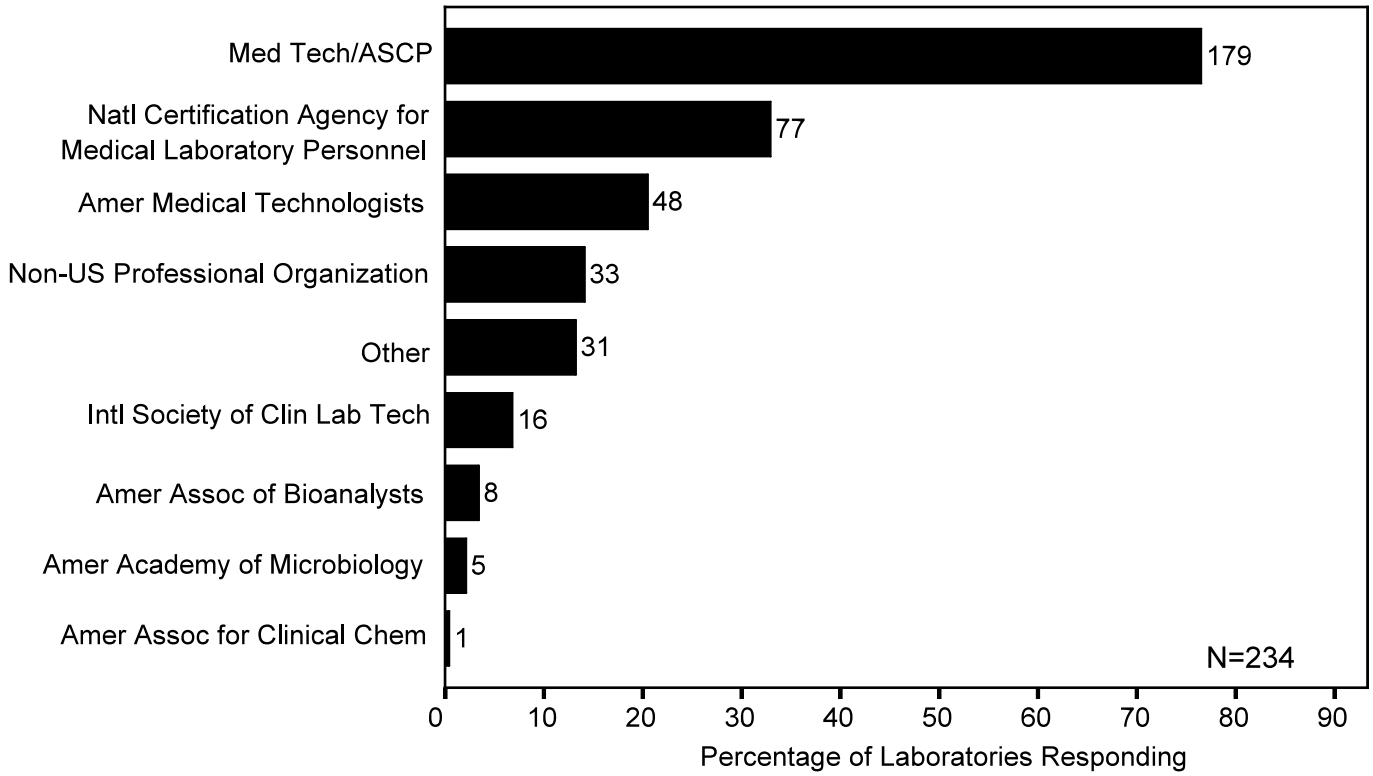


6.(c) Does your laboratory require that your retroviral testing personnel have certification by a professional organization? (Do not include certification or licensing by city, state, or country.)

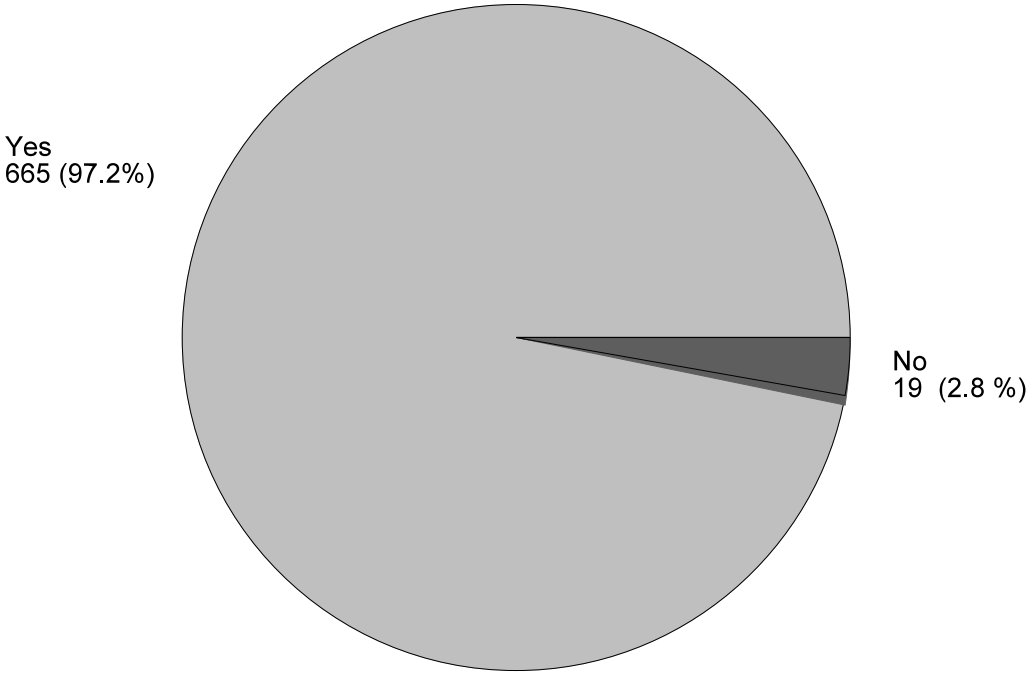


N=667

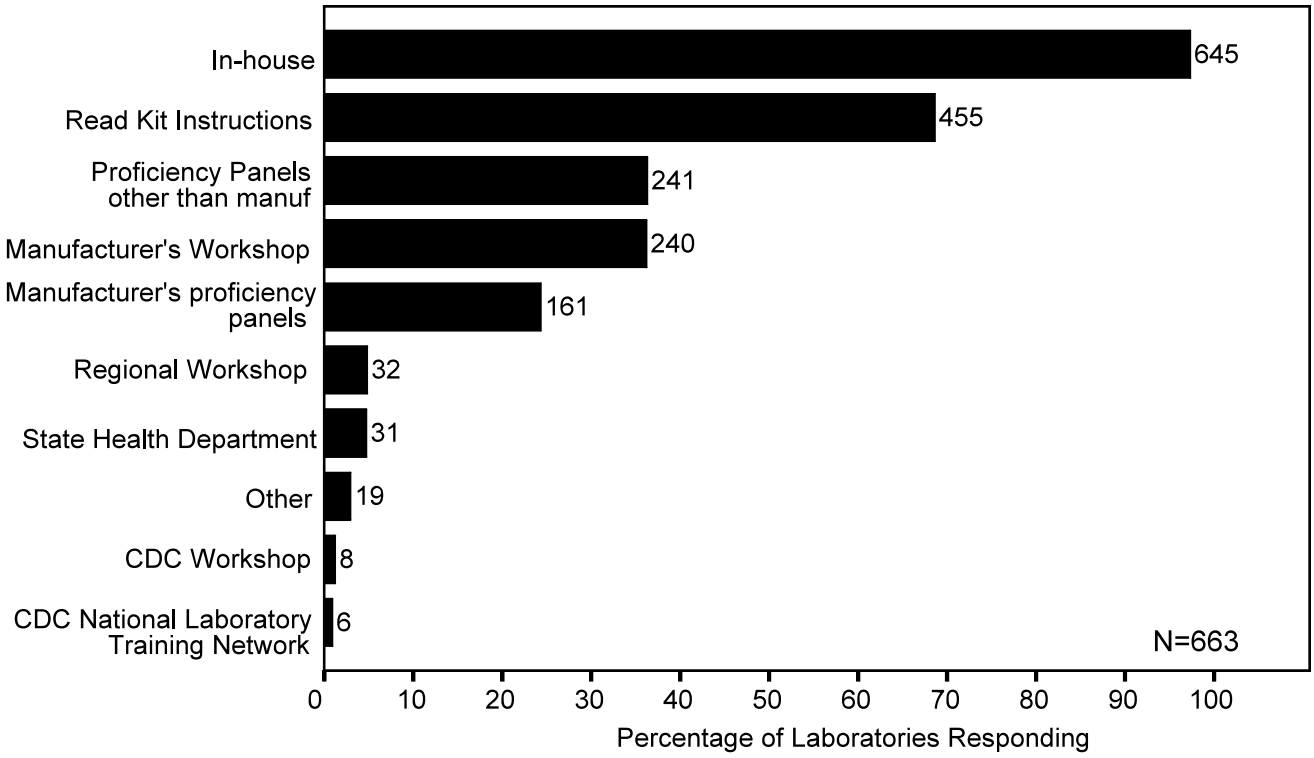
6.(d) If Yes, please check the *professional organizations* that have awarded the required *certification* to your *retroviral testing personnel* (Check all that apply.):



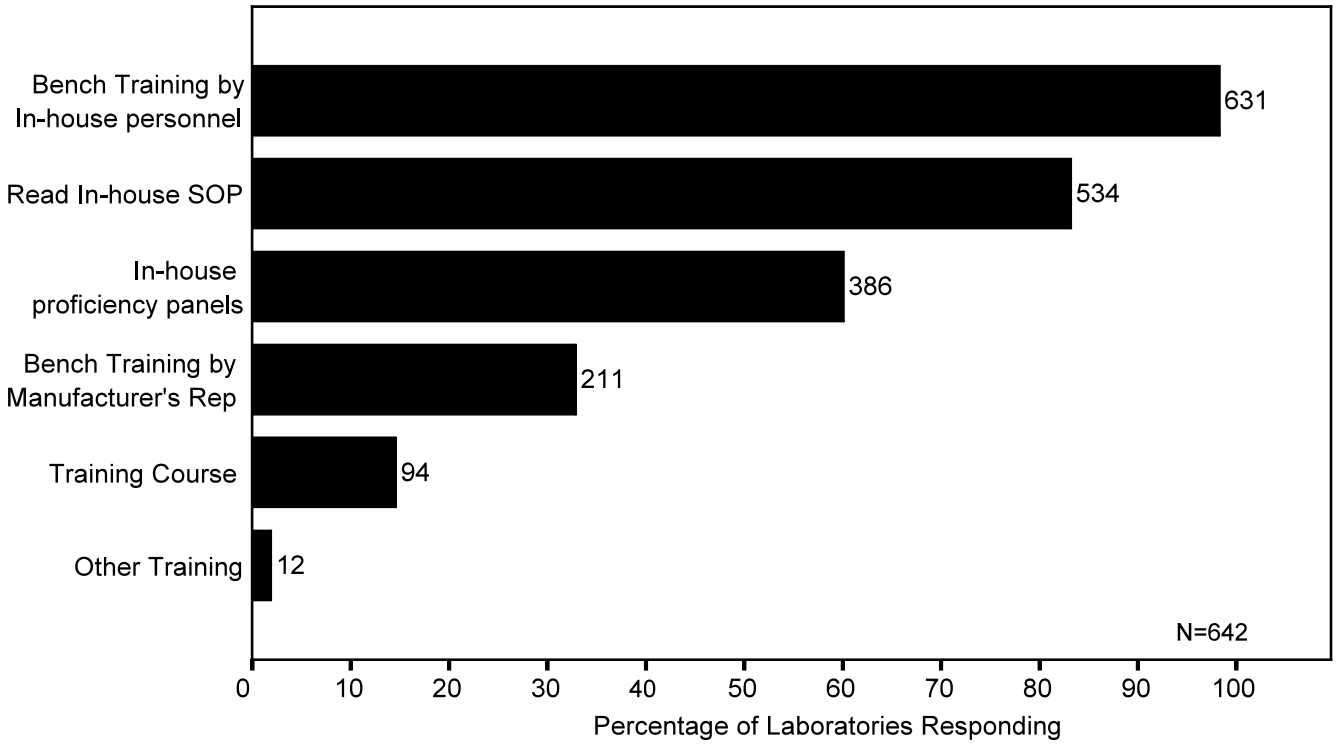
7.(a) Does your laboratory require personnel to have retroviral-specific training in testing before they are considered qualified to perform tests?



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



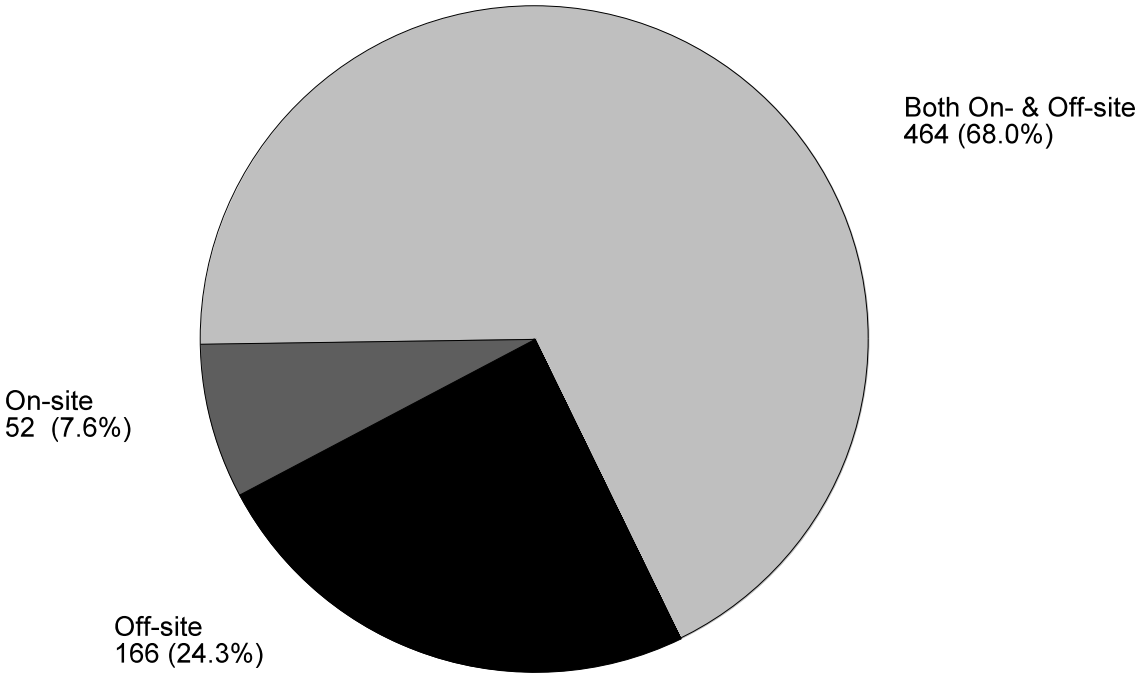
7.(c) If you selected "In-house" from question 7(b), please indicate the type of in-house training (Check <u>all</u> that apply.):



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.)

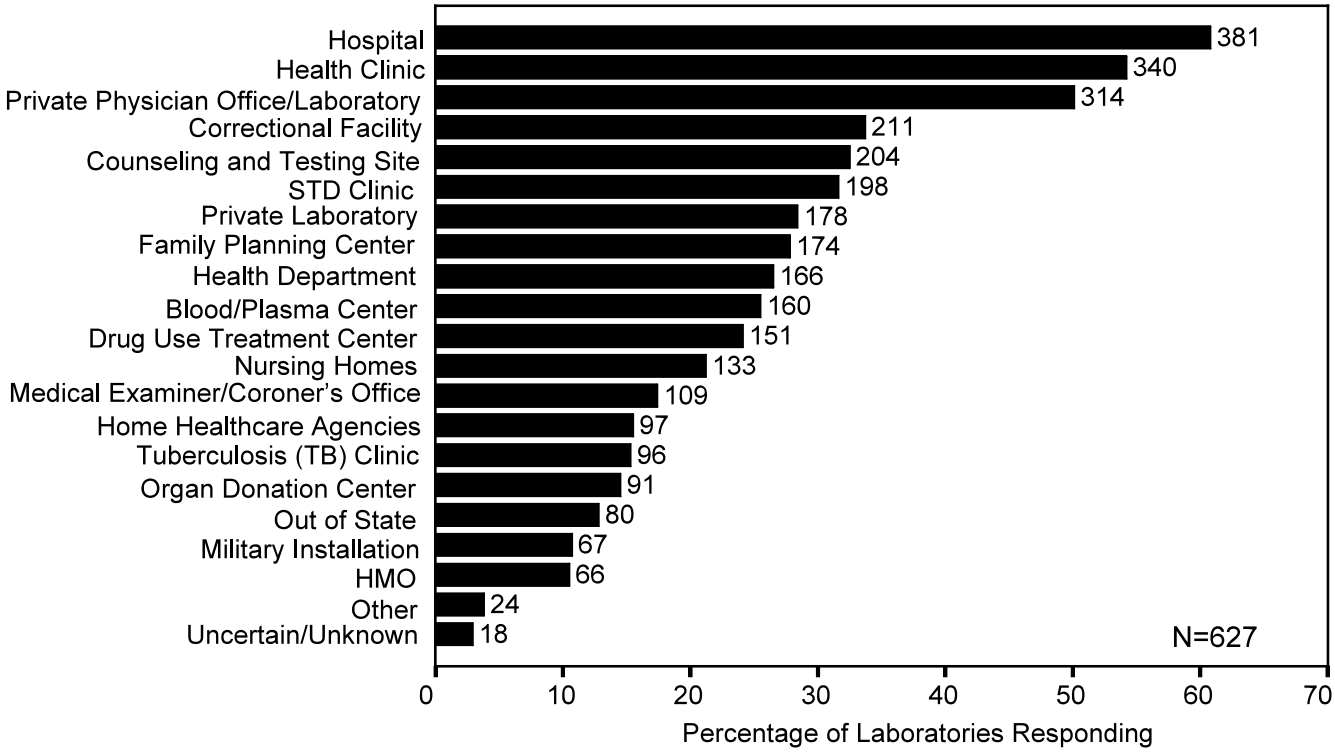
Type of Instruction	Instructions NOT Provided	Testing Laboratory	Associated Institution	Person Ordering Test	Other	N=
Collecting	21 (3.3%)	566 (87.8%)	86 (13.3%)	29 (4.5%)	21 (3.3%)	645
Labeling	20 (3.1%)	569 (88.1%)	81 (12.5%)	26 (4.0%)	24 (3.7%)	646
Transporting	22 (3.4%)	563 (88.1%)	81 (12.7%)	22 (3.4%)	25 (3.9%)	639

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>.)

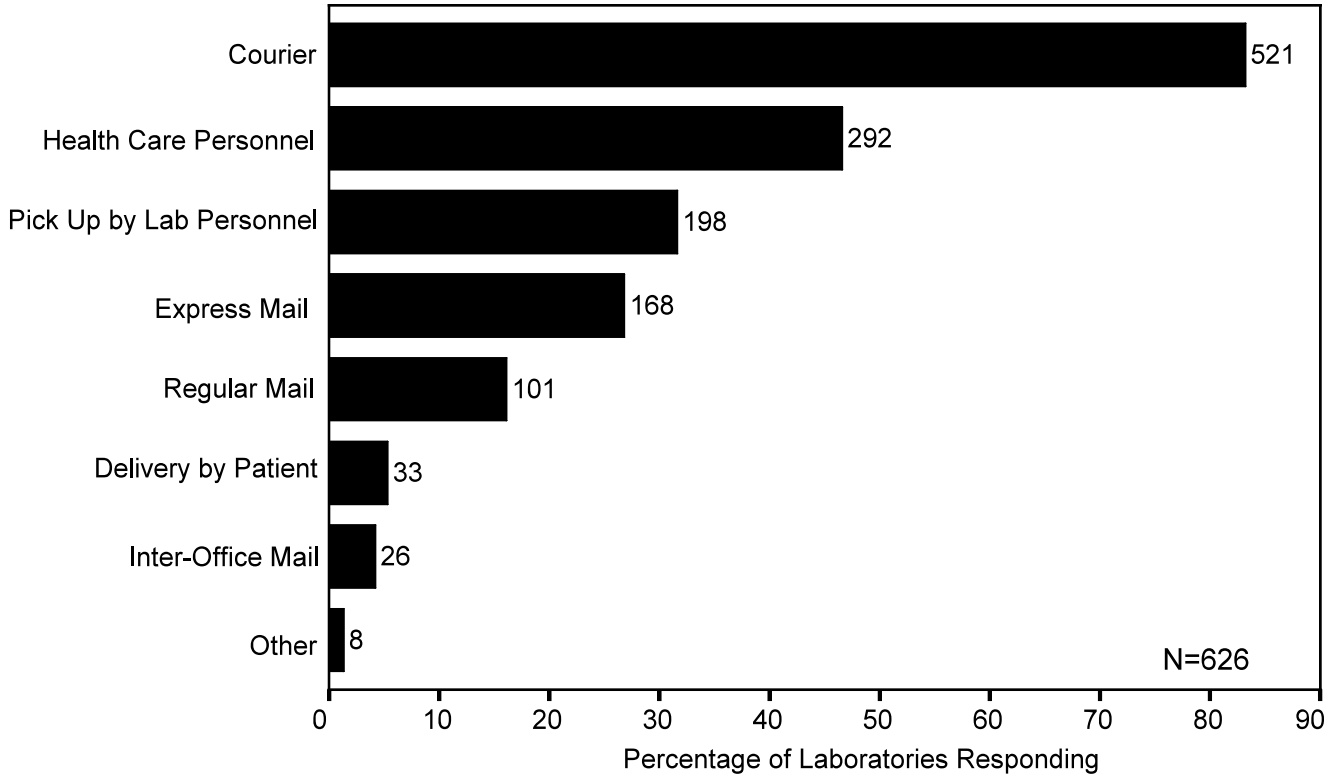


N=682

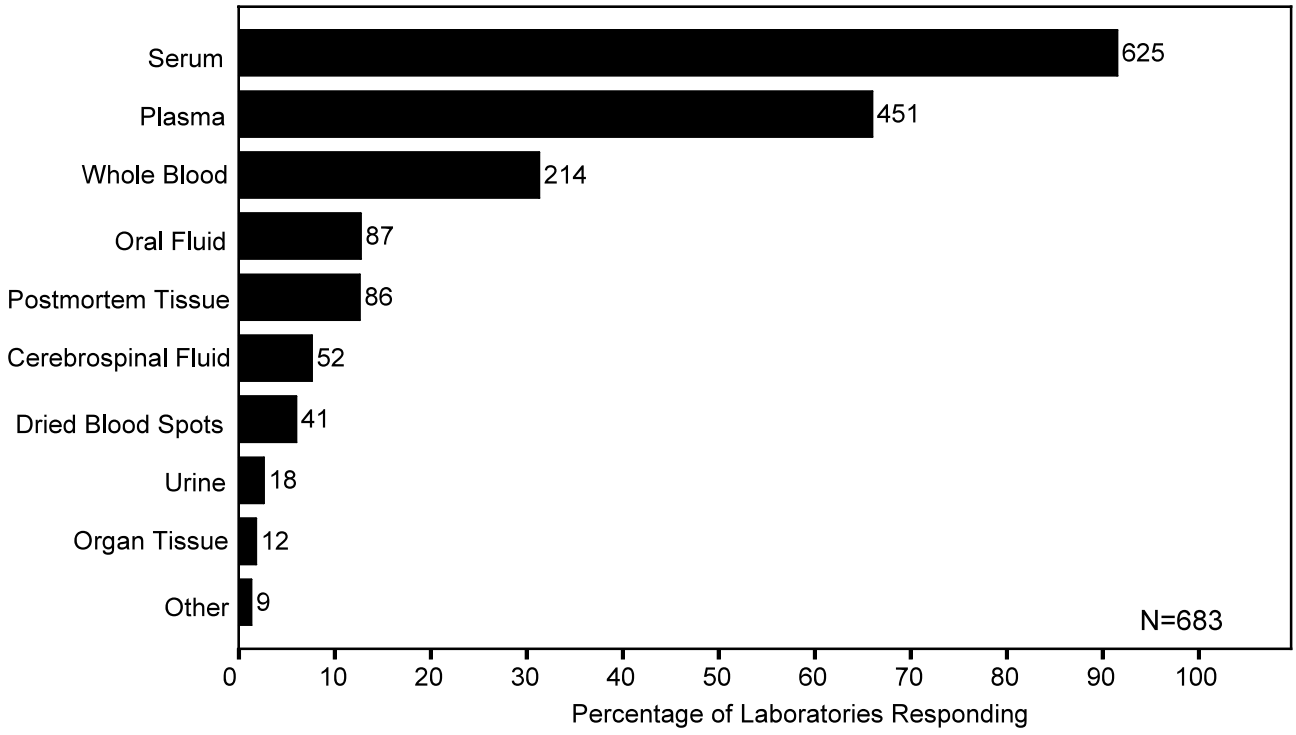
9.(b) If you perform retroviral testing on specimens <u>collected off-site</u>, please indicate where they are collected (Check <u>all</u> that apply.):



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>*infection*</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.):



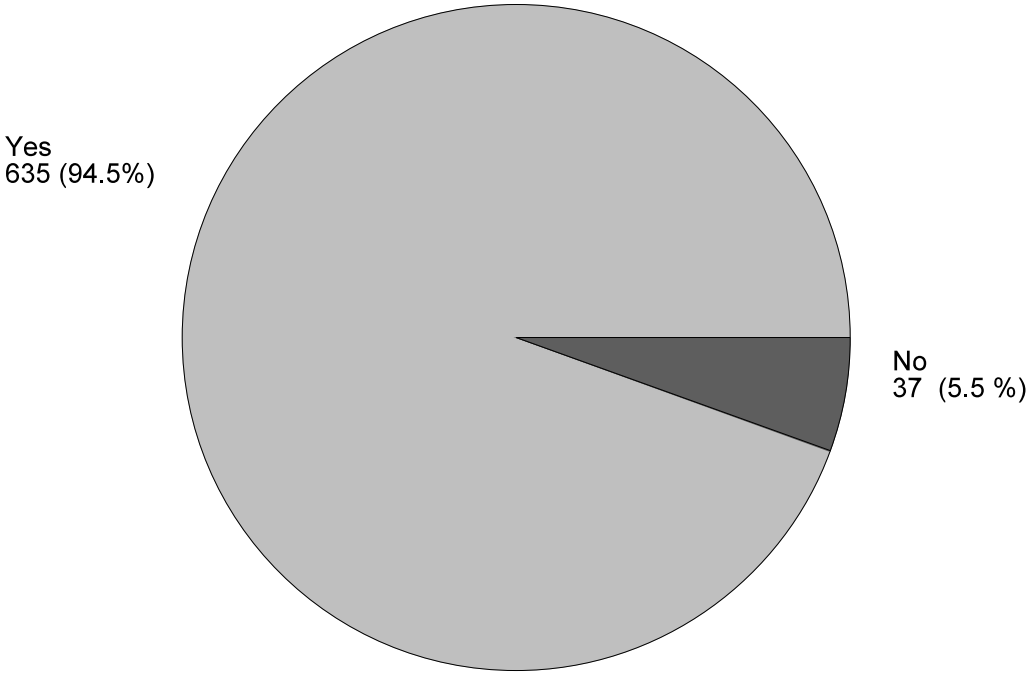
11. Please indicate which of the following procedures your laboratory routinely performs on a specimen before performing retroviral tests (Check <u>all</u> that apply.):

N=672

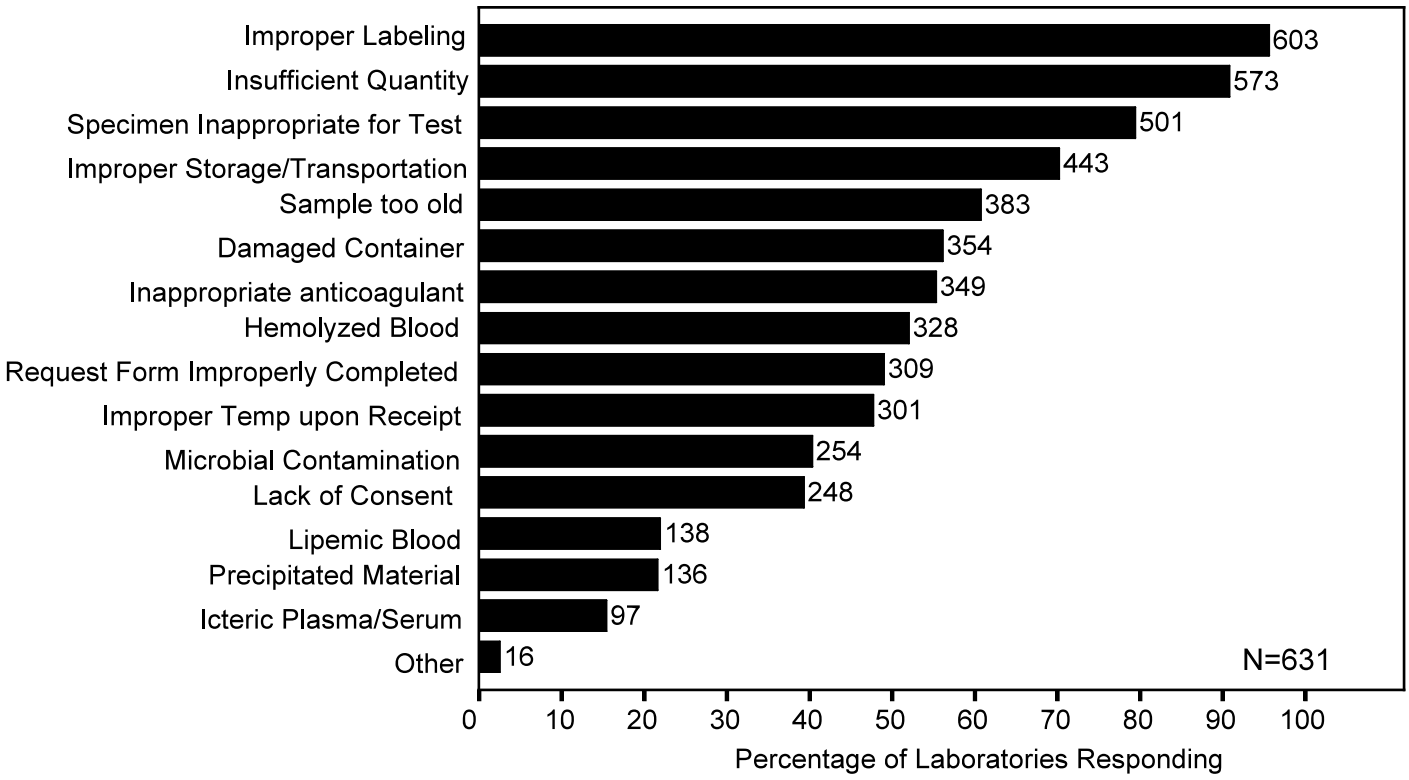
	Frequency of Laboratories Responding*		
Type of Specimen	Heat Inactivation	Clarification by Centrifugation or Filter	No Pretreatment
Whole Blood	6	171	77
Plasma	8	150	285
Serum	13	207	387
Oral Fluid	1	53	37
Urine	0	3	20
Postmortem	1	46	33
Dried Blood Spots	0	2	33
Organ Tissue	0	4	11
Cerebrospinal Fluid	1	9	41
Other	0	3	6

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

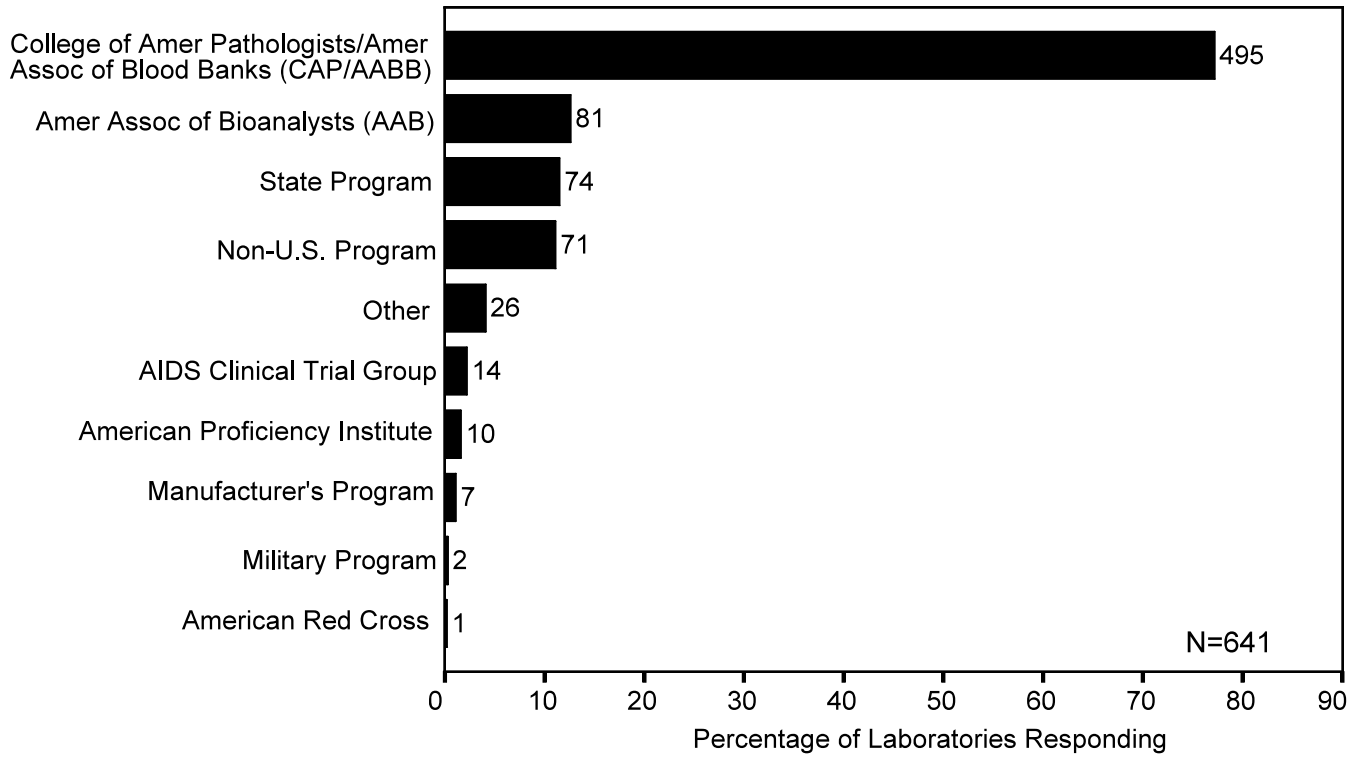
12.(a) Does your laboratory have <u>written</u> pre-test criteria for identifying specimens that are unsatisfactory for retroviral testing?



12.(b) Based upon your written pre-test criteria, please indicate which of the following conditions would exclude a specimen from <u>any retroviral</u> 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=273

	Step 1	Step 2	Step 3	Step 4	Step 5	Number of Laboratories	Percentage of Laboratories
Algorithm*	EIA-S**	EIA-D**	WB			74	27.1
	EIA-S	EIA-D	A			54	19.8
	EIA-S	EIA-D	WB	A		18	6.6
	EIA-S	EIA-D				15	5.5
	EIA-D	WB				7	2.6
	EIA-S	A				5	1.8
	EIA-S	EIA-D	WB	O		4	1.5
	EIA-S	EIA-D	WB	O	A	4	1.5
	EIA-S	EIA-D/A				4	1.5
	EIA-S	EIA-S	WB			4	1.5
	EIA-S					3	1.1
	EIA-S	EIA-D	IIF			3	1.1
	EIA-S	EIA-D	IIF	A		3	1.1
	EIA-S	EIA-D	IIF	WB		3	1.1
	EIA-S	EIA-D	IIF	WB	A	3	1.1
Other Algorithms						69	25.3

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 73 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=483

	Step 1	Step 2	Step 3	Step 4	Number of Laboratories	Percentage of Laboratories
Algorithm*	EIA 1/2-S**	EIA 1/2-D**	A		128	26.5
	EIA 1/2-S	EIA 1/2-D			63	13.0
	EIA 1/2-S	EIA 1/2-D	WB-1		36	7.5
	EIA 1/2-S	EIA 1/2-D	WB-1	A	23	4.8
	EIA 1/2-S	EIA 1/2-D	O		16	3.3
	EIA 1/2-S	EIA 1/2-D/A			8	1.7
	EIA 1/2-D	WB-1			6	1.2
	EIA 1/2-S	A			5	1.0
	EIA 1/2-D	A			4	0.8
	EIA 1/2-S				4	0.8
	EIA 1/2-S	EIA 1/2-D	WB-1	0	4	0.8
	EIA 1/2-S	EIA 1/2-D	WB-1	WB-2	4	0.8
	EIA 1/2-S	EIA 1/2-D	WB-1/WB-2		4	0.8
	EIA 1/2-S	EIA 1/2-D	WB-2		4	0.8
	EIA 1/2-S	EIA 1/2-S	A		4	0.8
Other Algorithms					170	35.2

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 161 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 performed these specific HIV tests. (Round off to the nearest year. If less than one year, round off to one year.)

N=628

	Frequency of Laboratories Responding*													
No of Yrs	EIA-1 Kit	EIA-1/2 Kit	EIA-2 Kit	WB-1	WB-2	IIF-1	IIF-2	RNA	DNA	PA	HIV-1 p24 Ag	HIV-1 Rapid Test	Viral Cult	Other
1-3	27	115	6	21	8	7	3	44	10	3	13	42	2	14
4-6	40	77	7	22	10	8	0	84	29	3	79	16	8	6
7-9	53	139	9	31	5	9	1	9	14	4	12	12	5	1
10-12	80	77	11	66	12	14	0	4	11	7	23	13	4	3
13-15	88	25	2	70	9	11	0	0	2	8	17	4	9	2
>15	55	13	1	27	0	3	0	1	0	2	0	0	3	1

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

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

N=621

No of Emp	EIA-1 Kit	EIA-1/2 Kit	EIA-2 Kit	WB-1	WB-2	IIF-1	IIF-2	RNA	DNA	PA	HIV-1 p24 Ag	HIV-1 Rapid Test	Viral Cult	Other
1-2	69	89	7	95	21	15	3	50	32	11	39	16	14	15
3-4	88	124	13	63	11	18	1	52	19	7	27	11	8	3
5-6	52	82	4	24	0	6	0	23	7	3	18	11	2	3
7-8	20	54	6	21	5	2	0	4	1	1	18	10	0	0
9-10	23	36	2	15	1	0	0	4	0	0	12	6	1	2
>10	14	47	1	8	0	1	0	3	1	0	20	17	1	0

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

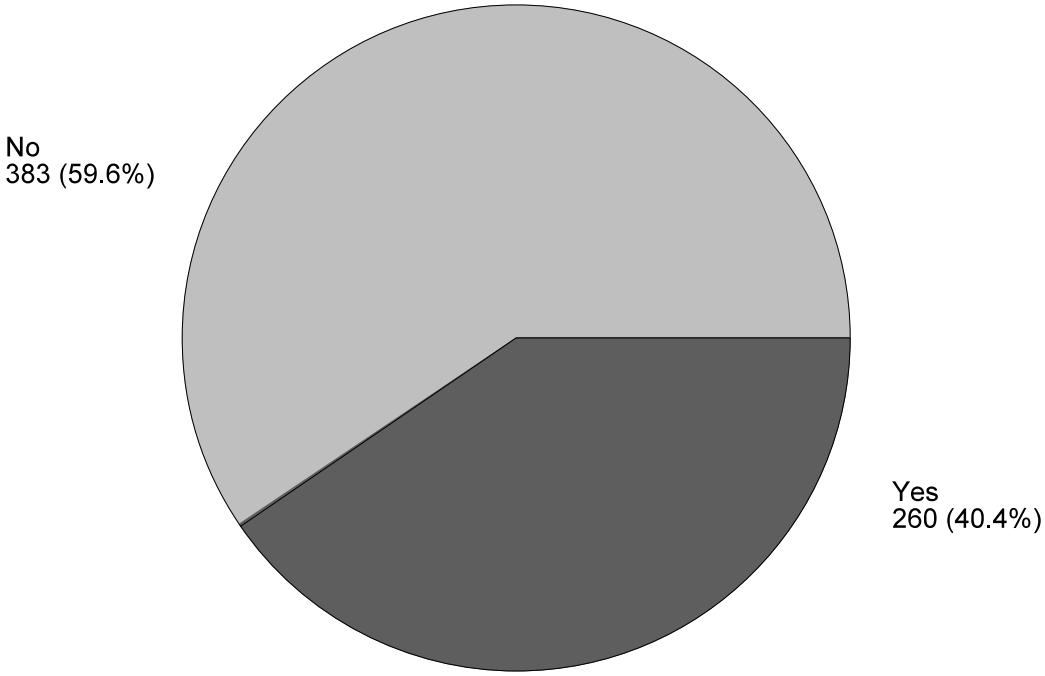
16. Please identify the source of written procedure(s) your laboratory follows for performing the following HIV-1 tests (Check all that apply only for the procedures performed in your laboratory.)

N=646

	Frequency of Laboratories Responding*			
Source of procedure	EIA	WB	IIF	Other
No Written Procedures	2	0	0	2
In-house Written Protocol	500	192	39	57
Manufacturer's Insert	556	228	37	58
Provided by State Health Department	41	20	4	1
Other Sources	22	13	4	1

* 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=643

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=259

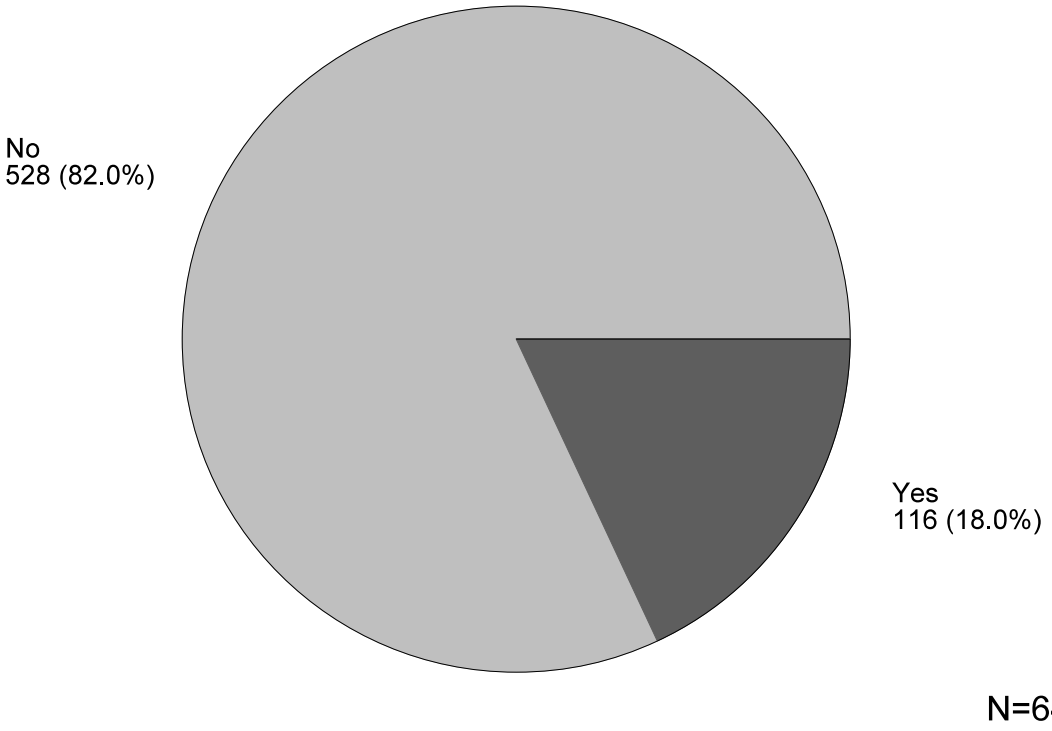
Band Patterns	Number of Laboratories	Percentage of Laboratories
Any two of p24, gp41, gp120/gp160	208	80.3
Other	16	6.2
Two env bands w/ or w/o gag or pol bands	13	5.0
One protein from each: gag (p17/18, p24, p55), and env (gp41, gp120, gp160), and pol (p31, p51, p65/66)	10	3.9
p24 or p31, and gp41 or gp120/gp160	7	2.7
p24 plus p31, and either gp41 or gp120/gp160)	4	1.5
p24 plus gp41	1	0.4

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

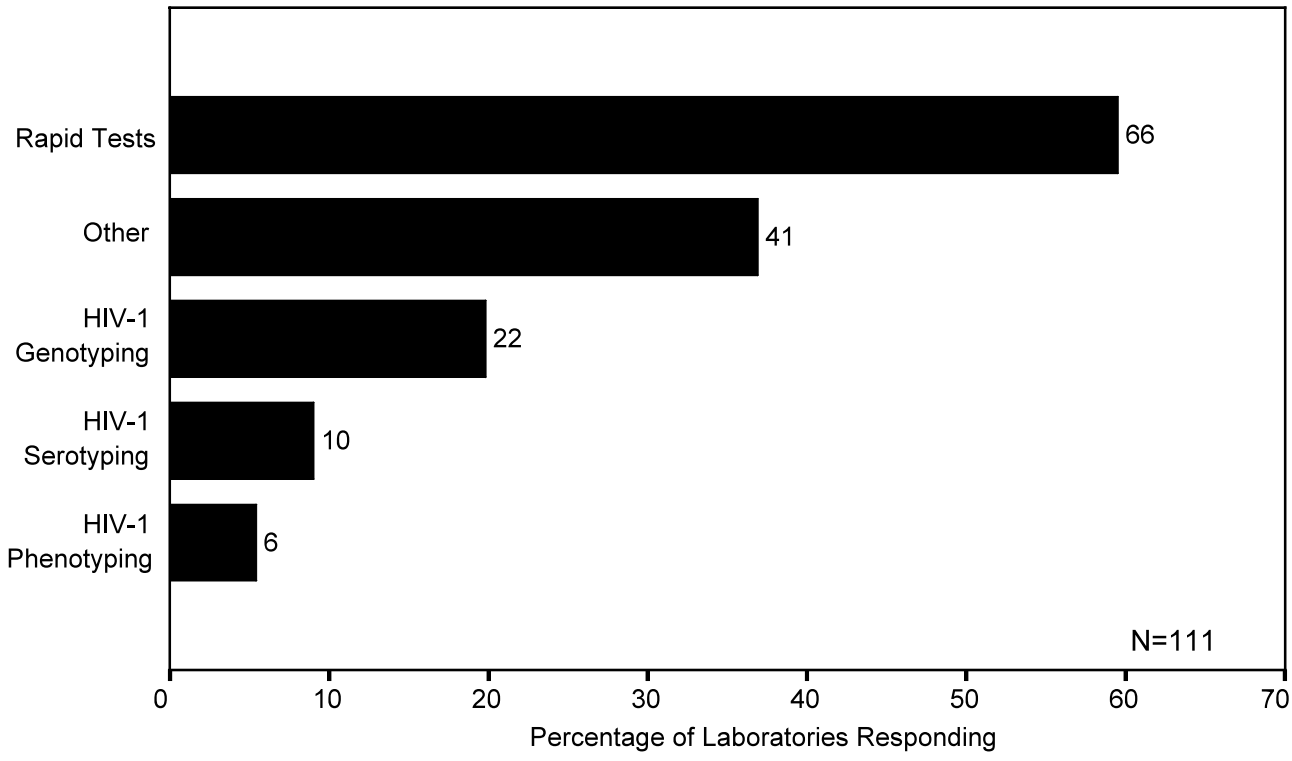
N=257

Band Patterns	Number of Laboratories	Percentage of Laboratories
No bands present	163	63.4
No HIV-1 specific protein band(s) (i.e., 17/18, 24, 31, 41, 51, 55, 65/66, 120, 160)	88	34.2
Other	6	2.3

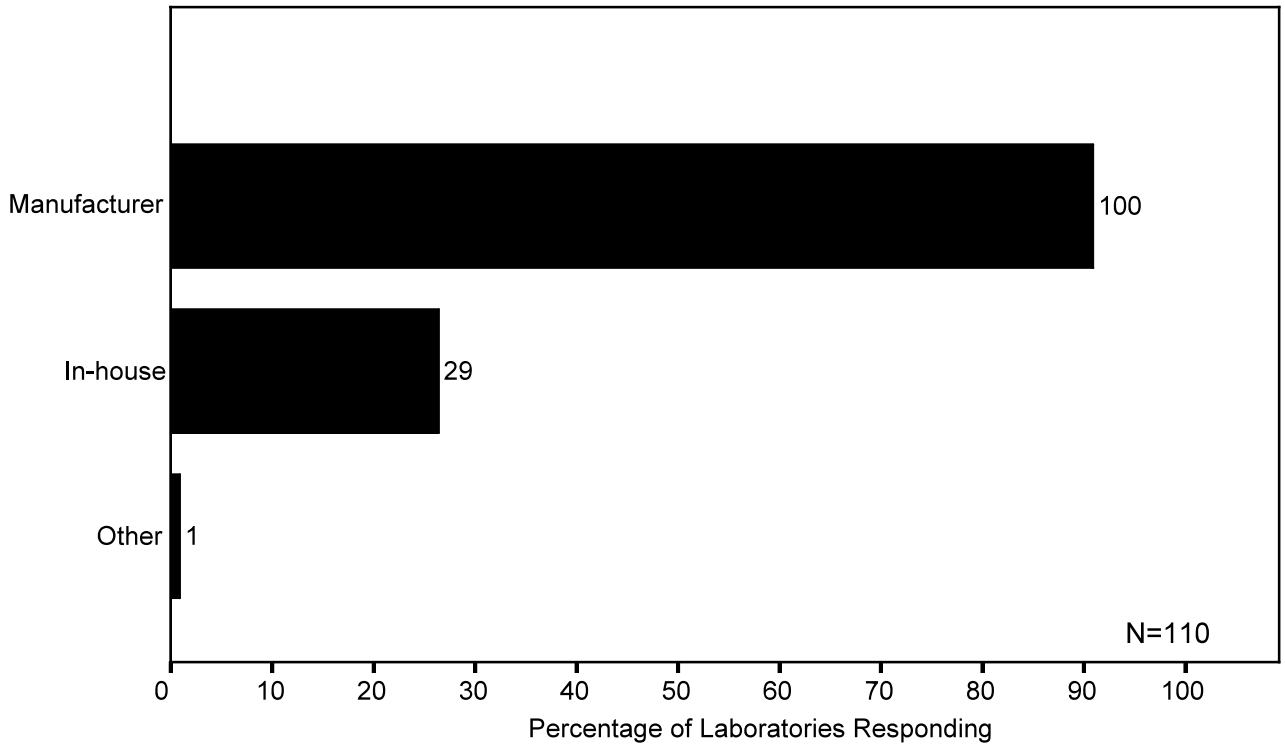
18.(a) Do you perform a test other than EIA antibody, WB, IIF, p24 Ag, or RNA to detect HIV-1 infection?



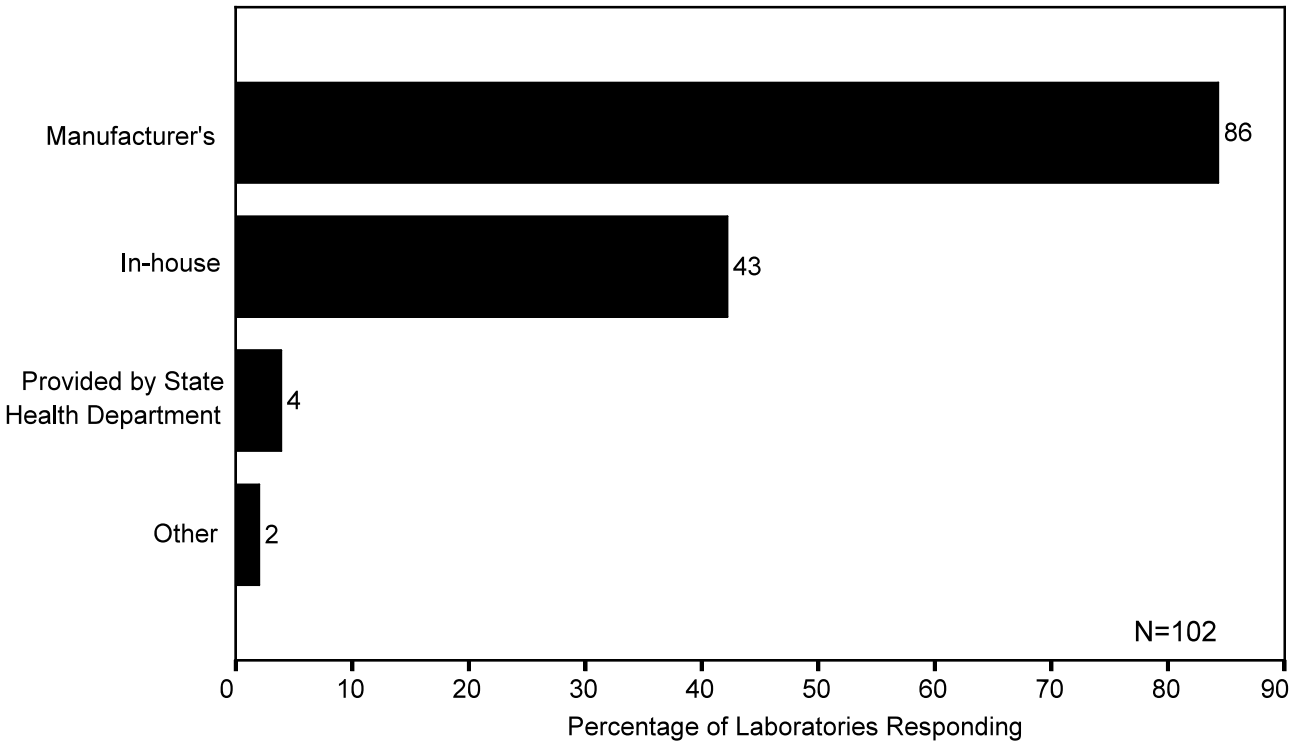
18.(b) If yes, indicate below the other HIV-1 tests performed in your laboratory (Check all that apply.):



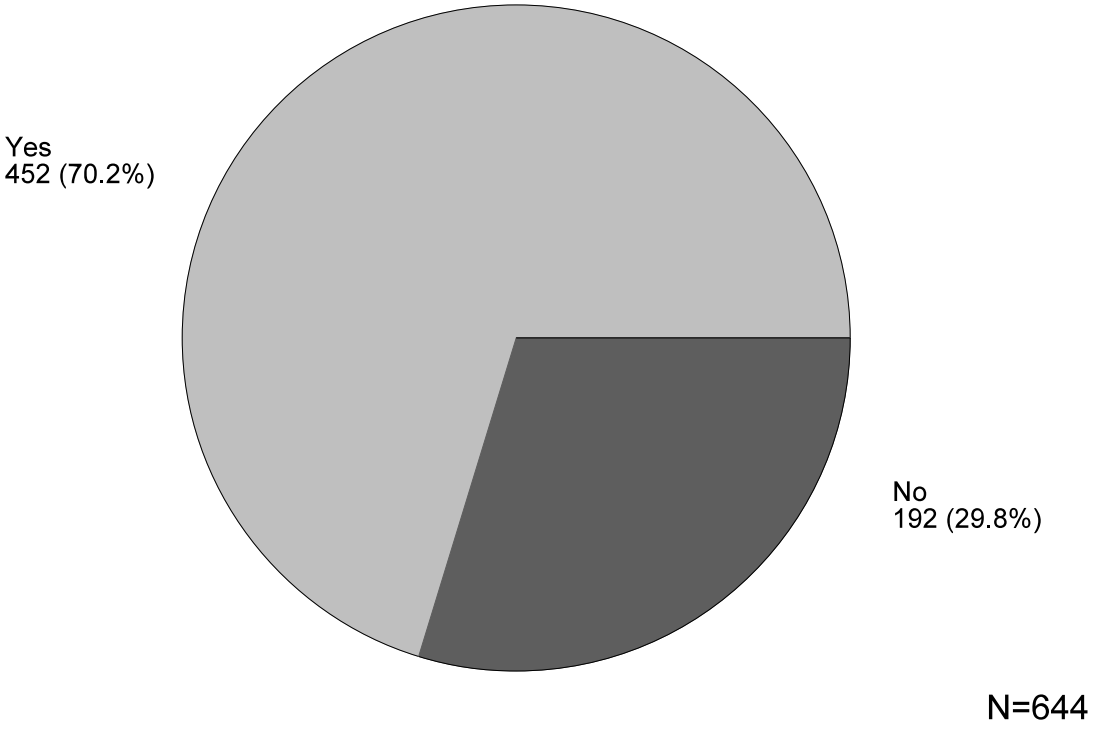
18.(c) Source of reagents for HIV-1 tests other than EIA antibody, WB, IIF, p24 Ag, and RNA as indicated in question 18(b). (Check all that apply.):



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



19.(a) Does your laboratory use controls in addition to the kit manufacturer controls?



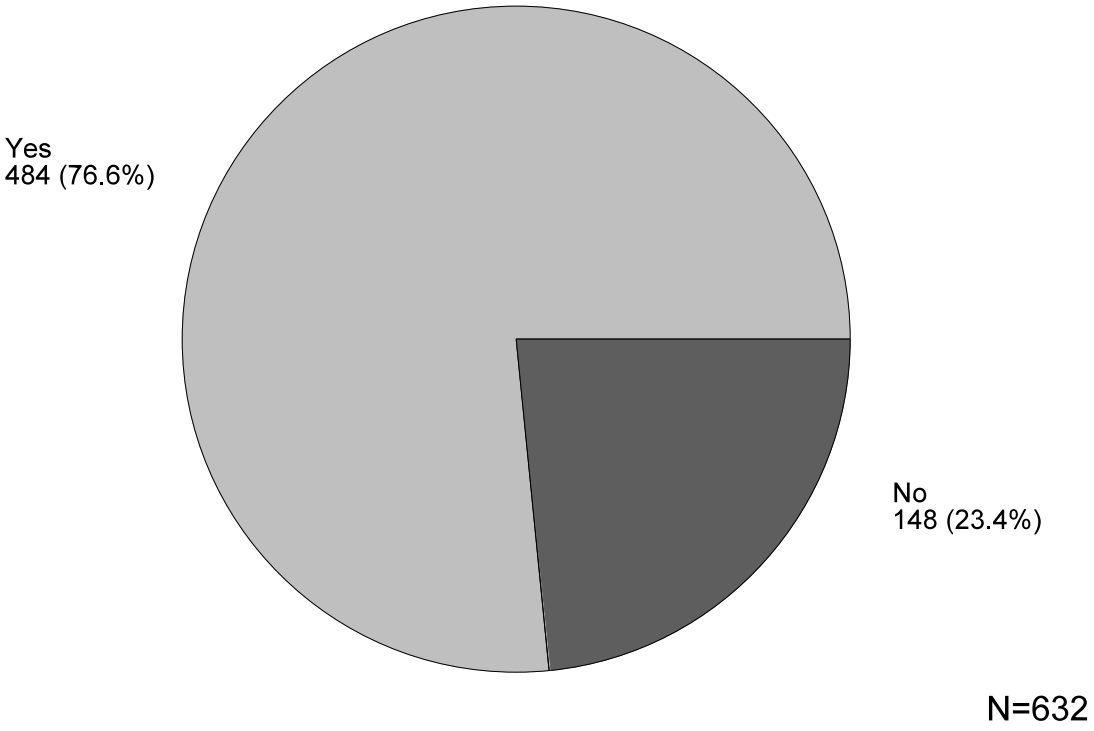
19.(b) If your laboratory uses controls in addition to the kit manufacturer controls, please indicate the frequency with which your laboratory uses HIV-1 control sera/plasma for each of the test methods below (Check <u>all</u> that apply.):

N=449

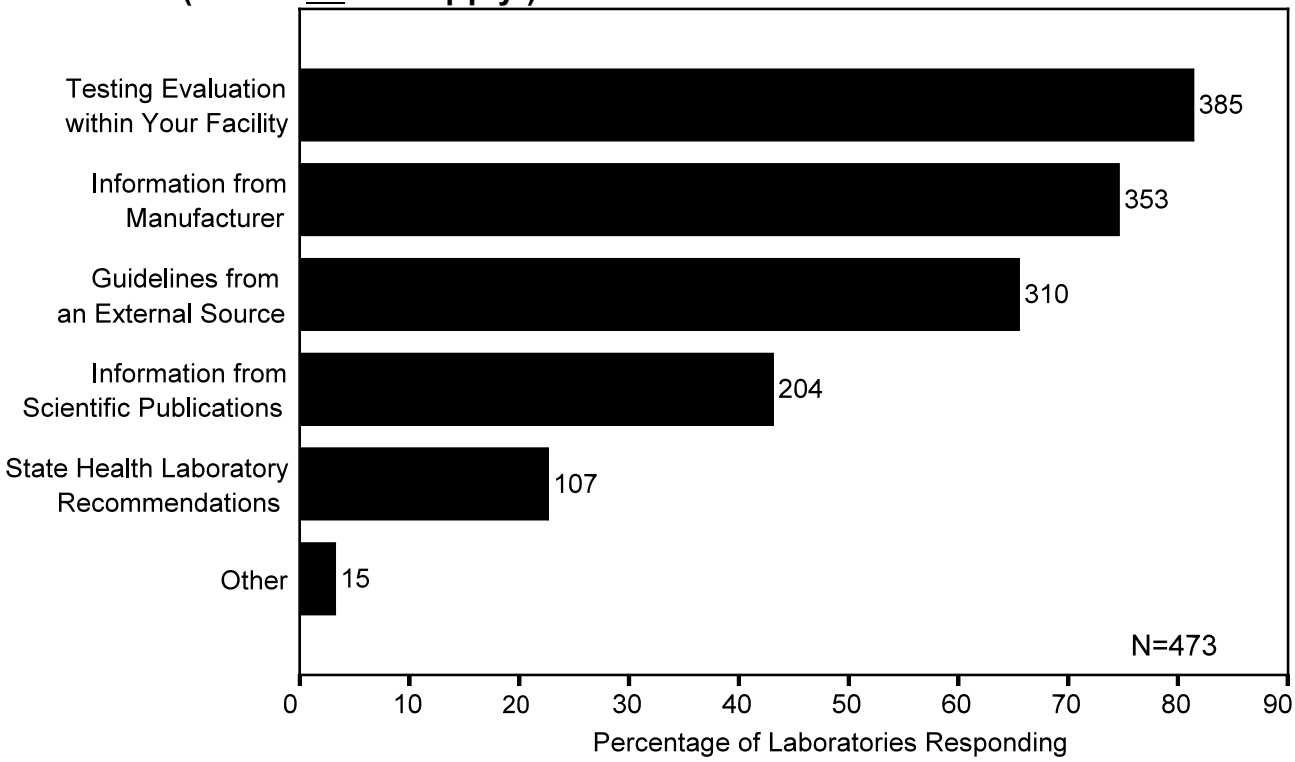
	Frequency of Laboratories Responding*				
Test Method	Each Test[a]	Each Set[b]	Two Each Day	Each Test Kit	Other Frequency
EIA	181	222	67	43	15
WB	6	84	10	37	4
IIF	8	17	3	5	2
Other	7	21	6	8	2

[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.

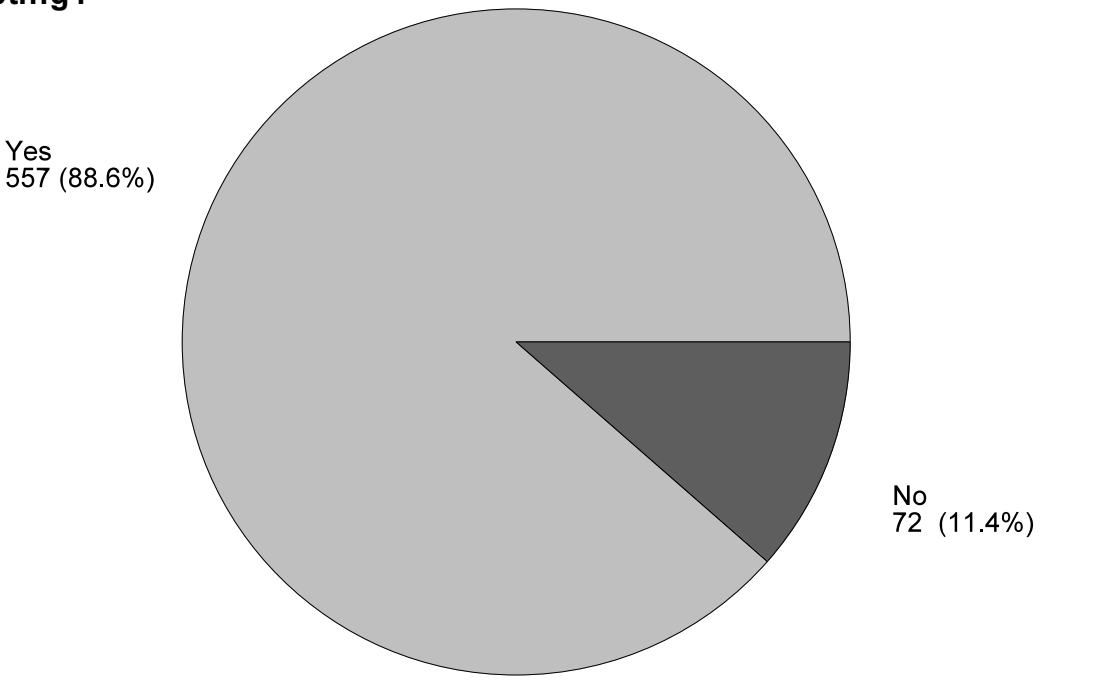
20.(a) Does your laboratory have *written criteria*, such as a validation protocol, for adopting a new test or a different manufacturer's test for HIV-1 testing?



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

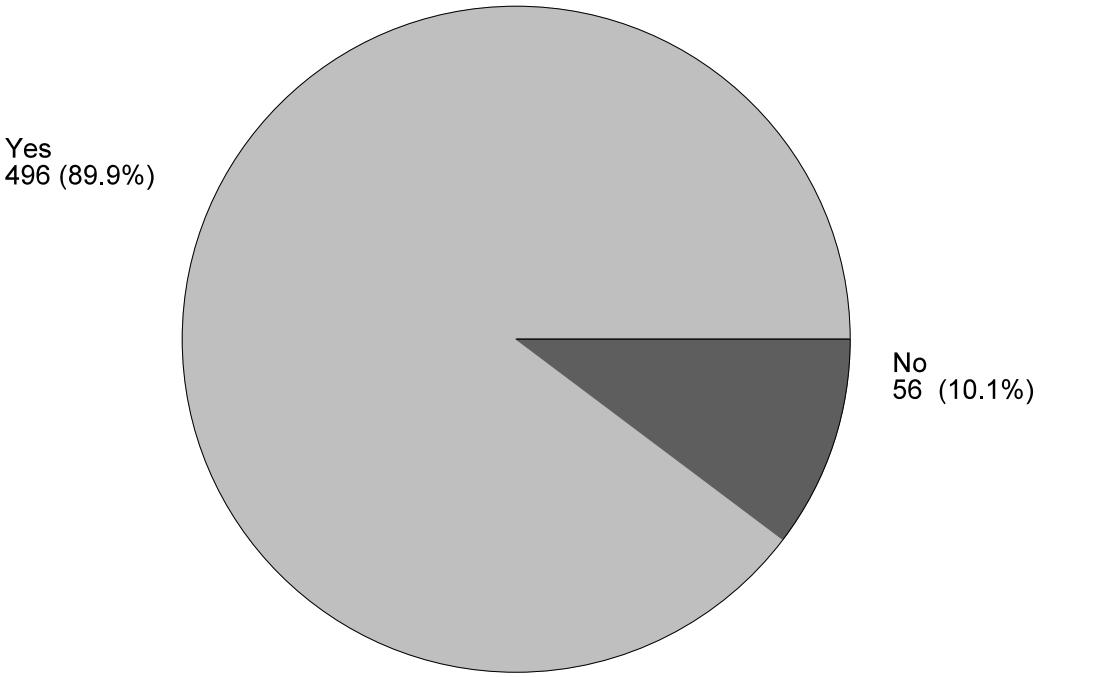


20.(c) Does your laboratory have a quality assurance plan that includes HIV testing?



N=629

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



N=552

21. This question refers to the volume of HIV-1 antibody testing performed in your laboratory. Responses should include the number of tests using HIV-1/HIV-2 kits to detect HIV-1 antibody. Responses should reflect the number of patient/donor specimens tested during the most recent representative month. (Round off to the nearest whole number.)

N=622

	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	8	265	237	219
10-99	82	204	182	153
100-999	279	50	51	34
1,000-9,999	201	3	2	1
10,000-99,999	40	0	0	0
>99,999	6	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=629

	Frequency of Laboratories Responding*		
Days Elapsed →	From Collection to Receipt in Laboratory	From Receipt to Specimen Tested	From Specimen Tested to Results Reported
1	487	371	478
2-3	111	202	91
4-5	8	31	15
6-7	4	7	4
>7	6	4	11

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

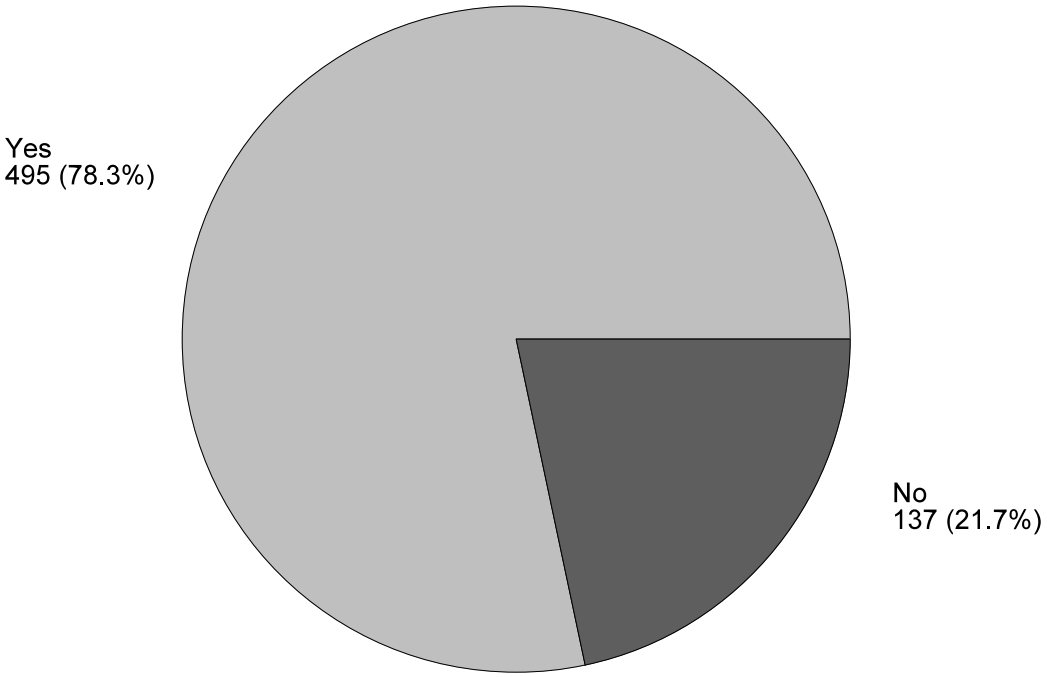
23. Approximately how much does your laboratory charge to perform the following tests? Please answer all areas applicable to your laboratory. (Round off to nearest U.S. dollar.)

N=440

	Frequency of Laboratories Responding*			
Approximate Charge by Laboratory	EIA	WB	IIF	Other
<$50	317	82	17	21
$50-$99	93	64	8	5
$100-$149	15	14	1	3
$150-$200	2	8	0	1
>$200	4	5	0	4

* 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?



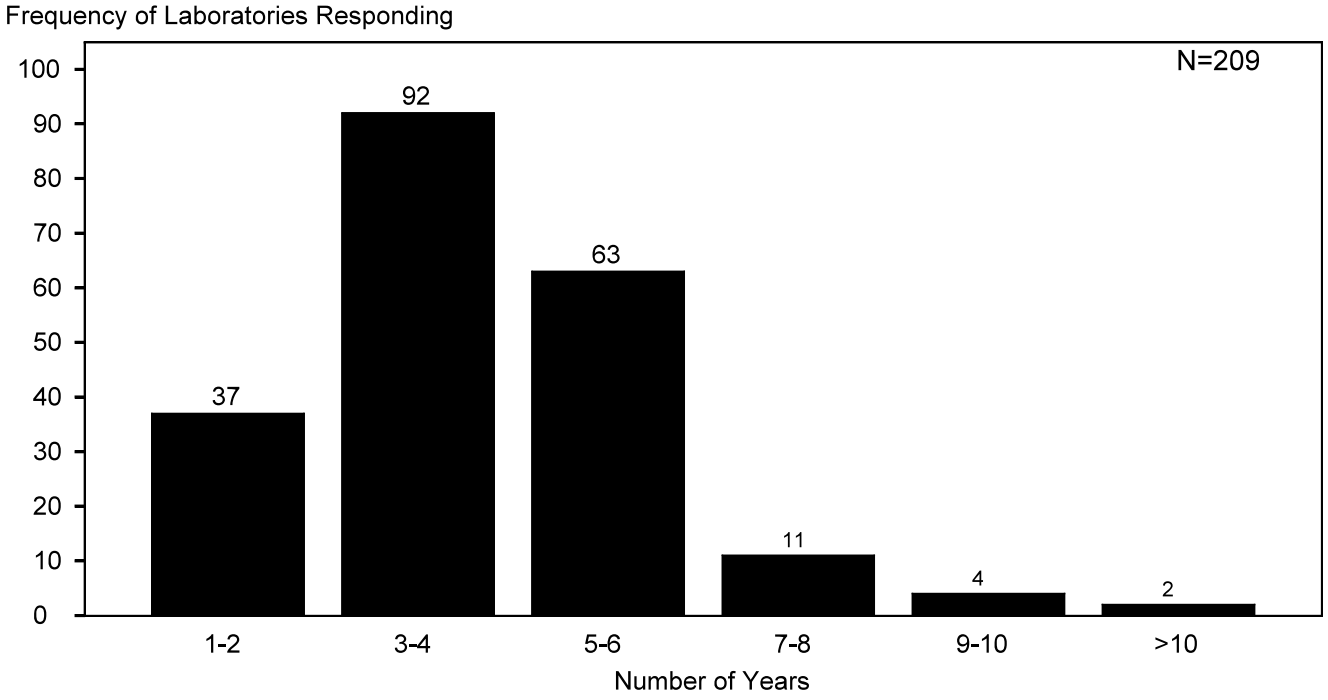
N=632

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 all that apply.):

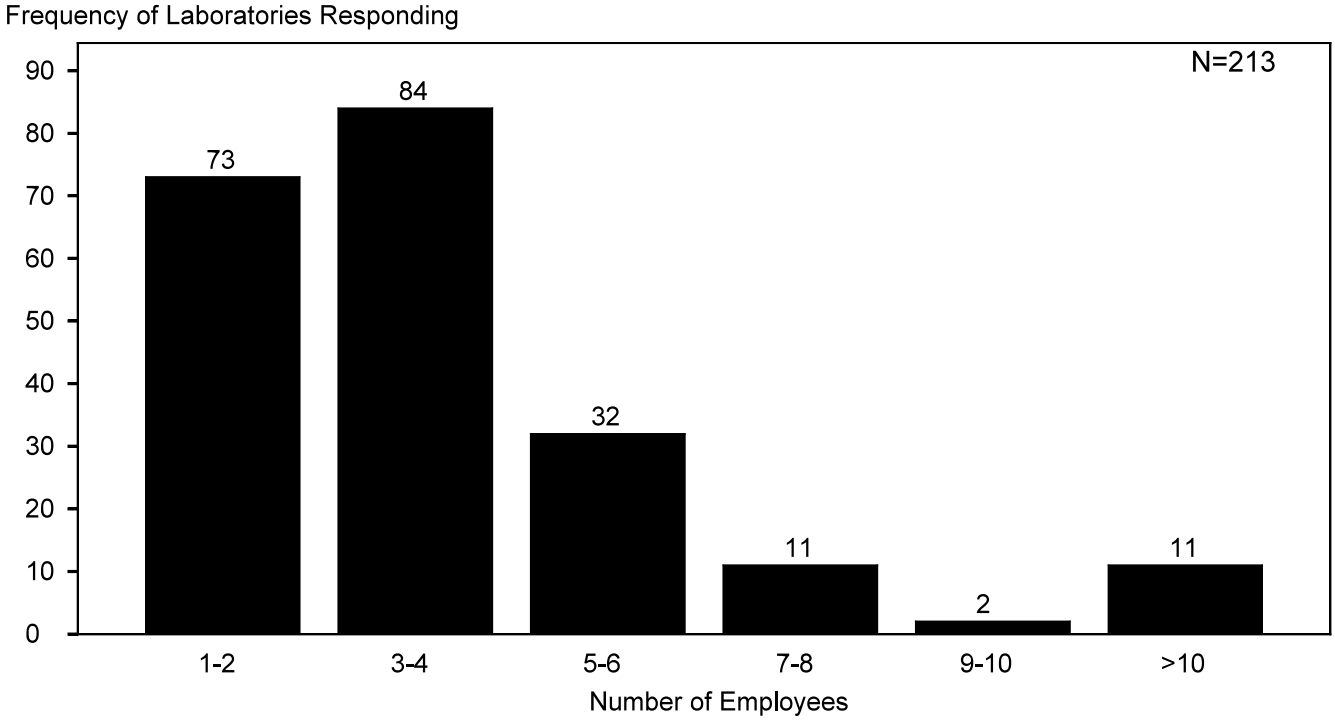
N=493

Test Type	Hospital	Health Department	Blood Bank	Independent	Other	Total
EIA HIV-1	1	20	3	26	7	57
EIA HIV-2	3	30	11	119	19	182
EIA HIV-1/HIV-2	4	20	3	34	10	71
WB HIV-1	19	84	15	231	19	368
WB HIV-2	6	50	9	198	31	294
IIF HIV-1	0	16	2	25	0	43
IIF HIV-2	0	6	0	26	0	32
Particle Agglutination	0	1	0	16	0	17
HIV-1 p24 Antigen	6	12	2	115	9	144
HIV-1 DNA	8	13	3	128	10	162
HIV-1 RNA	14	17	7	137	10	185
Viral Culture	2	3	0	55	2	62
Antiretroviral Resistance	3	8	0	93	5	109
Other	3	7	2	8	7	27

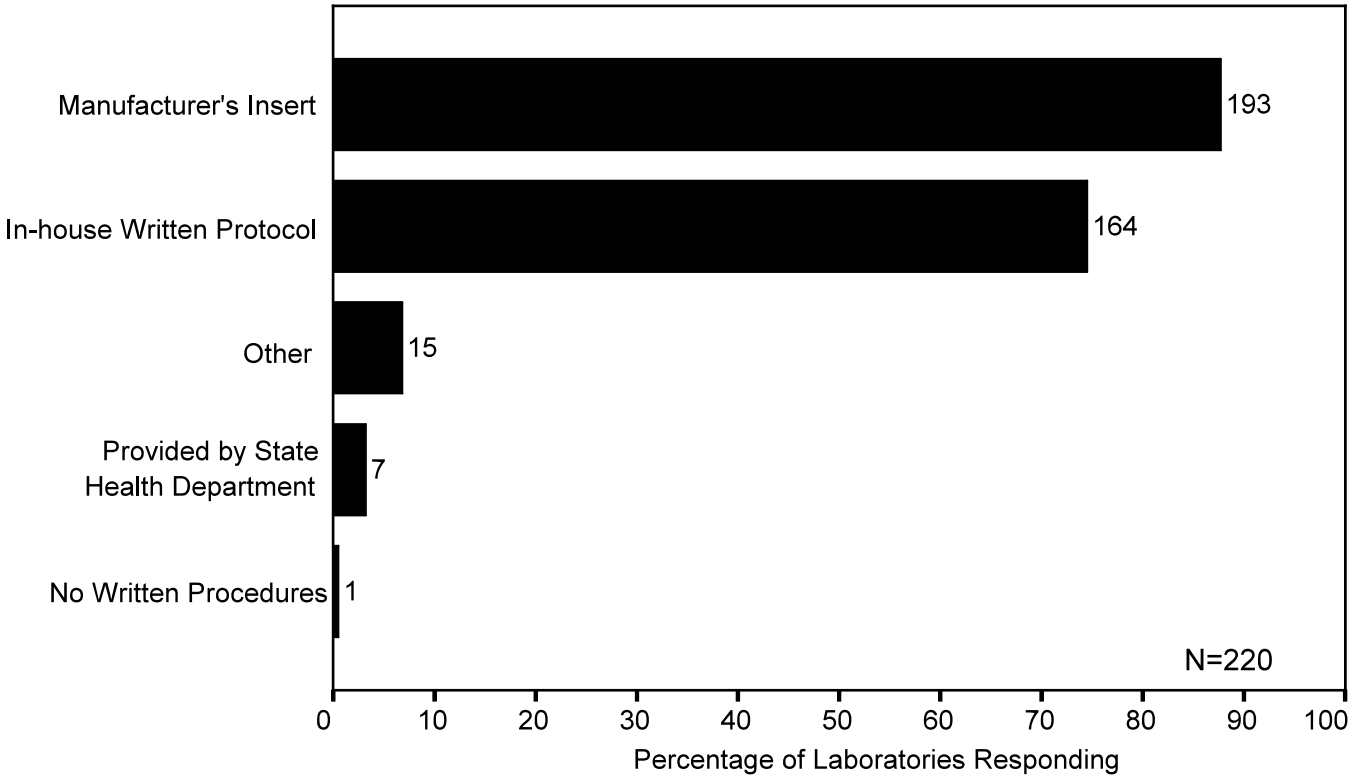
25. Please indicate the number of years your laboratory has performed HIV-1 RNA tests. (Round to the nearest year. If less than one year, round off to one year.)



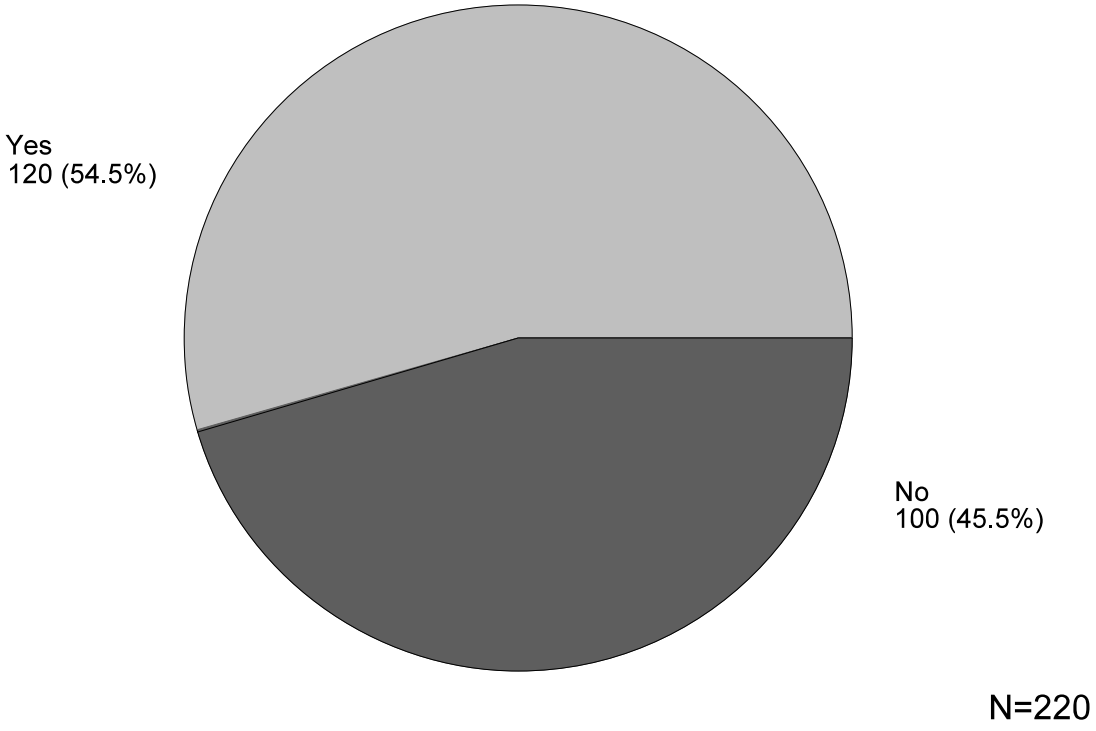
25. Please indicate the number of individual employees in your laboratory that currently perform HIV-RNA testing.



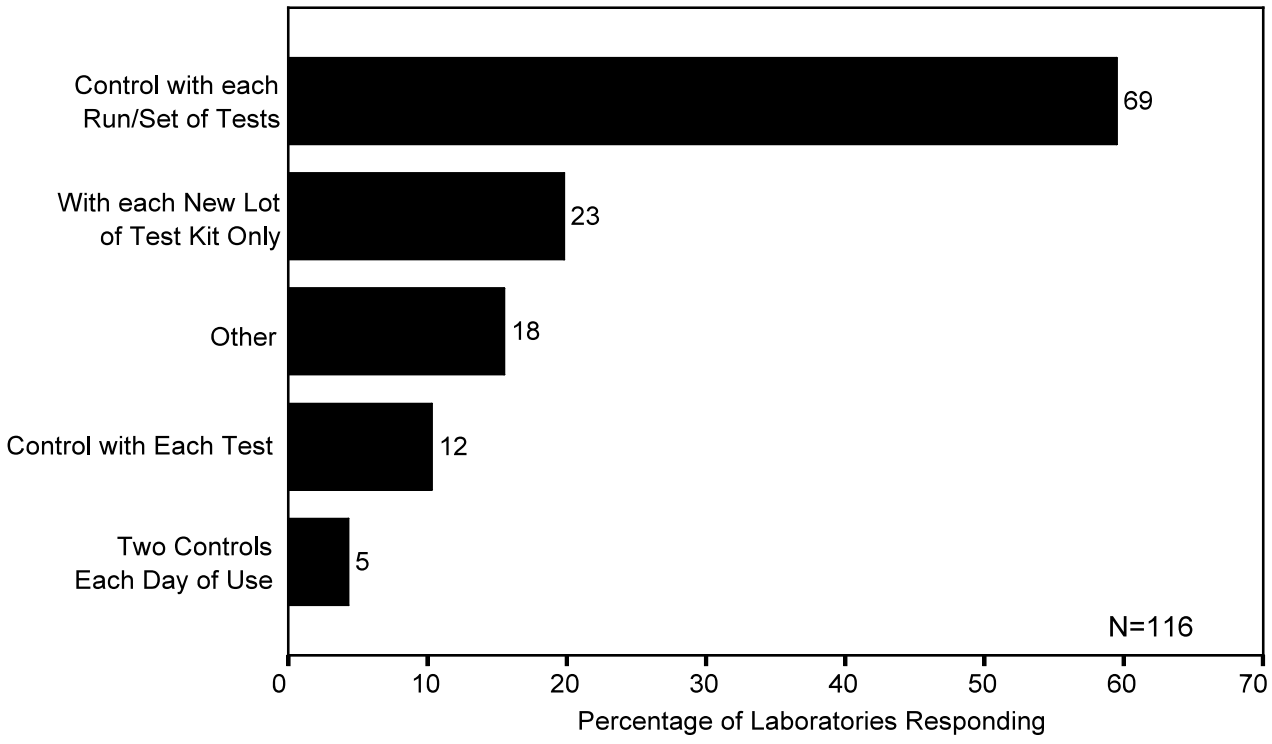
26. Please identify the source of written procedure(s) your laboratory follows for performing HIV-1 RNA tests. (Check all that apply.)



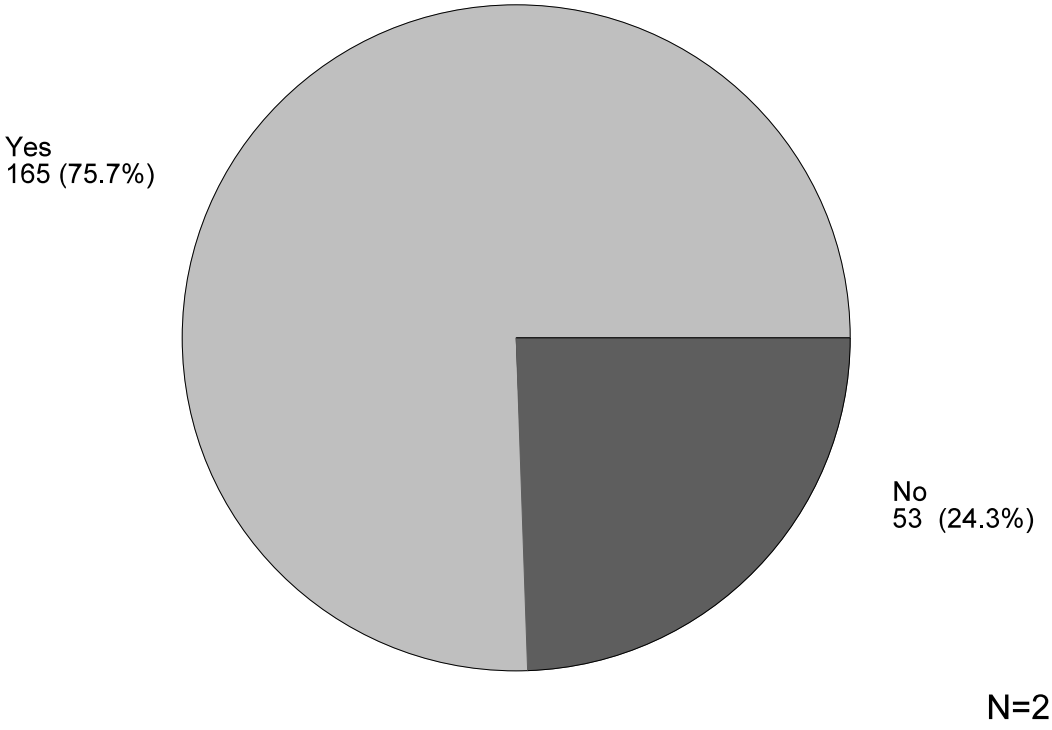
27.(a) Does your laboratory use controls in addition to the kit manufacturer controls?



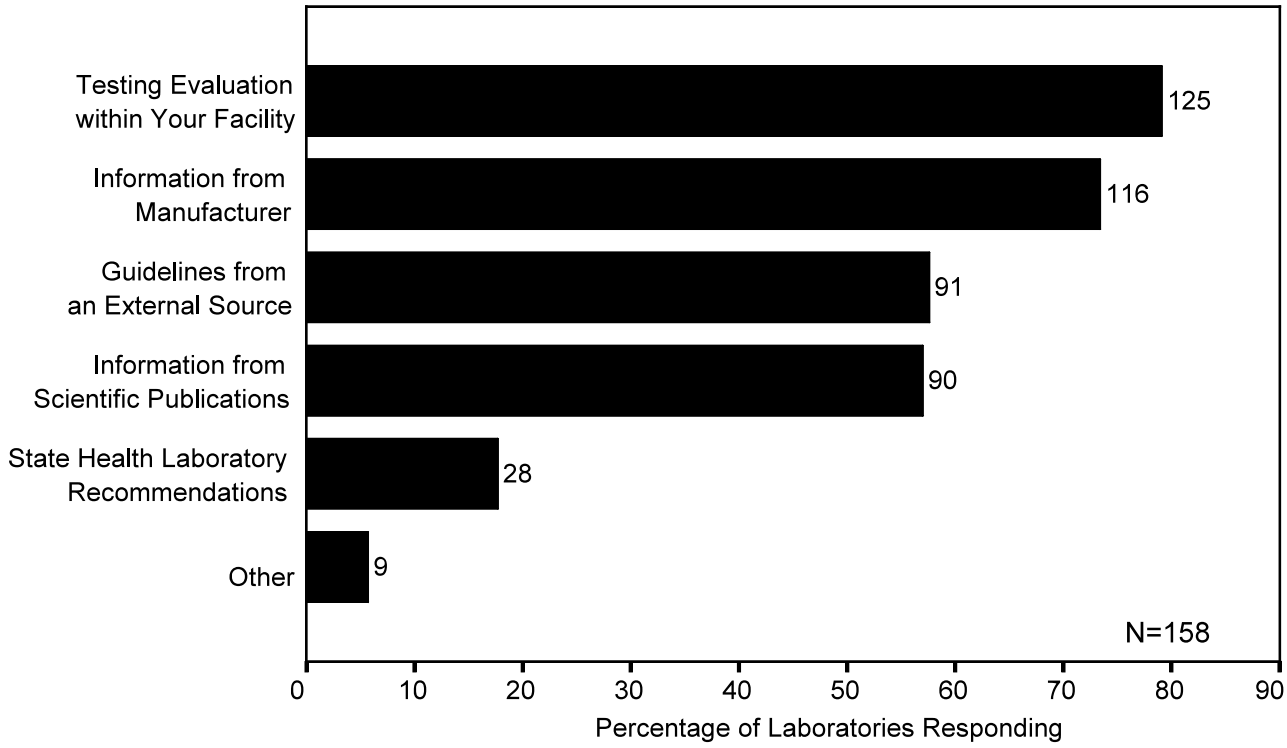
27.(b) If your laboratory uses controls in addition to the kit manufacturer controls, please indicate the frequency with which your laboratory uses HIV control sera/plasma for your HIV-1 RNA testing (Check all that apply.):



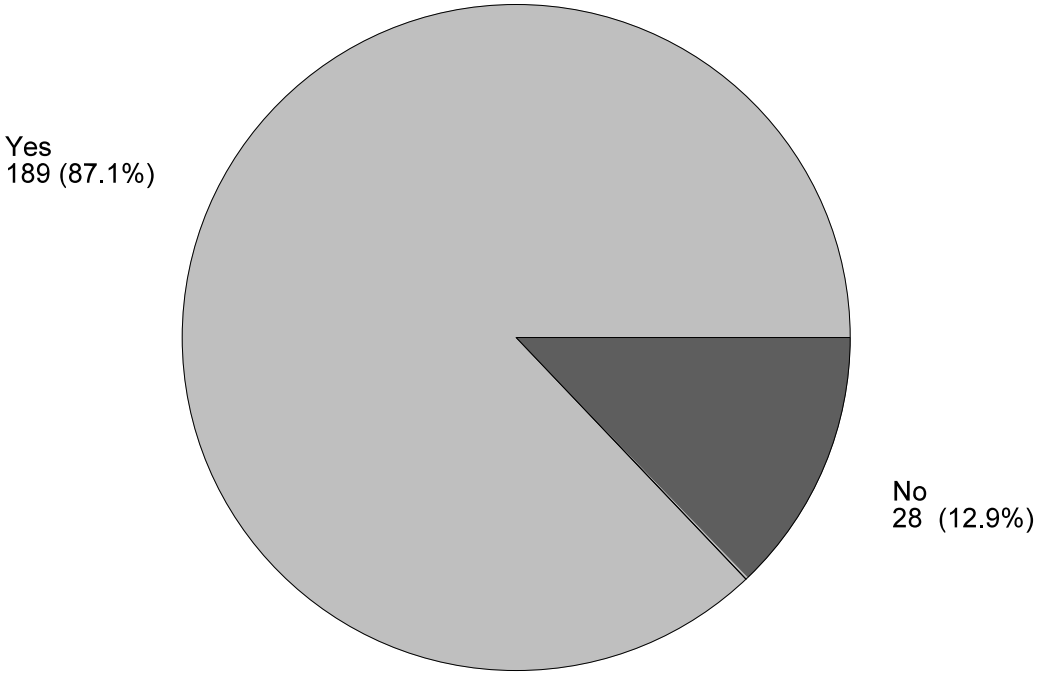
28.(a) Does your laboratory have *written criteria*, such as a validation protocol, for adopting a new test or a different manufacturer's test for HIV-1 RNA testing?



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

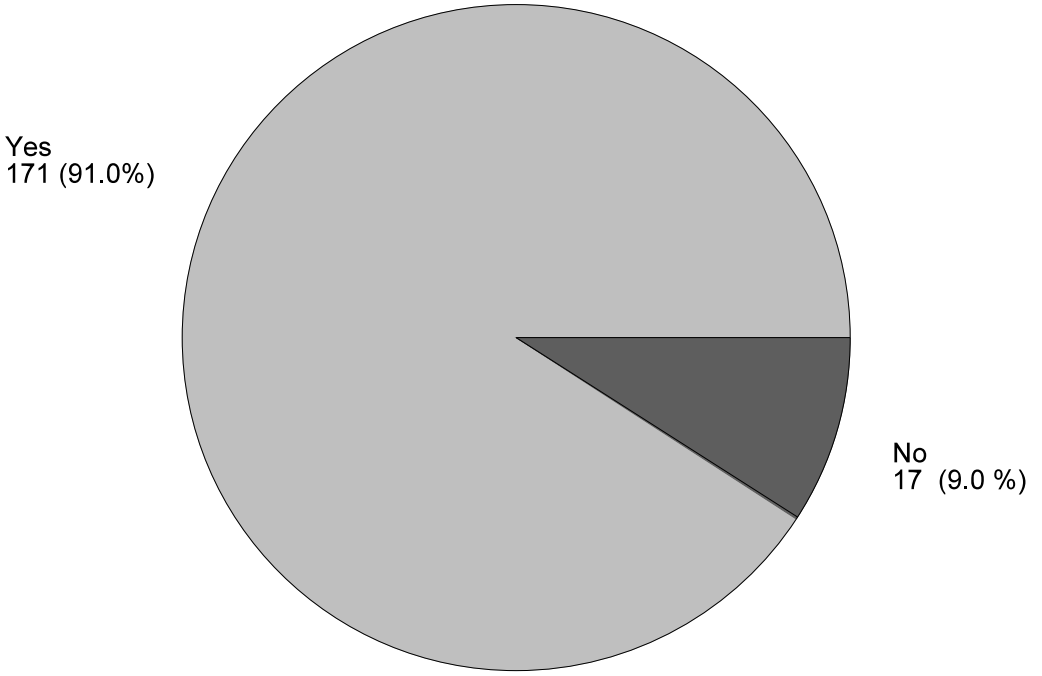


28.(c) Does your laboratory have a quality assurance plan that includes HIV-1 RNA determinations?



N=217

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



N=188

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=214

	Frequency of Laboratories Responding*	
Number During Most Recent Representative Month	Total Specimens Tested	Specimens with RNA Detected
<10	7	14
10-99	53	64
100-999	121	96
1,000-9,999	20	8
10,000-99,999	13	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=215

	Frequency of Laboratories Responding*		
Days Elapsed →	From Collection until Receipt in Laboratory	From Receipt to Specimen is Tested	From Specimen tested to Results Reported
1	168	43	145
2-3	36	76	30
4-5	0	50	16
6-7	4	26	5
>7	2	16	6

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

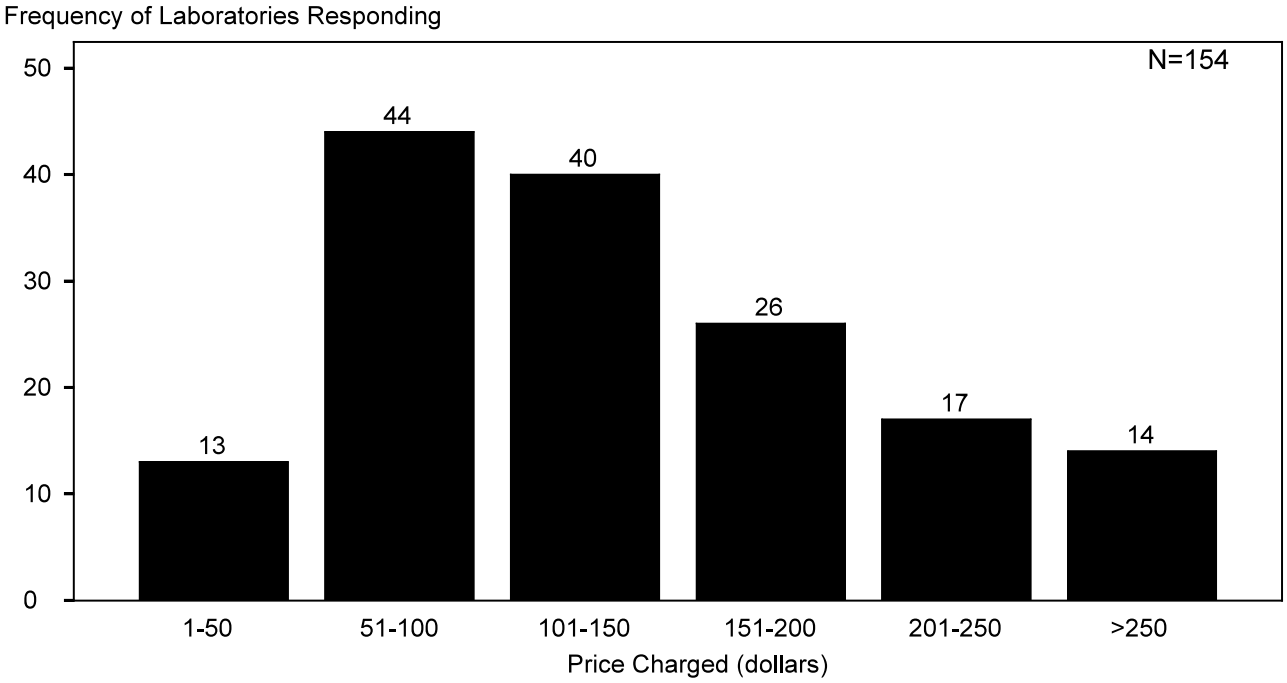
31. What is the temperature of specimens received by your laboratory? (Check <u>all</u> that apply to <u>HIV-1 RNA specimens received only in your laboratory</u>.)

N=216

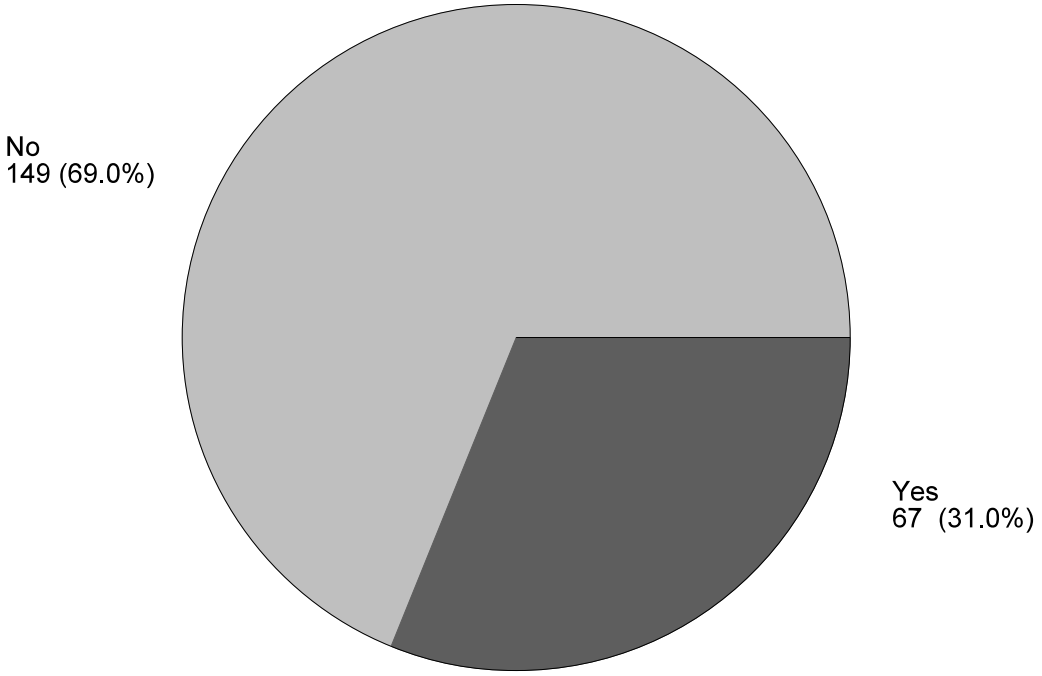
	Frequency of Laboratories Responding*		
Type of Specimen	Ambient	2-4 °C(refrigerated)	Frozen
Plasma	59	68	128
Serum	17	17	27
Whole Blood	96	27	2
Dried Blood Spots	7	1	1
Cerebrospinal Fluid	12	7	15
Other	5	2	3

* 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 RNA specimens to other laboratories outside your institution for additional testing?



N=216

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=64

Test Type	Hospital	Health Department	Blood Bank	Independent	Other	Total
EIA HIV-1	1	1	0	0	0	2
EIA HIV-2	0	1	1	3	1	6
EIA HIV-1/HIV-2	0	1	0	2	1	4
WB HIV-1	2	1	0	1	0	4
WB HIV-2	2	0	1	4	1	8
IIF HIV-1	0	0	0	1	0	1
IIF HIV-2	0	0	0	1	0	1
Particle Agglutination	0	0	0	0	0	0
HIV-1 p24 Antigen	2	1	0	5	1	9
HIV-1 DNA	5	3	1	17	1	27
Viral Culture	0	0	0	4	0	4
Antiretroviral Resistance	4	4	0	28	5	41
Other	0	0	2	12	3	17

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

N=174

	Frequency of Laboratories Responding*		
Number of Years	p24 Qualitative	p24 Neutralization	p24 Quantitative
1-3	13	5	3
4-6	106	49	8
7-9	15	6	2
10-12	18	16	10
13-15	14	9	6

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

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

N=172

	Frequency of Laboratories Responding*		
Number of Employees	p24 Qualitative	p24 Neutralization	p24 Quantitative
1-2	38	32	17
3-4	42	25	7
5-6	24	9	3
7-8	20	6	2
9-10	17	4	0
>10	24	7	1

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

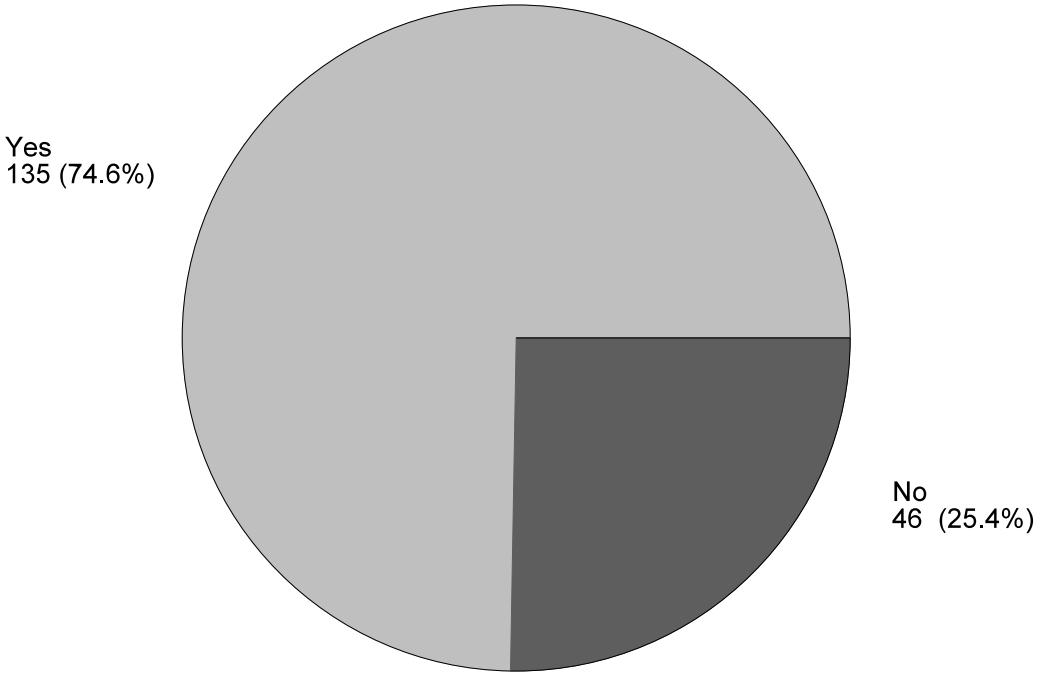
35. Please identify the source of written procedure(s) your laboratory follows for performing the following HIV-1 p24 antigen tests. (Check all that apply only for the procedures performed in your laboratory.)

N=182

	Frequency of Laboratories Responding*		
Source of procedure	p24 Qualitative	p24 Neutralization	p24 Quantitative
No Written Procedures	1	2	0
In-house Written Protocol	128	63	20
Manufacturer's Insert	156	75	25
Provided by State Health Department	6	2	1
Other Sources	10	1	3

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

36.(a) Does your laboratory use controls in addition to the kit manufacturer controls?



N=181

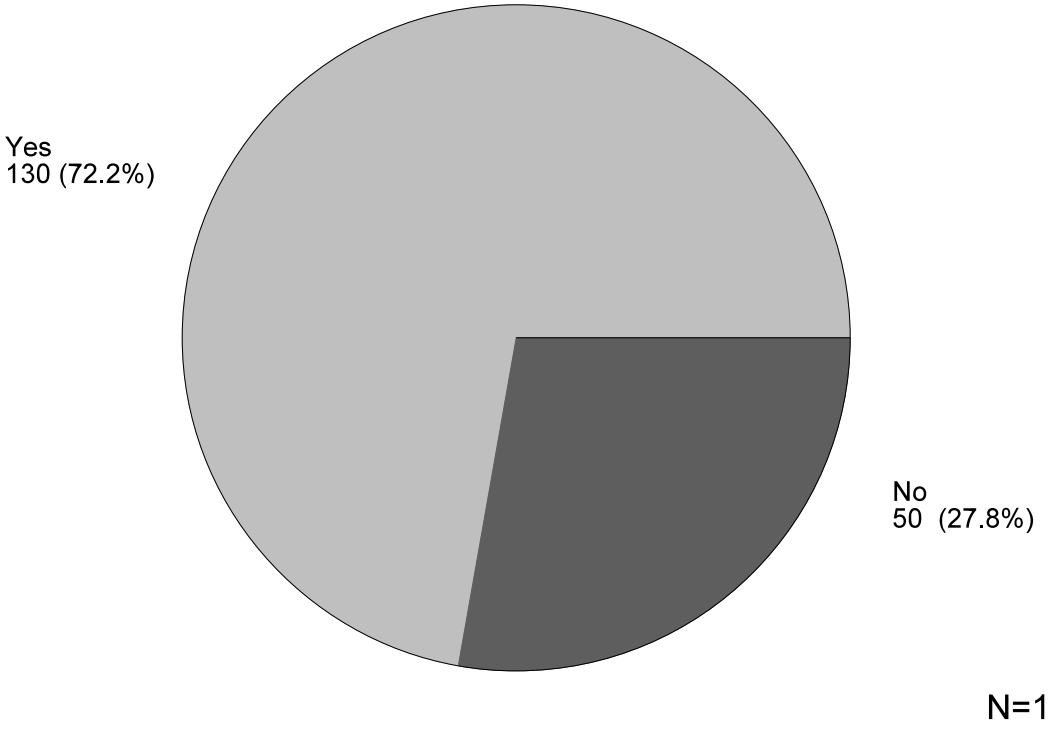
36.(b) If your laboratory uses controls in addition to the kit manufacturer controls, please indicate the frequency with which your laboratory uses HIV control sera/plasma for each of the HIV-1 p24 antigen tests below (Check <u>all</u> that apply.):

N=134

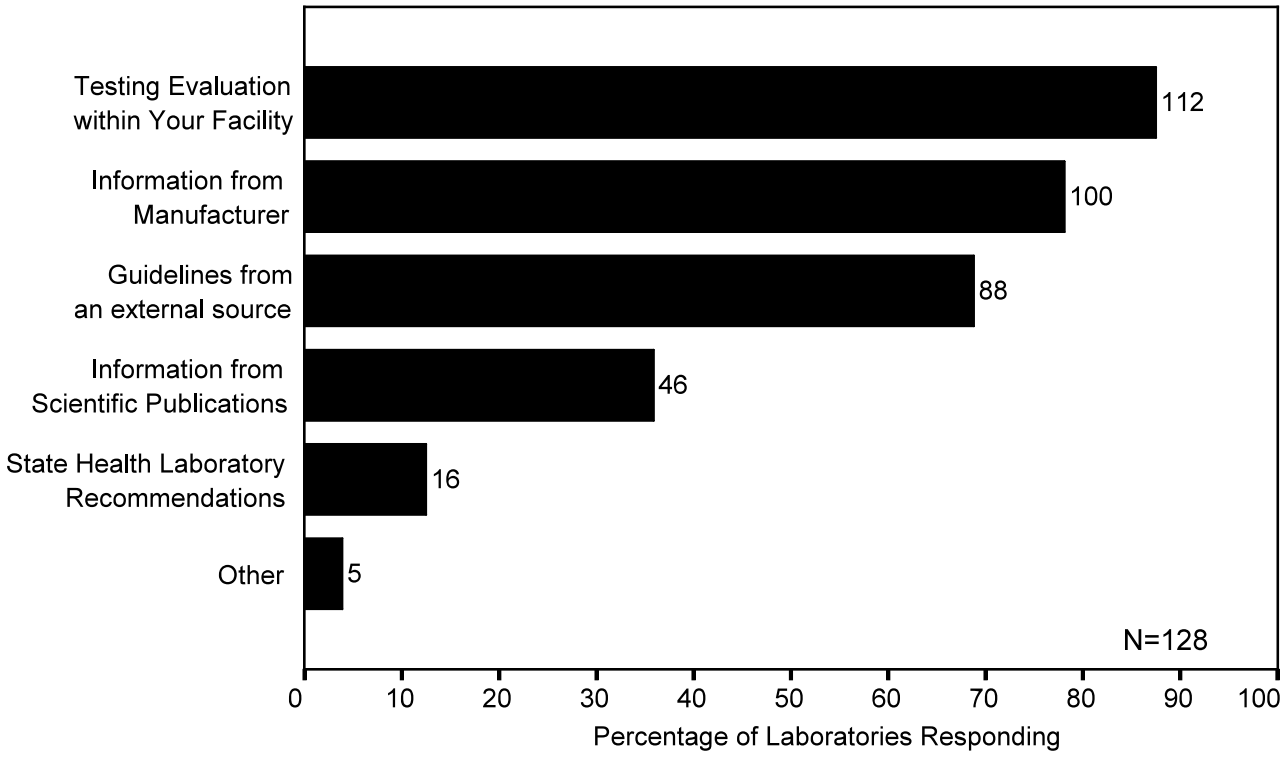
	Frequency of Laboratories Responding*				
Test Method	Each Test[a]	Each Set[b]	Two Each Day	Each Test Kit	Other Frequency
Qualitative	48	79	11	11	4
Neutralization	21	18	2	3	1
Quantitative	6	13	0	3	1

[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.

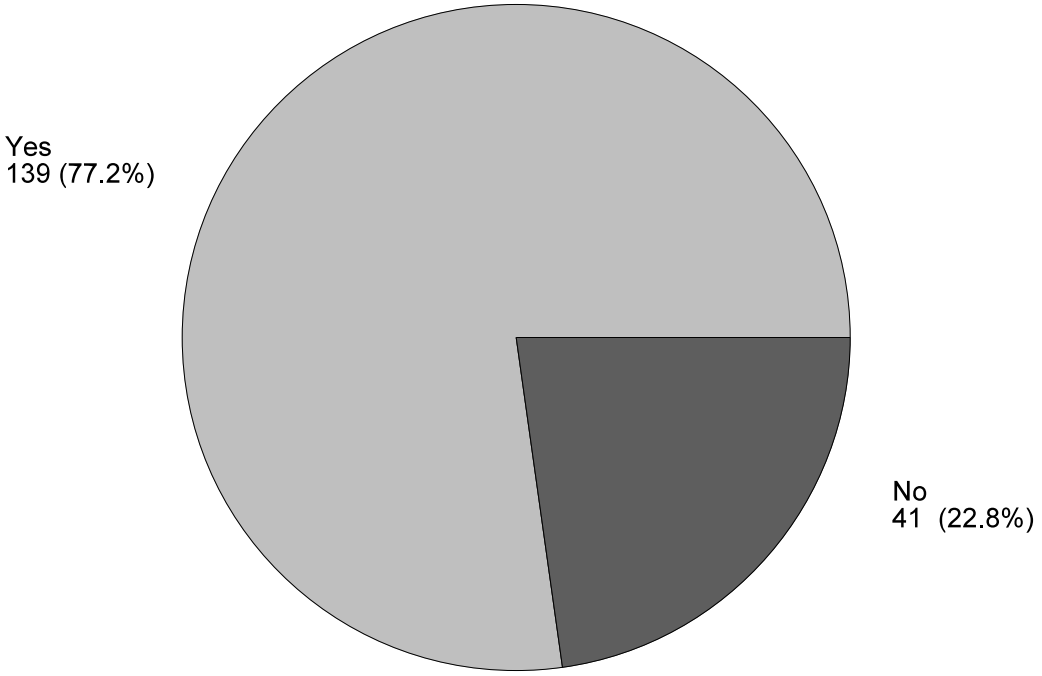
37.(a) Does your laboratory have *written criteria*, such as a validation protocol, for adopting a new test or a different manufacturer's test for HIV-1 p24 antigen testing?



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

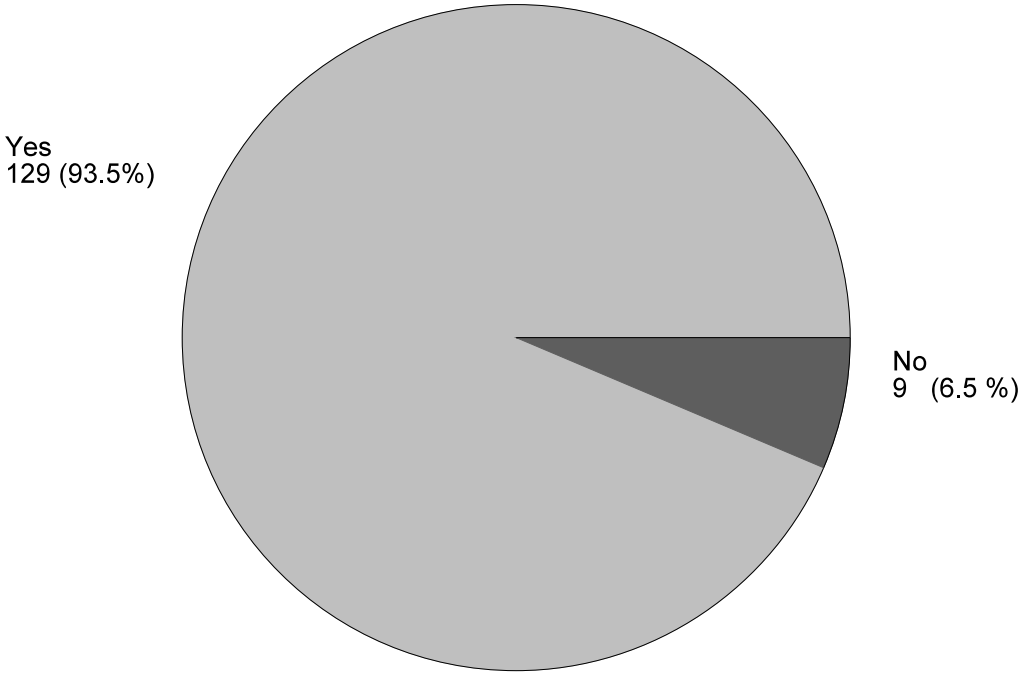


37.(c) Does your laboratory have a quality assurance plan that includes HIV-1 p24 antigen testing?



N=180

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



N=138

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=175

	Frequency of Laboratories Responding*			
Number During Most Recent Representative Month	Total Specimens Tested	Reactive by Qualitative Tests	Confirmed by Neutralization	p24 Antigen Quantitated
<10	24	65	39	10
10-99	40	13	3	2
100-999	43	3	0	3
1,000-9,999	48	0	0	0
10,000-99,999	15	0	0	0
>99,999	4	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=174

	Frequency of Laboratories Responding*		
Days Elapsed →	From Collection to Receipt in Laboratory	From Receipt to Specimen Tested	From Specimen tested to Results Reported
1	143	97	123
2-3	21	42	26
4-5	1	10	4
6-7	3	12	3
>7	1	9	9

* 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=179

	Frequency of Laboratories Responding*		
Type of Specimen	Ambient	2-4 °C (refrigerated)	Frozen
Plasma	70	65	28
Serum	95	78	28
Whole Blood	67	29	1
Dried Blood Spots	2	0	0
Other	2	1	3

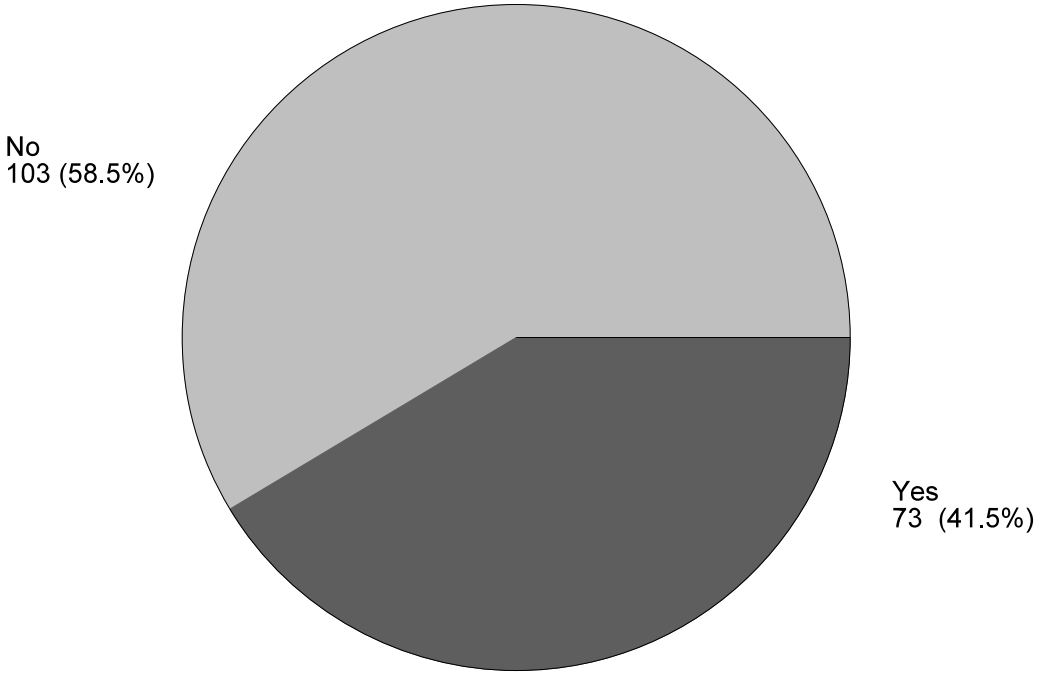
* The numbers in each column represent the frequency of laboratories that indicated the associated type of specimen.

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

N=141

Charge (in dollars)	p24 Ag Qualitative	p24 Ag Neutralization	p24 Ag Quantitative
1-25	50	11	3
26-50	19	3	3
51-75	12	6	3
76-100	12	4	1
>100	8	3	3

42.(a) Does your laboratory refer HIV-1 p24 antigen specimens to other laboratories for additional testing?



N=176

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=71

Test Type	Hospital	Health Department	Blood Bank	Independent	Other	Total
EIA HIV-1	0	0	1	3	0	4
EIA HIV-2	0	1	2	7	0	10
EIA HIV-1/HIV-2	0	1	1	3	0	5
WB HIV-1	0	3	2	14	1	20
WB HIV-2	0	0	1	15	1	17
IIF HIV-1	0	0	0	0	0	0
IIF HIV-2	0	0	0	0	0	0
Particle Agglutination	0	1	0	0	0	1
HIV-1 DNA	1	2	1	7	0	11
HIV-1 RNA	3	1	3	6	1	14
Viral Culture	0	0	0	1	0	1
Antiretroviral Resistance	0	0	0	4	0	4
p24 Ag Neutralization	3	1	13	34	4	55
p24 Ag Quantitative	0	0	1	7	1	9
Other	1	0	1	0	1	3

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=186

	Step 1	Step 2	Step 3	Step 4	Number of Laboratories	Percentage of Laboratories
Algorithm*	EIA-S**	EIA-D**			53	28.5
	EIA-S	EIA-D	A		51	27.4
	EIA-S	EIA-D	WB		20	10.8
	EIA-S				4	2.2
	EIA-S	EIA-D	WB	A	4	2.2
	EIA-D	EIA-D	WB		3	1.6
	EIA-S	WB			3	1.6
Other Algorithms					48	25.8

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 47 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 performed these specific HTLV-I/II tests. (Round off to the nearest year. If less than one year, round off to one year.)

N=179

	Frequency of Laboratories Responding*									
Number of Years	EIA	WB	IIF	PCR	PA	RIPA	Line Immunoassay	HTLV-I/II Antigen Detection	Viral Culture	Other
1 - 3	33	7	2	3	2	0	4	2	0	1
4 - 6	39	12	1	3	3	0	2	2	0	2
7 - 9	25	5	1	3	1	0	0	0	0	0
10 - 12	53	12	1	2	1	1	0	0	1	2
13 - 15	14	4	0	0	1	0	0	0	0	0
>15	1	0	0	0	0	0	0	0	0	0

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

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

N=177

	Frequency of Laboratories Responding*									
Number of Employees	EIA	WB	IIF	PCR	PA	RIPA	Line Immunoassay	HTLV-I/II Antigen Detection	Viral Culture	Other
1-2	30	18	3	9	3	1	3	0	1	2
3-4	34	14	1	2	4	0	1	1	0	0
5-6	28	3	0	0	0	0	1	1	0	2
7-8	21	0	0	0	0	0	1	0	0	0
9-10	20	1	0	0	0	0	0	1	0	0
>10	29	0	0	0	0	0	0	0	0	0

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

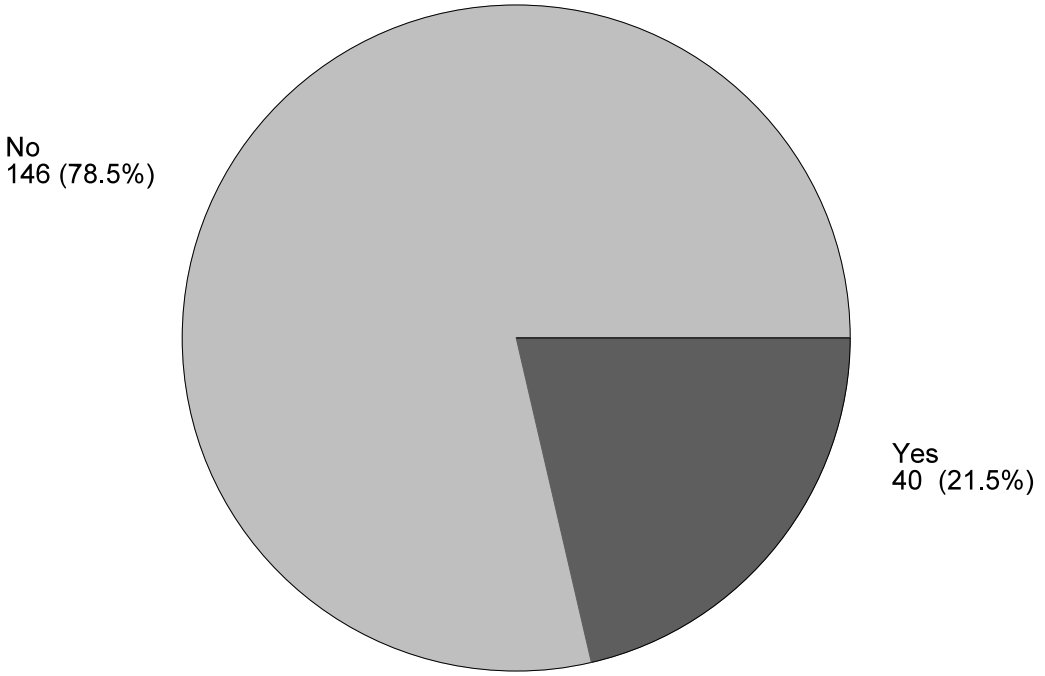
45. Please identify the source of written procedure(s) your laboratory follows for performing the following HTLV-I/II tests. (Check all that apply only for the procedures performed in your laboratory.)

N=189

	Frequency of Laboratories Responding*			
Source of procedure	EIA	WB	IIF	Other
No Written Procedures	1	0	0	1
In-house Written Protocol	134	24	3	12
Manufacturer's Insert	163	32	2	14
Provided by State Health Department	5	0	0	0
Other Sources	12	1	0	2

* 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?



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=37

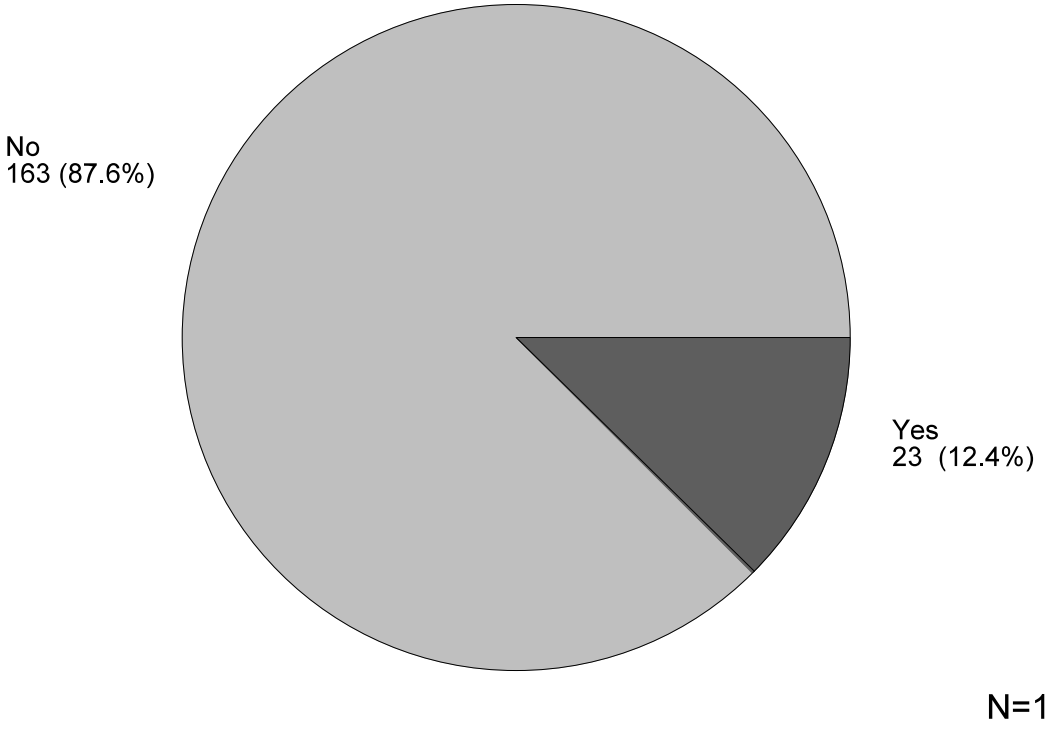
Band Patterns	Number of Laboratories	Percentage of Laboratories
Other	17	45.9
p24 and gp46 or r21e	8	21.6
One protein from each of the viral gene product groups: gag (19, p24) and env (gp21, gp 46, gp61/68)	7	18.9
p19 or p24, and gp46 or gp61/68	3	8.1
p24 and gp46 or gp61/68	1	2.7
Any HTLV-I/II specific protein bands	1	2.7

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

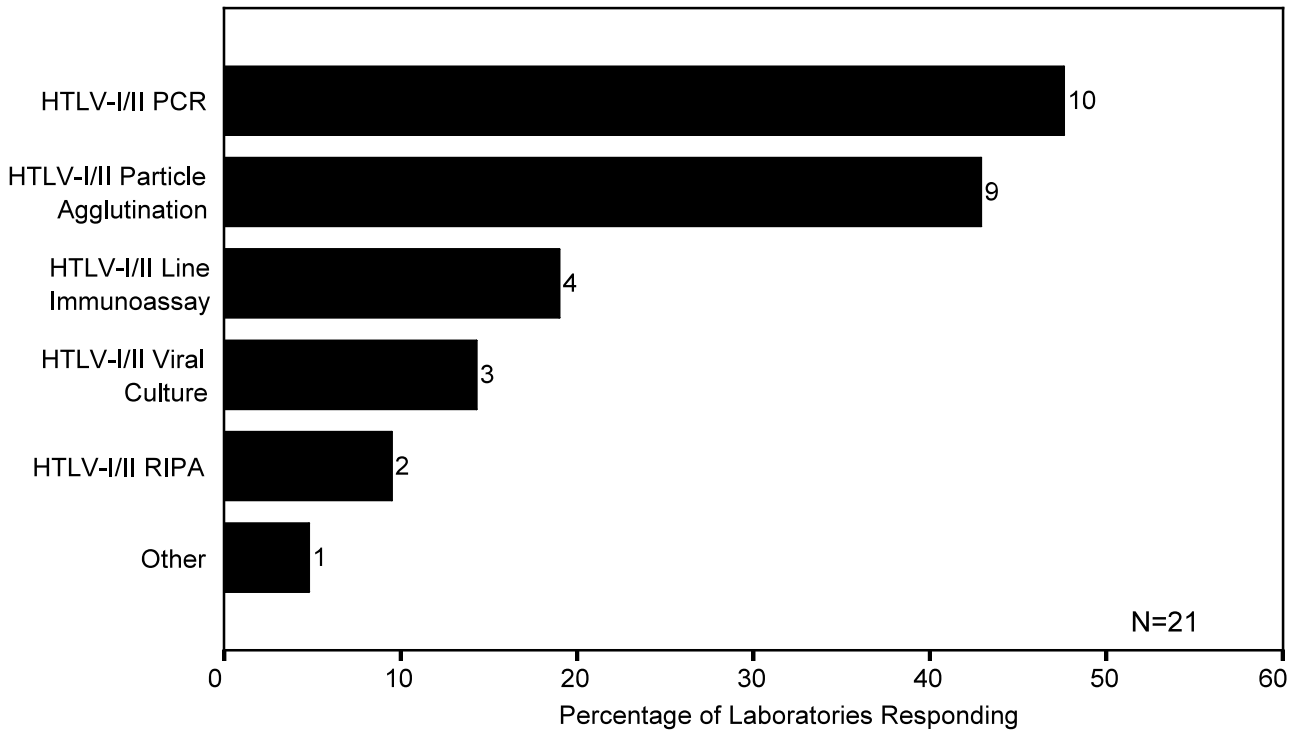
N=39

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)	20	51.3
No bands present	18	46.2
Other	1	2.6

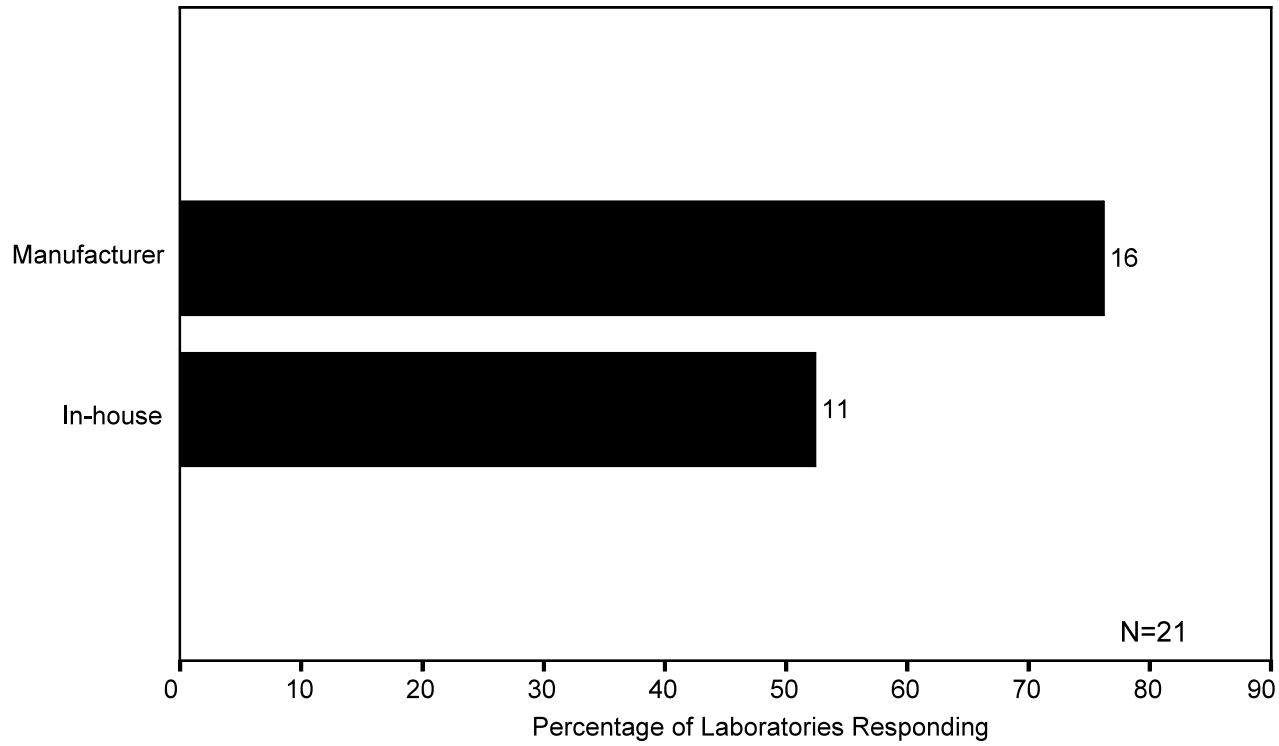
47.(a) Do you perform an HTLV-I/II antibody test <u>other than</u> EIA, WB, or IIF, <u>to detect HTLV-I/II infection</u>?



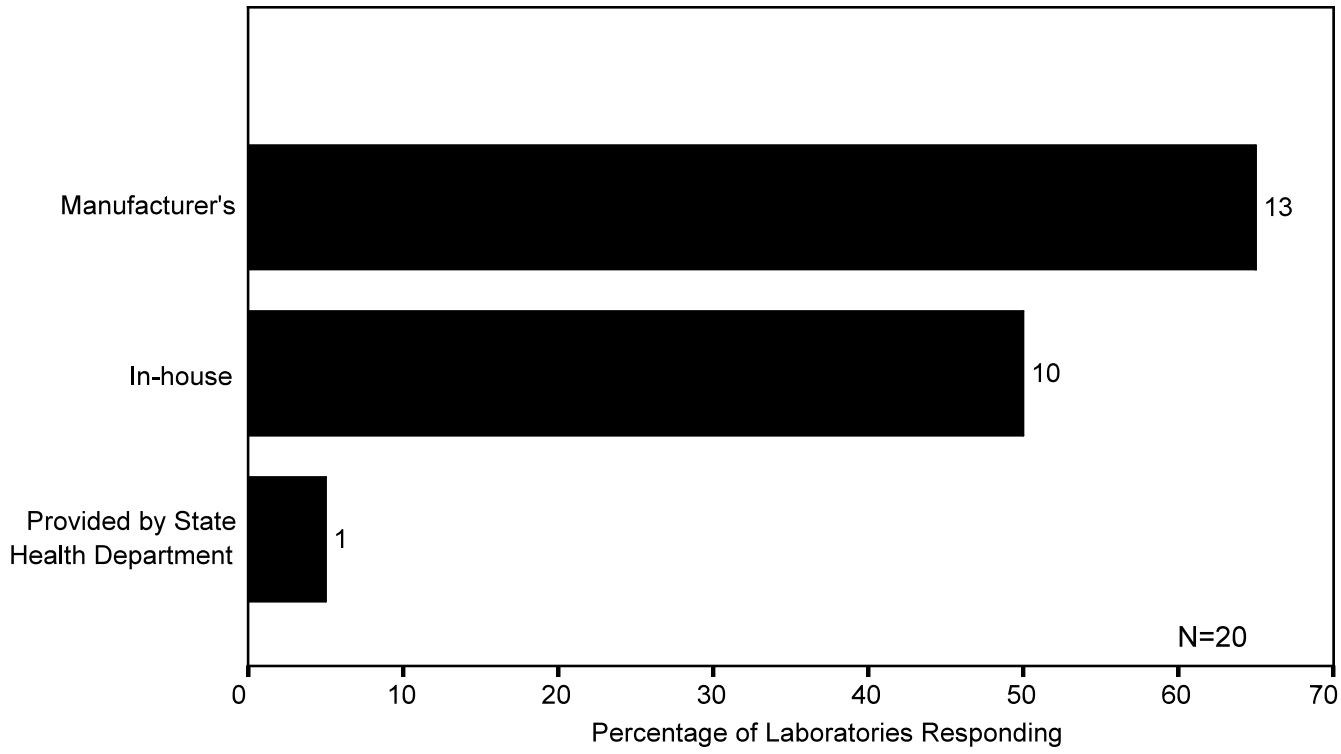
47.(b) If yes, indicate below the other tests performed in your laboratory (Check <u>all</u> that apply.):



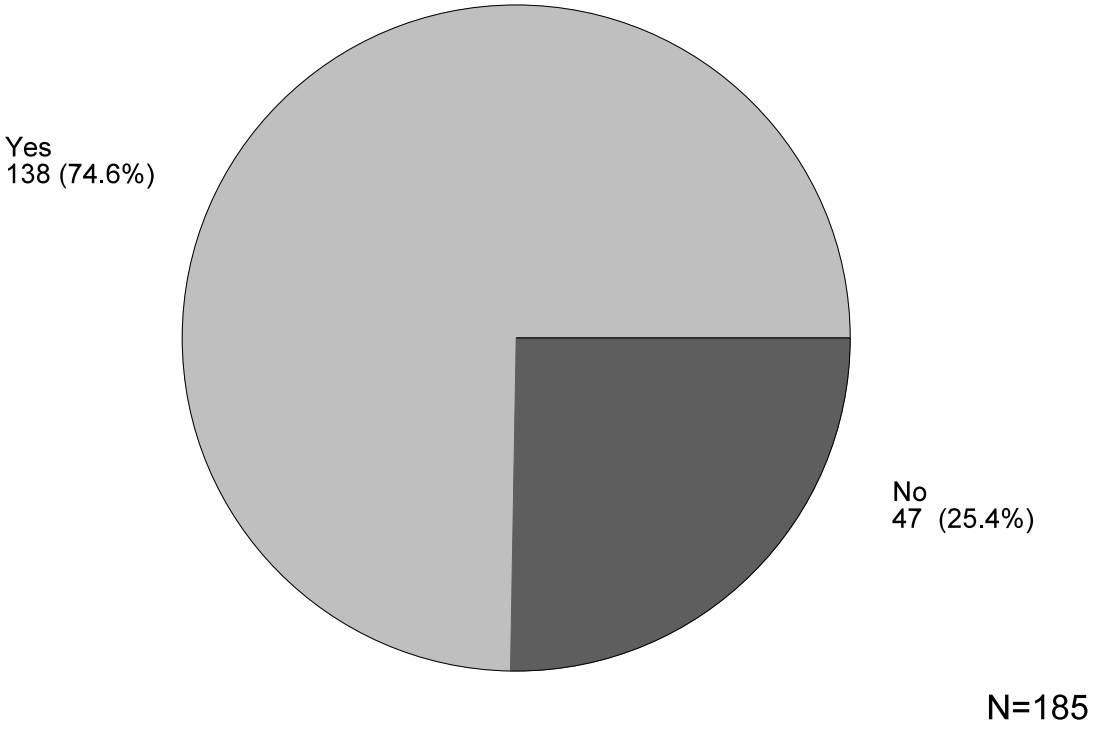
47.(c) Source of reagents for HTLV-I/II tests other than EIA, WB, and IIF as indicated in question 47(b) (Check all that apply.):



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



48.(a) Does your laboratory use controls in addition to the kit manufacturer controls?



48.(b) If your laboratory uses controls in addition to 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=137

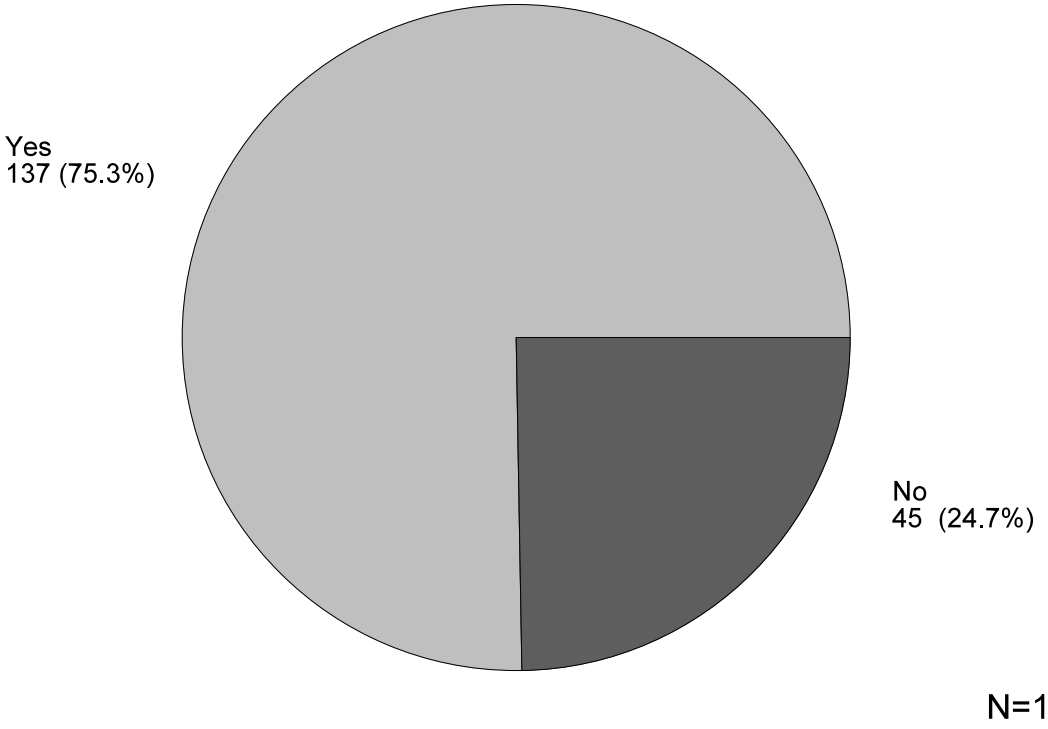
	Frequency of Laboratories Responding*				
Test Method	Each Test[a]	Each Set[b]	Two Each Day	Each Test Kit	Other Frequency
EIA	45	86	16	10	2
WB	3	14	2	1	0
IIF	1	4	0	1	0
Other	1	4	0	1	1

[a] An EIA plate, Western blot strip or IIF slide

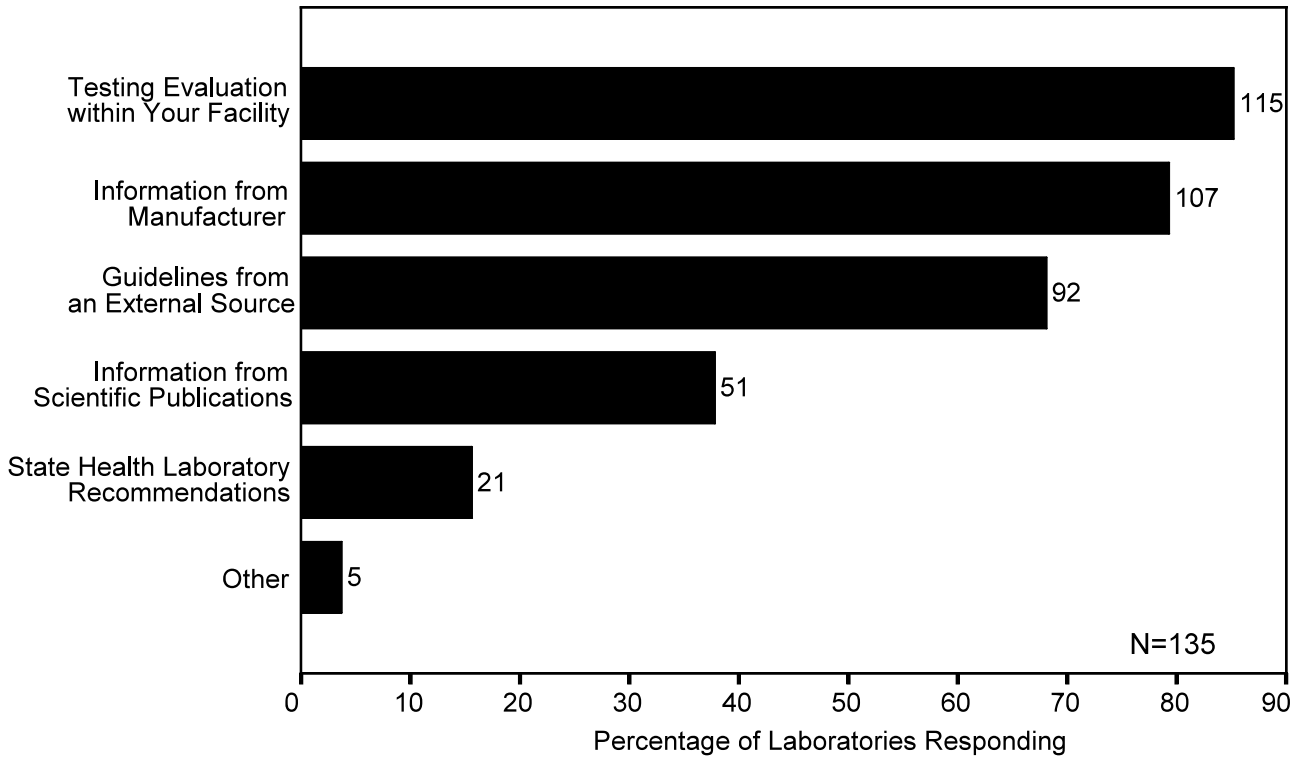
[b] A set of EIA plates, Western blot strips or IIF slides

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

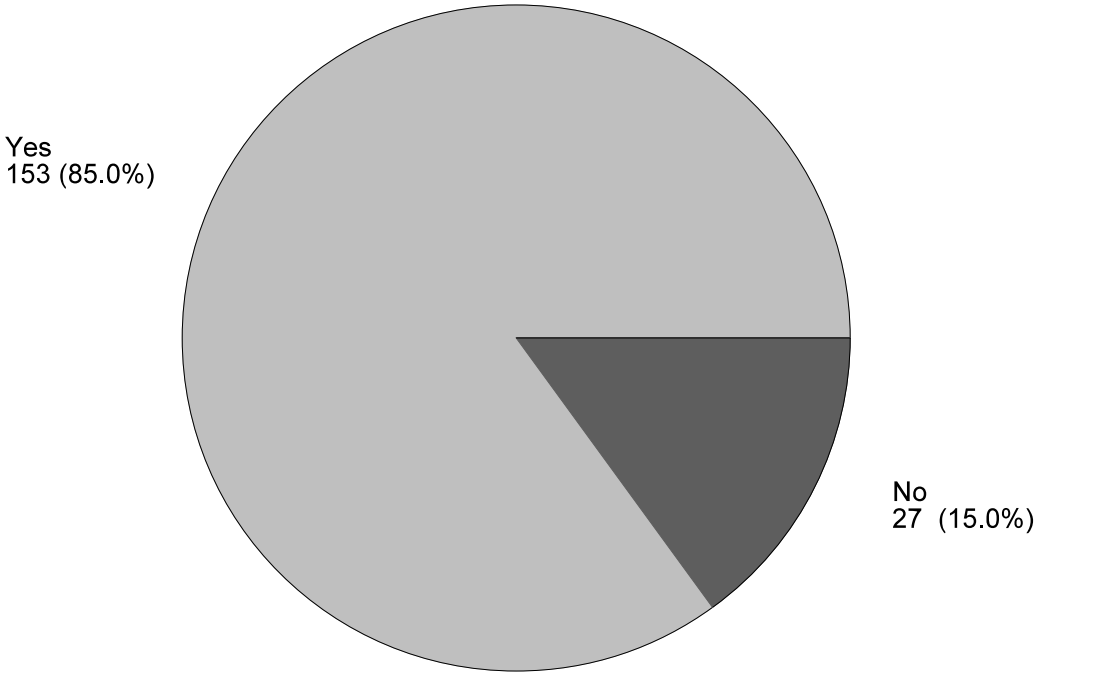
49.(a) Does your laboratory have *written criteria* for adopting a new test or a different manufacturer's test for HTLV-I/II testing?



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

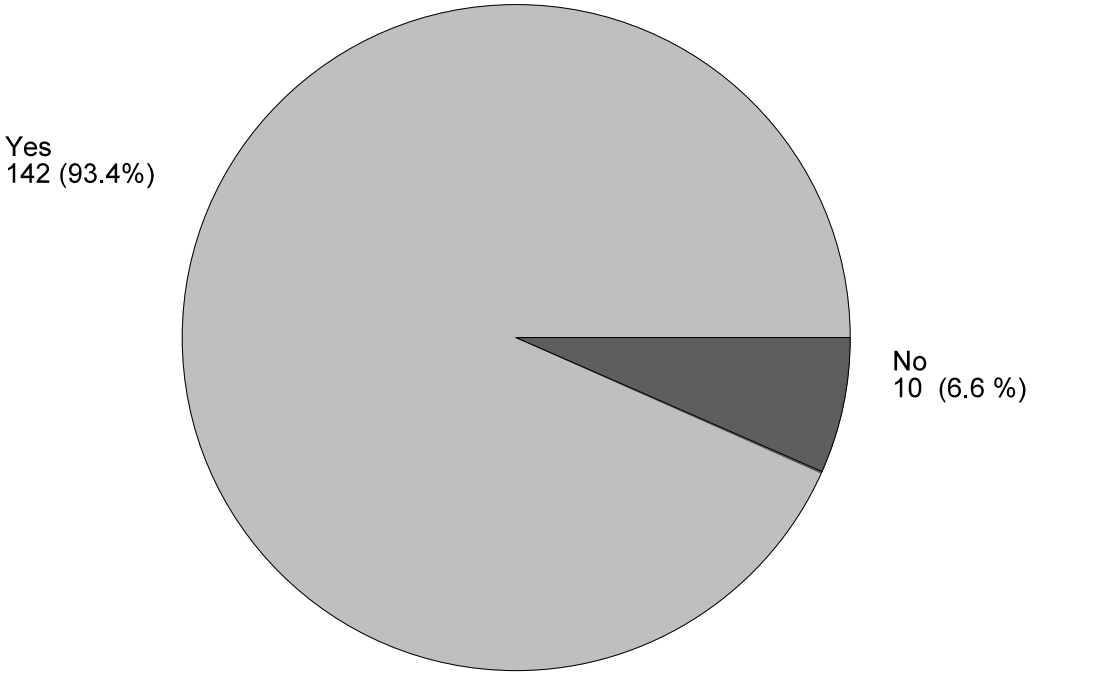


49.(c) Does your laboratory have a quality assurance plan that includes HTLV I/II testing?



N=180

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



N=152

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=180

	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	14	83	69	37
10-99	48	29	19	8
100-999	50	6	3	0
1,000-9,999	49	0	0	0
10,000-99,999	16	0	0	0
>99,999	0	0	0	0

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

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=176

	Frequency of Laboratories Responding*		
Days Elapsed →	From Collection to Receipt in Laboratory	From Receipt to Specimen Tested	From Specimen tested to Results Reported
1	152	92	132
2-3	15	50	26
4-5	2	15	3
6-7	3	11	2
>7	1	4	4

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

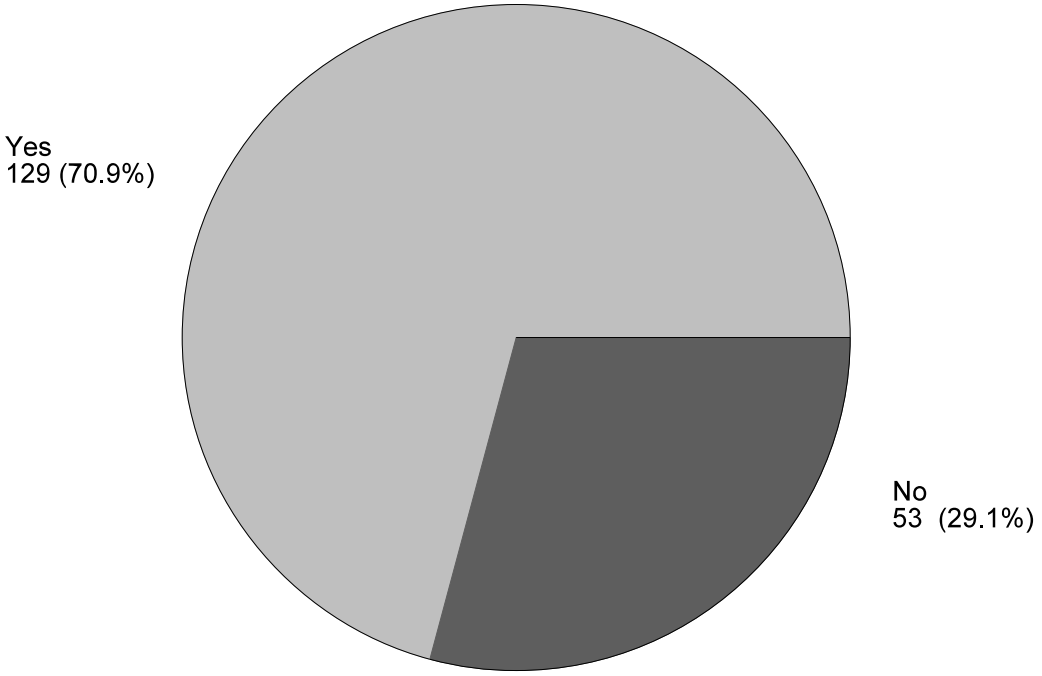
52. Approximately how much does your laboratory charge to perform an HTLV-I/II antibody? (Round off to nearest U.S. dollar.)

N=118

	Frequency of Laboratories Responding*			
Approximate Charge by Laboratory	EIA	WB	IIF	Other
<$50	75	6	3	2
$50-$99	28	13	0	1
$100-$149	9	6	0	2
$150-$200	3	2	0	0
>$200	1	0	0	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=182

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=128

Test Type	Hospital	Health Department	Blood Bank	Independent	Other	Total
EIA	0	2	10	22	3	37
WB	0	11	9	84	6	110
IIF	0	4	0	3	0	7
PA	0	0	0	2	0	2
RIPA	1	4	0	14	2	21
Line Immunoassay	0	0	0	2	0	2
PCR	2	5	0	14	4	25
Viral Culture	0	0	0	4	0	4
Antigen	0	0	0	2	0	2
Other	0	0	1	1	0	2